DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 412, 414, 416, and 419

[CMS-1736-P]

RIN 0938-AU12

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2021 based on our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, this proposed rule would establish and update the Overall Hospital Quality Star Rating beginning with the CY 2021; remove certain restrictions on the expansion of physician-owned hospitals that qualify as "high Medicaid facilities," and clarify that certain beds are counted toward a hospital's baseline number of operating rooms, procedure rooms, and beds; and add two new service categories to the OPD Prior Authorization Process.

DATES: To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on October 5, 2020.

ADDRESSES: In commenting, please refer to file code CMS-1736-P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions under the "submit a comment" tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1736-P,

P.O. Box 8013,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1736-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, we refer readers to the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at APCPanel@cms.hhs.gov.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email Scott.Talaga@cms.hhs.gov or Mitali Dayal via email Mitali.Dayal2@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at Anita.Bhatia@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Nicole Hewitt via email Nicole.Hewitt@cms.hhs.gov.

Blood and Blood Products, contact Josh McFeeters via email Joshua.McFeeters@cms.hhs.gov.

Cancer Hospital Payments, contact Scott Talaga via email Scott.Talaga@cms.hhs.gov.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email Chuck.Braver@cms.hhs.gov.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email AuSha.Washington@cms.hhs.gov.

Comprehensive APCs (C-APCs), contact Lela Strong-Holloway via email Lela.Strong@cms.hhs.gov, or Mitali Dayal via email Mitali.Dayal2@cms.hhs.gov.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email Anita.Bhatia@cms.hhs.gov.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Nicole Hewitt via email Nicole.Hewitt@cms.hhs.gov.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email Elise.Barringer@cms.hhs.gov.

Hospital Quality Star Rating Methodology, contact Annese Abdullah-Mclaughlin via email Annese.Abdullah-Mclaughlin@cms.hhs.gov.

Inpatient Only (IPO) Procedures List, contact Au'Sha Washington via email Ausha.Washington@cms.hhs.gov, or Allison Bramlett via email Allison.Bramlett@cms.hhs.gov, or Lela Strong-Holloway via email Lela.Strong@cms.hhs.gov.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule) , contact Lela Strong-Holloway via email Lela.Strong@cms.hhs.gov, or Elise Barringer via email Elise.Barringer@cms.hhs.gov.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email Scott.Talaga@cms.hhs.gov.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email Scott.Talaga@cms.hhs.gov.

OPPS Brachytherapy, contact Scott Talaga via email Scott.Talaga@cms.hhs.gov.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email Erick.Chuang@cms.hhs.gov, or Scott Talaga via email Scott.Talaga@cms.hhs.gov, or Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov, or Gil Ngan via email at Gil.Ngan@cms.hhs.gov or, or Cory Duke via email at Cory.Duke@cms.hhs.gov.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at NewTechAPCapplications@cms.hhs.gov.

OPPS Packaged Items/Services, contact Lela Strong-Holloway via email Lela.Strong@cms.hhs.gov, or Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at DevicePTapplications@cms.hhs.gov.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email Marina.Kushnirova@cms.hhs.gov.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at PHPPaymentPolicy@cms.hhs.gov.

Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services, contact Thomas Kessler via email at Thomas.Kessler@cms.hhs.gov.

Rural Hospital Payments, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

Skin Substitutes, contact Josh McFeeters via email Joshua.McFeeters@cms.hhs.gov.

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email Joshua.McFeeters@cms.hhs.gov.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Elise Barringer via email Elise.Barringer@cms.hhs.gov or at 410-786-9222.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov/. Follow the search instructions on that website to view public comments.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

The Addenda relating to the ASC payment system are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR and Defense Federal Acquisition Regulations (DFAR) apply.

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Regulations Text

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we propose to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2021. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

2. Summary of the Major Provisions

- *OPPS Update*: For CY 2021, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.6 percent. This increase factor is based

on the proposed hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment required by the Affordable Care Act of 0.4 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2021 would be approximately $83.9 billion, an increase of approximately $7.5 billion compared to estimated CY 2020 OPPS payments.

We propose to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

- *Partial Hospitalization Update:* For CY 2021 OPPS/ASC proposed rule, CMS is proposing to maintain the unified rate structure established in CY 2017, with a single PHP APC for each provider type for days with three or more services per day. CMS is proposing to use the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing policy, using updated data for each provider type and a cost floor equal to the CY 2019 final geometric mean per diem cost for each provider type. Accordingly, CMS is proposing to calculate the CY 2021 PHP APC per diem rate for HB PHPs based on updated cost data and to calculate the rate for CMHCs based on the proposed cost floor.

- *Changes to the Inpatient Only (IPO) List*: For CY 2021, we propose to eliminate the IPO list over the course of three calendar years beginning with the removal of approximately 300 musculoskeletal-related services. We are also soliciting comments on whether three years is an appropriate time frame for transitioning to eliminate the IPO list; other services that are candidates for

removal from the IPO list for CY 2021; and the sequence in which to remove additional clinical families and/or specific services from the IPO list in future rulemaking.

- *Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule)*: For CY 2021, we propose to continue a 2-year exemption from Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) referrals to Recovery Audit Contractors (RACs) and RAC reviews for "patient status" (that is, site-of-service) for procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on January 1, 2021. We are also seeking comments on whether the 2-year exemption period continues to be appropriate, or if a longer or shorter period may be more warranted.

- 340B-*Acquired Drugs:* We propose for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs. Similar to the 340B drug payment policy implemented in CY 2018, we are also proposing that Rural SCHs, PPS-exempt cancer hospitals and children's hospitals would be exempted from the 340B payment policy for CY 2021 and subsequent years. Finally, we note that we propose in the alternative to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.

- *Comprehensive APCs*: For CY 2021, we propose to create two new comprehensive APCs (C-APCs). These new C-APCs include the following: C-APC 5378 (Level 8 Urology and Related Services) and C–APC 5465 (Level 5 Neurostimulator and Related Procedures). Adding these C-APCs would increase the total number of C-APCs to 69.

- *Device Pass-Through Payment Applications*: For CY 2021, we have received five applications for device pass-through payments that we discuss in this proposed rule. Two of these

applications (CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope) have received preliminary approval for pass-through payment status through our quarterly review process. CMS is soliciting public comments on these five applications and will make a final determination on these applications in the CY 2021 OPPS/ASC final rule.

- *Changes to the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals*: For CY 2021 and subsequent years, we propose to change the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which we had previously required direct supervision. This would be consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. We also propose that, for CY 2021 and subsequent years, direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services would include virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician.

- *Cancer Hospital Payment Adjustment*: For CY 2021, we propose to continue to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we propose that a target PCR of 0.89 would be used to determine the CY 2021 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

- *ASC Payment Update*: For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2021, we propose to increase payment rates under the ASC payment system by 2.6 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a hospital market basket percentage increase of 3.0 percent minus a proposed multifactor productivity adjustment required by the Affordable Care Act of 0.4 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2021 would be approximately 5.45 billion, an increase of approximately 160 million compared to estimated CY 2020 Medicare payments.

- *Changes to the List of ASC Covered Surgical Procedures*: For CY 2021, we propose to add eleven procedures to the ASC covered procedures list (CPL), including total hip arthroplasty (CPT 27130). Additionally, we propose two alternatives for changing the way procedures are added to the ASC CPL. Under the first alternative, we propose to establish a nomination process beginning in CY 2021 for procedures that would be added beginning in CY 2022 under which external stakeholders, such as professional specialty societies, would use suggested parameters to nominate procedures that can be safely performed in the ASC setting and meet all other regulatory standards. CMS would review nominated procedures and propose and finalize procedures to be added to the ASC CPL through annual rulemaking.

Under the second alternative proposal, we would revise the criteria for covered surgical procedures for the ASC payment system under 42 CFR 416.166, by keeping the general standards and eliminating five of the general exclusions. The revised criteria would result in the addition of approximately 270 surgery or surgery-like codes to the CPL that are not on the CY 2020 IPO list.

Finally, we solicit comment on whether the conditions for coverage for ASCs should be revised if we adopt the second alternative proposal described above.

- *Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs:* For the Hospital OQR and ASCQR Programs, we propose to update and refine requirements to further meaningful measurement and reporting for quality of care provided in these outpatient settings while limiting compliance burden. We propose to revise and codify previously finalized administrative procedures and to propose and codify an expanded review and corrections process to further the programs' alignment while clarifying program requirements. We are not proposing any measure additions or removals for either program.

- *Overall Hospital Quality Star Ratings:* We propose to establish and update the methodology that would be used to calculate the Overall Hospital Quality Star Ratings beginning with 2021 and for subsequent years. CMS is proposing to, among other proposals, update and simplify how the ratings are calculated, reduce the total number of measure groups, and stratify the Readmission measure group based on the proportion of dual-eligible patients. These changes will simplify the methodology, and therefore, reduce provider burden, improve the predictability of the star ratings, and increase the comparability between hospital star ratings.

- *Addition of New Service Categories for Hospital Outpatient Department Prior Authorization Process:* We propose the addition of the following two categories of services to the prior authorization process beginning for dates of service on or after July 1, 2021: (1) cervical fusion with disc removal and (2) implanted spinal neurostimulators.

- *Clinical Laboratory Date of Service (DOS) Policy:* We propose to exclude cancer-related protein-based MAAAs, which are not generally performed in the HOPD setting, from the OPPS packaging policy and add them to the laboratory DOS provisions at § 414.510(b)(5).

- *Physician-Owned Hospitals:* We propose the (1) removal of unnecessary regulatory restrictions on high Medicaid facilities and (2) including beds in a physician-owned hospital's baseline consistent with state law.

3. Summary of Costs and Benefit

In sections XIX. and XX. of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 55 in section XIX.B of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2021 compared to all estimated OPPS payments in CY 2020. We estimate that the policies in this proposed rule would result in a 2.5 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2021, including beneficiary cost-sharing, to the approximately 3,628 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately 1.6 billion compared to CY 2020 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate a 1.3 percent increase in CY 2021 payments to CMHCs relative to their CY 2020 payments.

b. Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2021 IPPS proposed rule wage indexes would result in an estimated increase of 0.2 percent for urban hospitals under the

OPPS and an estimated increase of 0.4 percent for rural hospitals. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C. of this proposed rule.

c. Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2021 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural hospital payment adjustments. While we propose to implement the required reduction to the cancer hospital payment adjustment required by section 16002 of the 21st Century Cures Act for CY 2021, the target payment-to-cost ratio (PCR) for CY 2021 is 0.89, equivalent to the 0.89 target PCR for CY 2020, and therefore has no budget neutrality adjustment.

d. Impacts of the Proposed OPD Fee Schedule Increase Factor

For the CY 2021 OPPS/ASC, we propose to establish an OPD fee schedule increase factor of 2.6 percent and apply that increase factor to the conversion factor for CY 2021. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals would experience an increase of approximately 2.8 percent and that rural hospitals would experience an increase of 3.6 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals would experience an increase of 3.5 percent, minor teaching hospitals would experience an increase of 3.2 percent, and major teaching hospitals would experience an increase of 1.6 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.7 percent in payments, while hospitals with government ownership would experience a decrease of 0.3 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 4.4 percent in payments.

e. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2021 payment rates, compared to estimated CY 2020 payment rates, generally ranges between an increase of 2 and 5 percent, depending on the service, with some exceptions. We estimate the proposed impact of applying the hospital market basket update to ASC payment rates would increase payments by $160 million under the ASC payment system in CY 2021.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) (Pub. L. 109-432), enacted on December 20,

2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111-309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112-78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112-96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112-240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113-67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113-93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114-10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114-74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114-255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115-271), enacted on October 24, 2018.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section

1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the "2 times rule"). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as "transitional pass-through payments," for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us

to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals include:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106-113, and redesignated by section 202(a)(2) of Pub. L. 106-113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act, which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel--

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for covered ASC procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 19, 2018, for a 2-year period (84 FR 26117).

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 19, 2019. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, announce new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2018, we published a Federal Register

notice requesting nominations to fill vacancies on the Panel (83 FR 3715). As published in this notice, CMS is accepting nominations on a continuous basis.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 19, 2019, meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 19, 2019 Panel meeting, namely APC assignments for certain CPT codes, a comprehensive APC for skin substitute products, a comprehensive APC for autologous hematopoietic stem cell transplantation, and packaging policies, were discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61148). For discussions of earlier Panel meetings and recommendations, we refer readers to previously published

OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at http://facadatabase.gov.

F. Public Comments Received on the CY 2020 OPPS/ASC Final Rule with Comment Period

We received approximately 22 timely pieces of correspondence on the CY 2020 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 12, 2019 (84 FR 61142), most of which were outside of the scope of the final rule. In-scope comments related to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator "NI" in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule). Summaries of the public comments on topics that were open to comment and our responses to them will be set forth in various sections of the final rule with comment period under the appropriate subject-matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2021 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2021, and before January 1, 2022 (CY 2021), using the same basic methodology that we described in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61149), using updated CY 2019 claims data. That is, we propose to recalibrate the relative

payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2021, we began with approximately 167 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2019, and before January 1, 2020, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 87 million final action claims to develop the proposed CY 2021 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Addendum N to this proposed rule (which is available via the Internet on the CMS website) includes the proposed list of bypass codes for CY 2021. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2019 and, therefore, includes codes that were in effect in CY 2019 and used for billing, but were deleted for CY 2020. We propose to retain these deleted bypass codes on the proposed CY 2021 bypass list because these codes existed in CY 2019 and were covered OPD services in that period, and CY 2019 claims data were used to calculate proposed CY 2021 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more "pseudo" single procedure claims for ratesetting purposes. "Overlap bypass codes" that are members of the proposed multiple imaging composite APCs were identified by asterisks (*) in the third

column of Addendum N to the proposed rule. HCPCS codes that we propose to add for CY 2021 are identified by asterisks (*) in the fourth column of Addendum N.

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2021, we propose to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the CY 2021 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2019 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2018. For the proposed CY 2021 OPPS payment rates, we used the set of claims processed during CY 2019. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2019 (the year of claims data we used to calculate the proposed CY 2021 OPPS payment rates) and updates to the NUBC 2019 Data Specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

In accordance with our longstanding policy, we calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since

the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), we finalized our policy of creating new cost centers and distinct CCRs for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals used a less precise "square feet" allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while we recommended using two alternative allocation methods, "direct assignment" or "dollar value," as a more accurate methodology for directly assigning equipment costs, industry analysis suggested that approximately only half of the reported cost centers for CT scans and MRIs rely on these preferred methodologies. In response to concerns from commenters, we finalized a policy for the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847) to remove claims from providers that use a cost allocation method of "square feet" to calculate CCRs used to estimate costs associated with the APCs for CT and MRI. Further, we finalized a transitional policy to estimate the imaging APC relative payment weights using only CT and MRI cost data from providers that do not use "square feet" as the cost allocation statistic. We provided that this finalized policy would sunset in 4 years to provide sufficient time for hospitals to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes (78 FR 74847). Therefore, beginning in CY 2018 with the sunset of the transition policy, we would estimate the imaging APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed. However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228 and 59229) and in the CY 2019 OPPS/ASC final rule with comment period

(83 FR 58831), we finalized a policy to extend the transition policy for 1 additional year and we continued to remove claims from providers that use a cost allocation method of "square feet" to calculate CT and MRI CCRs for the CY 2018 OPPS and the CY 2019 OPPS.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228), some stakeholders have raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed (78 FR 74840 through 74847). Stakeholders noted that providers continue to use the "square feet" cost allocation method and that including claims from such providers would cause significant reductions in the imaging APC payment rates.

Table 1 demonstrates the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using "square feet" as the cost allocation method by extracting HCRIS data on Worksheet B–1. Table 2 provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 1: PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDERS USING "SQUARE FEET" AS THE COST ALLOCATION METHOD

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-2.6%
5522	Level 2 Imaging without Contrast	5.5%
5523	Level 3 Imaging without Contrast	4.1%
5524	Level 4 Imaging without Contrast	5.5%
5571	Level 1 Imaging with Contrast	6.7%
5572	Level 2 Imaging with Contrast	8.3%
5573	Level 3 Imaging with Contrast	2.1%
8005	CT and CTA without Contrast Composite	13.9%
8006	CT and CTA with Contrast Composite	10.9%
8007	MRI and MRA without Contrast Composite	7.0%
8008	MRI and MRA with Contrast Composite	7.3%

TABLE 2: PROPOSED CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0347	0.0491	0.0764	0.1016
Square Feet Only	0.0286	0.0444	0.0665	0.0928
Direct Assign	0.0472	0.0564	0.0935	0.1183
Dollar Value	0.0414	0.0553	0.0858	0.1128
Direct Assign and Dollar Value	0.0415	0.0555	0.0866	0.1131

Our analysis shows that since the CY 2014 OPPS in which we established the transition policy, the number of valid MRI CCRs has increased by 18.5 percent to 2,195 providers and the number of valid CT CCRs has increased by 16.3 percent to 2,275 providers. Table 1 displays the impact on proposed OPPS payment rates for CY 2021 if claims from providers that report using the "square feet" cost allocation method were removed. This can be attributed to the generally lower CCR values from providers that use a "square feet" cost allocation method as shown in Table 1.

We note that the CT and MRI cost center CCRs have been available for ratesetting since the CY 2014 OPPS in which we established the transition policy. Since the initial 4-year transition, we had extended the transition an additional 2 years to offer providers flexibility in applying cost allocation methodologies for CT and MRI cost centers other than "square feet." In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), we finalized a 2-year phased-in approach, as suggested by some commenters, that applied 50 percent of the payment impact from ending the transition in CY 2020 and 100 percent of the payment impact from ending the transition in CY 2021.

We believe we have provided sufficient time for providers to adopt an alternative cost allocation methodology for CT and MRI cost centers if they intended to do so and many providers continue to use the "square feet" cost allocation methodology, which we believe indicates that these providers believe

this methodology is a sufficient method for attributing costs to this cost center. Additionally, we generally believe that increasing the amount of claims data available for use in ratesetting improves our ratesetting process. Therefore, as finalized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), in the CY 2021 OPPS we are using all claims with valid CT and MRI cost center CCRs, including those that use a "square feet" cost allocation method, to estimate costs for the APCs for CT and MRI identified in Table 1.

As noted earlier, the Deficit Reduction Act (DRA) of 2005 requires Medicare to limit Medicare payment for certain imaging services covered by the Physician Fee Schedule (PFS) to not exceed what Medicare pays for these services under the OPPS. As required by law, for certain imaging series paid for under the PFS, we cap the technical component of the PFS payment amount for the applicable year at the OPPS payment amount (71 FR 69659 through 69661). As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74845), we have noted the potential impact the CT and MRI CCRs may have on other payment systems. We understand that payment reductions for imaging services under the OPPS could have significant payment impacts under the PFS where the technical component payment for many imaging services is capped at the OPPS payment amount. We will continue to monitor OPPS imaging payments in the future and consider the potential impacts of payment changes on the PFS and the ASC payment system.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2021. The Hospital OPPS page on the CMS website on which this proposed rule is posted (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the

process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html, includes information about obtaining the "OPPS Limited Data Set," which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD-10-CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2020 claims that were used to calculate the proposed payment rates for this CY 2021 OPPS/ASC proposed rule.

Previously, the OPPS established the scaled relative weights, on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2021, we propose to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2020 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2021 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier "PN", which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier "PN" from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2021 OPPS, we will continue to remove these claim lines with modifier "PN" from the ratesetting process.

For details of the claims accounting process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2021 OPPS/ASC proposed rule on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html

a. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This

methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, to address the differences in CCRs and to better reflect hospitals' costs, we propose to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also propose to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We propose to calculate the costs upon which the proposed CY 2021 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific, CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2021 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that we defined a comprehensive APC (C-APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C-APCs. We propose to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C-APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C-APCs (and, as a result, in the proposed payment rates of the C-APCs), we propose not to make separate payments for blood and blood products when they appear on the same claims as services assigned to the C-APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796)).

We refer readers to Addendum B of this proposed rule (which is available via the Internet on the CMS website) for the proposed CY 2021 payment rates for blood and blood products (which are generally identified with status indicator "R"). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

For CY 2021, we propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology.

(b) Payment for Blood Not Otherwise Classified (NOC) Code

Recently, providers and stakeholders in the blood products field have reported that product development for new blood products has accelerated. There may be several additional new blood products entering the market by the end of CY 2021, compared to only one or two new products entering the market over the previous 15 to 20 years. To encourage providers to use these new products,

providers and stakeholders requested that we establish a new HCPCS code to allow for payment for unclassified blood products prior to these products receiving their own HCPCS code. Under the OPPS, unclassified procedures are generally assigned to the lowest APC payment level of an APC family. However, since blood products are each assigned to their own unique APC, the concept of a lowest APC payment level does not apply in this context.

Starting January 1, 2020, we established a new HCPCS code, P9099 (Blood component or product not otherwise classified) which allows providers to report unclassified blood products. We assigned HCPCS code P9099 to status indicator "E2" (Not payable by Medicare when submitted on an outpatient claim) for CY 2020. We took this action because HCPCS code P9099 potentially could be reported for multiple products with different costs during the same period of time. Therefore, we could not identify an individual blood product HCPCS code that would have a similar cost to HCPCS code P9099, and were not able to crosswalk a payment rate from an established blood product HCPCS code to HCPCS code P9099. Some stakeholders expressed concerns that assigning HCPCS code P9099 to a non-payable status in the OPPS meant that hospitals would receive no payment when they used unclassified blood products. Also, claim lines billed with P9099 are rejected by Medicare, which prevents providers from tracking the utilization of unclassified blood products.

Because of the challenges of determining an appropriate payment rate for unclassified blood products, we are considering packaging the cost of unclassified blood products into their affiliated primary medical procedure. Although we typically do not package blood products under the OPPS, for unclassified blood products, we do not believe it is possible to accurately determine an appropriate rate that would apply for all of the products (potentially several, with varying costs) that may be reported using HCPCS code P9099. Packaging the cost of unclassified blood products into the payment for the primary medical service by assigning HCPCS code P9099 a status indicator of "N" would allow

providers to report the cost of unclassified blood products to Medicare. Over time, the costs of unspecified blood products would be reflected in the payment rate for the primary medical service if the blood product remains unclassified. However, we expect that most blood products would seek and be granted more specific coding such that the unclassified HCPCS code P9099 would no longer be applicable. We believe that packaging the costs of unclassified blood products would be an improvement over the current non-payable status for HCPCS code P9099 as it would allow for tracking of the costs and utilization of unclassified blood products.

Another option we considered, but ultimately rejected is similar to our policy under the OPPS to assign NOC codes to the lowest APC within the appropriate clinical family. We could crosswalk and assign the same payment rate for HCPCS code P9099 as HCPCS code P9043(Infusion, plasma protein fraction (human), 5 percent, 50 ml) , which is the lowest cost blood product with a proposed CY 2021 payment rate of $8.02 per unit. This option would provide a small, separate payment for each unclassified blood product service, and, similar to our proposal to package the costs of HCPCS code P9099 into their primary procedure, would allow for tracking of the cost utilization of unclassified blood products. However, given that the cross-walked payment rate is potentially significantly lower than the cost of the product, providers may find that packaging the cost of unclassified blood products into another medical service may generate more payment for the products over time.

Thus, for CY 2021, we propose to package the cost of unclassified blood products reported by HCPCS code P9099 into the cost of the associated primary procedure. We propose to change the status indicator for HCPCS code P9099 from “E2” (not payable by Medicare in the OPPS) to “N” (payment is packaged into other services in the OPPS). In addition, we also seek comment on the alternative proposal to make HCPCS code P9099 separately payable with a payment rate equivalent to the payment rate for the lowest cost blood product, HCPCS code P9043 (Infusion, plasma protein fraction (human), 5

percent, 50 ml), with a proposed CY 2021 payment rate of $8.02 per unit. If we were to adopt this option as our final policy, we would also change the status indicator for HCPCS code P9099 from "E2" (not payable by Medicare in the OPPS) to "R" (blood and blood products, paid under OPPS).

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2021, except where otherwise indicated, we propose to use the costs derived from CY 2019 claims data to set the proposed CY 2021 payment rates for brachytherapy sources because CY

2019 is the year of data we propose to use to set the proposed payment rates for most other items and services that would be paid under the CY 2021 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter), we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also propose to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110-275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2021 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the Internet on the CMS website) and identified with status indicator “U”.

For CY 2018, we assigned status indicator "U" (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2. For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2018 claims data available for the final CY2020 OPPS/ASC final rule with comment period, included two claims with a geometric mean cost of HCPCS code C2645 of $1.02 per mm^2. In response to comments from stakeholders, we agreed with commenters that given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of 1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020.

For CY 2021, we propose to continue to assign status indicator "U" to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter). For CY 2020, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2019 claims data available for the proposed CY 2021 rule, included one claim with over 4,000 units of HCPCS code C2645. The geometric mean cost of HCPCS code C2645 from this one claim is $1.07 per mm^2 for CY 2019. We do not believe that this one claim is adequate to establish an APC payment rate for HCPCS code C2645 and to discontinue our use of external data for this brachytherapy source. Therefore, for CY 2021, we propose to continue assigning the brachytherapy source described by

HCPCS code C2645 a payment rate of $4.69 mm^2 for CY 2021 through use of our equitable adjustment authority.

We continue to invite hospitals and other parties to submit recommendations to us for new codes to describe new brachytherapy sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C-APCs) for CY 2021

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C-APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C-APC policy (79 FR 66798 through 66810).

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C-APCs to be paid under the existing C-APC payment policy and added 1 additional level to both the Orthopedic Surgery and Vascular Procedures clinical families, which increased the total

number of C-APCs to 37 for CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C-APCs for a total of 62 C-APCs. In the CY 2018 OPPS/ASC final rule with comment period, we did not change the total number of C-APCs from 62. In the CY 2019 OPPS/ASC final rule with comment period, we created 3 new C-APCs, increasing the total number to 65 (83 FR 58844 through 58846).

Under our C-APC policy, we designate a service described by a HCPCS code assigned to a C-APC as the primary service when the service is identified by OPPS status indicator "J1". When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as "adjunctive services") and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C-APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive

services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C-APC policy is included in Addendum J to this proposed rule (which is available via the Internet on the CMS website).

The C-APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C-APCs and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C-APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator "J1", excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator "J1" are assigned to C-APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C-APC payment methodology to qualifying extended assessment and management encounters through the "Comprehensive Observation Services" C–APC (C–APC 8011). Services within this APC are assigned status indicator "J2". Specifically, we make a payment through C–APC 8011 for a claim that:

● Does not contain a procedure described by a HCPCS code to which we have assigned status indicator "T;"

● Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);

● Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

● Does not contain services described by a HCPCS code to which we have assigned status indicator "J1".

The assignment of status indicator "J2" to a specific combination of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C-APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C-APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator "J1" as a single "J1" unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C-APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator "J1" and later used to develop the geometric mean costs for the C-APC relative payment weights. (We note that we use the term "comprehensive" to describe the geometric mean cost of a claim reporting "J1" service(s) or the geometric mean cost of a C-APC, inclusive of all of the items and services included in the C-APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C-APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator "J1" according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator "J1" or units thereof, we identify one "J1" service as the primary

service for the claim based on our cost-based ranking of primary services. We then assign these multiple "J1" procedure claims to the C-APC to which the service designated as the primary service is assigned. If the reported "J1" services on a claim map to different C-APCs, we designate the "J1" service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple "J1" services on a claim map to the same C-APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator "J1" to the most appropriate C-APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired "J1" service code combinations or paired code combinations of "J1" services and certain add-on codes (as described further below) from the originating C-APC (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

● Frequency of 25 or more claims reporting the code combination (frequency threshold); and

● Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of this proposed rule, in the originating C-APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies

for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator "J1" (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C-APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of "J1" services (or combinations of "J1" services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C-APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C-APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be

appropriately reported in combination with a base code that describes a primary "J1" service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2021, we propose to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator "J1" and any number of units of a single add-on code for the primary "J1" service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C-APC within the same clinical family of C-APCs. As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the "J1" primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C-APC. We list the complexity adjustments for "J1" and add-on code combinations for CY 2021, along with all of the other proposed complexity adjustments, in Addendum J to this CY 2021 OPPS/ASC proposed rule (which is available via the Internet on the CMS website).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and are proposed to be reassigned to the next higher cost C-APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an

alphanumeric code with the first 4 digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C-APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that are proposed to be reassigned to C-APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed reassignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Exclusion of Procedures Assigned to New Technology APCs from the C-APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for the procedures. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C-APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator "J1", payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the

New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there is sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a "J1" service assigned to a C-APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that payment for services assigned to a New Technology APC procedures would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator "J2" when they are included on a claim with a "J2" service starting in CY 2020 (84 FR 61167).

(3) Additional C-APCs for CY 2021

For CY 2021 and subsequent years, we propose to continue to apply the C-APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C-APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are not proposing to convert any conventional APCs to C-APCs in CY 2021. However, as discussed in section III.D.7, we propose to create an additional level for Urology and Related Services C-APCs and, as discussed in section III.D.1, we propose to create an additional level for Neurostimulator and Related Procedures C-APCs Table 3 lists the proposed C-APCs for CY 2021, all of which were established in past rules. All C-APCs are displayed in Addendum J to this proposed rule (which is available via the Internet on the CMS website).

Addendum J to this proposed rule also contains all of the data related to the C-APC payment policy methodology, including the list of complexity adjustments and other information.

TABLE 3: CY 2021 C-APCs

C-APC	CY 2021 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	

C-APC	CY 2021 APC Group Title	Clinical Family	New C-APC
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	*
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	*
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures

INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

c. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. (We note that, in the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to delete the composite APC 8001 (LDR Prostate Brachytherapy Composite) for CY 2018 and subsequent years.) We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period

(76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

We propose to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79588 through 79589), we finalized a policy to combine the existing Level 1 and Level 2 hospital-based PHP APCs into a single hospital-based PHP APC, and thereby discontinue APCs 5861 (Level 1 - Partial Hospitalization (3 services) for Hospital-Based PHPs) and 5862 (Level - 2 Partial Hospitalization (4 or more services) for Hospital-Based PHPs) and replace them with APC 5863 (Partial Hospitalization (3 or more services per day)).

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate

for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE will continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We propose that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2021. In addition, we propose to set the proposed payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

We propose that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2021.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the "with contrast" composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at

least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the "with contrast" composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2021, we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2021 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2019 claims available for this CY 2021 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we have used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as "overlap bypass codes" that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2021 OPPS/ASC

proposed rule (which is available via the Internet on the CMS website) and are discussed in more detail in section II.A.1.b. of this CY 2021 OPPS/ASC proposed rule.

For this CY 2021 OPPS/ASC proposed rule, we were able to identify approximately 964,000 "single session" claims out of an estimated 4.9 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 14 percent of all eligible claims, to calculate the proposed CY 2021 geometric mean costs for the multiple imaging composite APCs. Table 4 of this CY 2021 OPPS/ASC proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2021.

Table 4 lists the HCPCS codes that we propose would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2021.

TABLE 4: PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2021 APC 8004 (Ultrasound Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $291.56**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2021 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $220.54**
70450	Ct head/brain w/o dye

70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2021 APC 8006 (CT and CTA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $425.30**
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye

73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2021 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $515.21**
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis

C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2021 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $828.42**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni

C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854), and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all

services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2021, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and outpatient hospital billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In CY 2021, we propose no changes to this policy. We will continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss the proposed changes to the packaging policies in CY 2021.

b. Packaging Policy for Non-Opioid Pain Management Treatments

(1) Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we requested stakeholder feedback on common clinical scenarios involving currently packaged items and services described by HCPCS codes that stakeholders believe should not be packaged under the OPPS. We also expressed interest in stakeholder feedback on common clinical

scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. Commenters who responded to the CY 2018 OPPS/ASC proposed rule expressed a variety of views on packaging under the OPPS. The public comments ranged from requests to unpackage most items and services that are unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52485), we reiterated our position with regard to payment for Exparel®, a non-opioid analgesic that functions as a surgical supply, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. We also stated in the CY 2018 OPPS/ASC final rule with comment period that we would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855 through 58860), we finalized a policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019 due to decreased utilization in the ASC setting.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. We used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies have reduced the use of non-opioid alternatives. For the

CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, the only drug that meets these criteria is Exparel.

(2) Evaluation and CY 2021 Proposal for Payment for Non-Opioid Alternatives

Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered OPD services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services)

assigned to C-APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Any revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B), which requires any adjustments to be made in a budget neutral manner.

As noted in the background section above, we conducted an evaluation to determine whether there are payment incentives for using opioids instead of non-opioid alternatives in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 through 61180). The results of our review and evaluation of our claims data did not provide evidence to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Higher utilization may be a potential indicator that the packaged payment is not causing an access to care issue and that the payment rate for the primary procedure adequately reflects the cost of the drug. Our updated review of claims data showed a continued decline in the utilization of Exparel® in the ASC setting, which supported our proposal to continue paying separately for Exparel® in the ASC setting. Decreased utilization could potentially indicate that the packaging policy is discouraging use of that treatment and that providers are choosing less expensive treatments. However, it is difficult to attribute causality of changes in utilization to Medicare packaging payment policy only. We believe that unpackaging and paying separately for Exparel addresses decreased utilization because it eliminates any potential Medicare payment disincentive for the use of this non-opioid alternative, rather than prescription opioids.

We believe we fulfilled the statutory requirement to review payments for opioids and evidence-based non-opioid alternatives to ensure that there are not financial incentives to use opioids instead of

non-opioid alternatives in CY 2020 OPPS/ASC rulemaking. We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. However, we do not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system.

Therefore, for CY 2021, we propose to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021.

c. Clinical Diagnostic Laboratory Tests Packaging Policy

(1) Background

Prior to CY 2014, clinical diagnostic laboratory tests were excluded from payment under the hospital OPPS because they were paid separately under the Clinical Laboratory Fee Schedule (CLFS). Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. Under this authority, the Secretary excluded from the OPPS those services that are paid under fee schedules or other payment systems. Because laboratory services are paid separately under the CLFS, laboratory tests were excluded from separate payment under the OPPS. We codified this policy at 42 CFR 419.22(l).

However, in CY 2014, we revised the categories of packaged items and services under the OPPS to include certain laboratory tests. We stated that certain laboratory tests, similar to other covered outpatient services that are packaged under the OPPS, are typically integral, ancillary, supportive, dependent, or adjunctive to a primary hospital outpatient service and should be packaged under the hospital OPPS. We stated that laboratory tests and their results support clinical decision making for a

broad spectrum of primary services provided in the hospital outpatient setting, including surgery and diagnostic evaluations (78 FR 74939). Consequently, we finalized the policy to package payment for most laboratory tests in the OPPS when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17)). In the same final rule, we clarified that certain laboratory tests would be excluded from packaging. Specifically, we stated that laboratory tests would be paid separately under the CLFS when the laboratory test is the only service provided to a beneficiary or when a laboratory test is conducted on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service or when the laboratory test is a molecular pathology test (78 FR 74942). As explained in the CY 2014 OPPS/ASC final rule, we excluded molecular pathology tests from packaging because we believe these tests are relatively new and may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we package (78 FR 74939). Based on these changes, we revised the regulation text at § 419.2(b) and § 419.22(l) to reflect this laboratory test packaging policy.

In CY 2016, we made some modifications to this policy (80 FR 70348 through 70350). First, we clarified that all molecular pathology tests would be excluded from our packaging policy, including any new codes that also describe molecular pathology tests. In the CY 2014 OPPS/ASC final rule, we stated that only those molecular pathology codes described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 were excluded from OPPS packaging (78 FR 74939 through 74942). However, in 2016, we expanded this policy to include not only the original code range but also all new molecular pathology test codes (80 FR 70348). Secondly, we excluded preventive laboratory tests from OPPS packaging and provided that they would be paid separately under the CLFS.

Laboratory tests that are considered preventive are listed in Section 1.2, Chapter 18 of the Medicare Claims Processing Manual (Pub. 100– 04). As stated in the CY 2016 OPPS/ASC final rule, we make an exception to conditional packaging of ancillary services for ancillary services that are also preventive services (80 FR 70348). For consistency, we excluded from OPPS packaging those laboratory tests that are classified as preventive services. In addition, we modified our conditional packaging policy so that laboratory tests provided during the same outpatient stay (rather than specifically provided on a same date of service as the primary service) are considered as integral, ancillary, supportive, dependent, or adjunctive to a primary service or services, except when a laboratory test is ordered for a different diagnosis and by a different practitioner than the practitioner who ordered the other hospital outpatient services. We explained in the CY 2016 OPPS/ASC final rule that this modification did not affect our policy to provide separate payment for laboratory tests: (1) If they are the only services furnished to an outpatient and are the only services on a claim and have a payment rate on the CLFS; or (2) if they are ordered for a different diagnosis than another hospital outpatient service by a practitioner different than the practitioner who ordered the other hospital outpatient service (80 FR 70349 through 70350).

In CY 2017, we modified the policy to remove the "unrelated" laboratory test exclusion and to expand the laboratory test packaging exclusion to apply to laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) under the CLFS. We clarified that the exception would only apply to those ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act, which are defined as tests that provide an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result (81 FR 79592-79594).

(2) Current Categories of Clinical Diagnostic Laboratory Tests Excluded from OPPS Packaging

Under our current policy, certain clinical diagnostic laboratory tests (CDLTs) that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or

services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. While we package most CDLTs under the OPPS, when a CDLT is listed on the CLFS and meets one of the following four criteria, we do not pay for the test under the OPPS, but rather, we pay for it under the CLFS when it is: (1) the only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act. Generally, when laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid under the CLFS instead of the OPPS.

(3) Proposed New Category of Laboratory Tests Excluded from OPPS Packaging

(a) Background on Protein-Based MAAAs

As part of recent rulemaking cycles, stakeholders have suggested that some protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) may have a pattern of clinical use that makes them relatively unconnected to the primary hospital outpatient service (84 FR 61439). In the CY 2018 OPPS/ASC final rule (82 FR 59299), we stated that stakeholders indicated that certain protein-based MAAAs, specifically those described by CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, are generally not performed in the HOPD setting and have similar clinical patterns of use as the DNA and RNA-based MAAA tests that are assigned to status indicator "A" under the OPPS and are paid separately under the CLFS. Notably, all of the tests described by these CPT codes (with the exception of CPT code 81490, which we discuss below) are cancer-related protein-based MAAAs. In the same final rule, stakeholders suggested that, based on the June 23, 2016 CLFS final rule entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' in which CMS defined an ADLT under section 1834A(d)(5)(A) of the Act to include DNA, RNA, and protein-based tests, they believe that the reference to "protein-based tests" in the definition applies equally to the tests they

identified, that is, protein-based MAAAs. Consequently, the stakeholders believed that protein-based MAAAs should be excluded from OPPS packaging and paid separately under the CLFS. We note that one of the protein-based MAAAs previously requested by stakeholders to be excluded from OPPS packaging policy is CPT code 81538 (Oncology (lung), mass spectrometric 8-protein signature, including amyloid a, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival), which has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018. Therefore, CPT code 81538 is currently excluded from the OPPS packaging policy and paid under the CLFS instead of the OPPS when it also meets the laboratory DOS requirements.

(b) CY 2021 Proposal for Cancer-Related Protein-Based MAAAs

Since publishing the CY 2020 OPPS/ASC final rule, we have continued to consider previous stakeholder requests to exclude some protein-based MAAAs from the OPPS packaging policy. After further review of this issue, we believe that cancer-related protein-based MAAAs, in particular, may be relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient. Similar to molecular pathology tests, which are currently excluded from the OPPS packaging policy, cancer-related protein-based MAAAs appear to have a different pattern of clinical use, which may make them generally less tied to the primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

As we noted above, commenters to the CY 2018 OPPS/ASC final rule identified specific cancer-related protein-based MAAAs as tests that are generally not performed in the HOPD setting (82 FR 59299). In fact, those tests identified by commenters are used to guide future surgical procedures and chemotherapeutic interventions. Treatments that are based on the results of cancer-related protein-based MAAAs are typically furnished after the patient is no longer in the hospital, in which case they are not tied to the same hospital outpatient encounter during which the specimen was collected.

For these reasons, we propose to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and pay for them separately under the CLFS.

The AMA CPT 2020 manual currently describes MAAAs, in part, as "procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (for example, proteins, polypeptides, lipids, carbohydrates)."[1] The code descriptors of MAAAs include several specifics, including but not limited to disease type (for example, oncology, autoimmune, tissue rejection), and material(s) analyzed (for example, DNA, RNA, protein, antibody). As the AMA CPT 2020 manual describes a MAAA, and the code descriptor of each MAAA distinguishes MAAAs that are cancer-related assays from those that test for other disease types, the AMA CPT manual is a useful tool to identify cancer-related MAAAs that are "protein-based". Accordingly, using the AMA CPT 2020 manual criteria to identify a MAAA that is cancer-related, and, of those tests, identifying the ones whose analytes test proteins, we have determined there are currently six cancer-related protein-based MAAAs: CPT codes 81500, 81503, 81535, 81536, 81538 and 81539. As discussed previously in this section, CPT code 81538 has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018 and therefore, is already paid under the CLFS instead of the OPPS when it meets the laboratory DOS requirements. As such, we propose to assign status indicator "A" ("Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS") to cancer-related protein-based MAAAs as described by CPT codes 81500, 81503, 81535, 81536, and 81539. We would apply this policy to cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future.

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[1] *Current Procedure Terminology* (CPT®) page 586, copyright 2020 American Medical Association. All Rights Reserved.

We note that commenters to the CY 2018 OPPS/ASC final rule also identified CPT code 81490 as a protein-based MAAA that should be excluded from the OPPS packaging policy and paid outside of the OPPS. However, the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we believe that payment for CPT code 81490 remains appropriately packaged under the OPPS.

We refer readers to section XVIII. of this proposed rule regarding our proposed revision to the laboratory date of service policy for cancer-related protein-based MAAAs.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61180 through 61182), we applied this policy and calculated the relative payment weights for each APC for CY 2020 that were shown in Addenda A and B to that final rule with comment period (which were made available via the Internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of that final rule with comment period. For CY 2021, as we did for CY 2020, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2021 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient),

representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2021, as we did for CY 2020, we propose to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2021, as we did for CY 2020, we propose to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61365 through 61369), we discuss our policy, implemented on January 1, 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based department (PBD) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible

effect on the scalar. Specifically, under this policy, there is no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. We note that the volume control method for clinic visit services furnished by non-excepted off-campus PBDs is subject to litigation. For a full discussion of this policy and the litigation, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2021 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2020 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2021 unscaled relative payment weights.

For CY 2020, we multiplied the CY 2020 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2019 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2021, we propose to apply the same process using the estimated CY 2021 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2020 estimated aggregate weight by the unscaled CY 2021 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. Click on the CY 2021 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

We propose to compare the estimated unscaled relative payment weights in CY 2021 to the estimated total relative payment weights in CY 2020 using CY 2019 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2021 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2021 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4443 to ensure that the proposed CY 2021 relative payment weights are scaled to be budget neutral. The proposed CY 2021 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of proposed rule) is included in the budget neutrality calculations for the CY 2021 OPPS.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule

increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32738), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2019 forecast of the FY 2021 market basket increase, the proposed FY 2021 IPPS market basket update was 3.0 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), provide adjustments to the OPD fee schedule increase factor for CY 2021.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "MFP adjustment"). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). According to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32739), the proposed MFP adjustment for FY 2021 was 0.4 percentage point.

Therefore, we propose that the MFP adjustment for the CY 2021 OPPS is 0.4 percentage point. We also propose that if more recent data become subsequently available after the publication of this

proposed rule (for example, a more recent estimate of the market basket increase and/or the MFP adjustment), we will use such updated data, if appropriate, to determine the CY 2021 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2021 OPPS/ASC final rule.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2021 an OPD fee schedule increase factor of 2.6 percent for the CY 2021 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.4 percentage point MFP adjustment).

We propose that hospitals that fail to meet the Hospital OQR Program reporting requirements would be subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIV. of the proposed rule.

The adjustment described in section 1833(t)(3)(F)(ii) was required only through 2019. The requirement in section 1833(t)(3)(F)(i) of the Act that we reduce the OPD fee schedule increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II), however, applies for 2012 and subsequent years, and thus, continues to apply. In the CY 2020 OPPS/ASC final rule with comment period, we inadvertently did not amend the regulation at 42 CFR 419.32(b)(1)(iv)(B) to reflect that the adjustment required by section 1833(t)(3)(F)(i) of the Act is the only adjustment under section 1833(t)(3)(F) that applies in CY 2020 and subsequent years. Accordingly, we propose to amend our

regulation at 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (b)(1)(iv)(B)(11) to provide that, for CY 2020 and subsequent years, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS.

To set the OPPS conversion factor for CY 2021, we propose to increase the CY 2020 conversion factor of $80.793 by 2.6 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose further to adjust the conversion factor for CY 2021 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 1.0017 for wage index changes. This adjustment was comprised of a 1.0027 proposed budget neutrality adjustment, using our standard calculation, of comparing proposed total estimated payments from our simulation model using the proposed FY 2021 IPPS wage indexes to those payments using the FY 2020 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9990 proposed budget neutrality adjustment for the proposed CY 2021 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner, consistent with the proposed FY 2021 IPPS wage index policy (85 FR 32706). We believe it is appropriate to ensure that this proposed wage index transition policy (that is, the proposed CY 2021 5 percent cap on wage index decreases) does not increase estimated aggregate payments under the OPPS beyond the payments that would be made without this transition policy. We propose to calculate this budget neutrality adjustment by comparing total estimated OPPS payments using the FY 2021 IPPS wage index, adopted on a calendar year basis for the OPPS, where a 5 percent cap on wage index decreases is not applied to total estimated OPPS payments where the 5 percent cap on wage index decreases is applied. These two proposed wage index budget neutrality adjustments would maintain budget neutrality for the proposed CY 2021 OPPS wage index (which, as we discuss in section II.C of the proposed rule, would use the FY 2021 IPPS post-reclassified wage index and any adjustments,

including without limitation any adjustments finalized under the IPPS related to the proposed adoption of the revised OMB delineations).

For the CY 2021 OPPS, we are maintaining the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We propose to calculate a CY 2021 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2021 payments under section 1833(t) of the Act, including the proposed CY 2021 cancer hospital payment adjustment, to estimated CY 2021 total payments using the CY 2020 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2021 estimated payments applying the proposed CY 2021 cancer hospital payment adjustment were the same as estimated payments applying the CY 2020 final cancer hospital payment adjustment. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 16002(b) of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we applied as stated in section II.F. of the proposed rule.

For this CY 2021 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2021 would equal approximately $783.2 million, which represented 0.93 percent of total projected CY 2021 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.88 percent estimate of pass-through

spending for CY 2020 and the 0.93 percent estimate of proposed pass-through spending for CY 2021, resulting in a proposed decrease to the conversion factor for CY 2021 of 0.05 percent.

We also estimate a 0.85 percent upward adjustment to nondrug OPPS payment rates as a result of our payment proposal for separately payable nonpass-through drugs purchased under the 340B Program. Applying the proposed payment policy for drugs purchased under the 340B Program, as described in section V.B.6. of this proposed rule, results in an estimated reduction of approximately $427 million in separately paid OPPS drug payments. To ensure budget neutrality under the OPPS after applying this proposed payment methodology for drugs purchased under the 340B Program, we propose to apply an offset of approximately $427 million to the OPPS conversion factor, which would result in an adjustment of 1.0085 to the OPPS conversion factor.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2021. We estimate for the proposed rule that outlier payments would be 1.01 percent of total OPPS payments in CY 2020; the 1.00 percent for proposed outlier payments in CY 2021 would constitute a 0.01 percent decrease in payment in CY 2021 relative to CY 2020.

For this CY 2021 OPPS/ASC proposed rule, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we propose to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.6 percent (that is, the proposed OPD fee schedule increase factor of 2.6 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2021 of $82.065 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of –1.632 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2021, we propose to amend § 419.32 by adding a new paragraph (b)(1)(iv)(B)(*11*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2020, CY 2021, and subsequent years to satisfy the statutory requirements of section 1833(t)(3)(F) of the Act. We propose to use a reduced conversion factor of $82.065 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of –1.632 in the conversion factor relative to hospitals that met the requirements).

For CY 2021, we propose to use a conversion factor of $83.697 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.6 percent for CY 2021, the required proposed wage index budget neutrality adjustment of approximately 1.0017, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.05 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2021 of $83.697.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment

adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2021 OPPS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (which is available via the Internet on the CMS website), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2021 pre-reclassified wage index that we would use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier

State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2021, we propose to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, we stated that the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2020 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of "frontier States" as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; and for FY 2020, 84 FR 42312.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2021 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. We refer readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) for a detailed discussion of all proposed changes to the FY 2021 IPPS wage indexes.

Furthermore, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and in each subsequent IPPS/LTCH PPS final rule, including the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes, such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13-01). This bulletin can be found at: https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), for purposes of the IPPS, we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13-01, effective October 1, 2014. For purposes of the OPPS, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66826 through 66828), we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13-01, effective January 1, 2015, beginning with the CY 2015 OPPS wage indexes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted revisions to statistical areas contained in OMB Bulletin No. 15-01, issued on July 15, 2015, which provided updates to and superseded OMB Bulletin No. 13-01 that was issued on February 28, 2013. For purposes of the OPPS, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79598), we adopted the revisions to the OMB statistical area delineations contained in OMB Bulletin No. 15-01, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes.

On August 15, 2017, OMB issued OMB Bulletin No. 17-01, which provided updates to and superseded OMB Bulletin No. 15-01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17-01 provided detailed information on the update to the statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and

Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58863 through 58865), we adopted the updates set forth in OMB Bulletin No. 17-01, effective January 1, 2019, beginning with the CY 2019 wage index.

On April 10, 2018 OMB issued OMB Bulletin No. 18-03 which superseded the August 15, 2017 OMB Bulletin No. 17-01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18-03. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However, as we stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32696 through 32697), the April 10, 2018 OMB Bulletin No. 18-03 and the September 14, 2018 OMB Bulletin No. 18-04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses, including some material modifications that have a number of downstream effects, such as IPPS hospital reclassification changes. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at https://www.whitehouse.gov/wpcontent/uploads/2018/09/Bulletin-18-04.pdf. According to OMB, "[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 (75 FR 37246), and Census Bureau data."

As noted previously, while OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations. Specifically, under the revised OMB delineations, there would be some new CBSAs, urban counties that would become rural, rural counties

that would become urban, and some existing CBSAs would be split apart. In addition, we stated in the FY 2021 IPPS/LTCH PPS proposed rule that the revised OMB delineations would affect various hospital reclassifications, the outmigration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ‘‘Lugar’’ hospitals) under section 1886(d)(8)(B) of the Act. We refer readers to the FY 2021 IPPS/LTCH PPS proposed rule for a complete discussion of the revised OMB delineations we propose to adopt under the IPPS and the effects of these revisions on the FY 2021 IPPS wage indexes (85 FR 32696 through 32707, 32717 through 32728). We stated in the FY 2021 IPPS/LTCH PPS proposed rule that we believe using the revised delineations based on OMB Bulletin No. 18–04 would increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. In addition, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to apply a 5 percent cap for FY 2021 on any decrease in a hospital's final wage index from the hospital's final wage index for FY 2020 as a proposed transition wage index to help mitigate any significant negative impacts of adopting the revised OMB delineations (85 FR 32706 through 32707).

As further discussed below, in this CY 2021 OPPS proposed rule, we propose to adopt these updated OMB delineations and related IPPS wage index adjustments to calculate the CY 2021 OPPS wage indexes. Similar to our discussion in the FY 2021 IPPS/LTCH PPS proposed rule, we believe using the revised delineations based on OMB Bulletin No. 18–04 would increase the integrity of the OPPS wage index system by creating a more accurate representation of geographic variations in wage levels.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: https://www.census.gov/geo/reference/county-changes.html (which, as of May 6, 2019, migrated to: https://www.census.gov/programs-surveys/geography.html). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2021, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2021 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2021. Therefore, any adjustments for the FY 2021 IPPS post-reclassified wage index, including, but not limited to, any adjustments that we may finalize related to the proposed adoption of the revised OMB delineations (such as a cap on wage index decreases and

revisions to hospital reclassifications), would be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. (We refer readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) and the proposed FY 2021 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2021 OPPS wage index, we refer readers to section II.B. of this CY 2021 OPPS/ASC proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In this CY 2021 OPPS/ASC proposed rule, we propose to continue this policy for CY 2021, and are including a brief summary of the major proposed FY 2021 IPPS wage index policies and adjustments that we propose to apply to these hospitals under the OPPS for CY 2021, which we have summarized below. We refer readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) for a detailed discussion of the proposed changes to the FY 2021 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that applies if the hospital were paid under the IPPS. For

CY 2021, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, the wage index that would apply for CY 2021 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and adjustments to the wage index finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities (84 FR 42325 through 42336). In addition, we propose that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include any adjustments we may finalize for the FY 2021 IPPS post-reclassified wage index related to the adoption of the revised OMB delineations, as discussed earlier in this proposed rule.

For CMHCs, for CY 2021, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. We also propose that the wage index that would apply to CMHCs would include any adjustments we may finalize for the FY 2021 IPPS post-reclassified wage index related to the adoption of the revised OMB delineations, as discussed earlier in this proposed rule In addition, we propose that the wage index that would apply to CMHCs for CY 2021 would continue to include the rural floor adjustment and adjustments to the wage index finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities. Also, we propose that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

Table 4 associated with the FY 2021 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2021 IPPS/ LTCH PPS proposed rule (available for download via the website above) identifies IPPS hospitals that would receive the out-migration

adjustment for FY 2021. We are including the outmigration adjustment information from Table 2 associated with the FY 2021 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this CY 2021 OPPS/ASC proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index. At this link, readers will find a link to the proposed FY 2021 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100-04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers

to the CY 2021 OPPS proposed rule Claims Accounting Narrative that is posted on our website. We propose to update the default ratios for CY 2021 using the most recent cost report data. We will update these ratios in the final rule with comment period if more recent cost report data are available.

We are no longer publishing a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html; click on the link on the left of the page titled "Hospital Outpatient Regulations and Notices" and then select the relevant regulation to download the statewide CCRs and upper limit in the downloads section of the webpage.

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) under Section 1833(t)(13)(B) of the Act for CY 2021

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs,

and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Pub. L. 105-33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2019. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For CY 2021, we propose to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2021

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress established section 1833(t)(7) of the Act, "Transitional Adjustment to Limit Decline in Payment," to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as "held harmless").

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a "pre-BBA amount." That is, cancer hospitals are permanently held harmless to their "pre-BBA amount," and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The "pre-BBA amount" is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The "pre-BBA amount" and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS,

outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the "target PCR") for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for

purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR was 0.90. For CY 2015, the target PCR was 0.90. For CY 2016, the target PCR was 0.92, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363). For CY 2017, the target PCR was 0.91, as discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79603 through 79604). For CY 2018, the target PCR was 0.88, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59265 through 59266). For CY 2019, the target PCR was 0.88, as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58871 through 58873). For CY 2020, the target PCR was 0.89, as discussed in the CY 2020 OPPS/ASC final rule with comment period (83 FR 61190 through 61192).

2. Proposed Policy for CY 2021

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114-255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals, using the most recent submitted or settled cost report data that were available at the time of the

development of the proposed rule, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act.

We are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2021. To calculate the proposed CY 2021 target PCR, we are using the same extract of cost report data from HCRIS, as discussed in section II.A. of this CY 2021 OPPS/ASC proposed rule and proposed rule, used to estimate costs for the CY 2021 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2019 claims data that we used to model the impact of the proposed CY 2021 APC relative payment weights (3,527 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2021 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2014 to 2019. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,464 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimate that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, after applying the 1.0 percentage point reduction, as

required by section 16002(b) of the 21st Century Cures Act, we propose that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.89 for each cancer hospital.

Table 5 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2021, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2021 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2021 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 5: ESTIMATED CY 2021 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2021 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	32.8%
050660	USC Norris Cancer Hospital	11.2%
100079	Sylvester Comprehensive Cancer Center	12.8%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.5%
220162	Dana-Farber Cancer Institute	35.8%
330154	Memorial Sloan-Kettering Cancer Center	39.4%
330354	Roswell Park Cancer Institute	13.6%
360242	James Cancer Hospital & Solove Research Institute	12.7%
390196	Fox Chase Cancer Center	10.4%
450076	M.D. Anderson Cancer Center	41.9%
500138	Seattle Cancer Care Alliance	44.8%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2020, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $5,075 (the fixed-dollar amount threshold) (84 FR 61192 through 61194). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2019 OPPS payments, using CY 2019 claims available for this CY 2021 OPPS/ASC proposed rule is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2019, we estimated that we paid the outlier target of 1.0 percent of total aggregated OPPS payments.

Using an updated claims dataset for this CY 2021 OPPS/ASC proposed rule, we estimate that we paid approximately 1.01 percent of the total aggregated OPPS payments in outliers for CY 2019.

For this CY 2021 OPPS/ASC proposed rule, using CY 2019 claims data and CY 2020 payment rates, we estimated that the aggregate outlier payments for CY 2020 would be approximately 1.01 percent of the total CY 2020 OPPS payments. We provided estimated CY 2021 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts - Provider-Specific Data file on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

2. Outlier Calculation for CY 2021

For CY 2021, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.C. of this CY 2021 OPPS/ASC proposed rule, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this CY 2021 OPPS/ASC proposed rule and proposed rule.

To ensure that the estimated CY 2021 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be

set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $5,300.

We calculated the proposed fixed-dollar threshold of $5,300 using the standard methodology most recently used for CY 2020 (84 FR 61192 through 61194). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2019 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2021 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2019 claims using the same inflation factor of 1.131096 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32098). We used an inflation factor of 1.06353 to estimate CY 2020 charges from the CY 2019 charges reported on CY 2019 claims. The methodology for determining this charge inflation factor is discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR inflation adjustment factor that we propose to apply for the FY 2021 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2021 OPPS outlier payments to determine the fixed-dollar threshold.

Specifically, for CY 2021, we propose to apply an adjustment factor of 0.975271 to the CCRs that were in the April 2020 OPSF to trend them forward from CY 2020 to CY 2021. The methodology for calculating the proposed adjustment is discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32098).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2020 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.976271 to approximate CY 2021 CCRs) to charges on CY 2019 claims that were adjusted (using the proposed charge inflation factor of 1.131096 to approximate CY 2021 charges). We simulated aggregated CY 2021 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2021 OPPS payments. We estimated that a proposed fixed-dollar threshold of $5,300, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in

reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, as we proposed, we are continuing the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIV. of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2021 OPPS/ASC proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS website) was calculated by multiplying the proposed CY 2021 scaled weight for the APC by the CY 2021 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results

in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

Below we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: "J1", "J2", "P", "Q1", "Q2", "Q3", "Q4", "R", "S", "T", "U", or "V" (as defined in Addendum D1 to the proposed rule, which is available via the Internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of "Q1" and "Q2") qualify for separate payment. We noted that, although blood and blood products with status indicator "R" and brachytherapy sources with status indicator "U" are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to the proposed rule (which are available via the Internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the "full" national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the "reduced" national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the

reporting ratio of 0.9805 times the "full" national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2021 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, for the CY 2021 OPPS wage index, we propose to adopt the updated OMB delineations based on OMB Bulletin No. 18-04 and any related IPPS wage index adjustments that may be finalized in the FY 2021 IPPS/LTCH PPS final rule, as discussed in section II.C. of this proposed rule. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2021 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) "Lugar" hospitals, and reclassifications under section

1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We also propose to continue to apply for the CY 2021 OPPS wage index any other adjustments for the FY 2021 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we propose to apply for the CY 2021 OPPS, we refer readers to section II.C. of this proposed rule.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108-173. Addendum L to this proposed rule (which is available via the Internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2021 IPPS, which are listed in Table 2 associated with the FY 2021 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. (Click on the link on the left side of the screen titled "FY 2021 IPPS Proposed Rule Home Page" and select "FY 2021 Proposed Rule Tables.") This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2021 full national unadjusted

payment rate for APC 5071 is $634.92. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $622.54. This reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

The proposed FY 2021 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2021 wage index policies, is 1.3376. The labor-related portion of the proposed full national unadjusted payment is approximately $509.56 (.60 * $634.92 * 1.3376). The labor-related portion of the proposed reduced national unadjusted payment is approximately $499.62 (.60 * $622.54 * 1.3376). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $253.97 (.40 * $634.92). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $249.02 (.40 * $622.54). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $763.53 ($509.56 + $253.97). The sum of the portions of the proposed reduced national adjusted payment is approximately $748.64 ($499.62 + $249.02).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the

Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2021, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment

amounts for services payable under the OPPS that would be effective January 1, 2021 are included in Addenda A and B to the proposed rule (which are available via the Internet on the CMS website).

As discussed in section XIV.E. of this proposed rule, for CY 2021, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.

- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or greater than the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is less than the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.

- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in

general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $126.99 is approximately 20 percent of the full national unadjusted payment rate of $634.92. For APCs with only a minimum unadjusted copayment in Addenda A and B to proposed rule (which are available via the Internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of proposed

rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B*.

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B*.

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The proposed unadjusted copayments for services payable under the OPPS that will be effective January 1, 2021, are shown in Addenda A and B to proposed rule (which are available via the Internet on the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the CY 2021 OPD fee schedule increase factor discussed in section II.B. of proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and consists of Category I, II, and III CPT codes. Level II, which is maintained by CMS, is a standardized coding system that is used primarily to identify products,

supplies, and services not included in the CPT codes. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alphanumeric codes), which are used primarily to identify drugs, devices, ambulance services, durable medical equipment, orthotics, prosthetics, supplies, temporary surgical procedures, and medical services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) while the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes and makes the codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the

annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes and finalize our proposals through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. Those items, procedures, or services not paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI. of this proposed rule (Proposed CY 2021 OPPS Payment Status and Comment Indicators), we discuss the various status indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this CY 2021 OPPS/ASC proposed rule.

1. April 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2020 update, 13 new HCPCS codes were established and made effective on April 1, 2020. These codes and their long descriptors are listed in Table 6. Through the April 2020 OPPS quarterly update CR (Transmittal 10013, Change Request 11691, dated March 25, 2020), we recognized several new HCPCS codes for separate payment under the OPPS. In this CY 2021 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed Table 6. The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. These new codes that are effective April 1, 2020 are assigned to comment indicator "NP" in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the complete list of comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule.

We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the Internet on the CMS website.

TABLE 6: NEW HCPCS CODES EFFECTIVE APRIL 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
C9053*	Injection, crizanlizumab-tmca, 1 mg	CH	G	9342
C9056**	Injection, givosiran, 0.5 mg	CH	G	9343
C9057#	Injection, cetirizine hydrochloride, 1 mg	CH	G	9344
C9058##	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	CH	G	9345
0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas	NP	E1	N/A
0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	NP	Q4	N/A
0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy	NP	Q4	N/A
0166U	Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	NP	Q4	N/A
0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood	NP	Q4	N/A
0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	NP	Q4	N/A
0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	NP	A	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis	NP	A	N/A
0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	NP	A	N/A

*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.

**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.

#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.

##HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.

2. July 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the July 2020 update, over 100 new codes were established and made effective July 1, 2020. The codes and long descriptors are listed in Table 7. Through the July 2020 OPPS quarterly update CR (Transmittal10207, Change Request 11814, dated July 2, 2020), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In this CY 2021 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes implemented on July 1, 2020, all of which are listed in Table 7. The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. These new codes that are effective July 1, 2020 are assigned to comment indicator "NP" in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the complete list of comment indicators and definitions used

under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the Internet on the CMS website.

TABLE 7: NEW HCPCS CODES EFFECTIVE JULY 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	NP	H	2029
C1849	Skin substitute, synthetic, resorbable, per square centimeter	NP	N	N/A
C9059	Injection, meloxicam, 1 mg	NP	G	9371
C9061	Injection, teprotumumab-trbw, 10 mg	NP	G	9355
C9063	Injection, eptinezumab-jjmr, 1 mg	NP	G	9357
C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	NP	G	9346
C9759	Transcatheter intraoperative blood vessel microinfusion(s) (for example, intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	NP	N	N/A
C9760	Non-randomized, non-blinded procedure for NYHA Class II, III, IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	NP	T	1589
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	NP	Q3	5524
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	NP	Q3	5524
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	NP	J1	5192
C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular	NP	J1	5193

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
	lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed			
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	J1	5193
C9767	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	J1	5194
G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (for example, transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	NP	J1	5193
G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (for example, vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	NP	J1	5194
J0223	Injection, givosiran, 0.5 mg	NP	G	9343
J0591	Injection, deoxycholic acid, 1 mg	NP	E1	N/A
J0691	Injection, lefamulin, 1 mg	NP	G	9332
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	NP	G	9362
J0791	Injection, crizanlizumab-tmca, 5 mg	NP	G	9359
J0896	Injection, luspatercept-aamt, 0.25 mg	NP	G	9347
J1201	Injection, Cetirizine hydrochloride, 0.5 mg	NP	G	9361
J1429	Injection, golodirsen, 10 mg	NP	G	9356
J1558	Injection, immune globulin (Xembify), 100 mg	NP	K	9372
J3399	Injection, Onasemnogene abeparvovec-xioi, per treatment, up to 5x1015 vector genomes	NP	K	9373

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	NP	G	9198
J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	NP	G	9354
J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dos	NP	N	N/A
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	NP	G	9364
J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	NP	N	N/A
J9246	Injection, melphalan (evomela), 1 mg	NP	K	9375
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	NP	G	9353
Q4227#	Amniocore, per square centimeter	NP	N	N/A
Q4228#	BioNextPATCH, per square centimeter	NP	N	N/A
Q4229#	Cogenex amniotic membrane, per square centimeter	NP	N	N/A
Q4230#	Cogenex flowable amnion, per 0.5 cc	NP	N	N/A
Q4231#	Corplex P, per cc.	NP	N	N/A
Q4232#	Corplex, per square centimeter	NP	N	N/A
Q4233#	Surfactor or Nudyn, per 0.5 cc	NP	N	N/A
Q4234#	Xcellerate, per square centimeter	NP	N	N/A
Q4235#	Amniorepair or altiply, per square centimeter	NP	N	N/A
Q4236#	CarePATCH, per square centimeter	NP	N	N/A
Q4237#	Cryo-cord, per square centimeter	NP	N	N/A
Q4238#	Derm-maxx, per square centimeter	NP	N	N/A
Q4239#	Amnio-maxx or Amnio-maxx lite, per square centimeter	NP	N	N/A
Q4240#	Corecyte, for topical use only, per 0.5 cc	NP	N	N/A
Q4241#	Polycyte, for topical use only, per 0.5 cc	NP	N	N/A
Q4242#	Amniocyte plus, per 0.5 cc	NP	N	N/A
Q4244#	Procenta, per 200 mg	NP	N	N/A
Q4245#	Amniotext, per cc	NP	N	N/A
Q4246#	Coretext or Protext, per cc	NP	N	N/A
Q4247#	Amniotext patch, per square centimeter	NP	N	N/A
Q4248#	Dermacyte Amniotic Membrane Allograft, per square centimeter	NP	N	N/A
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	NP	G	9367
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	NP	G	9345

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	NP	E2	N/A
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	NP	J1	5114
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	NP	T	5372
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	NP	T	5372
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	NP	T	5722
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure)	NP	N	N/A
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	NP	J1	5361
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	NP	J1	5361
0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent	NP	Q4	N/A
0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours	NP	Q4	N/A
0604T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment	NP	V	5012
0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center	NP	Q1	5741

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
	unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days			
0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days	NP	M	N/A
0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment	NP	V	5012
0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional	NP	S	5741
0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs	NP	E1	N/A
0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis	NP	E1	N/A
0611T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs	NP	E1	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report	NP	E1	N/A
0613T	Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed	NP	E1	N/A
0614T	Removal and replacement of substernal implantable defibrillator pulse generator	NP	J1	5231
0615T	Eye-movement analysis without spatial calibration, with interpretation and report	NP	Q1	5734
0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	NP	J1	5491
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	NP	J1	5492
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	NP	J1	5492
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	NP	J1	5375
0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	NP	A	N/A
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	NP	A	N/A
0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents	NP	Q4	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	NP	A	N/A
0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	NP	Q4	N/A
0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status	NP	A	N/A
0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction	NP	Q4	N/A
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)	NP	A	N/A
0180U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons	NP	A	N/A
0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1	NP	A	N/A
0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10	NP	A	N/A
0183U	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19	NP	A	N/A
0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2	NP	A	N/A
0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4	NP	A	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2	NP	A	N/A
0187U	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2	NP	A	N/A
0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4	NP	A	N/A
0189U	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2	NP	A	N/A
0190U	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3	NP	A	N/A
0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6	NP	A	N/A
0192U	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9	NP	A	N/A
0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26	NP	A	N/A
0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8	NP	A	N/A
0195U	KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)	NP	A	N/A
0196U	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3	NP	A	N/A
0197U	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1	NP	A	N/A
0198U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5	NP	A	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0199U	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12	NP	A	N/A
0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3	NP	A	N/A
0201U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2	NP	A	N/A

*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020.

**HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020.

#HCPCS codes Q4227 through Q4248: The availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR Part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR Part 1271.

3. October 2020 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2020 in the CY 2021 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2022 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2020 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2021, we propose to continue our established policy of assigning comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to those new HCPCS codes that are effective October 1, 2020 to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2021 OPPS/ASC final rule

with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

4. January 2021 HCPCS Codes

a. New Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule With Comment Period

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2021 in the CY 2021 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2022 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the HCPCS C-codes and G codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2021 OPPS/ASC final rule with comment period, January 2021 OPPS Update CR, and the CMS HCPCS website.

For CY 2021, we propose to continue our established policy of assigning comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2021 to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2021 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2021 OPPS update, we received the CPT codes that will be effective January 1, 2021 from AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS website).

We note that the new and revised CPT codes are assigned to comment indicator "NP" in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2021 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS website) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled "CY 2021 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code". The final CPT code numbers will be included in the CY 2021 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2021 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2021. Because the CPT codes listed in Addendum B appear with short descriptors only, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2021 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS website).

Finally, in Table 8, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

TABLE 8: COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II codes)	April 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2021	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to

identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the service.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2021, we propose that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described

in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the HOP Panel recommendations for specific services for the CY 2021 OPPS update will be discussed in the relevant specific sections throughout the CY 2021 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the "2 times rule"). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises

less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2021, we propose to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2021 OPPS update, we have identified the APCs with violations of the 2 times rule. Therefore, we propose changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2021 OPPS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2021 included in this proposed rule are related to changes in costs of services that were observed in the CY 2019 claims data newly available for CY 2021 ratesetting. Addendum B to this CY 2021 OPPS/ASC proposed rule identifies with a comment indicator "CH" those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2020 OPPS Addendum B Update (available via the Internet on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we propose to make for CY 2021, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2019 claims data available for this CY 2021 proposed rule, we found 18 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2021, and found that all of the 18 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2019 claims data available for this proposed rule. We note that we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule.

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we may accept the HOP Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 9 of this proposed rule lists the 18 APCs for which we propose to make an exception under the 2 times rule for CY 2021 based on the criteria cited above and claims data submitted between January 1, 2019, and December 31, 2019, and processed on or before December 31, 2019. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2019, and December 31, 2019, that were processed on or before June 30, 2020, and updated CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

TABLE 9: PROPOSED CY 2021 APC EXCEPTIONS TO THE 2 TIMES RULE

Proposed CY 2021 APC	Proposed CY 2021 APC Title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5112	Level 2 Musculoskeletal Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of "S" (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of "T" (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2020, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology - Level 1A ($0-$10)) through the highest cost band assigned to APC 1908 (New Technology - Level 52 ($145,001-$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example,

payment for New Technology APC 1507 (New Technology – Level 7 ($501 - $600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase adjusted for multifactor productivity. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374).

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. (We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.)

We note that, in a budget neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2021, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this CY 2021 OPPS/ASC proposed rule (which is available via the Internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC ratesetting calculations and, therefore, are not included in the assessment of the 2 times rule. As

we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58890), we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a service to a new technology APC allows us to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we determined in the CY 2019 OPPS/ASC final rule with comment period that it was appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determined the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). We have utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to estimate an appropriate payment amount for low-volume new technology services in the past (82 FR 59281). Although we have used this adjustment authority on a case-by-case basis in the past, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believe it is appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order to mitigate the wide payment fluctuations that have

occurred for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, we stated that we believe that it is appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has a low annual volume of claims, which, for purposes of this adjustment, we define as fewer than 100 claims annually. We adopted a policy to consider services with fewer than 100 claims annually as low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. We explained that we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the low-volume service. Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we stated that we believe using the median or arithmetic mean rather than the geometric mean (which "trims" the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of "outlier" claims; that is, claims with either a very low or very high payment rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. We also explained that we believe having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services

would help to create a more stable payment rate. Therefore, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we will seek public comments on which statistical methodology should be used for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we will use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other stakeholders, to determine the most appropriate payment rate. Once we identify the most appropriate payment rate for a service, we will assign the service to the New Technology APC with the cost band that includes its payment rate.

Accordingly, for CY 2021, we propose to continue the policy we adopted in CY 2019 under which we will utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using multiple years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC. Additional details on our policy is available in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893).

3. Procedures Assigned to New Technology APC Groups for CY 2021

As we described in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC.

In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC

assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2021, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902).

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1575, 5114, and 5414)

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which we propose to continue to assign to standard APCs, and one that we propose to continue to assign to a New Technology APC for CY 2021. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T describe procedures for the treatment of uterine fibroids, CPT code 0398T describes procedures for the treatment of essential tremor, and HCPCS code C9734 describes procedures for pain palliation for metastatic bone cancer.

For the procedure described by CPT code 0398T, we have identified 149 paid claims for CY 2019 with a geometric mean of $12,798.38. The number of claims for the service means that the procedure is no longer a low-volume new technology service, and we will use the geometric mean of the CY 2019 claims data to determine the cost of the service for its APC assignment. We reviewed the OPPS to determine whether CPT code 0398T could be assigned to a clinical APC. The most appropriate

clinical APC family for the service would be the Neurostimulator and Related Procedures APC series (APC 5461 – 5464). However, there is large payment rate difference between Level 2 Neurostimulator and Related Procedures (APC 5462) with a payment rate of $6,169.27 and Level 3 Neurostimulator and Related Procedures (APC 5463) with a payment rate of $19,737.37. Based on the geometric mean cost of CPT code 0398T available for this proposed rule, we believe the payment rate for APC 5462 would be too low for CPT code 0398T since it is more than $6,000 less than the geometric mean cost for CPT code 0398T, and we believe the payment rate for APC 5463 would be too high since it is around $6,800 more than the geometric mean cost for CPT code 0398T.

In addition, given the significant difference in the payment rate between APC 5462 and 5463, we believe a restructuring of this APC family would be appropriate. We believe creating an additional payment level between the two existing APC levels would allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Please refer to section III.D.1 for detailed explanation of our proposal to reorganize the Neurostimulator and Related Procedures APCs (APCs 5461 – 5464). Reorganizing the Neurostimulator and Related Procedures APCs would create a proposed Level 3 APC to be referred to as "Proposed APC 5463" with a payment rate of approximately $12,286 that is close to the geometric mean of CPT code 0398T which is approximately $12,798. The payment rate of proposed APC 5463 is representative of the cost of the service described by CPT code 0398T. Therefore, we propose to reassign the service described by CPT code 0398T to the proposed new Level 3 APC for Neurostimulator and Related Procedures (Proposed APC 5463) for CY 2021. The current and proposed APC assignments, status indicators, and payment rates for CPT code 0398T are found in Table 10. We refer readers to Addendum B of the proposed rule for the proposed payment rates for all codes reportable under the OPPS. Addendum B is available via the Internet on the CMS website.

TABLE 10: CY 2021 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRGFUS) PROCEDURE

CPT/ HCPCS Code	Long Descriptor	CY 2020 OPPS SI	CY 2020 OPPS APC	CY 2020 OPPS Payment Rate	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC	Proposed CY 2021 OPPS Payment Rate
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S	1575	$12,500.50	J1	5463	Refer to OPPS Addendum B.

b. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by the Food and Drug Administration (FDA) in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. Pass-through payment status was granted for the Argus® II device under HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) beginning October 1, 2013, and this status expired on December 31, 2015. We note that after pass-through payment status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. Consequently, for CY 2016, the device described by HCPCS code C1841 was assigned to OPPS status indicator "N" to indicate that

payment for the device is packaged and included in the payment rate for the surgical procedure described by CPT code 0100T. For CY 2016, the procedure described by CPT code 0100T was assigned to New Technology APC 1599, with a payment rate of $95,000, which was the highest paying New Technology APC for that year. This payment included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). However, stakeholders (including the device manufacturer and hospitals) believed that the CY 2016 payment rate for the procedure involving the Argus® II System was insufficient to cover the hospital cost of performing the procedure, which includes the cost of the retinal prosthesis at the retail price of approximately $145,000.

For CY 2017, analysis of the CY 2015 OPPS claims data used for the CY 2017 OPPS/ASC final rule with comment period showed 9 single claims (out of 13 total claims) for the procedure described by CPT code 0100T, with a geometric mean cost of approximately $142,003 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the CY 2015 OPPS claims data available for the final rule with comment period and our understanding of the Argus® II procedure, we reassigned the procedure described by CPT code 0100T from New Technology APC 1599 to New Technology APC 1906, with a final payment rate of $150,000.50 for CY 2017. We noted that this payment rate included the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

For CY 2018, the reported cost of the Argus® II procedure based on CY 2016 hospital outpatient claims data for 6 claims used for the CY 2018 OPPS/ASC final rule with comment period was approximately $94,455, which was more than $55,000 less than the payment rate for the procedure in CY 2017, but closer to the CY 2016 payment rate for the procedure. We noted that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS. In addition, the number of claims submitted has been very low and has not exceeded 10 claims within a

single year. We believed that it is important to mitigate significant payment differences, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data. In CY 2016, the payment rate for the Argus® II procedure was $95,000.50. The payment rate increased to $150,000.50 in CY 2017. For CY 2018, if we had established the payment rate based on updated final rule claims data, the payment rate would have decreased to $95,000.50 for CY 2018, a decrease of $55,000 relative to CY 2017. We were concerned that these large fluctuations in payment could potentially create an access to care issue for the Argus® II procedure, and we wanted to establish a payment rate to mitigate the potential sharp decline in payment from CY 2017 to CY 2018.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2018, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the payment rate for this procedure, despite the lower geometric mean costs available in the claims data used for the final rule with comment period. For CY 2018, we reassigned the Argus® II procedure to APC 1904 (New Technology—Level 50 ($115,001–$130,000)), which established a payment rate for the Argus® II procedure of $122,500.50, which was the arithmetic mean of the payment rates for the procedure for CY 2016 and CY 2017.

For CY 2019, the reported cost of the Argus® II procedure based on the geometric mean cost of 12 claims from the CY 2017 hospital outpatient claims data was approximately $171,865, which was approximately $49,364 more than the payment rate for the procedure for CY 2018. In the CY 2019 OPPS/ASC final rule with comment period, we continued to note that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS (83 FR

58897 through 58898). In addition, the number of claims submitted continued to be very low for the Argus® II procedure. We stated that we continued to believe that it is important to mitigate significant payment fluctuations for a procedure, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data because we are concerned that large decreases in the payment rate could potentially create an access to care issue for the Argus® II procedure. In addition, we indicated that we wanted to establish a payment rate to mitigate the potential sharp increase in payment from CY 2018 to CY 2019, and potentially ensure a more stable payment rate in future years.

As discussed in section III.C.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893), we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to establish a payment rate that is more representative of the likely cost of the service. We stated that we believed the likely cost of the Argus® II procedure is higher than the geometric mean cost calculated from the claims data used for the CY 2018 OPPS/ASC final rule with comment period but lower than the geometric mean cost calculated from the claims data used for the CY 2019 OPPS/ASC final rule with comment period.

For CY 2019, we analyzed claims data for the Argus® II procedure using 3 years of available data from CY 2015 through CY 2017. These data included claims from the last year that the Argus® II received transitional device pass-through payments (CY 2015) and the first 2 years since device pass-through payment status for the Argus® II expired. We found that the geometric mean cost for the procedure was approximately $145,808, the arithmetic mean cost was approximately $151,367, and the median cost was approximately $151,266. As we do each year, we reviewed claims data regarding hospital costs associated with new procedures. We regularly examine the claims data and any available

new information regarding the clinical aspects of new procedures to confirm that OPPS payments remain appropriate for procedures like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314). We noted that the proposed payment rate included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). For CY 2019, the estimated costs using all three potential statistical methods for determining APC assignment under the New Technology low-volume payment policy fell within the cost band of New Technology APC 1908, which is between $145,001 and $160,000. Therefore, we reassigned the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology - Level 52 ($145,001-$160,000)), with a payment rate of $152,500.50 for CY 2019.

For CY 2020, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2015 through CY 2018. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $146,059, the arithmetic mean cost to be approximately $152,123, and the median cost to be approximately $151,267. All of the resulting estimates from using the three statistical methodologies fell within the same New Technology APC cost band ($145,001– $160,000), where the Argus® II procedure was assigned for CY 2019. Consistent with our policy stated in section III.C.2, we presented the result of each statistical methodology in the proposed rule, and we sought public comments on which method should be used to assign procedures described by CPT code 0100T to a New Technology APC. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000. Accordingly, we assigned CPT code 0100T in APC 1908 (New Technology— Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2020.

For CY 2021, the number of reported claims for the Argus® II procedure continues to be very low with a substantial fluctuation in cost from year to year. The high annual variability of the cost of the Argus® II procedure continues to make it difficult to establish a consistent and stable payment rate for the procedure. As previously mentioned, in accordance with section 1833(t)(2)(B) of the Act, we are required to establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2021, we propose to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning the Argus® II procedure (CPT code 0100T) to a New Technology APC.

For CY 2021, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2016 through CY 2019. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $148,807, the arithmetic mean cost to be approximately $154,504, and the median cost to be approximately $151,974. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fall within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000.

Accordingly, we propose to maintain the assignment of the procedure described by CPT code 0100T in APC 1908 (New Technology - Level 52 ($145,001-$160,000)), with a proposed payment rate of $152,500.50 for CY 2021. We note that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). We refer readers to Addendum B to the proposed rule for the proposed payment rates for all codes reportable under the OPPS. Addendum B is available via the Internet on the CMS website.

c. Administration of Subretinal Therapies Requiring Vitrectomy.

CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is a gene therapy for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®), was approved by the FDA in December of 2017, and is indicated as an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[2] This therapy is administered through a subretinal injection, which stakeholders describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, "after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana." [1]

Stakeholders, including the manufacturer of Luxturna®, recommend HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[3] However, the manufacturer contends the administration is not currently described by any existing codes as HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself. For J3398, a typical patient would receive a standard dose of 150 billion vector genomes, with an approximate payment rate of $436,575 (we refer readers to Addendum B of this proposed rule for the proposed payment rate associated with J3398).

It is important to note that CPT code J3398 was granted drug pass-through status under the OPPS as of July 1, 2018 and is assigned to status indicator "G". (We refer readers to Addendum D of this proposed rule for the list of proposed status indicator definitions for CY2021). J3398 is scheduled to have its drug pass-through status expire June 30, 2021, at which point J3398 would be packaged into the payment for any primary service with which it is billed when that primary service is assigned to a

[2] Luxturna. FDA Package Insert. Available: https://www.fda.gov/media/109906/download
[3] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf

comprehensive APC (C-APC). A C-APC packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure (For a full discussion and background on C-APCs, see section II.A.2.b). Based on information from the manufacturer of Luxturna, we believe that CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) would commonly be billed with the service described by HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach), which describes the administration of the gene therapy, and which is assigned to a comprehensive APC, (APC 5492 - Level 2 Intraocular Procedures). Thus, when its pass-through status expires, payment for CPT code J3398, the primary therapy, would be inappropriately packaged into payment for HCPCS code 67036, its administration procedure.

CMS recognizes the necessity to accurately describe the unique administration procedure that is required to administer the therapy described by CPT J3398. We propose to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We believe that this new HCPCS code accurately describes the service associated with intraocular administration of HCPCS code J3398. CMS recognizes that HCPCS code 67036 represents a similar procedure and process that approximates similar resource utilization that is associated with C97X1. CMS also recognizes that it is not prudent for the code that describes the administration of this gene therapy, C97X1, to be assigned to the same C-APC that is assigned to HCPCS code 67036, as this would inappropriately package the primary therapy, J3398, into the code that represents the process to administer the gene therapy.

For CY 2021, we propose to assign the services described by C97X1 to a new technology payment band based on the geometric mean cost for HCPCS code 67036. For CY 2021, HCPCS code 67036 has a geometric mean cost of $3407.84. Therefore, for CY 2021 we propose to assign C97X1 to

APC 1561 – New Technology – Level 24 ($3001-$3500). Please see Table 11 for proposed descriptors and APC assignment.

TABLE 11: CY 2021 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C97X1 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 Placeholder HCPCS Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC
C97X1	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561

d. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500.

In claims data available for CY 2019 for this proposed rule, there were 4 claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we propose for CY 2021 to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the

geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $4,051, the arithmetic mean cost to be approximately $4,067, and the median cost to be approximately $4,067. All three potential statistical methodologies used to estimate the cost of the service procedure fall within the cost band for New Technology APC 1563, with the estimated cost being between $4,001 and $4,500. Accordingly, we propose to change the assignment of the HCPCS code C9751 to APC 1563 (New Technology - Level 26 ($4001-$4500)), with a proposed payment rate of $4,250.50 for CY 2021. Details regarding HCPCS code C9751 are shown in Table 12.

TABLE 12: CY 2021 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 HCPCS Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1563

e. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary

arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined that HeartFlow should receive a separate payment because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology - Level 16 ($1,401 - $1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500. We did not have Medicare claims data in CY 2019 for CPT code 0503T, and we continued to assign the service to New Technology APC 1516 (New Technology - Level 16 ($1,401 - $1,500)), with a payment rate of $1,450.50.

CY 2020 was the first year we had Medicare claims data to calculate the cost of HCPCS code 0503T. For the CY 2020 OPPS/ASC final rule, there were 957 claims with CPT code 0503T of which 101 of the claims were single frequency claims that were used to calculate the geometric mean of the procedure. We planned to use the geometric mean to report the cost of HeartFlow. However, the number of single frequency claims for CPT code 0503T was below the low-volume payment policy threshold for the proposed rule, and the number of single frequency claims was only two claims above the threshold for the new technology APC low-volume policy for the final rule. Therefore, we decided to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our new technology APC low-volume payment policy.

While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for Heartflow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was $768.26, the arithmetic mean cost for CPT code 0503T was $960.12 and that the median cost for CPT code 0503T was $900.28. Of the three cost methods, the highest amount was for the arithmetic mean. The arithmetic mean fell within the cost band for New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50. The arithmetic mean helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T that are available for this proposed rule. Specifically, using the most recently available data for this proposed rule (that is, CY 2019), we identified 2,820 claims billed with CPT code 0503T including 415 single frequency claims. These totals are well above the threshold of 100 claims for a procedure to be evaluated using the new technology APC low-volume policy. Therefore, we propose to use our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T.

Our analysis found the geometric mean cost for CPT code 0503T is approximately $851. Therefore, we propose to reassign the service described by CPT code 0503T in order to adjust the payment rate to better reflect the cost for the service. While we considered proposing to reassign CPT code 0503T to APC 5724 (Level 4 – Diagnostic Tests and Related Services), which has a payment rate of around $903 based on the clinical and resource similarity to other services within that APC, we did

not propose such reassignment because the payment rate for the new technology APC is closer to the geometric mean costs of CPT code 0503T. Nonetheless, we welcome comments on whether reassignment to the clinical APC would be more appropriate. Therefore, we propose to reassign the service described by CPT code 0503T to New Technology APC 1510 (New Technology - Level 10 ($801 - $900)), with a proposed payment rate of $850.50 for CY 2021.

f. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. Table 13 reports code descriptors, status indicators, and APC assignments for these CPT codes. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $ 2,750.50.

We have not received any claims that have been billed with CPT codes 78431, 78432, or 78433. Therefore, we propose to continue to assign these CPT codes to the same new technology APCs as they were in CY 2020. The proposed CY 2021 payment rate for the codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 13: CY 2021 OPPS APC AND STATUS INDICATOR FOR CPT CODES 78431, 78432, AND 78433 ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2020 OPPS SI	OPPS CY 2020 APC	Proposed CY 2021 OPPS SI	Proposed OPPS CY 2021 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress	S	1522	S	1522

	(exercise or pharmacologic), with concurrently acquired computed tomography transmission scan				
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	S	1523	S	1523
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1523

g. Pathogen Test for Platelets/Rapid Bacterial Testing

For the July 2017 update, the HCPCS Workgroup established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. This new code and the OPPS APC assignment was announced in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017). Because HCPCS code Q9987 represented a test to identify bacterial or other pathogen contamination in blood platelets, we assigned the code to a new technology APC, specifically, New Technology APC 1493 (New Technology-Level 1C ($21-$30)) with a status indicator "S" and a payment rate of $25.50. We note that temporary HCPCS code Q9987 was subsequently deleted on December 31, 2017, and replaced with permanent HCPCS code P9100 (Pathogen(s) test for platelets) effective January 1, 2018. For the January 2018 update, we continued to assign the new code to the

same APC and status indicator as its predecessor code. Specifically, we assigned HCPCS code P9100 to New Technology APC 1493 and status indicator "S". For the CY 2019 update, we made no change to the APC or status indicator assignment for P9100, however, for the CY 2020 update, we revised the APC assignment from New Technology APC 1493 to 1494 (New Technology - Level 1D ($31-$40) based on the latest claims data used to set the payment rates for CY 2020. We discussed the revision in the CY 2020 OPPS/ASC final rule (84 FR 61219) and indicated that the reassignment to APC 1494 appropriately reflected the cost of the service.

For the CY 2021 update, we believe that we have sufficient claims data to reassign the code from a New Technology APC to a clinical APC and note that HCPCS code P9100 has been assigned to a New Technology APC for over 3 years. As stated in section III.D. (New Technology APCs), a service is paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. We expect this to occur within two to three years from the time a new HCPCS code becomes effective. However, if we are able to collect sufficient claims data in less than 2 years, we would consider reassigning the service to an appropriate clinical APC. Since HCPCS code P9100 has been assigned to a new technology APC since July 2017, we believe that we should reassign the code to a clinical APC. Specifically, our claims data for this proposed rule shows a geometric mean cost of approximately $30 for HCPCS code P9100 based on 70 single claims (out of 1,835 total claims). Based on resource cost and clinical homogeneity to the other services assigned to APC 5732 (Level 2 Minor Procedures), we believe that HCPCS code P9100 should be reassigned to clinical APC 5732 whose geometric mean cost is approximately $33.

As we have stated several times since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For the CY 2021 OPPS update, based on claims submitted

between January 1, 2019, and December 30, 2019, our analysis of the latest claims data for this proposed rule supports reassigning HCPCS code P9100 to APC 5732 based on its clinical and resource homogeneity to the procedures and services in the APC. Therefore, we propose to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 for CY 2021. The proposed CY 2021 payment rate for HCPCS code P9100 can be found in Addendum B to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS Web site.

h. V-Wave Interatrial Shunt Procedure (HCPCS code C9758; APC 1589)

A randomized, double-blinded control IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, we created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart

catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology - Level 38 ($10,001-$15,000)).

No claims have been reported for HCPCS code C9758. Therefore, we propose to continue to assign the service to New Technology APC 1589 for CY 2021. Details about the HCPCS code and its APC assignment are shown in Table 14. The proposed CY 2021 payment rate for V-Wave interatrial shunt procedure can be found in Addendum B to proposed rule (which is available via the Internet on the CMS Web site).

TABLE 14: CY 2021 OPPS APC AND STATUS INDICATOR FOR V-WAVE INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	2021 OPPS SI	2021 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1589

i. Supervised Visits for Esketamine Self-Administration (HCPCS codes G2082 and G2083 APCs 1508 and 1511)

On March 5, 2019, the U.S. Food and Drug Administration (FDA) approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-

resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

A treatment session of esketamine consists of instructed nasal self-administration by the patient, followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established

patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration and includes 2 hours post-administration observation. HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology - Level 8 ($601 - $700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082, but involves the administration of more than 56 mg of esketamine. HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology - Level 11 ($901 - $1000)) with a payment rate of $950.50.

No Medicare OPPS claims have been reported for either HCPCS code G2082 or G2083. Therefore, we propose to continue to assign HCPCS code G2082 to New Technology APC 1508 and to assign HCPCS code G2083 to New Technology APC 1511. Details about the HCPCS codes and their APC assignments are shown in Table G15 below. The proposed CY 2021 payment rate for esketamine self-administration can be found in Addendum B to proposed rule (which is available via the Internet on the CMS Web site).

TABLE 15: CY 2021 OPPS APC AND STATUS INDICATOR FOR ESKETAMINE SELF-ADMINISTRATION HCPCS CODES ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2020 OPPS SI	OPPS CY 2020 APC	Proposed CY 2021 OPPS SI	Proposed OPPS CY 2021 APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1508	S	1508
G2083	Office or other outpatient	S	1511	S	1511

	visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation				

D. Proposed OPPS APC-Specific Policies

1. Neurostimulator and Related Procedures (APCs 5461 through 5465)

In the CY 2015 OPPS/ASC final rule (79 FR 66807 through 66808), we finalized a restructuring of what were previously several neurostimulator procedure-related APCs into a four-level series. Since CY 2015, the four-level APC structure for the series has remained unchanged. In addition to that restructuring, in the CY 2015 OPPS/ASC final rule, we also made the Level 2 through 4 APCs comprehensive APCs (79 FR 66807 through 66808). Later, in the CY 2020 OPPS final rule, we also established the Level 1 Neurostimulator and Related Procedure APC (APC 5461) as a comprehensive APC (84 FR 61162 through 61166).

In reviewing the claims data available for CY 2021 OPPS proposed rule, we believe that it is appropriate to create an additional Neurostimulator and Related Procedures level, between the current Level 2 and 3 APCs. Creating this APC allows for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPPS, we propose to establish a five-level APC structure for the Neurostimulator and Related Procedures series. We note that in addition to creating this new level, we also propose to assign CPT 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame

placement when performed) to this new Level 3 APC, as discussed in further detail in section III.C.3.A of this proposed rule with comment period.

Table 16 displays the proposed CY 2021 Neurostimulator and Related Procedures APC series' structure and APC geometric mean costs

TABLE 16: PROPOSED NEUROSTIMULATOR AND RELATED PROCEDURES APCS FOR CY 2021

APC	APC Descriptor	SI	CY 2020 OPPS Final Geometric Mean Cost	CY 2021 Proposed Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,080.60	$3,370.70
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,053.71	$6,105.05
5463	Level 3 Neurostimulator and Related Procedures	J1	$18,863.68	$12,286.43
5464	Level 4 Neurostimulator and Related Procedures	J1	$28,490.84	$20,032.49
5465	Level 5 Neurostimulator and Related Procedures	J1	N/A	$28,876.14

2. IDx-DR: Artificial Intelligence System to Detect Diabetic Retinopathy (APC 5732)

As stated in a press release issued by the FDA on April 11, 2018, the IDx-DR is the "first medical device to use artificial intelligence to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes" (https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye). Approved for marketing by the FDA in April 2018, the artificial intelligence algorithm provides a clinical decision without the need for a clinician to also interpret the image. A provider uploads the digital images of the patient's retinas to a cloud server on which the IDx-DR software is installed, and once analysis is completed, the provider is given one of the following two results:

- more than mild diabetic retinopathy detected: refer to an eye care professional; or
- negative for more than mild diabetic retinopathy; rescreen in 12 months.

The test itself generally takes about 5 minutes to complete and does not need to be performed by a clinician. The test associated with the IDx-DR technology will receive a new CPT code effective January 1, 2021, and with the establishment of the new code, the CPT Editorial Panel is also revising the descriptors associated with existing CPT codes 92227 and 92228 to appropriately differentiate them from the IDx-DR test.

Based on our evaluation of the service, we believe that IDx-DR is a diagnostic test that should be payable under the hospital OPPS, similar to existing CPT codes 92227 and 92228, which are assigned to APC 5732 (Level 2 Minor Procedures) and status indicator "Q1." Based on its clinical similarity to CPT codes 92227 (Remote imaging for detection of retinal disease (for example, retinopathy in a patient with diabetes) with analysis and report under physician supervision, unilateral or bilateral) and 92228 (Remote imaging for monitoring and management of active retinal disease (eg, diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral), we believe that the IDx-DR test should also be assigned to APC 5732 (Level 2 Minor Procedures) and status indicator "Q1." Consequently, we propose to assign the new IDx-DR CPT code to APC 5732 with a proposed payment rate of $33.16 for CY 2021. We note that we propose to assign the code to status indicator "Q1" to indicate that the code is conditionally packaged when performed with another service on the same day. Because the IDx-DR test will most often be performed as part of a visit, we believe that packaging the cost into the primary service is appropriate. We note that under the OPPS, the current E&M visit code (G0463) is paid separately when not billed with a C-APC, and we believe this payment includes the cost of providing the IDx-DR test. Generally, our process for tests with minimal costs is to package the cost into the primary service. Because the IDx-DR test will generally be part of another service provided on

the same day, and involve minimal cost, we believe that conditionally packaging the payment for the 5-minute IDx-DR test is appropriate for this test in the hospital outpatient setting.

In summary, we propose to assign the new CPT code associated with IDx-DR to APC 5732 and status indicator "Q1". Table 17 lists the proposed APC and SI for placeholder CPT code 9225X, which is associated with the IDx-DR test. The final CPT code number for placeholder code 9225X will be included in the CY 2021 OPPS/ASC final rule with comment period. The proposed CY 2021 payment rate for CPT code 9225X can be found in Addendum B to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS Web site. Furthermore, for discussion on the proposed PFS payment for placeholder CPT code 9225X, refer to the CY 2021 PFS Proposed Rule.

TABLE 17: PROPOSED CY 2021 APC AND SI ASSIGNMENTS FOR CPT CODES 92227, 92228, AND 9225X

CY 2020 CPT Code	Place-holder CPT Code	CY 2021 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
N/A	9225X	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral	NP	Q1	5732
92227	N/A	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral	N/A	Q1	5732
92228	N/A	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral	N/A	Q1	5732

3. Intraocular Procedures (APCs 5491 through 5495)

In prior years, CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) was assigned to the APC 5495 (Level 5 Intraocular

Procedures) based on its estimated costs. In addition, its relative payment weight has been based on its median cost under our payment policy for low-volume device-intensive procedures because the APC contained a low volume of claims. The low volume device-intensive procedures payment policy is discussed in more detail in section III.C.2. of the proposed rule.

In the CY 2019 OPPS, we assigned procedure code CPT code 0308T to the APC 5494 (Level 4 Intraocular Procedures) (83 FR 58917 through 58918). We made this change based on the similarity of the estimated cost for the single claim of $12,939.75 to that of the APC ($11,427.14). However, this created a discrepancy in payments between the OPPS setting and the ASC setting in which the ASC payments would be significantly lower than the OPPS payments for the same service because of the difference in estimated cost for the encounter determined under a comprehensive methodology within the OPPS and the estimated cost determined under the payment methodology for device intensive services within the ASC payment system.

In CY 2020 OPPS rulemaking, we reestablished APC 5495 (Level 5 Intraocular Procedures) because we believed that the procedure described by CPT code 0308T would be most appropriately placed in the APC based on its estimated cost (84 FR 61249 through 61250). Assignment of the procedure to the Level 5 Intraocular Procedures APC was consistent with its historical placement and would also address the large discrepancy in payment for the procedure between the OPPS and the ASC payment system. We note that we also implemented a policy where the payment for a service when performed in an ASC (84 FR 61399 through 61400), would be no higher than the OPPS payment rate for the service when performed in the hospital outpatient setting.

In reviewing the claims data available for CY 2021 ratesetting, there was a single claim containing the code 0308T that was unable to be used for the ratesetting process. In addition, this code and its APC have historically had relatively low claims volume for ratesetting purposes. While there are

no claims usable for ratesetting in the CY 2021 OPPS proposed data under our standard process, we still need to determine a payment weight for the APC. We believe that the most recently available data that we used to set payment for this service in the CY 2020 OPPS final rule is an appropriate proxy for both the procedure's estimated cost and its relative payment weight. We note that this proposed policy to use prior year claims data in ratesetting is similar to the application of a geometric mean cost floor to the Partial Hospitalization APCs, as initially established in the CY 2020 OPPS/ASC final rule (84 FR 61339 through 61347). Therefore, we believe it is appropriate to propose to use the median cost of $20,229.78 for CPT 0308T, calculated from claims data used in the CY 2020 OPPS final rule, to establish the payment weight for the CY 2021 OPPS for CPT code 0308T. We will continue to monitor the claims available for ratesetting as they are available for the CY 2021 OPPS final rule.

To summarize, for CY 2021, we propose to assign 0308T a payment weight based on the most recently available data, from the CY 2020 OPPS final rule, and therefore propose to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Under this proposal, the proposed CY 2021 OPPS payment rate for the service would be established based on the median cost, as discussed in section V.A.5. of the proposed rule, because it is a device intensive procedure assigned to an APC with fewer than 100 total annual claims within the APC. Therefore, the proposed APC assignment for CPT 0308T would be based on the CY 2019 OPPS final rule median cost of $20,229.78.

4. Musculoskeletal Procedures (APCs 5111 through 5116)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments towards prospective payment packages, we consolidated those individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 through 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series. While some commenters suggested APC reconfigurations and requests for change to APC assignments, many commenters requested that we maintain the current six level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we maintained the six level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 through 58921).

Based on the claims data available for this CY 2021 OPPS/ASC proposed rule, we continue to believe that the six-level APC structure for the Musculoskeletal Procedures APC series is appropriate. Therefore, we propose to maintain the APC structure for the CY 2021 OPPS update.

In the CY 2020 OPPS/ASC final rule, we discussed issues related to the APC assignment of CPT code 22869 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level) to APC 5115 (84 FR 61253 through 61254). Specifically, commenters believed that the code was inappropriately assigned to APC 5115 due to one hospital inaccurately reporting its costs and charges. While we recognized the concerns that the commenters described, we noted that it is generally not our policy to

judge the accuracy of hospital coding and charging for purposes of ratesetting. For the CY 2021 OPPS, the geometric mean cost of CPT code 22869 has increased slightly relative to the prior year, from $11,023.45 to $12,788.56. However, the geometric mean costs of the Level 5 and Level 6 Musculoskeletal Procedures APCs are $12,102.02 and $15,975.08, respectively, and so, based on the data that is available, we continue to believe that it is appropriate to assign CPT code 22869 to APC 5115 (Level 5 Musculoskeletal Procedures APC).

For the CY 2021 OPPS, we also propose to remove codes that were previously on the Inpatient Only List and assign them to clinical APCs. Many of these codes are being proposed for APC assignment to the Musculoskeletal Procedures APC series, and so there may be effects on the geometric means as the limited claims data for those codes is included in OPPS ratesetting. For a more detailed discussion of the proposal to remove certain codes from the inpatient only list, please see section IX.B. of this proposed rule,

Table 18 displays the proposed CY 2021 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

TABLE 18: PROPOSED MUSCULOSKELETAL PROCEDURES APCS FOR CY 2021

APC	Group Title	HCPCS Codes Assigned to APC in this CY 2021 OPPS/ASC Proposed Rule	CY 2020 Final APC Geometric Mean Cost	CY 2021 Proposed APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	103	$210.99	$206.66
5112	Level 2 Musculoskeletal Procedures	136	$1,326.17	$1,367.39
5113	Level 3 Musculoskeletal Procedures	411	$2,678.42	$2,777.09
5114	Level 4 Musculoskeletal Procedures	445	$5,852.95	$6,136.58
5115	Level 5 Musculoskeletal Procedures	120	$11,644.09	$12,101.07
5116	Level 6 Musculoskeletal Procedures	50	$15,602.23	$15,711.96

5. Noncontact Real-Time Fluorescence Wound Imaging/MolecuLight (APC 5722)

For the July 2020 update, the CPT Editorial Panel established two new codes, specifically, CPT codes 0598T and 0599T, to report noncontact real-time fluorescence wound imaging for bacterial presence in chronic and acute wounds. The codes and their long descriptors are listed in Table 7 (New HCPCS Codes Effective July 1, 2020) above. We note that CMS recently received a new technology application for the MolecuLight i: X procedure, which is described by CPT codes 0598T and 0599T. In determining the appropriate payment for CPT code 0598T, we considered whether there should be separate or conditionally packaged payment for the procedure since the use of the MolecuLight imaging device will most often involve another procedure or service during the same session (for example, debridement of the wound, laboratory service, or another skin-related procedure). In addition, we considered whether the code should be placed in either the Diagnostic Procedures or Minor Procedures APC group. Based on our review of the application and input from our physicians, we assigned CPT code 0598T to APC 5722 ((Level 2 Diagnostic Tests and Related Services) and status indicator "T" with a payment rate of $253.10 effective July 1, 2020. In addition, because CPT code 0599T is an add-on code, we assigned the code to status indicator "N" to indicate that the payment is included in the primary procedure. We note that the new technology application indicated a higher projected cost involving care in an operating room (OR), however, based on our review of the MolecuLight service, we removed all OR-associated costs because it is not clear to us that the test would routinely be performed in the OR setting. However, we are soliciting public comments from hospital-based providers that have used MolecuLight on the appropriate OPPS payment, particularly with respect to the cost of providing the service in the hospital outpatient setting as well as the performance of the procedure. We note, as indicated in Table 8 (Comment Timeframe for New and Revised HCPCS Codes), that we are seeking comments on CPT codes that are effective July 1, 2020 in this proposed rule, particularly with respect to

the APC and SI assignments, and will finalize them in the CY 2021 OPPS/ASC final rule with comment period.

In summary, we propose to assign CPT code 0598T to APC 5722 (Diagnostic Tests and Related Services) with status indicator "T" and CPT code 0599T to status indicator "N" for CY 2021. The proposed CY 2021 payment rate for CPT code 0598T can be found in Addendum B to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

6. Pathogen Test for Platelets / Rapid Bacterial Testing (APC 5732)

For CY 2020, the HCPCS code associated with pathogen test for platelets or rapid bacterial testing was assigned to a new technology APC 1494 (New Technology - Level 1D ($31-$40). For the CY 2021 update, we propose to revise the APC assignment for this HCPCS code from New Technology APC 1494 to clinical APC 5732 (level 2 Minor Procedures). Refer to section III.C. of this proposed rule for the full discussion on the proposal.

7. Urology and Related Services (APCs 5371 through 5378)

For the CY 2020 OPPS/ASC final rule with comment period (84 FR 61268), we received a public comment suggesting we revise the assignments for the services assigned to the Urology & Related Services APCs. The commenter specifically noted that a reorganization for APCs 5374 through 5376 would be appropriate but added that there are other inconsistencies across services within the urology APCs. We stated in that same final rule that we would consider revisions to the urology APCs in future rulemaking.

Currently, for CY 2020, there are seven levels of APCs for urology services. We have reviewed the CY 2020 geometric mean cost for APCs 5371 through 5377 and, after our analysis of the claims data for this proposed rule, we believe that a modification to the urology APCs is appropriate.

For the CY 2021 OPPS/ASC proposed rule, we evaluated the claims data and noted the large geometric mean cost differential between APC 5376 (level 6) and APC 5377 (level 7) has continued to grow. This differential in the geometric mean cost from APC 5376 to APC 5377 would have been about $9,700, with the geometric mean cost for APC 5377 being about 220 percent of the geometric mean cost of APC 5376. With claims data available for this CY 2021 OPPS proposed rule with comment period showing an unusually large difference between the geometric mean costs of the Level 6 Urology APC and the Level 7 Urology APC on both a dollar and percentage basis, we believe that creating an additional APC in the urology and related series will provide an appropriate structure distinguishing between clinical and cost similarity for the procedures in the different levels. Therefore, for CY 2021, we propose to create an additional urology and related services APC 5378 (level 8) and re-organize the current APC 5376 (level 6) and 5377 (level 7). As a result, we propose a total of eight levels in the urology and related services series. We believe this re-organization would address the lack of an appropriate level for procedures with geometric mean costs that fall between current APC 5376 and current APC 5377.

We note that the proposed re-organization re-assigns CPT 53440 (Male sling procedure) and CPT 0548T (Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy) from the current APC 5376 to APC 5377.

In addition, this proposed revision reassigns the following services from APC 5377 to APC 5378:

- CPT 54416 (Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session).
- CPT 53444 (Insert tandem cuff).

- CPT 54410 (Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session).
- CPT 54411 (Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue).
- CPT 54401 (Insertion of penile prosthesis; inflatable (self-contained)).
- CPT 54405 (Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir).
- CPT 53447 (Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session).
- CPT 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff).

We note that the APC reassignment for these 10 codes results in geometric mean costs for Levels 6, 7, and 8 of the urology APCs that we believe more appropriately align with the geometric mean costs for services in these APCs than the current structure. Specifically, as listed in Table19, the geometric mean cost of $8,089.78 for APC 5376, $11,275.15 for APC 5377, and $18,015.54 for APC 5378 reduces the unusually large gaps on both a dollar and percentage basis in geometric mean costs between each APC level.

TABLE 19: PROPOSED CY 2021 GEOMETRIC MEAN COST FOR THE UROLOGY AND RELATED APCS 5371 THROUGH 5378

APC	Group Title	SI	CY 2020 OPPS Geometric	Proposed CY 2021 OPPS Geometric

			Mean Cost	Mean Cost
5371	Level 1 Urology and Related Services	T	$229.83	$262.04
5372	Level 2 Urology and Related Services	T	$544.53	$565.10
5373	Level 3 Urology and Related Services	J1	$1,733.35	$1,758.24
5374	Level 4 Urology and Related Services	J1	$2,953.45	$3,010.01
5375	Level 5 Urology and Related Services	J1	$4,140.38	$4,324.38
5376	Level 6 Urology and Related Services	J1	$7,893.96	$8,089.78
5377	Level 7 Urology and Related Services	J1	$17,195.00	$11,275.15
5378	Level 8 Urology and Related Services	J1	N/A	$18,015.54

In summary, to lessen the large payment gaps on both a dollar and percentage basis between APCs 5376 and 5377, we propose to establish APC 5378 (Level 8 Urology and Related Services) with status indicator "J1" for CY 2021. The proposed CY 2021 payment rates for all the urology APCs, specifically APCs 5371 through 5378, can be found in Addendum A to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum A and D1 are available via the Internet on the CMS website.

IV. OPPS Payment for Devices

A. Proposed Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at 42 CFR 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of

the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at 42 CFR 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices.

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are 7 device categories eligible for pass-through payment: C1823-Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads); C1824-Generator, cardiac contractility modulation (implantable); C1982-Catheter, pressure-generating, one-way valve, intermittently occlusive; C1839-Iris prosthesis; C1734-Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable); C2596-Probe, image-guided, robotic, waterjet ablation; and C1748-Endoscope, single-use (that is disposable), Upper GI, imaging/illumination device (insertable).

The pass-through payment status of the device category for HCPCS code C1823 will end on December 31, 2021; the pass-through payment status of the device category for HCPCS code C1748 will end on June 30, 2022; and the pass-through payment status of the device categories for HCPCS codes C1824, C1982, C1839, C1734, and C2596 will end on December 31, 2022. Table 20 shows the expiration of transitional pass-through payments for these devices. All of these HCPCS codes will have pass-through payment status and will continue to receive pass-through payments in CY 2021.

Table 20: EXPIRATION OF TRANSITIONAL PASS-THROUGH PAYMENTS FOR CERTAIN DEVICES

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021
C1824	Generator, cardiac contractility modulation (implantable	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022

C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023

2. New Device Pass-Through Applications

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629). We note that, as discussed in section IV.A.4. of this CY 2021 OPPS/ASC proposed rule, we created an alternative pathway in the CY 2020 OPPS/ASC final rule that granted fast-track device pass-through payment under the OPPS for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications received on or after January 1, 2020. We refer readers to section IV.A.4. of this CY 2021 OPPS/ASC proposed rule for a complete discussion of this pathway.

As specified in regulations at 42 CFR 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not "insignificant" relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily

approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that receive Food and Drug Administration (FDA) marketing authorization and are granted a Breakthrough Device designation (84 FR 61295). Under this alternative pathway, devices that are granted a FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that have received FDA marketing authorization, are part of the Breakthrough Devices Program, and meet the other criteria in regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html, in the "Downloads" section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Payment for CY 2021

We received five complete applications by the March 1, 2020 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this CY 2021 OPPS/ASC proposed rule. We received one of the applications in the second quarter of 2019, two of the applications in the fourth quarter of 2019, and two of the applications in the first quarter of 2020. Two of the applications were approved for device pass-through payment during the quarterly review process: CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope. CUSTOM*FLEX*® ARTIFICIAL*IRIS* received fast-track approval under the alternative pathway effective January 1, 2020. EXALT™ Model D Single-Use Duodenoscope received fast-track approval under the alternative pathway effective July 1, 2020. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope are discussed below in section IV.2.b.1.

Applications received for the later deadlines for the remaining 2020 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2022 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment

application are included on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.

A discussion of the applications received by the March 1, 2020 deadline is presented below.

1. Alternative Pathway Device Pass-through Applications

We received three device pass-through applications by the March 2020 quarterly application deadline for devices that have received FDA marketing authorization and a Breakthrough Device designation from FDA, and therefore are eligible to apply under the alternative pathway. As stated above in section IV.2.a, under this alternative pathway, devices that are granted a FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but will need to meet the other requirements for pass-through payment status in our regulation at § 419.66.

(1) CUSTOM*FLEX*® ARTIFICIAL*IRIS*

VEO Ophthalmics submitted an application for a new device category for transitional pass-through payment status for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* by the June 2019 quarterly deadline. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* device is described as a foldable iris prosthesis that is custom-made for each individual patient who requires one. The applicant states that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* comes in two models-With Fiber or Fiber Free. The two models are identical in every respect except that the With Fiber model has a polyester meshwork layer embedded in it to provide adequate tear strength to withstand suturing.

The applicant provides that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is intended to serve as an artificial iris prosthesis, inserted at the time of cataract surgery or during a subsequent stand-alone procedure. The CustomFlexTM Artificial Iris is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other

conditions associated with full or partial aniridia. The conditions that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* treats are rare; congenital aniridia is present in approximately 1.8 in 100,000 live births (1 in 40,000 to 1 in 100,000),[4-2] congenital IridoCorneal Endothelial Syndrome (ICE) syndrome is even less common (incidence not available). Iris defects such as iatrogenic iridodialysis as a complication of cataract surgery has variable prevalence, ranging from 0-0.84 percent of surgeries,[3-8] and may occur in approximately 0.2 percent of blunt orbital trauma.[9] Although rare, these conditions are cosmetically and functionally limiting. The applicant provides that in addition to a noticeably absent or irregular iris/pupil, affected patients frequently experience photophobia (light sensitivity) and glare as well as symptoms such as dry eye.[10-11]

According to the applicant, currently available treatments for symptomatic glare, photophobia, and cosmesis are limited, and an FDA-approved, commercially available iris prosthesis fills a needed gap. Alternatives include tinted spectacles or contact lenses, iris reconstruction (for example,

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pupilloplasty or iridodialysis repair), and corneal tattooing.[10] Among these, tinted spectacles can provide some symptomatic relief, but the applicant states that they do not address the underlying problem and cannot be used in all settings. Iris reconstruction requires that sufficient iris tissue be present. Tinted contact lenses and corneal tattooing are cosmetically not ideal and have an associated risk of corneal infection (corneal ulcer and infectious keratitis). According to the applicant, in addition, corneal tattooing has risk of surface toxicity, anterior segment inflammation, and/or corneal epithelial defect. The only other artificial iris devices in the U.S. were previously available under FDA compassionate use exemption (Morcher 50F, 96F; Ophtec 311 aniridia lens).[10] However, these devices are no longer available following FDA approval of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted the CUSTOM*FLEX*® ARTIFICIAL*IRIS* premarket approval (PMA) (P170039) on May 30, 2018 for use in the treatment of full or partial aniridia resulting from congenital or acquired defects and was designated a Breakthrough Device by FDA on December 21, 2017. The applicant provided that there was a roughly 3-month market delay after receipt of PMA approval while final labeling in its printed form was submitted to FDA and FDA completed its review and approval process. The applicant notes that commercial availability of the device commenced on September 12, 2018 after it received FDA approval for the final labeling. We received the application for a new device category for transitional pass-through payment status for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* on May 31, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant states that the device is implanted via injection through a 2.75-4 mm clear corneal incision. Depending on the site of implantation (capsular bag, ciliary sulcus, sutured to sclera), the device is cut (trephined) to the correct

diameter. The device can also be sutured to an intraocular lens if an intraocular lens is also implanted at the time of surgery. The applicant further provides that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted. The applicant also claimed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Upon review, it does not appear that there are any other existing pass-through payment categories that might apply to the CUSTOMFLEX® ARTIFICIAL*IRIS* and we are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. As stated in section IV.2.a above, devices that apply under the alternative pathway for devices with a FDA marketing authorization and that have a Breakthrough Device designation are not subject to evaluation

for substantial clinical improvement (84 FR 61295). The CUSTOM*FLEX*® ARTIFICIAL*IRIS* received FDA marketing authorization and a Breakthrough Devices designation from FDA on December 21, 2017.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* would be reported with CPT code 66999 – Unlisted procedure, anterior segment of eye, which was assigned to APC 5491 (Level 1 Intraocular Procedures) for Calendar Year (CY) 2020. To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5491, which had a CY 2019 payment rate of $1,917. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 66999 had a device offset amount of $149.80 at the time the application was received. According to the applicant, the cost of the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is $7,700, for both the Fiber Free and with Fiber models.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is 402 percent of the applicable APC payment amount for the service related to the category of devices of $1,917 (($7,700/ $1,917) x 100= 402 percent). Therefore, we believe the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is 5,140 percent of the cost of the device-related portion of the APC payment amount for the related service of $150 (($7,700/ $150) x100= 5,140 percent).

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* and the portion of the APC payment amount for the device of $1,917 is 394 percent of the APC payment amount for the related service of $150 (($7,700-$150)/$1,917) x 100 = 394 percent). Therefore, we believe that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the third cost significance requirement.

We are inviting public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device pass-through payment criteria discussed in this section, including the cost criterion.

As stated above, we received the application for the CUSTOMFLEX® ARTIFICIAL*IRIS* application by the June 1, 2019 quarterly deadline and preliminarily approved for transitional pass-through payment under the alternative pathway for CY 2020, effective January 1, 2020. We are inviting public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have a FDA Breakthrough Device designation.

(2) EXALT™ Model D Single-Use Duodenoscope

Boston Scientific Corporation submitted an application before the March 2020 quarterly deadline for a new device category for transitional pass-through payment status for the EXALT™ Model D Single-Use Duodenoscope. The EXALT™ Model D Single-Use Duodenoscope is described as a sterile, single-use, flexible duodenoscope used to examine the duodenum and perform endoscopic retrograde cholangiopancreatography (ERCP) procedures by facilitating access to the pancreaticobiliary system. The applicant stated that it has designed the technology of the EXALT™ Model D Single-Use Duodenoscope to eliminate the risk of nosocomial infections due to improper reprocessing of a reusable duodenoscope. As stated above, the EXALT™ Model D Single-Use Duodenoscope is used during ERCP procedures that are performed to examine bile and pancreatic ducts. According to the applicant, the EXALT™ Model D Single-Use Duodenoscope enables passage and manipulation of accessory devices in the pancreaticobiliary system for diagnostic and therapeutic purposes, as necessary. During the ERCP procedure, the physician inserts the duodenscope through the patient's mouth, down the esophagus, into the stomach, and then into the first part of the small intestine (duodenum). The applicant stated that during ERCP a cannula is passed through the duodenoscope via a working channel and used to cannulate a small opening on the duodenal wall. Once that step is complete, the physician injects contrast while x-rays are taken to study the bile and/or pancreatic ducts. If the physician identifies an area that warrants further investigation, accessory devices can be inserted through the working channel of the scope and into the pancreaticobiliary system for diagnosis or treatment. According to the applicant, after the conclusion of the procedure, the single-use EXALT™ Model D Single-Use Duodenoscope device has no further medical use and is fully disposable.

With respect to the newness criterion at § 419.66(b)(1), FDA granted 510(k) premarket clearance (K193202) as of December 13, 2019. Prior to 510(k) clearance, the applicant received Breakthrough

Device designation from FDA on November 19, 2019. We received the application for a new device category for transitional pass-through payment status for the EXALT™ Model D Single-Use Duodenoscope on January 17, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the EXALT™ Model D Single-Use Duodenoscope meets the newness criterion.

With regard to the eligibility criterion at § 419.66(b)(3), according to the applicant, the EXALT™ Model D Single-Use Duodenoscope is integral to the ERCP service provided, is used for one patient only, and is surgically inserted as it is inserted through the patient's mouth, down the esophagus, into the stomach, and then into the first part of the small intestine. The applicant also stated that the EXALT™ Model D Single-Use Duodenoscope meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. With respect to the existence of a previous pass-through device category that describes EXALT™ Model D Single-Use Duodenoscope, the applicant suggested a category descriptor of "Duodenoscope, single-use." The applicant also provided an existing device category "C1749, Endoscope, retrograde imaging/illumination colonoscope device (implantable)," for pass-through payment for another endoscope and explained why they believe the category descriptor is not applicable to EXALT™ Model D Single-Use Duodenoscope. The applicant stated that HCPCS C1749 does not appropriately describe the EXALT Model D, as C1749 is intended to describe endoscopic imaging devices that are inserted through a colonoscope and into the

colon. The applicant argues that EXALT Model D is the first and only single-use duodenoscope through which devices can be passed, and it is utilized in ERCP procedures. The applicant further states that the scope that is the subject of this request provides access to a different part of the anatomy, specifically, the pancreaticobiliary system and facilitates access for diagnostic and therapeutic purposes, as opposed to the devices described by C1749, which are endoscopic imaging devices that are inserted through a colonscope and into the colon, providing access to a different part of the anatomy. Upon review, we agree with the applicant that it does not appear that there are any other existing pass-through payment categories that might apply and we are inviting public comment on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. As previously discussed in section 2.a above, we finalized the alternative pathway for devices that receive FDA marketing authorization and are granted a Breakthrough Device designation in the CY 2020 OPPS/ASC final rule (84 FR 61295). The EXALT™ Model D Single-Use Duodenoscope has marketing authorization and a Breakthrough Device designation from the FDA and therefore is not evaluated based on substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information

in support of the cost significance requirements. The applicant stated that the EXALT™ Model D Single-Use Duodenoscope would be reported with CPT code 43274 which is associated with APC 5331(Complex GI Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. We used APC 5331 for our calculations, which had a CY 2020 payment rate of $4,780.30 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 43274 had a device offset amount of $1,287.81 at the time the application was received. According to the applicant, the cost of the EXALT™ Model D Single-Use Duodenoscope is $2,930.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope is 61 percent of the applicable APC payment amount for the service related to the category of devices of $4,780.30 ($2,930/$4,780.30 x 100 = 61.3 percent). Therefore, we believe the EXALT™ Model D Single-Use Duodenoscope meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope is 228 percent of the cost of the device-related portion of the APC payment amount for

the related service of $1,287.81 ($2,930/$1,287.81) x 100 = 227.5 percent. Therefore, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope and the portion of the APC payment amount for the device of $1,287.81 is 34 percent of the APC payment amount for the related service of $4,780.30 (($2,930 - $1,287.81)/$4,780.30) x 100 = 34.4 percent). Therefore, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the third cost significance requirement. We are inviting public comment on whether the EXALT™ Model D Single-Use Duodenoscope meets the device pass-through payment criteria discussed in this section, including the cost criterion.

As specified above, the EXALT™ Model D Single-Use Duodenoscope application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2020. We are inviting public comment on whether the EXALT™ Model D Single-Use Duodenoscope should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have a FDA Breakthrough Device designation.

(3) BAROSTIM NEO™ System

CVRx, Inc. submitted an application for the BAROSTIM NEO™ System by the December 2019 quarterly deadline. The applicant provides that the BAROSTIM NEO™ is indicated for the treatment of symptoms of patients with advanced heart failure. The applicant asserts that the BAROSTIM therapy triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes of the progression of heart failure. According to the applicant, increased sympathetic and

decreased parasympathetic activity contribute to heart failure (HF) symptoms and disease progression. Barostim's mechanism of action is stimulating the carotid baroreceptor which results in centrally mediated reduction of sympathetic and increase in parasympathetic activity. A single 2mm coated electrode with a 7mm silicone backer is sutured to the carotid artery to activate the baroreceptors. It is connected to an implantable pulse generator in the chest which provides control of baroreflex activation energy. The BAROSTIM NEO™ System uses CVRx patented BAROSTIM THERAPY™ technology to trigger the body's own natural systems (baroreflex) by electrically activating the carotid baroreceptors, the body's natural cardiovascular regulation sensors.

According to the applicant, in conditions such as hypertension and heart failure, it is believed the baroreceptors, the body's natural sensors, are not functioning properly and are not sending sufficient signals to the brain. This results in the brain sending signals to other parts of the body (heart, blood vessels, kidneys) to constrict the blood vessels, retain water and salt by the kidneys and increase stress-related hormones. The applicant provides that when the baroreceptors are activated by the BAROSTIM NEO™ system, signals are sent through neural pathways to the brain. In response, the brain works to counteract this stimulation by sending signals to other parts of the body (heart, blood vessels, and kidneys) that relax the blood vessels and inhibit the production of stress-related hormones. These changes act to reduce cardiac after-load and enable the heart to increase blood output, while maintaining or reducing its workload. Parameters are programmed into the Implantable Pulse Generator (IPG) using telemetry via a wireless external programming system. The applicant states that the BAROSTIM NEO™ System is fully programmable to adjust the therapy to each patient's need.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted the BAROSTIM NEO™ System a premarket approval (P180050) and a Breakthrough Device designation on August 16, 2019 for the improvement of symptoms of heart failure – quality of life, six-minute hall walk, and

functional status – for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are New York Heart Association (NYHA) Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35 percent, a NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines. We received the application for a new device category for transitional pass-through payment status for the BAROSTIM NEO™ on November 27, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the BAROSTIM NEO™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of BAROSTIM NEO™ is integral to the service of providing baroflex therapy™, is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant also claimed the BAROSTIM NEO™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the BAROSTIM NEO™ meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. With respect to the existence of a previous pass-through device category that describes BAROSTIM NEO™, the applicant suggested a category descriptor of "Generator, neurostimulator (implantable), non-rechargeable with carotid sinus stimulation lead." The applicant also provided a list of current and expired device categories for pass-

through payment for other neurostimulation systems and their rationale for why they believe the category descriptors are not applicable to BAROSTIM NEO™.

The applicant stated that BAROSTIM NEO™ is not described by existing device category C1767, Generator, neurostimulator (implantable), non-rechargeable. The applicant stated that similar to the traditional spinal cord stimulation (SCS) systems included in this category, the BAROSTIM NEO™ System is not rechargeable; however, it is the only system that works to deliver CVRx's proprietary baroreflex activation therapy (BAT). The applicant provided that BAT uses afferent signaling to the brain by stimulating the carotid artery to reduce the sympathetic signal and increase the parasympathetic signal. The applicant stated that this unique therapy works to rebalance the autonomic input to the heart to improve heart failure symptoms.

Additionally, the applicant stated that traditional devices provide pain relief by disrupting the pain signals traveling between the spinal cord's nervous system and the brain, but the BAROSTIM NEO System uses the generator to stimulate the baroreceptors in the carotid artery to treat the symptoms of patients with advanced heart failure. The applicant stated that the BAROSTIM NEO generator is unique in its capability to drive electricity up to 20mA/100Hz with sufficient battery capacity to provide the required therapy through the BAROSTIM NEO™ carotid sinus lead. The applicant described that the BAROSTIM NEO™ carotid sinus lead is sutured to the carotid wall, where the baroreceptors (stretch fibers) are located. Electrical current radiating from the carotid sinus lead activates the baroreceptors. When activated, the baroreceptors send efferent signals through the Carotid Sinus Nerve to the brain. The brain interprets these afferent signals and reacts by reducing the sympathetic tone and increasing the parasympathetic tone. The applicant states that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to treat the symptoms of patients with advanced heart failure.

The applicant stated that BAROSTIM NEO™ is not described by existing device category C1823, Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads. The applicant states that existing device category C1823 is exclusively used to describe a complete system comprised of a generator implanted in the chest, a stimulation lead attached to the phrenic nerve and a sensing lead to control the function of the diaphragm for the treatment of moderate to severe central sleep apnea. The applicant states that the BAROSTIM NEO™ System utilizes a single stimulation lead positioned on the carotid artery to stimulate baroreceptors. The stimulation of the baroreceptors creates afferent nerve traffic through the Carotid Sinus Nerve, and results in the activation of the baroreflex. The applicant again states that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to improve quality of life and functional status in heart failure.

The applicant also provided that BAROSTIM NEO™ is not described by existing device category C1778, Lead, neurostimulator (implantable). The applicant stated that leads used in traditional neurostimulation are implanted on nerves (for example, spinal cord, peripheral nerves). The applicant stated that in contrast, the BAROSTIM NEO carotid sinus lead is sutured onto the carotid artery and is the only lead that is designed to be secured on an arterial wall to stimulate sensors located inside the arterial wall (baroreceptors). The applicant provided that stimulation is delivered to the arterial wall, where the baroreceptors (stretch fibers) are located. The applicant stated that the BAROSTIM NEO™ generator is uniquely designed to send electric current via the BAROSTIM NEO™ carotid sinus lead and that the BAROSTIM NEO™ carotid sinus lead is uniquely designed to only interface with the BAROSTIM NEO generator. Again, the applicant provided that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to treat the symptoms of patients with advanced heart failure.

We are concerned that the BAROSTIM NEO™ System may be appropriately described by existing pass-through payment categories. Specifically, we believe that Barostim may be appropriately described by C1767 as the Barostim device consists of a generator, a neurostimulator, and a lead. We are inviting public comment on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. As stated in section 2.a above, devices that apply under the alternative pathway for devices with a FDA marketing authorization and that have a Breakthrough Device designation are not subject to evaluation for substantial clinical improvement (84 FR 61295). Barostim has FDA marketing authorization and a Breakthrough Device designation.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the BAROSTIM NEO™ would be reported with CPT code 0266T, which they consider to be a total system code. CPT code 0266T is assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5464, which has a CY 2020 payment rate of

$29,115.50. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 0266T had a device offset amount of $24,253 at the time the application was received. According to the applicant, the cost of the BAROSTIM NEO™ is $35,000.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $35,000 for the BAROSTIM NEO™ is 120 percent of the applicable APC payment amount for the service related to the category of devices of $29,116 (($35,000/29,116) x100= 120.2 percent). Therefore, we believe the BAROSTIM NEO™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $35,000 for the BAROSTIM NEO™ is 144 percent of the cost of the device-related portion of the APC payment amount for the related service of $24,253 (($35,000/ $24,253) x 100= 144.3 percent). Therefore, we believe that the BAROSTIM NEO™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $35,000 for BAROSTIM NEO™ and the portion of the APC payment amount for the device of $24,253 is 37 percent of the APC payment amount

for the related service of $29,116 (($35,000- $24,253)/ $29,116) x 100 = 36.9 percent). Therefore, we believe that the BAROSTIM NEO™ System meets the third cost significance requirement.

We are inviting public comment on whether the BAROSTIM NEO™ System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

2. Traditional Device Pass-through Applications

(1) Hemospray® Endoscopic Hemostat

Cook Medical submitted an application for a new device category for transitional pass-through payment status for the Hemospray® Endoscopic Hemostat (Hemospray) for CY 2021. Hemospray® Endoscopic Hemostat is a prescription use device consisting of a hemostatic agent and a delivery system. The hemostatic agent is an inert, bentonite powder, naturally sourced from aluminum phyllosilicate clay, developed for endoscopic hemostasis. According to the applicant, Hemospray® is indicated by the FDA for hemostasis of nonvariceal gastrointestinal bleeding. Using an endoscope to access the gastrointestinal tract, the Hemospray delivery system is passed through the accessory channel of the endoscope and positioned just above the bleeding site without making contact with the GI tract wall. The Hemospray® powder is propelled through the application catheter, either a 7 or 10 French polyethylene catheter, by release of CO_2 from the cartridge located in the device handle and sprayed onto the bleeding site. Bentonite can absorb five to ten times its weight in water and swell up to 15 times its dry volume. Bentonite rapidly absorbs water and becomes cohesive to itself and adhesive to tissue, forming a physical barrier to aqueous fluid (for example, blood). Hemospray® is not absorbed by the body and does not require removal as it passes through the GI tract within 72 hours. Hemospray® is single-use and disposable.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted a *de novo* request classifying the Hemospray® Endoscopic Hemostat (Hemospray®) as a Class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on May 7, 2018. We received the application for

a new device category for transitional pass-through payment status for the Hemospray® Endoscopic Hemostat on December 2, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether Hemospray® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Hemospray® is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed that Hemospray® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether Hemospray® meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not yet identified an existing pass-through payment category that describes Hemospray®. We are inviting public comment on whether Hemospray® meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. The

applicant stated that Hemospray® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of Hemospray® on endoscopic hemostasis outcomes, rebleeding occurrence, and mortality.

According to the applicant, Hemospray® is a topically applied mineral powder that offers a novel primary treatment option for endoscopic bleeding management, serves as an option for patients who fail conventional endoscopic treatments, and serves as an alternative to interventional radiology hemostasis (IRH) and surgery. Broadly, the applicant outlined two treatment areas in which it stated Hemospray® would provide a substantial clinical improvement: 1) as a primary treatment or a rescue treatment after the failure of a conventional method, and 2) in use for the treatment of malignant lesions. The applicant provided seven articles specifically for the purpose of addressing the substantial clinical improvement criterion.

The first article provided by the applicant was a prospective single armed multicenter phase two safety and efficacy study performed in France.[15] From March 2013 to January 2015, 64 endoscopists in 20 centers enrolled 202 patients in the study in which Hemospray® was used as either a first line treatment (46.5 percent) or salvage therapy (53.5 percent) following unsuccessful treatment with another method. The indication for Hemospray® as a first-line therapy or salvage therapy was at the discretion of the endoscopist. Of the 202 patients, the mean age was 68.9, 69.3 percent were male, and all patients were classified into four primary etiologic groups: ulcers (37.1 percent), malignant lesions (30.2 percent), post-endoscopic bleeding (17.3 percent), and other (15.3 percent). Patients were further classified by the American Society of Anesthesiologist (ASA) physical status scores with 4.5 percent as a normal healthy patient, 24.3 percent as a patient with mild systemic disease, 46 percent as a patient

[5] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: a multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

with severe systemic disease, 22.8 percent as a patient with severe systemic disease that is a constant threat to life, and 2.5 percent as a moribund patient who is not expected to survive without an operation.[6] [7] Immediate hemostasis was achieved in 96.5 percent across all patients; among treatment subtypes immediate hemostasis was achieved in 96.8 percent of first-line treated patients and 96.3 percent of salvage therapy patients. At day 30 the overall rebleeding was 33.5 percent of 185 patients with cumulative incidences of 41.4 percent for ulcers, 37.7 percent for malignant lesions, 17.6 percent for post-endoscopic bleedings, and 25 percent for others. When Hemospray® was used as a first-line treatment, rebleeding at day 30 occurred in 26.5 percent (22/83) of overall lesions, 30.8 percent of ulcers, 33.3 percent of malignant lesions, 13.6 percent of post-endoscopic bleedings, and 22.2 percent of other. When Hemospray® was used as a salvage therapy, rebleeding at day 30 occurred in 39.2 percent (40/102) of overall lesions, 43.9 percent of ulcers, 50.0 percent of malignant lesions, 25.0 percent of post-endoscopic bleedings, and 26.3 percent for others. According to the article, the favorable hemostatic results seen from Hemospray® are due to its threefold mechanism of action: formation of a mechanical barrier; concentration of clotting factors at the bleeding site; and enhancement of clot formation.[8] No severe adverse events were noted, however the authors note the potential for pain exists due to the use of carbon dioxide. Lastly, the authors stated that while Hemospray® was found to reduce the need for radiological embolization and surgery as salvage therapies, it was not found to be better than other hemostatic methods in terms of preventing rebleeding of ulcers.

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[6] Ibid.
[7] ASA House of Delegates / Executive Committee. (2014, October 15). *ASA Physical Status Classification System*. Retrieved from American Society of Anesthesiologists: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system
[8] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: a multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

The applicant provided a second article consisting of an abstract from another systematic review article.[9] The abstract purports to cover a review of prospective, retrospective, and randomized control trials evaluating Hemospray® as a rescue therapy. Eighty-five articles were initially identified and 23 were selected for review. Of those, 5 studies were selected which met the inclusion criteria of the analysis. The median age of patients was 69; 68 percent were male. The abstract concludes that when used as a rescue therapy after the failure of conventional endoscopic modalities, in nonvariceal gastrointestinal bleeding, Hemospray® seems to have significantly higher rates of immediate hemostasis.

A third article provided by the applicant described a single-arm retrospective analytical study of 261 enrolled patients conducted at 21 hospitals in Spain.[10] The mean age was 67 years old, 69 percent of patients were male, and the overall technical success, defined as correct assembled and delivery of Hemospray® to a bleeding lesion, was 97.7 percent (95.1 percent - 99.2 percent). The most common causes of bleeding in patients were peptic ulcer (28 percent), malignancy (18.4 percent), therapeutic endoscopy-related (17.6 percent), and surgical anastomosis (8.8 percent). Overall, 93.5 percent (89.5 percent to 96 percent) of procedures achieved hemostasis. Recurrent bleeding, defined as 1) a new episode of bleeding symptoms, 2) a decrease in hemoglobin of >2 g/dL within 48 hours of an index endoscopy or > 3g/dL in 24 hours, or 3) direct visualization of active bleeding at the previously treated lesion on repeat endoscopy, had a cumulative incidence at 3 and 30 days of 16.1 percent (11.9 percent - 21 percent) and 22.9 percent (17.8 percent - 28.3 percent) respectively. The overall risk of Hemospray® failure at 3 and 30 days was 21.1 percent (16.4 percent-26.2 percent) and 27.4 percent (22.1 percent -

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[9] Moole, V., Chatterjee, T., Saca, D., Uppu, A., Poosala, A., & Duvvuri, A. A Systematic review and meta-analysis: analyzing the efficacy of hemostatic nanopowder (TC-325) as rescue therapy in patients with nonvariceal upper gastrointestinal bleeding. Gastroenterology 2019; 156(6), S-741

[10] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et. al. Hemostatic spray TC-325 for GI bleeding in a nationwide study: survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581-590.

32.9 percent) respectively with no statistically significant differences (p = 0.07) between causes at 30 days (for example, peptic ulcer, malignancy, anastomosis, therapeutic endoscopy-related, and other causes). With the use of multivariate analysis spurting bleeding vs. nonspurting bleeding (subdistribution hazard ratio [sHR] 1.97 (1.24-3.13)), hypotension vs. normotensive (sHR 2.14 (1.22-3.75)), and the use of vasoactive drugs (sHR 1.80 (1.10-2.95)) were independently associated with Hemospray® failure. The overall 30-day survival was 81.9 percent (76.5 percent-86.1 percent) with 46 patients dying during follow-up and 22 experiencing bleeding related deaths; twenty patients (7.6 percent) with intraprocedural hemostasis died before day 30. The authors indicated the majority of Hemospray® failures occurred within the first 3 days and the rate of immediate hemostasis was similar to literature reports of intraprocedural success rates of over 90 percent. The authors stated that the hemostatic powder of Hemospray® is eliminated from the GI tract as early as 24 hours after use, which could explain the wide ranging recurrent bleeding percentage. The authors reported that importantly, adverse events are rare, but cases of abdominal distension, visceral perforation, transient biliary obstruction, and splenic infarct have been reported; one patient involved in this study experienced an esophageal perforation without a definitive causal relationship.

A fourth article provided by the applicant described a single-arm multicenter prospective registry involving 314 patients in Europe which collected data on days 0, 1, 3, 7, 14, and 30 after endotherapy with Hemospray®.[11] The outcomes of interest in this study were immediate endoscopic hemostasis (observed cessation of bleeding within 5 minutes post Hemospray® application) with secondary outcomes of rebleeding immediately following treatment and during follow-up, 7 and 30 day all-cause mortality, and adverse events. The sample was 74 percent male with a median age of 71 with the most

[11] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019

common pathologies of peptic ulcer (53 percent), malignancy (16 percent), post-endoscopic bleeding (16 percent), bleeding from severe inflammation (11 percent), esophageal variceal bleeding (2.5 percent), and cases with no obvious cause (1.6 percent). The median baseline Blatchford score (BS) and RS were 11 and 7 respectively. The BS ranges from 0 to 23 with higher scores indicating increasing risk for required endoscopic intervention and is based upon the blood urea nitrogen, hemoglobin, systolic blood pressure, pulse, presence of melena, syncope, hepatic disease, and/or cardiac failure.[12] The RS ranges from 0 to 11 with higher scores indicating worse potential outcomes and is based upon age, presence of shock, comorbidity, diagnosis, and endoscopic stigmata of recent hemorrhage.[13] Immediate hemostasis was achieved in 89.5 percent of patients following the use of Hemospray®; only the BS was found to have a positive correlation with treatment failure in multivariate analysis (OR 1.21 (1.10-1.34)). Rebleeding occurred in 10.3 percent of patients who achieved immediate hemostasis again with only the BS having a positive correlation with rebleeding (OR: 1.13 (1.03-1.25)). At 30 days the all-cause mortality was 20.1 percent with 78 percent of these patients having achieved immediate endoscopic hemostasis and a cause of death resulting from the progression of other comorbidities. A subgroup analysis of treatment type (monotherapy, combination therapy, and rescue therapy groups) was performed showing no statistically significant difference in immediate hemostasis across groups (92.4 percent, 88.7 percent, and 85.5 percent respectively). Higher all-cause mortality rates at 30 days were highest in the monotherapy group (25.4 percent, p=0.04) as compared to all other groups. According to the authors, in comparison to major recent studies they were able to show lower rebleeding rates overall and in all subgroups despite the high-risk population.[14] The authors further note limitations in that the

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[12] Saltzman, J. (2019, October). Approach to acute upper gastrointestinal bleeding in adults. (M. Feldman, Editor) Retrieved from UpToDate: https://www.uptodate.com/contents/approach-to-acute-upper-gastrointestinal-bleeding-in-adults

[13] Ibid.

[14] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019

inclusion of patients was nonconsecutive and at the discretion of the endoscopist, at the time of the endoscopy, which allows for the potential introduction of selection bias, which may have affected these study results.

The fourth article also described the utility of Hemospray® in the treatment of malignant lesions. According to the applicant, malignant lesions pose a significant clinical challenge as successful hemostasis rates are as low as 40 percent with high recurrent bleeding over 50 percent within 1 month following standard treatments.[15] [16] The applicant added that bleeding from tumors is often diffuse and consists of friable mucosa decreasing the utility of traditional treatments (for example, ligation, cautery). From the fourth article, the applicant noted that 50 patients were treated for malignant bleeding with an overall immediate hemostasis in 94 percent of patients.[17] Of the 50 patients, 33 were treated with Hemospray® alone, 11 were treated with Hemospray® as the final treatment, and 4 were treated with Hemospray® as a rescue therapy of which 100 percent, 84.6 percent and 75 percent experienced immediate hemostasis respectively.[18] Similarly, from the first discussed article, the applicant noted that among malignant bleeding patients, 95.1 percent achieved immediate hemostasis with lower rebleeding rates at 8 days when Hemospray® was used as a primary treatment as compared to when used as a rescue therapy (17.1 percent vs. 46.7 percent respectively).[19] The applicant concluded that Hemospray® may provide an advantage as a primary treatment to patients with malignant bleeding.

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[15] Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489-95.
[16] Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.
[17] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019
[18] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019
[19] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: a multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

The applicant provided a fifth article, which consisted of a journal pre-proof article detailing a 1:1 randomized control trial of 20 patients treated with Hemospray® versus the standard of care (for example, thermal and injection therapies) in the treatment of malignant gastrointestinal bleeding.[20] The goals of this pilot study were to determine the feasibility of a definitive trial. The primary outcome of the study was immediate hemostasis (absence of bleeding after 3 minutes) with secondary outcomes of recurrent bleeding at days 1, 3, 30, 90, and 180 and adverse events at days 1, 30, and 180. The mean age of patients was 67.2, 75 percent were male, and on average patients presented with 2.9 ± 1.7 comorbidities. All patients had active bleeding at endoscopy and the majority of patients had an ASA score of 2 (45 percent) or 3 (40 percent). Immediate hemostasis was achieved in 90 percent of Hemospray® patients and 40 percent of standard of care patients (5 injection alone, 3 thermal, 1 injection with clips, and 1 unknown). Of those patients in the control group, 83.3 percent crossed over to the Hemospray® treatment. One patient died while being treated with Hemospray® from exsanguination; post-mortem examination demonstrated that bleeding was caused by rupture of a malignant inferior mesenteric artery aneurysm. Overall, 86.7 percent of patients treated with Hemospray® initially or as crossover treatment achieved hemostasis. Recurrent bleeding was lower in the Hemospray® group (20 percent) as compared to the control group (60 percent) at 180 days. Forty percent of the treated group received blood transfusions as compared to 70 percent of the control group. The overall length of stay was 14.6 days among treated patients as compared to 9.4 in the control group. Mortality at 180 days was 80 percent in both the treated and control groups. The authors noted the potential for operator bias in the use of Hemospray® prior to switching to another method when persistent bleeding exists. Lastly, the authors noted that while they did not occur during this study, there

[20] Chen Y-I, Wyse J, Lu Y, Martel M, Barkun AN, TC-325 hemostatic powder versus current standard of care in managing malignant GI bleeding: a pilot randomized clinical trial. Gastrointestinal Endoscopy (2019), doi: https://doi.org/10.1016/j.gie.2019.08.005.

are concerns around the risks of perforation, obstruction, and systemic embolization with the use of Hemospray®.

A sixth article provided by the applicant was a case-controlled study with 10 patients with active upper gastrointestinal bleeding from tumor compared with 10 conventional therapy patients selected as historical controls, matched by type of tumor[21]. The study evaluated efficacy for tumor-related bleeding and compared Hemospray® to conventional therapies, specifically examining 14-day rebleeding rates, lengths of hospital stay (LOS), and mortality rate at 30-day follow up. Historical controls were selected from patient medical records from 2010 to 2014. Among the patients who received Hemospray®, the 14-day rebleeding rate (10 percent vs. 30 percent; P=0.60). and the 30-day mortality rates (10 percent vs. 30 percent, P=0.7) were three times lower compared to the control group; neither rate was statistically significant. There was no difference in LOS between the Hemospray® and conventional therapy patients.

A seventh article provided by the applicant described a single-arm multicenter retrospective study from 2011 to 2016 involving 88 patients who bled as a result of either a primary GI tumor or metastases to the GI tract.[22] In this study the authors define immediate hemostasis as no further bleeding at least one minute after treatment with Hemospray® and recurrent bleeding was suspected if one of seven criteria were met: (1) hematemesis or bloody nasogastric tube >6 hours after endoscopy; (2) melena after normalization of stool color; (3) hematochezia after normalization of stool color or melena; (4) development of tachycardia or hypotension after >1 hour of vital sign stability without other cause; (5) decrease in hemoglobin level greater than or equal to 3 hours apart; (6) tachycardia or hypotension

[21] Pittayanon, R., Prueksapanich, P., & Rerknimitr, R. (2016). The efficacy of Hemospray in patients with upper gastrointestinal bleeding from tumor. Endoscopy international open, 4(09), E933-E936.
[22] Pittayanon R, Rerknimitr R, Barkun A. Prognostic factors affecting outcomes in patients with malignant GI bleeding treated with a novel endoscopically delivered hemostatic powder. Gastrointest Endosc 2018; 87:991-1002.

that does not resolve within 8 hours after index endoscopy; or (7) persistent decreasing hemoglobin of >3 g/dL in 24 hours associated with melena or hematochezia). The sample for this study consisted of 88 patients (with a mean age of 65 years old and 70.5 percent male) of which 33.3 percent possessed no co-morbid illness, and 25 percent were on current antiplatelet / anticoagulant medication. The mean BS was 8.7 plus or minus 3.7 with a range from 0 to 18. Overall, 72.7 percent of patients had a stage 4 adenocarcinoma, squamous cell carcinoma, or lymphoma. Immediate hemostasis was achieved in 97.7 percent of patients. Recurrent bleeding occurred among 13 of 86 (15 percent) and 1 of 53 (1.9 percent) at 3 and 30 days, respectively. A total of 25 patients (28.4 percent) died during the 30-day follow up period. Overall, 27.3 percent of patients re-bled within 30 days after treatment of which half were within 3 days. Using multivariate analysis, the authors found patients with good performance status, no end-stage cancer, or receiving any combination of definitive hemostasis treatment modalities had significantly greater survival. The authors acknowledged the recurrent bleeding rate post Hemospray® treatment at 30 days of 38 percent is comparable with that seen in sole conventional hemostatic techniques and state this implies that Hemospray® does not differ from conventional techniques and remains unsatisfactory.

Ultimately, the applicant concluded nonvariceal gastrointestinal bleeding is associated with significant morbidity and mortality in older patients with multiple co-morbid conditions. Inability to achieve hemostasis and early rebleeding are associated with increased cost and greater resource utilization. According to the applicant, patients with bleeding from malignant lesions have few options that can provide immediate hemostasis without further disrupting fragile mucosal tissue and worsening the active bleed. The applicant stated Hemospray® is an effective agent that provides immediate hemostasis in patients with GI bleeding as part of multimodality treatment, as well as when used to rescue patients who have failed more conventional endoscopic modalities. Furthermore, the applicant

stated that in patients with malignant bleeding in the GI tract, Hemospray® provides a high rate of immediate hemostasis and fewer recurrent bleeding episodes, which, in combination with definitive cancer treatment, may lead to improvements in long term survival. Lastly, the applicant stated Hemospray® is an important new technology that permits immediate and long-term hemostasis in GI bleeding cases where standard of care treatment with clip ligation or cautery are not effective.

We note that the majority of studies provided lack a comparator when assessing the effectiveness of Hemospray®. Three of the articles provided are systematic reviews of the literature. While we find these articles helpful in establishing a background for the use of Hemospray®, we are concerned that they may not provide strong evidence of substantial clinical improvement. Four studies appear to be single-armed studies assessing the efficacy of Hemospray® in the patient setting. In all of these articles, comparisons are made between Hemospray® and standard of care treatments; however, without the ability to control for factors such as study design, patient characteristics, etc., it is difficult to determine if any differences seen result from Hemospray® or confounding variables. Furthermore, within the retrospective and prospective studies lacking a control subset, some level of selection bias appears to potentially be introduced in that providers may be allowed to select the manner and order in which patients are treated, thereby potentially influencing outcomes seen in these studies.

Additionally, one randomized control trial provided by the applicant appears to be in the process of peer-review and is not yet published. Furthermore, this article is written as a feasibility study for a potentially larger randomized control trial and contains a sample of only 20 patients. This small sample size leaves us concerned that the results are not representative of the larger Medicare population. Lastly, as described we are concerned the control group can receive one of multiple treatments which lack a clear designation methodology beyond physician choice. For instance, 50 percent of the control patients received injection therapy alone, which according to the literature provided by the applicant is not an

acceptable treatment for endoscopic bleeding. Accordingly, it is not clear whether performance seen in the treated group as compared to the control group is due to Hemospray® itself or due to confounding factors.

Third, we are concerned with the samples chosen in many of the studies presented. Firstly, the Medicare population is approximately 54 percent female and 46 percent male. [23] Many of the samples provided by the applicant are overwhelmingly male. Secondly, many of the studies provided were performed in European and other settings outside of the United States. We are therefore concerned that the samples chosen within the literature provided may not represent the Medicare population.

Lastly, we are concerned about the potential for adverse events resulting from Hemospray®. It is unclear from the literature provided by the applicant what the likelihood of these events is and whether or not an evaluation for the safety of Hemospray® was performed. About one-third of the articles submitted specifically addressed adverse events with Hemospray®. However, the evaluation of adverse events was limited and most of the patients in the studies died of disease progression. A few of the provided articles mention the potential for severe adverse reactions (for example, abdominal distension, visceral perforation, biliary obstruction, splenic infarct). Specifically, one article[24] recorded adverse events related to Hemospray®, including abdominal distention and esophageal perforation.

According to information submitted by the applicant, Cook Medical is voluntarily recalling Hemospray® Endoscopic Hemostat due to complaints received that the handle and/or activation knob on the device in some cases has cracked or broken when the device is activated and in some cases has caused the carbon dioxide cartridge to exit the handle. The applicant stated that Cook Medical has

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[23]https://www.cms.gov/files/document/2018-mdcr-enroll-ab-5.pdf

[24] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et. al. Hemostatic spray TC-325 for GI bleeding in a nationwide study: survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581-590.

received 1 report of a superficial laceration to the user's hand that required basic first aid; however, there have been no reports of laceration, infection, or permanent impairment of a body structure to users or to patients due to the carbon dioxide cartridge exiting the handle. The applicant stated that Cook Medical has initiated an investigation and will determine the appropriate corrective action(s) to prevent recurrence of this issue. According to the applicant, although the recall does restrict availability of the device, they wish to continue their application as they believe the use of Hemospray® significantly improves clinical outcomes for certain patient populations compared to currently available treatments.

Based upon the evidence presented, we are inviting public comments on whether the Hemospray® Endoscopic Hemostat meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Hemospray® would be reported with HCPCS codes 43227, 43255, 44366, 44378, 44391, 45334, and 45382. To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5312, which had a CY 2020 payment rate of $1,004.10 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 45382 had a device offset amount of $33.54 at the time the application was received. According to the applicant, the cost of the Hemospray® Endoscopic Hemostat is $2,500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of

$2,500 for Hemospray® is 249 percent of the applicable APC payment amount for the service related to the category of devices of $1004.10 (($2,500/$1,004.10) x 100 = 249 percent). Therefore, we believe Hemospray® meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,500 for Hemospray® is 7,454 percent of the cost of the device-related portion of the APC payment amount for the related service of $33.54 (($2,500/$33.54) x 100 = 7,453.8 percent). Therefore, we believe that Hemospray® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,500 for Hemospray® and the portion of the APC payment amount for the device of $33.54 is 246 percent of the APC payment amount for the related service of $1004.10 t (((($2,500-$33.54)/$ 1004.10) x 100 = 245.6 percent). Therefore, we believe that Hemospray® meets the third cost significance requirement.

We are inviting public comment on whether the Hemospray® Endoscopic Hemostat meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) The SpineJack® Expansion Kit

Stryker, Inc., submitted an application for a new device category for transitional pass-through payment status for the SpineJack® Expansion Kit (hereinafter referred to as the SpineJack® system) by

the March 2020 quarterly deadline. The applicant described the SpineJack® system as an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs) and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement.

The applicant described the SpineJack® system as including two cylindrical implants constructed from Titanium-6-Aluminum-4-Vanadium (Ti6Al4V) with availability in three sizes: 4.2 mm (12.5 mm expanded), 5.0 mm (17 mm expanded) and 5.8 mm (20 mm expanded). The applicant explained implant size selection is based upon the internal cortical diameter of the pedicle. According to the SpineJack® system Instructions for Use, the use of two implants is recommended to treat a fractured VB. According to the applicant, multiple VBs can also be treated in the same operative procedure as required. Additionally, the applicant explained that titanium alloy allows for plastic deformation when it encounters the hard cortical bone of the endplate yet still provides the lift force required to restore midline VB height in the fractured vertebra. The applicant stated that the SpineJack® system notably contains a self-locking security mechanism that restricts further expansion of the device when extreme load forces are concentrated on the implant. As a result, the applicant stated that this feature significantly reduces the risk of vertebral endplate breakage while it further allows functional recovery of the injured disc.[25]

The applicant stated that the implants are then progressively expanded though actuation of an implant tube that pulls the two ends of the implant towards each other in situ to mechanically restore VB height. The applicant explained that the mechanical working system of the implant allows for a

[25] Vanni D et al. "Third-generation percutaneous vertebral augmentation systems." *Journal of Spine Surgery.* 2016, vol 2(1), pp. 13-20.

progressive and controlled reduction of the vertebral fracture.[26] The applicant stated that when expanded, each SpineJack® implant exerts a lifting pressure on the fracture through a mechanism that may be likened to the action of a scissor car jack, and that the longitudinal compression on the implant causes it to open in a craniocaudal direction. The applicant explained that the implant is locked into the desired expanded position as determined and controlled by the treating physician.[27]

The applicant further explained that the expansion of the SpineJack® implants creates a preferential direction of flow for the bone cement and once the desired expansion has been obtained, polymethylmethacrylate (PMMA) bone cement is deployed from the center of the implant into the VB. The applicant stated that when two implants are symmetrically positioned in the VB, this allows for a more homogenous spread of PMMA bone cement. The applicant stated that the interdigitation of bone cement creates a broad supporting ring under the endplate, which is essential to confer stability to the VB.

According to the applicant, osteoporosis is one of the most common bone diseases worldwide that disproportionately affects aging individuals. The applicant explained that in 2010, approximately 54 million Americans aged 50 years or older had osteoporosis or low bone mass[28], which resulted in more than 2 million osteoporotic fragility fractures in that year alone.[29] The applicant stated it has been estimated that more than 700,000 VCFs occur each year in the United States (U.S.),[30] and of these

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[26] Vanni D., et al., "Third-generation percutaneous vertebral augmentation systems," *J. Spine Surg.*, 2016, vol. 2(1) pp. 13-20.
[27] Noriega D. et al., "Clinical Performance and Safety of 108 SpineJack Implantations: 1-Year Results of a Prospective Multicentre Single-Arm Registry Study," *BioMed Res. Int*., 2015, vol. 173872.
[28] National Osteoporosis Foundation. (2019). What is osteoporosis and what causes it? Available from: https://www.nof.org/patients/what-is-osteoporosis/.
[29] King A and Fiorentino D. "Medicare payment cuts for osteoporosis testing reduced use despite tests' benefit in reducing fractures." *Health Affairs (Millwood),* 2011, vol. 30(12), pp. 2362-2370.
[30] Riggs B and Melton L. "The worldwide problem of osteoporosis: Insights afforded by epidemiology." *Bone,* 1995, vol. 17(Suppl 5), pp. 505-511.

VCFs, about 70,000 result in hospital admissions with an average length of stay of 8 days per patient.[31] Furthermore, the applicant noted that in the first year after a painful vertebral fracture, patients have been found to require primary care services at a rate 14 times greater than the general population.[32] The applicant explained that medical costs attributed to VCFs in the U.S. exceeded $1 billion in 2005 and are predicted to surpass $1.6 billion by 2025.[33]

The applicant explained that osteoporotic VCFs occur when the vertebral body (VB) of the spine collapses and can result in chronic disabling pain, excessive kyphosis, loss of functional capability, decreased physical activity, and reduced quality of life. The applicant stated that as the spinal deformity progresses, it reduces the volume of the thoracic and abdominal cavities, which may lead to crowding of internal organs. The applicant noted that the crowding of internal organs may cause impaired pulmonary function, abdominal protuberance, early satiety and weight loss. The applicant indicated that other complications may include bloating, distention, constipation, bowel obstruction, and respiratory disturbances such as pneumonia, atelectasis, reduced forced vital capacity and reduced forced expiratory volume in 1 second.

The applicant explained that the SpineJack® implants provide symmetric, broad load support for osteoporotic vertebral collapse, which is based upon precise placement of bilateral "struts" that are encased in PMMA bone cement, whereas BKP and vertebroplasty (VP) do not provide structural support via an implanted device. The applicant explained that the inflatable balloon tamps utilized in BKP are not made from titanium and are not a permanent implant. According to the applicant, the balloon tamps are constructed from thermoplastic polyurethane, which have limited load bearing

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[31] Siemionow K and Lieberman I. "Vertebral augmentation in osteoporotic and osteolytic fractures: Current Opinion in Supportive and Palliative Care." 2009, vol. 3(3), pp. 219-225.
[32]Wong C and McGirt M. "Vertebral compression fractures: A review of current management and multimodal therapy." *Journal of Multidisciplinary Healthcare,* 2013, vol 6, pp. 205-214.
[33] Burge R et al. "Incidence and economic burden of osteoporosis-related fractures in the United States: 2005-2025." *Journal of Bone and Mineral Research*. 2007, vol 22(3), pp. 465-475.

capacity. The applicant noted that although the balloon tamps are expanded within the VB to create a cavity for bone cement, they do not remain in place and are removed before the procedure is completed. The applicant explained that partial lift to the VB is obtained during inflation, resulting in kyphotic deformity correction and partial gains in anterior VB height restoration, but inflatable balloon tamps are deflated prior to removal so some of the VB height restoration obtained is lost upon removal of the bone tamps. According to the applicant, BKP utilizes the placement of PMMA bone cement to stabilize the fracture and does not include an implant that remains within the VB to maintain fracture reduction and midline VB height restoration.

The applicant stated that if VB collapse is >50 percent of the initial height, segmental instability will ensue. As a result, the applicant explained that adjacent levels of the VB must support the additional load and this increased strain on the adjacent levels may lead to additional VCFs. Furthermore, the applicant summarized that VCFs also lead to significant increases in morbidity and mortality risk among elderly patients, as evidenced by a 2015 study by Edidin et al., in which researchers investigated the morbidity and mortality of patients with a newly diagnosed VCF (n = 1,038,956) between 2005 to 2009 in the U.S. Medicare population. For the osteoporotic VCF subgroup, the adjusted 4-year mortality was 70 percent higher in the conservatively managed group than in the balloon kyphoplasty procedures (BKP)-treated group, and 17 percent lower in the BKP group than in the vertebroplasty (VP) group. According to the applicant, when evaluating treatment options for osteoporotic VCFs, one of the main goals of treatment is to restore the load bearing bone fracture to its normal height and stabilize the mechanics of the spine by transferring the adjacent level pressure loads across the entire fractured vertebra and in this way, the intraspinal disc pressure is restored and the risk of adjacent level fractures (ALFs) is reduced.

The applicant explained that treatment of osteoporotic VCFs in older adults most often begins with conservative care, which includes bed rest, back bracing, physical therapy and/or analgesic medications for pain control. According to the applicant, for those patients that do not respond to conservative treatment and continue to have inadequate pain relief or pain that substantially impacts quality of life, vertebral augmentation (VA) procedures may be indicated. The applicant explained that VP and BKP are two minimally invasive percutaneous VA procedures that are most often used in the treatment of osteoporotic VCFs and another VA treatment option includes the use of a spiral coiled implant made from polyetheretherketone (PEEK), which is part of the Kiva® system.

According to the applicant, among the treatment options available, BKP is the most commonly performed procedure and the current gold standard of care for VA treatment. The applicant stated that it is estimated that approximately 73 percent of all vertebral augmentation procedures performed in the United States between 2005 and 2010 were BKP.[34] According to the applicant, the utilization of the Kiva® system is relatively low in the U.S. and volume information was not available in current market research data.[35]

The applicant stated that VA treatment with VP may alleviate pain, but it cannot restore VB height or correct spinal deformity. The applicant stated that BKP attempts to restore VB height, but the temporary correction obtained cannot be sustained over the long term. The applicant stated that the Kiva® implant attempts to mechanically restore VB height, but it has not demonstrated superiority to BKP for this clinical outcome.[36]

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[34] Goz V et al. "Vertebroplasty and kyphoplasty: National outcomes and trends in utilization from 2005 through 2010." *The Spine Journal.* 2015, vol. 15(5), pp. 959-965.
[35] Lin M. "Minimally invasive vertebral compression fracture treatments. *Medtech 360, Market Insights, Millennium Research Group*. 2019.
[36] Ibid.

The applicant provided additional detail comparing the construction and mechanism of action for other VA treatments, provided below. According to the applicant the Kiva® system is constructed of a nitinol coil and PEEK-OPTIMA sheath, with sizes including a 4-loop implant (12 mm expanded) and a 5-loop implant (15 mm expanded) and unlike the SpineJack® system, is not made of titanium and does not include a locking scissor jack design. The applicant stated that the specific mechanism of action for the Kiva® system is different from the SpineJack® system. The applicant explained that during the procedure that involves implanting the Kiva® system, nitinol coils are inserted into the VB to form a cylindrical columnar cavity. The applicant stated that the PEEK-OPTIMA is then placed over the nitinol coil. The applicant explained that the nitinol coil is removed from the VB and the PEEK material is filled with PMMA bone cement. The applicant stated that the deployment of 5 coils equates to a maximum height of 15 mm. The applicant stated that the lifting direction of the Kiva implant is caudate and unidirectional. According to the applicant, in the KAST (Kiva Safety and Effectiveness Trial) pivotal study, it was reported that osteoporotic VCF patients treated with the Kiva® system had an average of 2.6 coils deployed.[37] Additionally, in a biomechanical comparison conducted for the Kiva® system and BKP using a loading cycle of 200-500 Newtons in osteoporotic human cadaver spine segments filled with bone cement, there were no statistically significant differences observed between the two procedures for VB height restoration, stiffness at high or low loads, or displacement under compression.[38]

The applicant summarized the differences and similarities of the SpineJack®, BKP, and PEEK coiled implant as follows: (1) with respect to construction, SpineJack® is made of Titanium-6-

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[37] Tutton S et al. KAST Study: The Kiva system as a vertebral augmentation treatment - a safety and effectiveness trial: A randomized, noninferiority trial comparing the Kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. *Spine*. 2015; 40(12):865-875.

[38] Wilson D et al. An ex vivo biomechanical comparison of a novel vertebral compression fracture treatment system to kyphoplasty. *Clinical Biomechanics*. 2012; 27(4):346-353.

Aluminum-4-Vanadium compared to thermoplastic polyurethanes for BKP and nitinol and PEEK for the PEEK coiled implant; (2) with respect to mechanism of action, the SpineJack® uses a locking scissor jack encapsulated in PMMA bone cement compared to hydrodynamic cavity creation and PMMA cavity filler for BKP and coil cavity creation and PEEK implant filled with PMMA bone cement for the PEEK coiled implant; (3) with respect to plastic deformation, SpineJack® and BKP allow for plastic deformation while the PEEK coiled implant does not; (4) with respect to craniocaudal expansion, SpineJack® allows for craniocaudal expansion, whereas BKP and the PEEK coiled implant do not; (5) with respect to bilateral load support, SpineJack® provides bilateral load support whereas BKP and the PEEK coiled implant do not; and (6) with respect to lift pressure of >500 N, SpineJack® provides lift pressure of >500 N whereas BKP and the PEEK coiled implant do not. The applicant summarized that the SpineJack® system is uniquely constructed and utilizes a different mechanism of action than BKP, which is the gold standard of treatment for osteoporotic VCFs, and that the construction and mechanism of action of the SpineJack® system is further differentiated when compared with the PEEK coiled implant.

With respect to the newness criterion, the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, based on a determination of substantial equivalence to a legally marketed predicate device. The applicant explained that although the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, due to the time required to prepare for supply and distribution channels, it was not available on the U.S. market until October 2018. As we discussed previously, the SpineJack® Expansion Kit is indicated for use in the reduction of painful osteoporotic VCFs and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cements. We received the application for a new device category for transitional pass-through payment status for the SpineJack® Expansion Kit on February 4, 2020, which is within 3 years of the date of the

initial FDA marketing authorization. We are inviting public comments on whether the SpineJack® Expansion Kit meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the SpineJack® Expansion Kit is integral to the service of reducing painful osteoporotic vertebral compression fractures (VCFs), is used for one patient only, comes in contact with human skin, and is surgically implanted or inserted into the patient. Specifically, the applicant explained that the SpineJack® system is designed to be implanted into a collapsed vertebral body (VB) via a percutaneous transpedicular approach under fluoroscopic guidance. According to the applicant, the implants remain within the VB with the delivered bone cement. The applicant also claimed the SpineJack® Expansion Kit meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the SpineJack® Expansion Kit meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant describes the SpineJack® Expansion Kit as an implantable fracture reduction system used to treat vertebral compression fractures (VCFs). The applicant reported that it does not believe that the SpineJack® Expansion Kit is described by an existing category and requested category descriptor "Vertebral body height restoration device, scissor jack (implantable)." We have identified one existing pass-through payment categories that may be applicable to SpineJack® Expansion Kit. The SpineJack® Expansion

Kit may be described by HCPCS code C1821 (interspinous process distraction device (implantable)). We are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. With respect to the substantial clinical improvement criterion, the applicant submitted 8 studies and 19 other references to support assertions that the treatment of osteoporotic vertebral compression fracture (VCF) patients with the SpineJack® system represents a substantial clinical improvement over existing technologies because clinical research supports that it reduces future interventions, hospitalizations, and physician visits through a decrease in adjacent level fractures (ALFs), which the applicant stated are clinically significant adverse events associated with osteoporotic VCF. The applicant also stated that treatment with the SpineJack® system greatly reduces pain scores and pain medication use when compared to BKP, which the applicant stated is the current gold standard in vertebral augmentation (VA) treatment.

The applicant explained that the SpineJack® system has been available for the treatment of patients with osteoporotic VCFs for over 10 years in Europe. The applicant explained that, as a result, the SpineJack® implant has been extensively studied, and claims from smaller studies are supported by the results from a recent, larger prospective, randomized study known as the SAKOS (SpineJack® versus

Kyphoplasty in Osteoporotic Patients) study. The applicant cited the SAKOS study[39] in support of multiple substantial clinical improvement claims: reduction in adjacent level fractures, superiority in mid-vertebral body height restoration, and pain relief. The applicant explained that the SAKOS study was the pivotal trial conducted in support of the FDA 510(k) clearance for the SpineJack® system and that the intent of the study was to compare the safety and effectiveness of the SpineJack® system with the KyphX Xpander Inflatable Bone Tamp (BKP) for treatment of patients with painful osteoporotic VCFs in order to establish a non-inferiority finding for use of the SpineJack® system versus balloon kyphoplasty procedure (BKP).

The SAKOS study is a prospective, international, randomized, non-inferiority study comparing a titanium implantable vertebral augmentation device (TIVAD), the SpineJack® system, versus BKP in the reduction of vertebral compression fractures with a 12-month follow-up. The primary endpoint was a 12-month responder rate based on a composite of three components: (1) reduction in VCF fracture-related pain at 12 months from baseline by >20 mm as measured by a 100-mm Visual Analog Scale (VAS) measure; (2) maintenance or functional improvement of the Oswestry Disability Index (ODI) score at 12 months from baseline; and (3) absence of device-related adverse events or symptomatic cement extravasation requiring surgical reintervention or retreatment at the index level. If the primary composite endpoint was successful, a fourth component (absence of ALF) was added to the three primary components for further analysis. If the analysis of this additional composite endpoint was successful, then midline target height restoration at 6 and 12 months was assessed. According to the applicant, freedom from ALFs and midline VB height restoration were two additional superiority measures that were tested. According to the SAKOS study, secondary clinical outcomes included

[39] Noriega, D., et al., "A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study)," *The Spine Journal*, 2019, vol. 19(11), pp. 1782-1795.

changes from baseline in back pain intensity, ODI score, EuroQol 5-domain (EQ-5D) index score (to evaluate quality of life), EQ-VAS score, ambulatory status, analgesic consumption, and length of hospital stay. Radiographic endpoints included restoration of vertebral body height (mm), and Cobb angle at each follow-up visit. Adverse events (AEs) were recorded throughout the study period. The applicant explained that researchers did not blind the treating physicians or patients, so each group was aware of the treatment allocation prior to the procedure; however, the three independent radiologists that performed the radiographic reviews were blinded to the personal data of the patients, study timepoints, and results of the study.

The SAKOS study recruited patients from 13 hospitals across 5 European countries and randomized 152 patients with osteoporotic vertebral compression fractures (OVCFs) (1:1) to either SpineJack® or BKP procedures. Specifically, patients were considered eligible for inclusion if they met a number of criteria, including: (1) at least 50 years of age; (2) had radiographic evidence of one or two painful VCF between T7 and L4, aged less than 3 months, due to osteoporosis; (3) fracture(s) that showed loss of height in the anterior, middle, or posterior third of the VB ≥15 percent but ≤40 percent; and (4) patient failed conservative medical therapy, defined as either having a VAS back pain score of ≥50 mm at 6 weeks after initiation of fracture care or a VAS pain score of ≥70 percent mm at 2 weeks after initiation of fracture care. Eleven of the originally recruited patients were subsequently excluded from surgery (9 randomized to SpineJack® and 2 to BKP). A total of 141 patients underwent surgery, and 126 patients completed the 12-month follow-up period (61 TIVAD and 65 BKP). The applicant contended that despite the SAKOS study being completed outside the U.S., results are applicable to the Medicare patient population, noting that 82 percent (116 of 141) of the patients in the SAKOS trial that received treatment (SpineJack® system or BKP) were age 65 or older. The applicant explained further that the FDA evaluated the applicability of the SAKOS clinical data to the U.S. population and FDA

concluded that although the SAKOS study was performed in Europe, the final study demographics were very similar to what has been reported in the literature for U.S.-based studies of BKP. The applicant also explained that FDA determined that the data was acceptable for the SpineJack® system 510(k) clearance, including two clinical superiority claims versus BKP.

The SAKOS study reported that analysis on the intent to treat population using the observed case method resulted in a 12-month responder rate of 89.8 percent and 87.3 percent, for SpineJack® and BKP respectively (p=0.0016). The additional composite endpoint analyzed in observed cases resulted in a higher responder rate for SpineJack® compared to BKP at both 6 months (88.1 percent vs. 60.9 percent; p<0.0001) and 12 months (79.7 percent vs. 59.3 percent; p<0.0001). Midline VB height restoration, tested for superiority using a *t* test with one-sided 2.5 percent alpha in the ITT population, was greater with SpineJack® than BKP at 6 months (1.14±2.61 mm vs 0.31±2.22 mm; p=0.0246) and at 12 months (1.31±2.58 mm vs. 0.10±2.23 mm; p=0.0035), with similar results in the per protocol (PP) population.

Also, according to the SAKOS study, decrease in pain intensity versus baseline was more pronounced in the SpineJack® group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021). At 12 months, the difference in pain intensity was no longer statistically significant between the groups, and pain intensity at 5 days post-surgery was not statistically different between the groups. The SAKOS study publication also reported that at each timepoint, the percentage of patients with reduction in pain intensity >20 mm was ≥90 percent in the SpineJack® group and ≥80 percent in the BKP group, with a statistically significant difference in favor of SpineJack® at 1-month post-procedure (93.8 percent vs 81.4 percent; p=0.03). The study also reported: (1) no statistically significant difference in disability (ODI score) between groups during the follow-up period, although there was a numerically greater improvement in the SpineJack® group at most time points; (2) at each time point, the percentage of patients with maintenance or improvement in functional capacity was at or close to 100 percent; and

(3) in both groups, a clear and progressive improvement in quality of life was observed throughout the 1-year follow-up period without any statistically significant between-group differences.

In the SAKOS study, both groups had similar proportions of VCFs with cement extravasation outside the treated VB (47.3 percent for TIVAD, 41.0 percent for BKP; p=0.436). No symptoms of cement leakage were reported. The SAKOS study also reported that the BKP group had a rate of adjacent fractures more than double the SpineJack® group (27.3 percent vs. 12.9 percent; p=0.043). The SAKOS study also reported that the BKP group had a rate of non-adjacent subsequent thoracic fractures nearly 3 times higher than the SpineJack® group (21.9 percent vs. 7.4 percent) (a p-value was not reported for this result). The most common AEs reported over the study period were backpain (11.8 percent with SpineJack®, 9.6 percent with BKP), new lumbar vertebral fractures (11.8 percent with SpineJack®, 12.3 percent with BKP), and new thoracic vertebral fractures (7.4 percent with SpineJack®, 21.9 percent with BKP). The most frequent SAEs were lumbar vertebral fractures (8.8 percent with SpineJack®; 6.8 percent with BKP) and thoracic vertebral fractures (5.9 percent with SpineJack®, 9.6 percent with BKP). We also note that the length of hospital stay (in days) for osteoporotic VCF patients treated in the SAKOS trial was 3.8 ± 3.6 days for the SpineJack® group and 3.3 ±2.4 days for the BKP group (p = 0.926, Wilcoxon test).

The applicant also submitted additional studies, which are described in more detail in this section, related to the applicant's specific assertions regarding substantial clinical improvement.

As stated previously, the applicant stated that the SpineJack® system represents a substantial clinical improvement over existing technologies because it will reduce future interventions, hospitalizations, and physician visits through a decrease in ALFs. The applicant explained that ALFs are considered clinically significant adverse events associated with osteoporotic VCFs, citing studies by

Lindsay et al.[40] and Ross et al.[41] The applicant explained that these studies reported, respectively, that having one or more VCFs (irrespective of bone density) led to a 5-fold increase in the patient's risk of developing another vertebral fracture, and the presence of two or more VCFs at baseline increased the risk of ALF by 12-fold. The applicant stated that analysis of the additional composite endpoint in the SAKOS study demonstrated statistical superiority of the SpineJack® system over BKP ($p<0.0001$) for freedom from ALFs at both 6 months (88.1 percent vs. 60.9 percent) and 12 months (79.7 percent vs. 59.3 percent) post-procedure. The applicant noted that the results were similar on both the intent to treat and PP patient populations. In addition, the applicant stated the SpineJack® system represents a substantial clinical improvement because in the SAKOS study, compared to patients treated with the SpineJack® system, BKP-treated patients had more than double the rate of ALFs (27.3 percent vs. 12.9 percent; $p=0.043$) and almost triple the rate of non-adjacent thoracic VCFs (21.9 percent vs. 7.4 percent).

The applicant also stated superiority with respect to mid-vertebral body height restoration with the SpineJack® system. The applicant explained that historical treatments of osteoporotic VCFs have focused on anterior VB height restoration and kyphotic Cobb angle correction; however, research indicates that the restoration of middle VB height may be as important as Cobb angle correction in the prevention of ALFs.[42] According to the applicant, the depression of the mid-vertebral endplate leads to decreased mechanics of the spinal column by transferring the person's weight to the anterior wall of the level adjacent to the fracture, and as a result the anterior wall is the most common location for ALFs. The applicant further stated that by restoring the entire fracture, including mid-VB height, the vertebral

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[40] Lindsay R. et al., "Risk of new vertebral fracture in the year following a fracture," *Journal of the American Medical Association*, 2001, vol. 285(3), pp. 320-323.
[41] Ross P. et al., Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Annals of Internal Medicine*. 1991, vol. 114(11), pp. 919-923.
[42] Lin J et al. Better height restoration, greater kyphosis correction, and fewer refractures of cemented vertebrae by using an intravertebral reduction device: A 1-year follow-up study. *World Neurosurgery*. 2016; 90:391-396.

disc above the superior vertebral endplate is re-pressurized and transfers the load evenly, preventing ALFs.[43] The applicant stated that the SpineJack® system showed superiority over BKP with regard to midline VB height restoration at both 6 and 12 months, pointing to the SAKOS study results in the intent to treat population at 6 months (1.14±2.61 mm vs 0.31±2.22 mm; p=0.0246) and 12 months (1.31±2.58 mm vs. 0.10±2.23 mm; p=0.0035) post-procedure. The applicant noted that similar results were also observed in the PP population (134 patients in the intent-to-treat population without any major protocol deviations).

The applicant also provided two prospective studies, a retrospective study, and two cadaveric studies in support of its assertions regarding superior VB height restoration. The applicant stated that in a prospective comparative study by Noriega D., et al.,[44] VB height restoration outcomes utilizing the SpineJack® system were durable out to 3 years. This study was a safety and clinical performance pilot that randomized 30 patients with painful osteoporotic vertebral compression fractures to SpineJack® (n=15) or BKP (n=15).[45] Twenty-eight patients completed the 3-year study (14 in each group). The clinical endpoints of analgesic consumption, back pain intensity, ODI, and quality of life were recorded preoperatively and through 36-months post-surgery.[46] Spine X-rays were also taken 48 hours prior to the procedure and at 5 days, 6, 12, and 36 months post-surgery.[47] The applicant explained that over the 3-year follow-up period, VB height restoration and kyphosis correction was better compared to BKP, specifically that VB height restoration and kyphotic correction was still evident at 36 months with a greater mean correction of anterior VB height (10 ± 13 percent vs 2 ± 8 percent for BKP, p = 0.007) and

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[43] Tzermiadianos M., et al., "Altered disc pressure profile after an osteoporotic vertebral fracture is a risk factor for adjacent vertebral body fracture," *European Spine Journal*, 2008, vol. 17(11), pp. 1522-1530.
[44] Noriega D., et al., "Long-term safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study," *Osteoporosis International*, 2019, vol. 30, pp. 637-645.
[45] Ibid.
[46] Ibid.
[47] Ibid.

midline VB height (10 ± 11 percent vs 3 ± 7 percent for BKP, p = 0.034), while there was a larger correction of the VB angle (− 4.97° ± 5.06° vs 0.42° ± 3.43°; p = 0.003) for the SpineJack® group. The applicant stated that this study shows superiority with regards to VB height restoration.

The applicant stated that Arabmotlagh M., et al., also supported superiority with regard to VB height restoration. Arabmotlagh M., et al. reported an observational case series (with no comparison group) of SpineJack®. They enrolled 42 patients with osteoporotic vertebral compression fracture of the thoracolumbar, who were considered for kyphoplasty, 31 of whom completed the clinical and radiological evaluations up to 12 months after the procedure.[48] According to materials provided by the applicant, the purpose of the study was to evaluate the efficacy of kyphoplasty with the SpineJack® system to correct the kyphotic deformity and to analyze parameters affecting the restoration and maintenance of spinal alignment. The applicant explained that the mean VB height calculated prior to fracture was 2.8 cm (standard deviation (SD) of 0.47), which decreased to 1.5 cm (SD of 0.59) after the fracture. According to the applicant, following the procedure performed with the SpineJack® device, the VB height significantly increased to 1.9 cm (SD of 0.64; p<0.01), but was reduced to 1.8 cm (SD of 0.61; p<0.01) at 12 months post-procedure. We note that according to Arabmotlagh M., et al., these results were specifically for mean anterior VB height. The study does not appear to report results for midline VB height.[49] The applicant also stated that the mean kyphotic angle (KA) calculated prior to fracture was -1° (SD of 5.8), which increased to 13.4° (SD of 8.1) after the fracture. The applicant also stated that following the procedure performed with the SpineJack® device, KA significantly decreased to

[48] Arabmotlagh M., et al., "Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture," *Journal of Orthopaedic Research*, 2018. Doi: 10.1002.jor.24180.
[49] Arabmotlagh M., et al., "Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture," *Journal of Orthopaedic Research*, 2018. Doi: 10.1002.jor.24180.

10.8° (SD of 9.1; $p<0.01$); however, KA correction was lost at 12 months post-procedure with an increase to 13.3° (SD of 9.5; $p<0.01$).

The applicant provided a Lin et al., retrospective study of 75 patients that compared radiologic and clinical outcomes of kyphoplasty with the SpineJack® system to vertebroplasty (VP) in treating osteoporotic vertebral compression fractures to support its assertions regarding superiority with regard to midline VB height restoration.[50] The applicant stated that the radiologic outcomes from this study were: (1) the mean KA and mean KA restoration were more efficient after SpineJack® than VP at all time points (up to 1 year), except for mean KA observed postoperatively at 1 week; and (2) the mean middle VB heights and mean VB height restoration were more favorable after SpineJack® than VP.[51] We note that this study did not compare the SpineJack® system to BKP, which the applicant stated is the gold-standard in vertebral augmentation.

In the two cadaveric studies, Kruger A., et al. (2013) and Kruger A., et al. (2015), wedge compression fractures were created in human cadaveric vertebrae by a material testing machine and the axial load was increased until the height of the anterior edge of the VB was reduced by 40 percent.[52] The VBs were fixed in a clamp and loaded with 100 N in a custom made device. In Kruger A., et al. (2013), vertebral heights were measured at the anterior wall as well as in the center of the vertebral bodies in the medial sagittal plane in 36 human cadaveric vertebrae pre- and post-fracture as well as after treatment and loading in (twenty-seven vertebrae were treated with SpineJack® with different cement volumes (maximum, intermediate, and no cement), and 9 vertebrae were treated with BKP). In Kruger A., et al.

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[50] Lin J., et al., "Better Height Restoration, Greater Kyphosis Correction, and Fewer Refractures of Cemented Vertebrae by Using an Intravertebral Reduction Device: a 1-Year Follow-up Study," *World Neurosurg*. 2016, vol. 60, pp. 391-396.
[51] Ibid.
[52] Kruger A., et al., "Height restoration and maintenance after treating unstable osteoporotic vertebral compression fractures by cement augmentation is dependent on the cement volume used," *Clinical Biomechanics*, 2013, vol. 28, pp. 725-730; and Kruger A., et al., "Height restoration of osteoporotic vertebral compression fractures using different intervertebral reduction devices: a cadaveric study," *The Spine Journal*, 2015, vol. 15, pp. 1092-1098.

(2015), anterior, central, and posterior height as well as the Beck index were measured in 24 vertebral bodies pre-fracture and post-fracture as well as after treatment (twelve treated with SpineJack® and twelve treated with BKP). The applicant stated that Kruger A., et al. (2013) showed superiority on VB height restoration and height maintenance, and summarized that: (1) height restoration was significantly better for the SpineJack® group compared to BKP; (2) height maintenance was dependent on the cement volume used; and (3) the group with the SpineJack® without cement nevertheless showed better results in height maintenance, yet the statistical significance could not be demonstrated.[53] The applicant stated that Kruger A., et al. (2015) showed superiority on VB height restoration, because the height restoration was significantly better in the SpineJack® group compared with the BKP group. The applicant explained that the clinical implications include a better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity, which may relate to clinical outcome and the biological healing process.[54]

The applicant also stated that use of the SpineJack® system represents a substantial clinical improvement with respect to pain relief. According to the applicant, pain is the first and most prominent symptom associated with osteoporotic VCFs, which drives many elderly patients to seek hospital treatment and negatively impacts on their quality of life. The applicant provided the SAKOS randomized controlled study, a prospective consecutive observational study, and a retrospective case series to support its assertions regarding pain relief with the SpineJack® system. The applicant cited the SAKOS trial for statistically significant greater pain relief achieved at 1 month and 6 months after surgery with the SpineJack® system. The applicant summarized that in the SAKOS trial: (1) progressive improvement in pain relief was observed over the follow-up period in the SpineJack® system group

[53] Ibid.
[54] Ibid.

only; (2) the decrease in pain intensity versus baseline was more pronounced in the SpineJack® system group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021); and (3) at each time point, the percentage of patients with reduced pain intensity >20 mm was ≥90 percent in the SpineJack® system group and ≥80 percent in the BKP group, with a statistically significant difference in favor of the SpineJack® system at 1 month post-procedure (93.8 percent vs 81.5 percent; p=0.030). The applicant also noted that although continued pain score improvements were seen out to 1 year for patients treated with the SpineJack® system, the difference between the treatment groups did not meet statistical significance (p=0.061). The applicant also explained that in the SAKOS study, at 5 days after surgery, there were significantly fewer patients taking central analgesic agent medications in the SpineJack® implant-treated group as compared to those in the BKP-treated group (SJ 7.4 percent vs. BKP 21.9 percent, p=0.015). According to the applicant, central analgesic agents included medications such as non-steroidal anti-inflammatory drugs (NSAIDS), salicylates, or opioid analgesics.

The applicant also cited a prospective consecutive observational study by Noriega D., et al. for statistically significant pain relief immediately after surgery and at both 6 and 12 months. Noriega D., et al. was a European multicenter, single-arm registry study that aimed to confirm the safety and clinical performance of the SpineJack® system for the treatment of vertebral compression fractures of traumatic origin (no comparison procedure).[55] The study enrolled 103 patients (median age: 61.6 years) with 108 VCFs due to trauma (n=81), or traumatic VCF with associated osteoporosis (n=22) who had a SpineJack® procedure. Twenty-three patients withdrew from the study before the 12-month visit. The study reported a significant improvement in back pain at 48 hours after SpineJack® procedure, with the mean VAS pain score decreasing from 6.6 ± 2.6 cm at baseline to 1.4 ±1.3 cm (mean change: -5.2 ± 2.7

[55] Noriega D., et al., "Clinical performance and safety of 108 SpineJack implantations: 1-year results of a prospective multicentre single arm registry study." *BioMed Research International*. 2015, 173872.

cm; p<0.001) (median relative decrease in pain intensity of 81.5 percent) for the total study population. Noriega D., et al. also reported that the improvement was maintained over the 12-month follow-up period and similar results were observed with both pure traumatic VCF and traumatic VCF in patients with osteoporosis. The traumatic VCF with osteoporosis sub-group had a mean change of -5.5 (SD=1.9) (median relative change of 81.0 percent) (p<0.001) at 48 hours post-surgery (n=22), and -5.7 (SD=2.3) mean change (90.3 percent median relative change) (p<0.001) at 12 months (n=16). The applicant stated that this study supported a claim of statistically significant pain relief immediately after surgery and at both 6 and 12 months. The applicant summarized that (1) pain relief and improvements in pain scores were statistically significant immediately after treatment (48-72 hours) and at 6 and 12 months following surgery (p<0.001); and (2) the mean improvement between baseline and at 48-72 hours after the procedure (n=31) was − 4.6 (2.6) (p<0.001), while the mean improvement between baseline and at the 12-month follow-up (n=22) was − 6.0 (3.4) (p<0.001). We note that Noriega D., et al. did not report results for 6 months (although it does include results for 3 months versus baseline) and does not include the results of mean improvement stated by the applicant.[56] It is also unclear if the applicant intended to rely on the overall results of the study or the subgroup of traumatic VCF with osteoporosis.

The applicant also cited a retrospective case series, Renaud C., et al., for statistically significant pain relief after surgery with the SpineJack® system. Renaud C., et al., included 77 patients with a mean age of 60.9 years and 83 VCFs (51 due to trauma and 32 to osteoporosis) treated with 164 SpineJack® devices (no comparison procedure).[57] The applicant summarized that: (1) pain relief was statistically significant (p<0.001), with a pain score decrease from 7.9 pre-operatively to 1.8 at 1 month after the

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[56] Ibid.

[57] Renaud C., "Treatment of vertebral compression fractures with the cranio-caudal expandable implant SpineJack: Technical note and outcomes in 77 consecutive patients." *Orthopaedics & Traumatology: Surgery & Research,* 2015, vol. 101, pp. 857-859.

procedure; (2) the pain score improvement was 77 percent at hospital discharge and gradually increased to 86 percent after 1 year following surgery; and (3) the study outcomes demonstrated that the SpineJack® system provided both immediate and long-lasting pain relief.

We note that the results of the SAKOS trial do not appear to have been corroborated in any other randomized controlled study. Additionally, although the applicant stated that BKP is the gold standard in VA, there appears to be a lack of data comparing the SpineJack® system to other existing technology, such as the PEEK coiled implant (Kiva® system), particularly since the PEEK coiled system was considered the predicate device for the SpineJack 510(k). Furthermore, there appears to be a lack of data comparing the SpineJack® system to conservative medical therapy. We note there is an active study posted on clinicaltrials.gov comparing SpineJack® system to conservative orthopedic management consisting of brace and pain medication in acute stable traumatic vertebral fractures in subjects aged 18 to 60 years old. The clinicaltrials.gov entry indicates that findings should be forthcoming in 2020. Additionally, we note that the recent systematic reviews of the management of vertebral compression fracture (Buchbinder et al. for Cochrane (2018), Ebeling et al. (2019) for the American Society for Bone and Mineral Research (ASBMR)), do not support vertebral augmentation procedures due to lack of evidence compared to conservative medical management.[58] The ASBMR recommended more rigorous study of treatment options including "larger sample sizes, inclusion of a placebo control and more data on serious AEs (adverse events)."

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[58] Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., "Percutaneous vertebroplasty for osteoporotic vertebral compression fracture," *Cochrane Database Syst Rev*. 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A., Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A., Bouxsein M.L., "The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report." *J Bone Miner Res*., 2019, vol. 34(1), pp. 3-21.

We are inviting public comment on whether the SpineJack® system meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the SpineJack® system would be reported with CPT code 22513, which is assigned to APC 5114 (Level 4 Musculoskeletal Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5114, which has a CY 2019 payment rate of $5,891.95. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 22513 had a device offset amount of $1,127 at the time the application was received. According to the applicant, the cost of the SpineJack® system is $5,623.[59]

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $5,622.64 for the SpineJack® system is 94 percent of the applicable APC payment amount for the service related to the category of devices of SpineJack® system (($5,622.64/$5,981.28) x 100= 94 percent). Therefore, we believe the SpineJack® system meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost

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needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $5,622.64 for the SpineJack® system is 499 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,126.87(($5,622.64/$1,126.87) x 100= 499 percent). Therefore, we believe that the SpineJack® system meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $5,622.64 for the SpineJack® system and the portion of the APC payment amount for the device of $1,126.87 is 75 percent of the APC payment amount for the related service of $5,987.28 (($5,622.64-$1,126.87)/$5,981.28)= 75.2 percent). Therefore, we believe that the SpineJack® Expansion Kit meets the third cost significance requirement.

We are inviting public comment on whether the SpineJack® Expansion Kit meets the device pass-through payment criteria discussed in this section, including the cost criterion.

3. Technical Clarification to the Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Certain Transformative New Devices

As described previously, in the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that receive Food and Drug Administration (FDA) marketing authorization and are granted a Breakthrough Device designation (84 FR 61295 through 61297). Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for purposes of determining device pass-through payment status, but will need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Similarly, in the FY 2020 IPPS/LTCH PPS final rule, we

finalized an alternative pathway for new technology add-on payments for certain transformative new devices. Under the existing regulations at § 412.87(c), to be eligible for approval for IPPS new technology add-on payments under this alternative pathway, the device must be part of the FDA's Breakthrough Devices Program and have received FDA marketing authorization.

We have received questions from the public regarding CMS's intent with respect to the "marketing authorization" required for purposes of approval under the alternative pathway for certain transformative new devices at § 412.87(c). Some of the public appear to assert that so long as a technology has received marketing authorization for any indication, even if that indication differs from the indication for which the technology was designated by FDA as part of the Breakthrough Devices Program, the technology would meet the marketing authorization requirement at § 412.87(c). Because of this potential confusion, we clarified in the FY 2021 IPPS/LTCH PPS proposed rule that an applicant cannot combine a marketing authorization for an indication that differs from the technology's indication under the Breakthrough Device Program, and for which the applicant is seeking to qualify for the new technology add-on payment, for purposes of approval under the alternative pathway for certain transformative devices (85 FR 32692).

We are clarifying in this proposed rule that the same policy applies for purposes of the OPPS alternative pathway policy. Specifically, we are clarifying that under the OPPS, in order to be eligible for the alternative pathway, the device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation and we are making a conforming change to the regulations at 419.66(c)(2). We also note that the transitional pass-through payment application for the device must be received within 2 to 3 years of the initial FDA marketing authorization (or a verifiable market delay) for the device for the indication covered by the Breakthrough Devices Program designation.

In summary, in this CY 2021 OPPS/ASC proposed rule, we propose to amend the regulations in § 419.66(c)(2)(ii) to state that "A new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation."

4. Comment Solicitation on Continuing to Provide Separate Payment in CYs 2022 and Future Years for Devices With OPPS Device Pass-Through Payment Status During the COVID-19 Public Health Emergency (PHE).

In this proposed rule, we are soliciting comments on whether we should adjust future payments for devices currently eligible to receive transitional pass-through payments that may have been impacted by the PHE, and if so, how we should implement that adjustment and for how long the adjustment should apply. On January 31, 2020, HHS Secretary Azar determined that a PHE exists retroactive to January 27, 2020[60] under section 319 of the Public Health Service Act (42 U.S.C. 247d) in response to COVID-19, and on April 21, 2020 Secretary Azar renewed, effective April 26, 2020 and again effective July 25, 2020, the determination that a PHE exists.[61] On March 13, 2020, the President of the United States declared that the COVID-19 outbreak in the United States constitutes a national emergency,[62] retroactive to March 1, 2020. Due to the PHE, we received multiple inquiries from stakeholders regarding potential adjustments to the pass-through payment for devices with OPPS transitional pass-through payment status that may be impacted by the PHE. According to stakeholders, healthcare resources have been triaged to assist in the COVID-19 pandemic response effort, which has reduced utilization for devices receiving transitional pass-through payment, particularly for devices used in

[60] https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.
[61] https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.
[62] https://www.whitehouse.gov/presidentialactions/proclamation-declaring-nationalemergency-concerning-novel-coronavirus-diseasecovid-19-outbreak/.

services that could be considered elective. Stakeholders cited the CMS recommendations issued on March 18, 2020 to postpone elective surgeries due to the COVID-19 PHE[63]. Stakeholders claim that devices on pass-through status are frequently used during such elective procedures, and that CMS's ability to calculate appropriate payment for services that include these devices once the devices transition off of pass-through status could be hindered by a reduction in claims being submitted with these devices during the PHE.

Transitional pass-through payment for devices is described in section 1833(t)(6) of the Act. It is intended as an interim measure to allow for adequate payment of new innovative technology while we collect the necessary data to incorporate the costs for these items into the procedure APC rate (66 FR 55861). As previously stated, transitional pass-through payments for devices can be made for a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment was made for the device.

In response to stakeholder concerns regarding reduced utilization of procedures that include pass-through devices during the PHE, we are specifically requesting public comment on utilizing our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for some period of time after pass-through status ends for these devices in order to account for the period of time that utilization for the devices was reduced due to the PHE. Any rulemaking on this issue in response to this comment solicitation would be included in the CY 2022 OPPS/ASC proposed rule and would consider the impact of the PHE on devices with OPPS device pass-through payment status during the PHE. Note that OPPS device pass-through payment status generally lasts three years, and none of the

[63] https://www.cms.gov/newsroom/press-releases/cms-releases-recommendations-adult-elective-surgeries-non-essential-medical-surgical-and-dental.

devices with less than three years of pass-through payment status at the start of the PHE have pass-through payment status set to end before December 31st, 2021.

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of this CY 2021 OPPS/ASC proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422). For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, the device-intensive methodology assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code

level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APCs were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of APC assignment.

Under our existing policy, procedures that meet the criteria listed below in section IV.B.1.b. of this CY 2021 OPPS/ASC proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3. and IV.B.4. of the CY 2021 OPPS/ASC proposed rule, respectively.

b. Use of the Three Criteria to Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy--which includes the three criteria listed previously--to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from stakeholders that the criteria excluded some procedures that stakeholders believed should qualify as device-intensive procedures. Specifically, we were persuaded by stakeholder arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive

procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of

41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code

does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have little or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at outpatientpps@cms.hhs.gov. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

In response to stakeholder requests for additional detail on our device-intensive methodology, we have updated our claims accounting narrative with a description of our device offset percentage calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2021 OPPS/ASC proposed rule on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

For CY 2021, we are not proposing any changes to our device-intensive policy.

The full listing of the proposed CY 2021 device-intensive procedures can be found in Addendum P to this CY 2021 OPPS/ASC proposed rule (which is available via the Internet on the CMS website).

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule

with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is "Implantable/insertable device, not otherwise classified".

We are not proposing any changes to this policy for CY 2021.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device

offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the "FB" modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the "FC" modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the "FB" and "FC" modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy,

hospitals are required to report on the claim the amount of the credit in the amount portion for value code "FD" (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the "FD" value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code "FD" when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified

device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. Although we adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual, we inadvertently did not make conforming changes to the regulation text. In particular, we did not change our regulation at 42 CFR 419.45(b)(1) and (2), which describes the amount of the reduction in the APC payment in situations where the beneficiary receives an implanted device that is replaced without cost to the provider or the beneficiary or where the provider receives a full or partial credit for the cost of a replaced device and which continues to state that the amount of the reduction is the device offset amount. Therefore, in this CY 2021 OPPS/ASC proposed rule, we are changing our regulation at § 419.45(b)(1) and (2) to conform with the policy we adopted in CY 2014. In particular, we are revising our regulations at § 419.45(b)(1) to state that, for situations in which a beneficiary has received an implanted device that is replaced without cost to the provider or the beneficiary, or where the provider receives full credit for the cost of a replaced device, the amount of reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional pass-through status under § 419.66. Additionally, we are revising our regulation at § 419.45(b)(2) to state that, for situations in which the provider receives partial credit for the cost of a replaced device, but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the replacement device being implanted, the amount of the reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional-pass through status under § 419.66. The revisions to § 419.45(b)(1) and (2) appear in section XXVII. of this proposed rule.

5. Payment Policy for Low-Volume Device-Intensive Procedures

In CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We noted that, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45656), we proposed to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs). We believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we proposed and finalized a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we established our current policy that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated

using the median cost instead of the geometric mean cost, for the reasons described previously for the policy applied to the procedure described by CPT code 0308T in CY 2016. The CY 2018 final rule geometric mean cost for the procedure described by CPT code 0308T (based on 19 claims containing the device HCPCS C-code, in accordance with the device-intensive edit policy) was $21,302, and the median cost was $19,521. The final CY 2018 payment rate (calculated using the median cost) was $17,560.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58951), for CY 2019, we continued with our policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For more information on the specific policy for assignment of low-volume device-intensive procedures for CY 2019, we refer readers to section III.D.13. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58917 through 58918).

For CY 2020, we finalized our policy to continue establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. In CY 2020, this policy applied to CPT code 0308T which we assigned to APC 5495 (Level 5 Intraocular Procedures) in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61301).

For CY 2021, we propose to continue our current policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. For CY 2021, this policy would not apply to any procedure. As discussed in section ,III.D.3., we received no claims data with CPT code 0308T for this OPPS/ASC proposed rule, which we previously assigned as a low-volume

device-intensive procedure for CY 2017 through CY 2020. As such, we propose to assign 0308T a payment weight based on the most recently available data, from the CY 2020 OPPS final rule, and therefore propose to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Additionally, in the absence of CY 2019 claims data for this CY 2021 OPPS/ASC proposed rule, we propose to use the most recently available data, from the CY 2020 OPPS final rule, to establish the device offset percentage for 0308T. Therefore, the proposed CY 2021 device offset percentage for CPT code 0308T is based on the CY 2020 OPPS final rule device offset percentage of 82.21 percent for CPT code 0308T. For more discussion on the APC assignment and payment rate for CPT code 0308T, see section III.D.3. of this proposed rule.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. Throughout the proposed rule, the term "biological" is used because this is the term that appears in section 1861(t) of the Act. A "biological" as used in the proposed rule includes (but is not necessarily limited to) a "biological product" or a "biologic" as defined under section 351 of the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. "Current" refers to those types of drugs

or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain "new" drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as "drugs." As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2021 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B to the proposed rule (which are available via the Internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a

basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In the proposed rule, the term "ASP methodology" and "ASP-based" are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

The pass-through application and review process for drugs and biologicals is described on our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.

2. Three-Year Transitional Pass-Through Payment Period for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for newly approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a product's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs whose pass-through payment status is ending during the calendar year will continue to be included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2020

There are 28 drugs and biologicals whose pass-through payment status will expire during CY 2020 as listed in Table 21. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2017 through December 31, 2020. However, there are two groups of drugs and biologicals included in Table 21 whose current period of OPPS pass-through payment is less than 3 years. The first group are five drugs and biologicals that have already had 3 years of pass-through payment status but for which pass-through payment status was extended for an additional 2 years from October 1, 2018 until September 30, 2020 under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141). The drugs covered by this provision include: HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries); HCPCS code J1097 (Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml); HCPCS code Q4195 (Puraply, per square centimeter); HCPCS code Q4196 (Puraply am, per square centimeter); and HCPCS code Q9950 (Injection, sulfur hexafluoride lipid microspheres, per ml). The second group are two diagnostic radiopharmaceuticals, HCPCS code Q9982 (Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries) and HCPCS code Q9983 (Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries) whose pass-through payment status was extended for an additional 9 months from January

1, 2020 to September 30, 2020 under Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020, which amended section 1833(t)(6) of the Social Security Act and added a new section 1833(t)(6)(J) to the Act.

In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be $130 for CY 2021), as discussed further in section V.B.2. of this proposed rule. We proposed that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we proposed to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for non-340B drugs for CY 2021, as discussed further in section V.B.3. of this proposed rule).

The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of this proposed rule (which is available via the Internet on the CMS website).

TABLE 21: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL EXPIRE BETWEEN MARCH 31, 2020 AND DECEMBER 31, 2020

CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017	03/31/2020
J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017	03/31/2020
J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	03/31/2020
J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487	04/01/2017	03/31/2020
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	04/01/2017	03/31/2020
J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	03/31/2020
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018	03/31/2020
J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	06/30/2020
J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017	06/30/2020
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	09/30/2020
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	G	9324	10/01/2018	09/30/2020
J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017	09/30/2020
J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	09/30/2020
J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	09/30/2020
J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	09/30/2020
Q4195	Puraply, per square centimeter	G	9175	01/01/2019	09/30/2020
Q4196	Puraply am, per square centimeter	G	9176	01/01/2019	09/30/2020
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	09/30/2020
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2020	09/30/2020
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2020	09/30/2020
J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018	12/31/2020
J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018	12/31/2020
J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	12/31/2020
J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	12/31/2020

CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	12/31/2020
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	12/31/2020
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	12/31/2020
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	12/31/2020

4. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2021

We propose to end pass-through payment status in CY 2021 for 26 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2018 and January 1, 2019, are listed in Table 22. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2021, are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2021, we propose to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2021. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise

applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2021 minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6. of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We propose to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2021 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2021, consistent with our CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2021, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at

ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of the proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we propose to have pass-through payment status expire between March 31, 2021 and December 31, 2021 are shown in Table 22.

TABLE 22: PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING DURING CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
J0185	J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J0517	J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021
J2797	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018	03/31/2021
J3304	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J7203	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021
J7318	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021
J9311	J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
Q2041	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells,	G	9035	04/01/2018	03/31/2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		including leukapheresis and dose preparation procedures, per therapeutic dose				
Q2042	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018	03/31/2021
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021
A9513	A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021
J3398	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021
J7170	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021
J9057	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
Q9991	Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021
Q9992	Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/01/2018	06/30/2021
J1454	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
Q5105	Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
A9590	A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021
J0222	J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
J0291	J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1943	J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
J2798	J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
J9204	J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021

5. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing in CY 2021

We propose to continue pass-through payment status in CY 2021 for 46 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status beginning between April 1, 2019 and April 1, 2020 are listed in Table 23. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2021, are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2021, we propose to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2021. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise

applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2021 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We propose to continue to update pass-through payment rates on a quarterly basis on our website during CY 2021 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2021, consistent with our CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2021, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-

through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of the proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we propose to have pass-through payment status expire after December 31, 2021 are shown in Table 23.

TABLE 23: PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS CONTINUING THROUGH CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9041	C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0642	J0642	Injection, levoleucovorin (khapzory), 0.5 mg	G	9334	01/01/2020	03/31/2022
J1095	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022
J3031	J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	03/31/2022
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
J9119	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
Q5108	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022
J9036	J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J9356	J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022
C9054	C9054	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022
C9055	C9055	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
C9056	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
C9053	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9342	04/01/2020	03/31/2023
C9057	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9344	04/01/2020	03/31/2023

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, Trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
C9058	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
C9059	C9059	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
C9061	C9061	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9063	C9063	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
C9122	C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023

6. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

Under the regulations at 42 CFR 419.2(b), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also under 42 CFR 419.2(b), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin

substitutes and other surgical-supply drugs and biologicals. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2021, as we did in CY 2020, we propose to continue to apply the same policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes are identified in Table 24.

TABLE 24: PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2021

CY 2021 APC	CY 2021 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast

CY 2021 APC	CY 2021 APC Title
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

We propose to continue to post annually on our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108-173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085

through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $130 for CY 2020 (84 FR 61312 through 61313).

Following the CY 2007 methodology, for this CY 2021 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2021 and rounded the resulting dollar amount ($130.95) to the nearest $5 increment, which yielded a figure of $130. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS' Office of the Actuary. For this CY 2021 OPPS/ASC proposed rule, based on these calculations using the CY 2007 OPPS methodology, we propose a packaging threshold for CY 2021 of $130.

b. Proposed Packaging of Payment for HCPCS Codes that Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold ("Threshold-Packaged Drugs")

To determine the proposed CY 2021 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called "threshold-packaged" drugs) that had a HCPCS code in CY 2019 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2019 claims processed before January 1, 2020 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of the proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2021: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2021, we use the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we propose for separately payable drugs and biologicals (other than 340B drugs) for CY 2021, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2021 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2019 (data that were used for payment purposes in the physician's office setting, effective April 1, 2020) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2021, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2019 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the Internet on the CMS website) because these are the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2020. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2019 hospital claims data to determine their per day cost.

We propose to package items with a per day cost less than or equal to $130, and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2019 HCPCS codes that were reported to the CY 2020 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the Internet on the CMS website) for proposed payment in CY 2021.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2021 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2019, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2020, along with updated hospital claims data from CY 2019. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this CY 2021 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for the final rule with comment period will be based on ASP data from the second quarter of CY 2020. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2020. These payment rates would then be updated in the January 2021 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2021. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2019 claims data and update cost report information available for the CY 2021 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drugs' HCPCS codes'

packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2021 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2020. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2021, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would continue to receive separate payment in CY 2021.

- HCPCS codes for drugs and biologicals that were packaged in CY 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would remain packaged in CY 2021.

- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2021 but that then have per-day costs greater than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would receive separate payment in CY 2021.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as "policy-packaged" drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: "We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy" (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category

described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

d. Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2021.

For CY 2021, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2019 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this CY 2021 OPPS/ASC proposed rule, and as is our current policy for determining the packaging status of other drugs, we used the mean unit cost

available from the CY 2019 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2021 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2021 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2021 is displayed in Table 25.

TABLE 25: PROPOSED HCPCS CODES TO WHICH THE CY 2021 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 Status Indicator (SI)
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

2. Payment for Drugs and Biologicals Without Pass-Through Status that are not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a "specified covered outpatient drug" (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the "statutory default." Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section

1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[64]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2021 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2020.

b. Proposed CY 2021 Payment Policy

For CY 2021, we propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at

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[64] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.

ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) . We propose to pay for separately payable nonpass-through drugs acquired with a 340B discount at a net rate of ASP minus 28.7 percent (as described in section V.B.6). We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58979 through 58981), and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327) for more information about our current payment policy for drugs and biologicals acquired with a 340B discount.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data is not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). In the CY 2020 OPPS/ASC final rule with comment period, we adopted a policy to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC under section

1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) (84 FR 61318). For CY 2021, we propose to continue to utilize a 3-percent add-on instead of a 6-percent add-on for WAC-based drugs pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also propose to apply this provision to non-SCOD separately payable drugs. Because we propose to establish the average price for a WAC-based drug under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable WAC-based drugs at the same amount under the OPPS. We propose that, if finalized, our proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the payment amount for these drugs (proposed as a net rate of WAC minus 28.7 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

We propose that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also propose that the budget neutral weight scalar would not be applied in determining payments for these separately payable drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the Internet on the CMS website), which illustrate the proposed CY 2021 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1,

2020, or WAC, AWP, or mean unit cost from CY 2019 claims data and updated cost report information available for the proposed rule. In general, these published payment rates are not the same as the actual January 2021 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2021 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2020 (July 1, 2020 through September 30, 2020) will be used to set the payment rates that are released for the quarter beginning in January 2021 near the end of December 2020. In addition, payment rates for drugs and biologicals in Addenda A and B to the proposed rule for which there was no ASP information available for April 2020 are based on mean unit cost in the available CY 2019 claims data. If ASP information becomes available for payment for the quarter beginning in January 2021, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for the proposed rule (reflecting April 2020 ASP data) that do not have ASP information available for the quarter beginning in January 2021. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2019 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the proposed rule are not for January 2021 payment purposes and are only illustrative of the CY 2021 OPPS payment methodology using the most recently available information at the time of issuance of the proposed rule.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC proposed

rule (82 FR 33630), for CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we noted that, with respect to comments we received regarding OPPS payment for biosimilar biological products, in the CY 2018 PFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products is based on the policy established under the CY 2018 PFS final rule.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), after consideration of the public comments we received, we finalized our proposed payment policy for biosimilar biological products, with the following technical correction: all biosimilar biological products are eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367). We adopted this policy in the CY 2018 OPPS/ASC final rule with comment period because we believe that biosimilars without pass-through payment status acquired under the 340B Program should be treated in the same manner as other drugs and biologicals acquired through the 340B Program. As noted earlier, biosimilars with pass-through payment status are paid their own ASP+6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program

are also paid their own ASP plus 6 percent of the reference product's ASP. If a biosimilar does not have ASP pricing, but instead has WAC pricing, the WAC pricing add-on of either 3 percent or 6 percent is calculated from the biosimilar's WAC and is not calculated from the WAC price of the reference product.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. In addition, we noted that we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also stated that we believe this approach is more consistent with the payment methodology for 340B-acquired drugs and biologicals, for which the 22.5 percent reduction is calculated based on the drug or biological's ASP, rather than the ASP of another product. In addition, we explained that we believed that paying for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than 22.5 percent of the reference product's ASP, will more closely approximate hospitals' acquisition costs for these products.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), we proposed changes to our Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus

22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP. This proposal was finalized without modification in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977).

For CY 2021, we propose to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also propose to continue our current policy for paying for nonpass-through biosimilars acquired under the 340B program, except that we propose to pay for these biosimilars at the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 28.7 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. ASP minus 28.7 percent reflects the proposed net payment rate.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2021, we propose to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2021. Therefore, we propose for CY 2021 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also propose to

rely on CY 2019 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2021 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website).

4. Payment for Blood Clotting Factors

For CY 2020, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (83 FR 58979). That is, for CY 2020, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2020 updated furnishing fee was $0.226 per unit.

For CY 2021, we propose to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in

the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we propose to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on our website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

We propose to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes But Without OPPS Hospital Claims Data

For CY 2021, we propose to continue to use the same payment policy as in CY 2020 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442

through 70443). The proposed CY 2021 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the Internet on the CMS website.

6. CY 2021 OPPS Payment Methodology for 340B Purchased Drugs

a. Overview and Background

Section Overview

Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. This payment is governed by section 1847A of the Act, which generally sets a default rate of average sales price (ASP) plus 6 percent for certain drugs; however, the Secretary has statutory authority to adjust that rate under the OPPS. As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program. As described in the following sections, the United States District Court for the District of Columbia (the district court) concluded that the Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals on their acquisition costs. Although HHS disagrees with that ruling and appealed the decision, HHS meanwhile gathered the relevant survey data from 340B hospitals. As described in detail below, those survey data confirm that the ASP minus 22.5 percent rate is generous to 340B hospitals, and the survey data supports an even lower payment rate. The following sections expand upon the points discussed in this overview.

Background

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the OPPS payment methodology for drugs and biologicals (hereinafter referred to collectively as

"drugs") acquired under the 340B Program. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We stated our belief that such changes would allow Medicare beneficiaries (and the Medicare program) to pay a more appropriate amount when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. We stated that our goal was to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Critical access hospitals are not paid under the OPPS and therefore, are not subject to the OPPS payment policy for 340B-acquired drugs. We also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment in CY 2018. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79706), we implemented section 603 of the Bipartisan Budget Act of 2015. As a general matter, applicable items and services furnished in certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered outpatient services for purposes of payment under the OPPS and are paid "under the applicable payment system," which is generally the Physician Fee Schedule (PFS).

However, consistent with our policy to pay separately payable, covered outpatient drugs and biologicals acquired under the 340B Program at ASP minus 22.5 percent, rather than ASP+6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy effective for CY 2019 and subsequent years.

We clarified in the CY 2019 OPPS/ASC proposed rule (83 FR 37125) that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and that it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP are paid an adjusted amount of 69.46 percent of AWP. The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we apply the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, we implemented modifier "JG", effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals or those hospitals paid under the Maryland waiver), or excepted from the 340B drug payment policy for CY 2018, were required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals were excepted from the 340B payment adjustment. These hospitals were required to report informational modifier "TB" for

340B-acquired drugs, and continue to be paid ASP+6 percent. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifiers "JG" and "TB".

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 for CY 2019 and adopted a policy to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321) we continued the 340B policies that were implemented in CY 2018 and CY 2019.

Our CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs are the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association, et al. v. Azar, et al.*, the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.[65] In that same decision, the district court recognized the "'havoc that piecemeal review of OPPS payment could bring about' in light of the budget neutrality requirement," and ordered supplemental briefing on the appropriate remedy.[66] On May 6, 2019, after briefing on remedy, the district court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019 (which had been finalized since the Court's initial order was entered) also exceeded his authority.[67] Rather than ordering HHS to pay plaintiffs their alleged underpayments, however, the district court recognized that crafting a remedy is "no easy task, given Medicare's complexity,"[68] and initially remanded the issue to

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[65] *American Hosp. Ass'n, et al. v. Azar, et al.*, No. 1:18-cv-2084 (D.D.C. Dec. 27, 2018).
[66] *Id.* at 35 (quoting *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).
[67] *See* May 6, 2019 Memorandum Opinion, Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS at10-12.
[68] *Id.* at 13.

HHS to devise an appropriate remedy while also retaining jurisdiction. The district court acknowledged that "if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services."[69] *Id.* at 19. "And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect."[70]

We respectfully disagreed with the district court's understanding of the scope of the Secretary's adjustment authority. On July 10, 2019, the district court entered final judgment. The agency appealed to the D.C. Circuit, and on July 31, 2020 the court entered an opinion reversing the district court's judgement in this matter. Nonetheless, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the CY 2020 OPPS/ASC proposed rule was issued, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters within CY 2018 and 2019. We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years if the district court's ruling is upheld on appeal. The district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available.[71] No 340B hospital disputed in the rulemakings for CY 2018 and 2019 that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B program, which is significant because 340B hospitals have internal data

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[69] *Id.* at 19.
[70] *Id.* (citing Declaration of Elizabeth Richter).
[71] *See American Hosp. Assoc. v. Azar*, 348 F. Supp. 3d 62, 82 (D.D.C. 2018

regarding their own drug acquisition costs. We stated in the CY 2020 OPPS/ASC final rule with comment period that we thus anticipated that survey data collected for CY 2018 and 2019 would confirm that the ASP minus 22.5 percent rate is a conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program. We also explained that a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion.

We noted that under current law, any changes to the OPPS must be budget neutral, and reversal of the payment adjustment for 340B drugs, which raised rates for non-drug items and services by an estimated $1.6 billion for 2018 alone, could have a significant economic impact on the approximately 3,900 facilities that are paid for outpatient items and services covered under the OPPS. In addition, we stated that any remedy that increases payments to 340B hospitals could significantly affect beneficiary cost-sharing. The items and services that could be affected by the remedy were provided to millions of Medicare beneficiaries, who, by law, are required to pay cost-sharing for most items and services, which is usually 20 percent of the total Medicare payment rate. Accordingly, we solicited comments on how to formulate an appropriate remedy in the event of an unfavorable decision on appeal. Those comments are summarized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61323 through 61327).

b. Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs (SCODs)

As discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61326), we announced in the ***Federal Register*** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for the fourth quarter of CY 2018 and the first quarter of CY 2019. We noted that the survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years in the event of an adverse decision on appeal in the pending litigation. We explained that our current

policy to adjust payment for drugs acquired under the 340B program was the subject of litigation and while we believed we would prevail on appeal, we also believed it was prudent to use the Secretary's existing authority to collect survey data to set OPPS payment rates for drugs acquired under the 340B Program at rates based on hospitals' costs to acquire such drugs. We believe it is appropriate for the Medicare program to pay for SCODs purchased under the 340B program at a rate that approximates what hospitals actually pay to acquire the drugs, and we believe it is inappropriate for Medicare to subsidize other programs through Medicare payments for separately payable drugs. We stated that this approach will ensure that the Medicare program uses Medicare trust fund dollars prudently, while maintaining beneficiary access to these drugs and allowing beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs.

Section 1833(t)(14)(D)(i)(I) of the Act required the Comptroller General of the United States to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD and, not later than April 1, 2005, to furnish data from such surveys to the Secretary for purposes of setting payment rates under the OPPS for SCODs for 2006. The Comptroller General was then required to make recommendations to the Secretary under section 1833(t)(14)(D)(i)(II) of the Act regarding the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii). Clause (ii) of section 1833(t)(14)(D) of the Act provides that the Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for SCODs for use in setting payment rates under subparagraph (A) of section 1833(t)(14).

In response to the requirements at section 1833(t)(14)(D)(i)(I) and (II) of the Act, the Government Accountability Office (GAO) surveyed hospitals and prepared a report that included its

recommendations for the Secretary regarding the frequency and methodology for subsequent surveys.[72] While GAO recognized that collecting accurate and current drug price data was important to ensure the agency does not pay too much or too little for drugs, GAO's 2006 report recommended that CMS conduct a streamlined hospital survey once or twice per decade because of the significant operational difficulties and burden that such a survey would place on hospitals and CMS.[73] In response to questions about whether the data undercounted rebates, GAO acknowledged that their data did not include drug rebates or 340B rebates as part of its calculation.[74] In the CY 2006 OPPS final rule, we explained that the data collected by the GAO was ultimately not used to set payment rates, in part because the data did not fully account for rebates from manufacturers or other price concessions or payments from group purchasing organizations made to hospitals (70 FR 68640). Instead, we adopted a policy to pay hospitals at ASP+6 percent because we believed ASP+6 percent was a reasonable level of payment for both the hospital acquisition and pharmacy overhead cost of drugs and biologicals (70 FR 68642).

Between 2006 and 2017, we have generally paid for separately payable drugs for which ASP data is available at ASP plus 6 percent. Beginning in 2018, we adopted the current policy to pay for 340B-acquired drugs at ASP – 22.5 percent to better align Medicare payment with acquisition costs for 340B-acquired drugs. The Medicare Payment Advisory Commission (MedPAC) has consistently stated that Medicare should institute policies that improve the program's value to beneficiaries and taxpayers. For example, in its March 2019 Report to the Congress, MedPAC noted that outpatient payments increased in part due to rapid growth in Part B drug spending. MedPAC stated this rapid growth in

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[72] https://www.gao.gov/new.items/d06372.pdf.

[73] *Id.* at 18.

[74] https://www.gao.gov/new.items/d06372.pdf (Appendix I: Purchase Price for Drug SCODs).

OPPS specifically, was "largely driven by the substantial margins for drugs obtained through the 340B Drug Pricing Program."[75] While we continue to believe that ASP+6 percent represents a reasonable proxy for Part B drug acquisition costs for most hospitals, we do not believe the same is true for hospitals that acquire Part B drugs under the 340B program since such hospitals are able to purchase drugs at deeply discounted 340B ceiling prices or at even lower "sub-ceiling" prices. For this reason, we concluded that it was appropriate to survey 340B hospitals to gather drug acquisition cost data for drugs acquired under the 340B program to allow us to pay hospitals for these drugs at amounts that approximate the hospitals' acquisition costs.

Population of Surveyed Hospitals

Because of our longstanding belief that ASP plus 6 percent is a reasonable proxy for hospital acquisition costs and overhead for separately payable drugs, we did not believe it was necessary or appropriate to burden hospitals that are not eligible to acquire drugs under the 340B program with a drug acquisition cost survey where we have a proxy for hospital acquisition costs for those drugs. ASP data does not, however, include 340B drug prices. (CY 2011 OPPS/ASC final rule with comment period (75 FR 71800, 71960)). When GAO surveyed hospitals in 2005, it found that the survey "created a considerable burden for hospitals as the data suppliers and considerable costs for GAO as the data collector," and recommended that CMS survey hospitals only once or twice per decade to "occasionally validat[e] CMS's proxy for SCODs' average acquisition costs – the [ASP] data that manufacturers report." GAO Report to Congress: *Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS*, 4 (April 2006). Section 1833(t)(14)(D)(ii) requires the Secretary, in conducting periodic subsequent surveys, to take into account GAO's recommendations on the frequency and methodology of subsequent surveys. We considered GAO's

[75] http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0

conclusion that the 2005 survey created "considerable burden" for hospitals and, thus, only surveyed 340B hospitals given our belief that the current payment rate for non-340B hospitals continues to be an appropriate rate. For the same reason, we also limited the data we requested from 340B hospitals to acquisition costs for 340B-acquired drugs, rather than for drugs purchased outside the 340B program for 340B participating hospitals. We note that section 1833(t)(14)(D)(ii) refers to use of surveys conducted by the Secretary to determine the hospital acquisition costs for SCODs in setting payment rates under subparagraph (A). Therefore, we believe it is appropriate to read the two provisions together that permit the Secretary to survey 340B hospitals only and formulate a 340B payment policy for this hospital group that is distinct from the payment policy for non-340B hospitals.

Survey Methodology

Under the authority at section 1833(t)(14)(D)(ii) to conduct periodic subsequent surveys to determine hospital acquisition costs, we administered the survey to 1,422 340B entities between April 24 and May 15, 2020. We requested that all hospitals that participated in the 340B program, including rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals (which are currently exempt from the Medicare 340B payment rate adjustment), supply their average acquisition cost for each SCOD purchased under the 340B program during in the last quarter of CY 2018 (October 1, 2018 through December 31, 2018) and/or first quarter of 2019 (January 1, 2019 through March 31, 2019), which could be the 340B ceiling price, a 340B sub-ceiling price, or another amount, depending on the discounts the hospital received when it acquired a particular drug. The ceiling price is the maximum amount covered entities may permissibly be required to pay for a drug under section 340B(a)(1) of the Public Health Service Act, so we would not expect any 340B hospital to have acquisition costs for any acquired drug that are greater than the ceiling price. For this reason, where the acquisition price for a particular drug was not available or submitted in response to the survey, we stated

that we would use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost in order to produce the most conservative drug discount for when data was missing or not submitted.

We incorporated valuable input from stakeholders on the development and construction of the 340B acquisition cost survey. We collected the stakeholders' input in two rounds of public comment through the survey Paperwork Reduction Act (PRA) submission process. We published the initial 340B drug hospital acquisition cost survey proposal in the Federal Register (84 FR 51590) for a 60-day public comment period that began September 30, 2019 and ended November 29, 2019. After incorporating comments from the 60-day public comment period, we released a revised 340B acquisition cost survey proposal in the Federal Register (85 FR 7306) for a 30-day public comment period from February 7, 2020 to March 9, 2020.

After incorporating the stakeholders' comments and suggestions from the second public comment period, OMB approved CMS' survey design (OMB control number 0938-1374, expires 10/31/2021), and CMS released the 340B acquisition cost survey to the relevant 340B hospitals under the OPPS. As mentioned earlier in this section, the survey was open from April 24, 2020, to May 15, 2020. The survey sample was 100 percent of the potential respondent universe, or all hospitals that acquired drugs under the 340B Program and were paid for those drugs under OPPS in the fourth quarter of 2018 and/or the first quarter of 2019. We provided respondents with two options to complete the survey: the Detailed Survey and the Quick Survey.

Respondents that selected the Detailed Survey provided acquisition costs for each individual SCOD. We requested that these respondents report the net acquisition cost for each SCOD that they acquired under the 340B program (that is, the sub-ceiling price after all applicable discounts). We stated that if the acquisition cost for the SCOD was unknown, the respondent may leave the field blank and we would use the 340B ceiling price as a proxy for the acquisition cost for that drug. In the survey

instructions, we stated that acquisition cost for purposes of the survey meant the price that the hospitals paid upon receiving the product, including, but not limited to, prices paid for 340B drugs purchased via a replenishment model under the 340B program, or under penny pricing. We explained that applicable discounts are any discounts below the discounted ceiling price. We also made clear that for purposes of the survey the 340B drug acquisition cost should be reported regardless of whether the drug was dispensed at all, or whether the drug was dispensed in multiple settings. We only requested the acquisition cost of the drugs acquired under the 340B program during the specified timeframes: the fourth quarter of 2018 and/or the first quarter of 2019. We also stated that acquisition costs for drugs acquired by 340B hospitals outside of the 340B program should not be submitted in response to the survey.

The Quick Survey option allowed the hospital to indicate that it preferred that CMS utilize the 340B ceiling prices obtained from (HRSA) as reflective of their hospital acquisition costs. Additionally, we stated that in instances where the acquisition price for a particular drug is not available or submitted in response to the survey, we would use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost because the price for a drug acquired under the 340B program cannot be higher than the 340B ceiling price by statute. Finally, we noted that where a hospital did not affirmatively respond to the Detailed or Quick Survey within the open period of response, we would use the 340B ceiling prices in lieu of their responses because the ceiling price represents the highest possible price that a 340B hospital could permissibly be required to pay for a 340B-acquired drug.

c. Analysis of Hospital Acquisition Cost Survey Data for 340B Drugs

The results of the survey, which closed on May 15, 2020 are as follows: Seven percent (n=100) of surveyed hospitals affirmatively responded via the Detailed Survey option; 55 percent (n=780) of surveyed hospitals affirmatively responded via the Quick Survey option; and the remaining 38 percent

(n=542) of surveyed hospitals did not respond affirmatively to either survey option. As previously noted, we applied 340B ceiling prices for hospitals that did not affirmatively respond to the survey; such action may skew the survey results towards the *minimum* average discount (that is, the ceiling price) that a 340B hospital would receive on a drug.

We also examined the hospital characteristics of those hospitals that submitted either a Detailed or Quick Survey to the general 340B survey population. The characteristics we analyzed included hospital bed count, teaching hospital status, hospital type, and geographic classification as a rural or urban hospital. Our findings showed that the survey respondent hospitals were generally similar to the general 340B survey population.

d. Proposed Payment Policy for Drugs Acquired under the 340B Program for CY 2021 and Subsequent Years

(1) Grouping Hospitals by 340B Covered Entity Status

Section 1833(t)(14)(A)(iii)(I) authorizes the Secretary to set the amount of payment for SCODs at an amount equal to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D). In this proposed rule, we are exercising the authority to vary the amount of payment for the group of hospitals that is enrolled in the 340B program because their drug acquisition costs vary significantly from those not enrolled in that program. Section 1833(t)(14)(A)(iii) of the Act allows the Secretary to exercise discretion to vary payment by hospital group, "as defined by the Secretary based on the volume of covered OPD services or other relevant characteristics." We believe that is it within the Secretary's authority to distinguish between hospital groups based on whether or not they are covered entities under section 340B(a)(4) of the PHSA

that are eligible to receive drugs and biologicals at discounted rates under the 340B program. We believe that the significant drug acquisition cost discounts that 340B covered entity hospitals receive enable these hospitals to acquire drugs at much lower costs than non-340B hospitals incur for the same drugs. Accordingly, we propose to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I).

(2) Applying a Single Reduction Amount to ASP for 340B-Acquired Drugs

Section 1833(t)(14)(A)(iii)(I) provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug "as determined by the Secretary taking into account" the survey data collected under subparagraph (D). We interpret the reference to acquisition costs being "determined" by the Secretary, "taking into account" survey data, to give us discretion to determine the appropriate payment rate based on data collected from the hospital acquisition cost survey for 340B drugs. We propose to apply a single discount factor to ASP for drugs acquired by 340B hospitals in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs. We note that 340B ceiling prices are protected from disclosure both because the prices themselves are sensitive, and because they could potentially be used to reverse-engineer average manufacturer prices, which are protected under section 1927(b)(3)(D). We also pledged confidentiality of individual responses regarding acquisition prices for each SCOD to the extent required by law. Given that the survey data is heavily weighted towards 340B ceiling prices (because 340B ceiling prices were used for any SCODs within the Detailed Survey for which a hospital did not provide responses, for hospitals that selected the Quick Survey option, and for hospitals that did not affirmatively respond) and since ceiling prices are protected by law from public disclosure, we are instead proposing to establish one aggregate discount amount relative to ASP for SCODs acquired under the 340B program rather than proposing drug-specific prices, which could reveal sensitive or protected pricing information.

(3) Methodology to Calculate ASP Reduction Amount Based on Survey Data

As described in detail in the following sections, we analyzed the survey results and applied various statistical methodologies to determine an appropriate average or typical amount by which to reduce ASP that would approximate hospital acquisition costs for 340B drugs and biologicals. In fairness to hospitals, we generally chose methodologies that yield the most conservative reduction to ASP when establishing the payment rate, and thus would be most generous to hospitals. This includes the use of 340B ceiling prices, which must be kept confidential, where applicable in the survey results. Based on our analysis of the available information, we estimate that the typical acquisition cost for 340B drugs for hospitals paid under the OPPS is ASP minus 34.7 percent.

We determined the average discount of 34.7 percent by assessing a number of factors including: multiple measures of central tendencies (arithmetic mean, median, geometric mean); the effect of including penny priced drugs; mapping of multi-source NDCs to a single HCPCS code; weighting values by volume/utilization; and applying trimming methodologies to remove anomalous or outlier data. The analysis of each of these variables is discussed in the next section.

(a) Selecting an averaging methodology

When determining the appropriate average reduction amount relative to ASP for 340B drugs, we assessed multiple measures of central tendencies, including the arithmetic mean, median, and geometric mean, on the typical 340B discount based on drug acquisition cost survey data. Based upon the cumulative data from the Detailed Survey option, the Quick Survey option, and imputed responses for hospitals that did not affirmatively respond, we analyzed the effects of each averaging method, combining the data from all three sources in both survey quarters (fourth quarter 2018 and first quarter 2019). Using the raw data without accounting for outliers, we determined that the arithmetic mean would result in an average discount from ASP of approximately 66.3 percent; the median would result in

an average discount from ASP of approximately 70.4 percent, and the geometric mean would result in an average discount from ASP of approximately 58.3 percent.

Under the OPPS, we generally calculate resource costs for a given service using the geometric mean. The geometric mean minimizes the effects of the outliers without ignoring them. Minimizing outliers is consistent with our methodology to estimate an average or typical 340B discount that is representative across all 340B SCODs. Therefore, we propose to utilize the geometric mean discount to ASP from both survey quarters -- 2018 Q4 and 2019 Q1 -- as a component of our overall analysis of the survey data. Without any further adjustments, applying the geometric mean to the survey results would result in an average drug acquisition cost estimate of ASP minus 58.3 percent for 340B acquired drugs.

(b) Volume Weighting Survey Data

While we realize the geometric mean minimizes the effects of some outliers, it does not take into consideration several other important factors. Notably, we believe that in calculating the average discount that 340B drugs receive relative to ASP, we should take into account how often those drugs were billed by all hospitals under the OPPS for 2018 and 2019, to give a better reflection of each drug's overall utilization under the OPPS. Therefore, we volume-weighted the drug discounts determined from the survey to mirror the drug utilization in the OPPS. That is, drugs that were commonly used were assigned a higher weight while those less commonly used were assigned a lower weight. We incorporated volume weighting into our analysis by assessing the utilization rate of each individual drug (using its HCPCS code) under the OPPS for CY 2018 and CY 2019. Specifically, we calculated the average discount by taking the utilization of each drug under the OPPS into account to arrive at a case-weighted average for each HCPCS code. For example, a highly utilized HCPCS code for an oncology drug would be weighted higher than that of a drug for snake anti-venom that has a relative low utilization in the OPPS. The data for CY 2018 Q4 was volume weighted based upon OPPS utilization

during CY 2018 as determined using OPPS claims data. The data for CY 2019 Q1 was volume weighted based upon OPPS utilization during CY 2019 as determined using OPPS claims data. This resulted in a change in the geometric mean to an average discount of 58.0 percent from 58.3 percent non-weighted.

(c) Addressing HCPCS Code with Multiple NDCs

In addition, a small portion of the SCODs that were subject to the 340B drug acquisition cost survey contain multiple NDCs that map to a single HCPCS code. This is because these drugs are multiple source drugs, meaning that they were manufactured by different entities and have varying package sizes or strengths, and thus, multiple different NDCs for the same drug. For payment purposes under the OPPS, we pay for drug products based on the drug's HCPCS code, regardless of which NDC is used. Hospitals that completed the Detailed Survey option were instructed to report their average acquisition costs for each drug during the surveyed quarters per HCPCS code. However, for those hospitals that opted for the Quick Survey option or that did not affirmatively respond, we were unable to determine which combination of NDCs mapped to the HCPCS codes these entities would have used during the given quarters. Therefore, we analyzed the effects of averaging all of the NDCs' acquisition costs for a given HCPCS when determining the average discount, as well as selecting the NDC with the highest acquisition cost for a given HCPCS code and using that NDC's acquisition cost amount to determine the average discount. When we calculate the average discount using an average of the acquisition costs for all of the NDCs assigned to the HCPCS code, the average volume weighted geometric mean discount off of ASP is 58.0 percent. The 58.0 percent was calculated by taking all of the various NDCs (across various manufacturers, package sizes, and strengths) for the same drug and averaging the unit costs together in order to arrive at a single amount for each HCPCS code for a drug. When we calculated the average discount using the highest acquisition cost NDC for each HCPCS code for a drug, the average volume weighted geometric mean discount from ASP is 47.0 percent. This was

achieved by analyzing all of the various NDCs (across various manufacturers, package sizes, and strengths) assigned to the HCPCS code for the same drug and selecting the NDC that has the highest unit cost in order to arrive at a single cost for each HCPCS code. Consistent with the general principle of choosing the methodological approach that is most generous to hospitals, we propose to use the highest acquisition cost NDC for each HCPCS code for a drug to determine the average 340B discount.

(d) Addressing Penny Pricing in the Survey Data

As part of our analysis of the survey data, we examined the effect of including "penny priced" drugs on the average discount off of ASP. The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA).[76] The calculation of the 340B ceiling price is defined in section 340B(a)(1) of the PHSA. Penny pricing occurs when, under section 1927(c)(2)(A) of the Social Security Act, the AMP increases at a rate faster than inflation, in which case the manufacturer is required to pay an additional rebate amount, which is reflected in an increased URA and could result in a 340B ceiling price of zero. We propose to exclude penny priced drugs to remove outliers that may distort the average discount in order to provide the most conservative estimate of the average 340B discount from ASP. HRSA noted in the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation Final Rule (82 FR 1210) that although infrequent, that there are instances when the 340B ceiling price is zero. HRSA did not believe that it is consistent with the statutory scheme to set the price at zero. In this

[76] https://www.hrsa.gov/opa/updates/2015/may.html

circumstance, HRSA required that manufacturers charge a $0.01 for the drug, which they believed best effectuates the statutory scheme by requiring a payment.[77]

We acknowledge that penny pricing of drugs is not intended to be permanent and, by its very nature, is dynamic, meaning the select group of drugs to which penny pricing applies could vary from quarter to quarter. We analyzed the inclusion and exclusion of penny pricing on the overall average discount of 340B drugs compared to ASP. As expected, we found that the excluding penny pricing provides a much more conservative estimate of the average 340B discount from ASP relative to including penny pricing. When we excluded penny pricing, the geometric mean volume weighted average discount, using the highest NDC for a drug's HCPCS code, decreased to 40.9 percent from 47.0 percent. We observed penny pricing in less than 10 percent of the drugs surveyed. Because penny pricing is dynamic and the drugs to which it applies may vary from quarter to quarter, we believe it is appropriate to propose to exclude penny pricing from our survey analysis, although we acknowledge that penny pricing, when it does apply, represents the acquisition cost for the drug to which it applies.

We are concerned that including a discount of a penny priced drug from the two quarters surveyed may inappropriately increase the average discount, where the drug may not have been priced based on penny pricing in following or preceding quarters. However, it also is the case that a drug could have penny pricing for any given quarter and it could be appropriate to include penny priced drugs in the calculation of the average acquisition cost because in such cases, penny prices do represent the maximum (ceiling) price the 340B hospital would pay for that drug. Nonetheless, in order to provide for a more conservative discount estimate, we propose to exclude penny priced drugs at this time from our analysis, but we welcome public comment on whether such policy accurately represents 340B -drug acquisition costs.

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[77] https://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf

(e) Addressing Outliers

In response to the Detailed Survey, hospitals provided some drug acquisition cost data that exceeded 340B ceiling prices, and in some cases even exceeded the ASP or ASP+6 percent payment rate for certain drugs. As previously noted, covered entities cannot be required to pay more than the ceiling price to acquire a drug under the 340B program. Therefore, we attributed any Detailed Survey acquisition cost data greater than the ceiling price to potential data entry error, for instance, miscalculation or incorrect decimal point placement. However, because hospitals may have been overcharged for their drug acquisition costs and could have accurately reported acquisition costs greater than the HRSA ceiling price, we did not eliminate these data from our calculations. Instead, consistent with our standard methodology for processing extreme outliers under the OPPS, we excluded responses for any SCODs that were three standard deviations from the geometric mean. We believe applying a three standard deviation limit to the reported acquisition data is appropriate because it removes outliers from both the high and low reported values. In addition, applying a three standard deviations limit may be more representative of the respondents' acquisition cost, even though it may not eliminate some data values that are above the ceiling price. While this approach means that some values above the ceiling price will be included in our data analysis, we are not proposing to trim them because we propose to apply a standard trimming methodology. The cumulative application of this trimming methodology, along with other methodologies applied to the survey data described above, results in an average acquisition cost for drugs that hospitals acquire under the 340B program of ASP minus 34.7 percent. For the reasons previously discussed, we propose to exclude survey data from the Detailed Survey that is more than three standard deviations from the mean. We note that we also explored capping any survey submissions received at the 340B ceiling price, as no covered entity can be required to pay more than the ceiling price. This approach, holding all other methodological approaches constant, would have

resulted in an average acquisition cost of ASP minus 41.5 percent for drugs acquired under the 340B program.

Table 26, Aggregate 340B Drug Program Cost Savings Percentage Relative to ASP, shows the aggregate 340B drug program discount percentage relative to ASP using several different statistical measures. In this table, we outlined some additional figures following a similar path as described above. For example, we arrived at the 33.8 percent figure in the table under median, and penny pricing excluded, by initially choosing the median as the averaging methodology, and then performing trimming methodologies as described above, which include volume weighting by HCPCS, using the highest NDC per HCPCS, and using only data within three standard deviations of the median. This would have resulted in a final proposed discount of 33.8 percent. While this final discount appears more generous to hospitals than our proposal, we do not believe it is appropriate. Specifically, we believe using the geometric mean as outlined in the methodology above is the most generous methodology for establishing a final discount amount that also maintains accuracy and consistency with past OPPS practices. As described previously, under the OPPS, we generally calculate resource costs for a given service using the geometric mean. The geometric mean minimizes the effects of the outliers without ignoring them. As an additional example, under the arithmetic mean methodology with penny pricing included in table 26, the final determined discount was determined to be 23.1 percent. We arrived at this figure of 23.1 percent by initially choosing the arithmetic mean as the averaging methodology, and then performing trimming methodologies as described above, with the exception of including penny prices in this figure. Similar to the discussion above regarding the use of the median, we do not think utilizing the arithmetic mean is appropriate or consistent with the averaging methodologies historically used under the OPPS. The arithmetic mean could easily skew towards outlier data and anomalous data not captured by previously described trimming methodologies. Additionally, with this 23.1 percent figure, while

penny pricing is a valid maximum (i.e., ceiling) price for drugs to which it applies, as noted above we believe it would be appropriate to exclude penny priced drugs for purposes of our proposal.

We believe the manner in which we arrived at the proposed payment amount of ASP minus 34.7 percent for 340B-acquired drugs is the most appropriate and accurate method of determining the average discount or typical discount. We believe it is reflective of stakeholder's actual acquisition costs, and is as generous as possible without compromising accuracy. We also believe the geometric mean is the most appropriate averaging methodology as it mitigates the effects of outliers relative to the arithmetic mean and median and is consistent with OPPS payment methodologies. Although ceiling prices are protected by statute and the respondents to the survey were given a pledge of confidentiality, we are exploring and seek comment on the possibility of providing microdata to qualified researchers through their restricted access infrastructure, in accordance with best practices for transparency.

Table 26: AGGREGATE 340B DRUG PROGRAM COST SAVINGS PERCENTAGE RELATIVE TO ASP*

	Weighted by HCPCS Volume, Highest NDC per HCPCS used, and only Data with 3 Standard Deviations of the Mean					
	With Penny Pricing Included			With Penny Pricing Excluded		
	Arithmetic Mean	Median	Geometric Mean	Arithmetic Mean	Median	Geometric Mean
Average 2018Q4-2019Q1	23.1%	39.6%	39.4%	20.3%	33.8%	34.7%

* Based on Combined Survey Data.

(4) Determining an Add-on Payment for 340B Drugs

Under the OPPS, Medicare pays separately payable drugs at rates that approximate their acquisition costs, such as at ASP or WAC. These drugs typically also receive an add-on payment. Under the OPPS, section 1833(t)(14)(E) authorizes, but does not require, the Secretary to make an adjustment

to payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs.

In the MedPAC report from 2005, [78] MedPAC recommended that the Secretary:

- establish separate, budget neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals;
- define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;
- instruct hospitals to submit charges for those APCs; and
- base payment rates for the handling fee APCs on submitted charges, reduced to costs.

Because we took a conservative approach in estimating the average acquisition costs for 340B-acquired drugs, we do not believe that it is imperative to establish an add-on for overhead and handling as we believe that such a conservative estimate may already account for the costs of overhead and handling. In addition, our current 340B drug payment policy under the OPPS pays separately payable drugs at ASP minus 22.5 percent with no add-on payment because this payment rate represents the minimum average discount that a 340B entity would receive on a drug. We believe hospitals receive a significant margin on 340B drugs under our current policy, so an additional add-on payment is not necessary. Nonetheless, under the methodology in section 1847A, the Part B payments for separately payable drugs and biologicals furnished by practitioners and certain suppliers generally include an add-on set at 6 percent of the ASP for the specific drug. As discussed in the CY 2019 Physician Fee Schedule final rule with comment period (83 FR 59661-59662) the 6 percent add-on is widely believed to include services associated with drug acquisition that are not separately paid for, such as handling, storage, and other overhead. We realize that the acquisition costs for drugs acquired under the 340B

[78] http://medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0

program are significantly lower than for those drugs purchased outside of the 340B program, so we did not find it appropriate to base the add-on for 340B drugs on the 340B acquisition cost as previously discussed. However, we believe that it is reasonable to assume that a given drug will have similar overhead and other administrative costs regardless of whether the drug was purchased under the 340B Program or a by non-340B entity. Additionally, utilizing a drug add-on will ensure a level of payment parity with the add-on that applies to Part B drugs outside of the 340B program.

Therefore, for CY 2021 and subsequent years, we propose to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent. Under this payment methodology, each drug would receive the same add-on payment regardless of whether it is paid at the 340B rate or at the traditional ASP rate for drugs not purchased under the 340B program. We note that this add-on percentage would be more generous to hospitals than adding 6 percent of the reduced 340B rate. As an example, assuming a non-340B drug is paid its ASP of $1,000 and $60 for the 6 percent add-on, the 340B rate would be $653 ($1,000 - $347) plus $60 or $713 total, instead of $653 plus $39.18 (6 percent of the reduced rate of $653) which would equal $39.18 or $692.18 total. We propose that this payment methodology would be our Medicare payment policy for 340B-acquired drugs going forward for CY 2021 and subsequent years.

(5) 340B Payment Policy for Drugs for which ASP is Unavailable

As we clarified in the CY 2019 OPPS/ASC proposed rule, the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. We propose the 340B payment adjustment for WAC-priced drugs mirror that of ASP payment with payment being WAC minus 34.7 percent plus 6 percent of the drug’s WAC, except for when WAC

plus 3 percent policy applies under 1847A(c)(4) and as discussed in V.B.2.b., for which we would propose a payment rate of WAC minus 34.7 percent plus 3 percent of the drug's WAC. Previously, AWP-priced drugs have had a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. The 69.46 percent of AWP was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent. Similarly, for CY 2021, we propose to pay for drugs paid at AWP under the 340B program at 95 percent AWP first reduced by 6 percent to generate a value that is similar to ASP or WAC with no percentage mark up. Then we propose to apply the net 28.7 percent reduction resulting in a payment rate of 63.90 percent of AWP.

(6) 340B Payment Policy Exemptions

In the CY 2018 OPPS/ASC proposed rule, we sought public comment on whether, due to access to care issues, certain groups of hospitals, such as those with special adjustments under the OPPS (for example, children's hospital or PPS-exempt cancer hospitals) should be excepted from a policy to adjust OPPS payments for drugs acquired under the 340B program. Specifically, in accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. This means that these hospitals are permanently held harmless to their "pre-BBA amount," and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure. Taking into consideration the comments regarding

rural hospitals, we believed further study on the effect of the 340B drug payment policy was warranted for classes of hospitals that receive statutory payment adjustments under the OPPS. Accordingly, we believed and continue to believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology.

In addition to the children's and PPS-exempt cancer hospitals, Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

For CY 2021 and subsequent years, similar to previous years, we propose that rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals would be excepted from the 340B payment adjustment and that these hospitals continue to report informational modifier "TB" for 340B-acquired drugs, and continue to be paid ASP+6 percent. We may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction, in future rulemaking.

As discussed in section V.B.2.c. of the CY 2019 OPPS/ASC proposed rule, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP. Similarly, for CY 2021, we propose to pay nonpass-through biosimilars acquired under the 340B Program at the biosimlar's ASP minus the net payment discount reduction, 34.7 percent plus an add on of 6 percent, of the biosimilar's ASP, for a net payment rate of the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP.

e. Alternative Proposal to Continue Policy to Pay ASP-22.5 Percent

Previously, we adopted the OPPS 340B payment policy based on the average minimum discount for 340B-acquired drugs being approximately ASP minus 22.5 percent. The estimated discount was based on a MedPAC analysis identifying 22.5 percent as a conservative minimum discount that 340B entities receive when they purchased drugs under the 340B program, which we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52496). We continue to believe that ASP minus 22.5 percent is an appropriate payment rate for 340B-acquired drugs under the authority of 1833(t)(14)(A)(iii)(II) for the reasons we stated when we adopted this policy in CY 2018 (82 FR 59216). On July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that this interpretation of the statute was reasonable. Therefore, we also propose in the alternative that the agency could continue the current Medicare payment policy for CY 2021. If adopted, this proposed policy would continue the current Medicare payment policy for CY 2021 and subsequent years.

Summary

In summary, we propose for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent using the authority under section 1833(t)(14)(A)(iii)(I) of the Act. This proposal includes our previously discussed methodology used to arrive at the 34.7 percent

average discount that we propose to apply to all drugs acquired under the 340B program. This methodology includes using the geometric mean of the survey data, volume weighting the average based upon utilization of the drug in the OPPS, using the highest priced NDC when multiple NDCs are available for a single HCPCS code, eliminating penny pricing from the average, and eliminating any data outside of 3 standard deviations from the mean when calculating the average discount of 34.7 percent. Our intent is that, if finalized, this payment methodology would apply begin January 1, 2021 and any changes to this permanent payment policy would be required to be adopted through notice and comment rulemaking. We are also proposing that Rural SCHs, PPS-exempt cancer hospitals and children's hospitals would be exempted from the 340B payment policy for CY 2021 and subsequent years. Finally, we note that we propose in the alternative to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs as we prevailed on appeal to the D.C. Circuit in the litigation.

7. Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933).

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin

substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277); APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277); or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273). In CY 2020, the payment rate for APC 5053 (Level 3 Skin Procedures) was $497.02, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,622.74, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,766.13. This information also is available in Addenda A and B of the CY 2020 OPPS/ASC final rule with comment period, correction notice (which is available via the Internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we propose to continue it for CY 2021. Under this current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period

(80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years, we adopted a policy where we determined the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high cost group. In addition, we assigned any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group (84 FR 61327 through 61328).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group which, under current payment rates, can be a difference of approximately $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented

since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it does not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). We stated in the CY 2018 OPPS/ASC proposed rule that the goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017 was to maintain similar levels of payment for skin substitute products for CY 2018 while we study our skin substitute payment methodology to determine whether refinement to the existing policies are consistent with our policy goal of providing payment stability for skin substitutes.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347) that we would continue to study issues related to the payment of skin substitutes and take these comments into consideration for future rulemaking. We received many responses to our request for comments in the CY 2018 OPPS/ASC proposed rule about possible refinements to the existing payment methodology for skin substitutes that would be consistent with our policy goal of providing payment stability for these products. In addition, several stakeholders have made us aware of additional concerns and recommendations since the release of the CY 2018 OPPS/ASC final rule with comment period. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 through 58968), we

identified four potential methodologies that have been raised to us that we encouraged the public to review and provide comments on. We stated in the CY 2019 OPPS/ASC final rule with comment period that we were especially interested in any specific feedback on policy concerns with any of the options presented as they relate to skin substitutes with differing per day or per episode costs and sizes and other factors that may differ among the dozens of skin substitutes currently on the market.

For CY 2020, we sought more extensive comments on the two policy ideas that generated the most comment from the CY 2019 comment solicitation. One of the ideas was to establish a payment episode between 4 to 12 weeks where a lump-sum payment would be made to cover all of the care services needed to treat the wound. There would be options for either a complexity adjustment or outlier payments for wounds that require a large amount of resources to treat. The other policy idea would be to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products.

b. Discussion of CY 2019 and CY 2020 Comment Solicitations for Episode-Based Payment for Graft Skin Substitute Procedures

The methodology that commenters discussed most in response to our comment solicitation in CY 2019 and that stakeholders raised in subsequent meetings we have had with the wound care community has been a lump-sum "episode-based" payment for a wound care episode. Commenters that supported an episode-based payment believe that it would allow health care professionals to choose the best skin substitute to treat a patient's wound and would give providers flexibility with the treatments they administer. These commenters also believe an episode-based payment helps to reduce incentives for providers to use excessive applications of skin substitute products or use higher cost products to generate more payment for the services they furnish. In addition, they believe that episode-based payment could help with innovations with skin substitutes by encouraging the development of products

that require fewer applications. These commenters noted that episode-based payment would make wound care payment more predictable for hospitals and provide incentives to manage the cost of care that they furnish. Finally, commenters for an episode-based payment believe that workable quality metrics can be developed to monitor the quality of care administered under the payment methodology and limit excessive applications of skin substitutes.

However, many commenters opposed establishing an episode-based payment. One of the main concerns of commenters who opposed episode-based payment was that wound care is too complex and variable to be covered through such a payment methodology. These commenters stated that every patient and every wound is different; therefore, it would be very challenging to establish a standard episode length for coverage. They noted that it would be too difficult to risk-stratify and specialty-adjust an episode-based payment, given the diversity of patients receiving wound care and their providers who administer treatment, as well as the variety of pathologies covered in treatment. Also, these commenters questioned how episodes would be defined for patients when they are having multiple wounds treated at one time or have another wound develop while the original wound was receiving treatment. These commenters expressed concerns that episode-based payment would be burdensome both operationally and administratively for providers. They believe that CMS will need to create a large number of new APCs and HCPCS codes to account for all of the patient situations that would be covered with an episode-based payment, which would increase burdens on providers. Finally, these commenters had concerns about the impacts of episode-based payment on the usage of higher cost skin substitute products. They believe that a single payment could discourage the use of higher-cost products because of the large variability in the cost of skin substitute products, which could limit innovations for skin substitute products.

The wide array of views on episode-based payment for skin substitute products and the unforeseen issues that may arise from the implementation of such a policy encouraged us to continue to study the issues with episode-based payment. Therefore, we sought further comments from stakeholders and other interested parties regarding skin substitute payment policies that could be applied in future years to address concerns about excessive utilization and spending on skin substitute products, while avoiding administrative issues such as establishing additional HCPCS codes to describe different treatment situations.

One possible policy construct that we sought comments on was whether to establish a payment period for skin substitute application services (CPT codes 15271 through 15278 and HCPCS codes C5271 through C5278) between 4 weeks and 12 weeks. Under this option, we could also assign CPT codes 15271, 15273, 15275, and 15277, and HCPCS codes C5271, C5273, C5275, and C5277 to comprehensive APCs with the option for a complexity adjustment that would allow for an increase in the standard APC payment for more resource-intensive cases. Our research has found that most wound care episodes require one to three skin substitute applications. Those cases would likely receive the standard APC payment for the comprehensive procedure. Then the complexity adjustment could be applied for the relatively small number of cases that require more intensive treatments.

Several commenters were in favor of establishing a comprehensive APC with either an option for a complexity adjustment or outlier payments to pay for higher cost skin substitute application procedures. The commenters supported the idea of having a traditional comprehensive APC payment for standard wound care cases with a complexity adjustment or outlier payment to handle complicated or costly cases. However, they also expressed concerns about how many payment levels would be available in the skin substitute procedures APC group since a complexity adjustment can only be used if there is an existing higher-paying APC to which the service receiving the complexity adjustment may be

assigned. A couple of commenters wanted more opportunities for services to receive a complexity adjustment through using clusters of procedure codes that reflect the full range of wound care services a beneficiary receives instead of using code pairs to determine if a complexity adjustment should apply. Other commenters suggested that episodic payments be risk-adjusted to account for clinical conditions and co-morbidities of beneficiaries with outlier payments and that complexity adjustments be linked to beneficiaries with more comorbidities.

Some commenters opposed the idea of a complexity adjustment for skin substitute application procedures. The commenters stated there was not enough detail in the comment solicitation to understand how a complexity adjustment would work with an episodic payment arrangement. Commenters also expressed concerns that payment rates for comprehensive APCs may not be representative of the wound care services that would be paid within those APCs. One commenter stated that payment policy is not the right way to resolve issues with the over-utilization and inappropriate use of skin substitutes because they are concerned that major changes in payment methodology, such as episodic payment, could lead to serious issues with the care beneficiaries receive. In recent meetings, stakeholders have expressed concerns that establishing a comprehensive APC for graft skin substitute procedures could lead to other unrelated wound care services such as hyperbaric oxygen treatments being bundled into those procedures. Some stakeholders have provided suggestions to provide additional payment for the treatment of complicated wounds, similar to a complexity adjustment, without bundling unrelated wound care services.

The additional comments we received in CY 2020 related to including a complexity adjustment with an episode-based payment, along with the comments we received on episode-based payment in general from the CY 2019 comment solicitation show, that there are many issues that continue to require study for this payment methodology. In addition, we also need more time to assess the benefits and

drawbacks of episode-based payment as compared to other possible options to change the payment methodology for graft skin substitute procedures. Therefore in CY 2021, we will continue our review of the feasibility of using episode-based payment for graft skin substitute procedures, and we will not propose any episode-based payment for these procedures.

c. Discussion of CY 2019 and CY 2020 Comment Solicitations to Have a Single Payment Category for Graft Skin Substitute Procedures

Another policy option on which we solicited comments in CY 2019 and CY 2020 was to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products. Under this option, the only available procedure codes to bill for graft skin substitute procedures would be CPT codes 15271 through 15278. HCPCS codes C5271 through C5278 would be eliminated. Providers would bill CPT codes 15271 through 15278 without having to consider either the MUC or PDC of the graft skin substitute product used in the procedure. There would be only one APC for the graft skin substitute application procedures described by CPT codes 15271 (Skin sub graft trnk/arm/leg), 15273 (Skin sub grft t/arm/lg child), 15275 (Skin sub graft face/nk/hf/g), and 15277 (Skn sub grft f/n/hf/g child). The payment rate would be the geometric mean of all graft skin substitute procedures for a given CPT code that are covered through the OPPS. For example, under the current skin substitute payment policy, there are two procedure codes (CPT code 15271 and HCPCS code C5271) that are reported for the procedure described as "*application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*".

Commenters and stakeholders who support this option believed it would remove the incentives for manufacturers to develop and providers to use high cost skin substitute products and would lead to the use of lower cost, quality products. Commenters and stakeholders note that lower Medicare

payments for graft skin substitute procedures would lead to lower copayments for beneficiaries. In addition, commenters and stakeholders believe a single payment category would reduce incentives to apply skin substitute products in excessive amounts. Commenters and stakeholders also believe a single payment category is clinically justified because they stated that many studies have shown that no one skin substitute product is superior to another. Supporters of a single payment category believed it would simplify coding for providers and reduce administrative burden. Finally, some stakeholders believe that a single payment category policy could serve as a transitional payment policy for graft skin substitute products while we continue to study the feasibility of establishing an episode-based payment for skin substitutes.

Most commenters and stakeholders were opposed to a single payment category for skin substitute products. Commenters and stakeholders stated that the large difference in resource costs between higher cost and lower cost skin substitute products would provide an incentive for hospitals to use the most inexpensive products, which would hurt both product innovation and the quality of care beneficiaries receive. Commenters and stakeholders were concerned that a single payment category would encourage providers to choose financial benefit over clinical efficacy when determining which skin substitute products to use.

These commenters and stakeholders also stated that a single payment category would increase incentives for providers to use cheaper products that require more applications to generate more revenue and emphasize volume over value. A couple of commenters believed that overall Medicare spending on skin substitutes would be higher with a single payment category than under the current payment methodology, which has separate payment for higher cost and lower cost skin substitutes. The reason spending would go up according to the commenters is the overpayment for low cost skin substitutes by

Medicare would exceed the savings Medicare would receive on reduced payments for higher cost skin substitutes.

Further, commenters and stakeholders stated that a single payment rate would lead to too much heterogeneity in the products receiving payment through the skin substitute application procedures. That is, the same payment rate would apply to skin substitute products whether they cost less than $10 per cm^2 or over $200 per cm^2 and regardless of the type of wound they treat. Commenters and stakeholders would prefer to have multiple payment categories where the payment rate is more reflective of the cost of the product. Commenters and stakeholders believe that a single payment category would discourage providers from treating more complicated wounds and wounds larger than 100 cm^2.

The responses to the comment solicitation demonstrated the potential of a single payment category to reduce the cost of wound care services for graft skin substitute procedures for both beneficiaries and Medicare in general. In addition, a single payment category may help to lower administrative burden for providers. Conversely, we are cognizant of other commenters' concerns that a single payment category may hinder innovation of new graft skin substitute products and cause some products that are currently well-utilized to leave the market. Nonetheless, we are persuaded that a single payment category could potentially provide a more equitable payment for many products used with graft skin substitute procedures, while recognizing that procedures performed with expensive skin substitute products would likely receive substantially lower payment.

We believe some of the concerns commenters who oppose a single payment category for skin substitute products raised might be mitigated if stakeholders have a period of time to adjust to the changes inherent in establishing a single payment category. Accordingly in CY 2020, we solicited public comments that provide additional information about how commenters believe we should transition from the current low cost/high cost payment methodology to a single payment category.

Such suggestions to facilitate the payment transition from a low cost/high cost payment methodology to a single payment category methodology included--

- Delaying implementation of a single category payment for 1 or 2 years after the payment methodology is adopted; and
- Gradually lowering the MUC and PDC thresholds over 2 or more years to add more graft skin substitute procedures into the current high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category.

Those commenters in favor of a single payment category did not see a need for a transition period or wanted only a one-year transition period. Conversely, those commenters opposed to a single payment category either who did mention the idea of a transition period or wanted it to last multiple years, with one commenter suggesting a transition period of four years. In the end, having a transition period before establishing a single payment category did not affect the views of commenters who were initially opposed to establishing a single payment category as they continued to be against the policy option.

Based on the comments received regarding establishing a single payment category for graft skin substitute procedures, we need more time to consider the trade-offs between potential benefits of a single category against the potential substantial drawbacks. We also need to consider the merits of this policy option compared to episode-based payment for graft skin substitute procedures. Therefore, we are not proposing a single payment category for graft skin substitute procedures for CY 2021.

d. Proposals for Packaged Skin Substitutes for CY 2021

For CY 2021, consistent with our policy since CY 2016, we propose to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total

units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 through CY 2018 final rules with comment period, we analyzed CY 2019 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2021 MUC threshold is $47 per cm^2 (rounded to the nearest $1) and the proposed CY 2021 PDC threshold is $936 (rounded to the nearest $1). We also propose to clarify that our definition of skin substitutes includes synthetic skin substitute products in addition to biological skin substitute products as described in section V.B.7.d. of this proposed rule. We also want to clarify that the availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2021, as we did for CY 2020, we propose to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we propose to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2021, we propose that any skin substitute product that was assigned to the high cost group in CY 2020 would be assigned to the high cost group for CY 2021, regardless of whether it exceeds or falls below the CY 2021 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2021, we propose to continue to assign skin substitutes with pass-through payment status to the high cost category. We propose to assign skin substitutes with pricing information but without

claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we propose to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we propose to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We propose to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of this proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2021 MUC and PDC thresholds. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436). Table 27 displays the final CY 2021 cost category assignment for each skin substitute product.

TABLE 27: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2021

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Proposed CY 2021 High/Low Cost Assignment
C1849	Skin substitute, synthetic	High	High
C9363	Integra meshed bil wound mat	High	High*
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High*
Q4110	Primatrix	High	High*
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Proposed CY 2021 High/Low Cost Assignment
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High*
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	Low	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High*
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Proposed CY 2021 High/Low Cost Assignment
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	Low	High
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	Low
Q4190	Artacent ac 1 sq cm	Low	High
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	High
Q4194	Novachor 1 sq cm	High	High*
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	Low	High
Q4200	Skin te 1 sq cm	Low	High
Q4201	Matrion 1 sq cm	Low	Low
Q4203	Derma-gide, 1 sq cm	High	High*
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	Low	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	Low	Low
Q4210	Axolotl graf dualgraf sq cm	Low	Low
Q4211	Amnion bio or axobio sq cm	Low	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	Low	Low
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	Low	High
Q4227	Amniocore per sq cm	Low	Low
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	Low	Low
Q4232	Corplex, per sq cm	Low	Low
Q4234	Xcellerate, per sq cm	Low	High
Q4235	Amniorepair or altiply sq cm	Low	Low
Q4236	Carepatch per sq cm	Low	Low

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Proposed CY 2021 High/Low Cost Assignment
Q4237	cryo-cord, per sq cm	Low	Low
Q4238	Derm-maxx, per sq cm	Low	Low
Q4239	Amnio-maxx or lite per sq cm	Low	Low
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2021, but are assigned to the high cost group because they were assigned to the high cost group in CY 2020.

e. Proposal to Allow Synthetic Skin Graft Sheet Products to Be Reported with Graft Skin Substitute Procedure Codes

The CY 2014 OPPS/ASC final rule with comment period describes skin substitute products as "... a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers…[T]hese products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue." (78 FR 74930 through 74931) The CY 2014 final rule also described skin substitutes as "…a class of products that we treat as biologicals…" and mentioned that prior to CY 2014, skin substitutes were separately paid in the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931).

The 2014 rule did not specifically mention whether synthetic products could be considered to be skin substitute products in the same manner as biological products, because there were no synthetic products at that time that were identified as skin substitute products. Then in 2018, a manufacturer made a request that an entirely synthetic product that it claimed is used in the same manner as biological skin substitutes receive a HCPCS code that would allow the product to be billed with graft skin substitute procedure codes, including CPT codes 15271 through 15278 and C5271 through C5278 starting in 2019.

Initially, the synthetic product was not described as a graft skin substitute product. However, we now believe that both biological and synthetic products could be considered to be skin substitutes for Medicare payment purposes.

This view is supported by a paper referenced in a report we cited in the CY 2014 OPPS/ASC final rule with comment period titled ''Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2'', which is available on the AHRQ Web site at: https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf. That paper, titled "Regenerative medicine in dermatology: biomaterials, tissue engineering, stem cells, gene transfer and beyond" by Dieckmann et al.[79], states that skin substitutes should be divided into two broad categories: biomaterial and cellular. The paper explains that "…biomaterial skin substitutes do not contain cells (acellular) and are derived from natural or synthetic sources…"[80] The paper continues by describing biomaterial skin substitutes further: "Synthetic sources include various degradable polymers such as polylactide and polyglycolide. Whether natural or synthetic, the biomaterial provides an extracellular matrix that allows for infiltration of surrounding cells."[81] The paper by Dieckmann et al. confirms that skin substitute products may be synthetic products as well as biological products.

Therefore, for CY 2021 we propose to include synthetic products in addition to biological products in our description of skin substitutes. Our new description would define skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. We also propose to retain the additional

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[79] Dieckmann C, Renner R, Milkova L, et al. Regenerative medicine in dermatology: biomaterials, tissue engineering, stem cells, gene transfer and beyond. Exp Dermatol 2010 Aug;19(8):697-706.

[80] Ibid, Dieckmann C, Renner R, Milkova L, et al.

[81] Ibid, Dieckmann C, Renner R, Milkova L, et al.

description of skin substitute products from the CY 2014 OPPS final rule which states "…that skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue…" (78 FR 74930 through 74931).

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an "applicable percentage," currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2021 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2021. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778)

describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2020 or beginning in CY 2021. The sum of the proposed CY 2021 pass-through spending estimates for these two groups of device categories equaled the proposed total CY 2021 pass-through spending estimate for device categories with pass-through payment status. We based the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2021, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition

contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Our estimate of drug and biological pass-through payment for CY 2021 for this group of items is $473.4 million, as discussed below, because we propose that most nonpass-through separately payable drugs and biologicals would be paid under the CY 2021 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which are currently generally paid at ASP minus 22.5 percent, but for which we propose to pay a net rate of ASP minus 28.7 percent, and because we proposed to pay for CY 2021 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of this CY 2021 OPPS/ASC proposed rule.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section V.B.1.c. of this CY 2021 OPPS/ASC proposed rule. We propose that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2020. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2021 was not $0, as discussed below. In section V.A.6. of this CY 2021 OPPS/ASC proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-

packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we propose to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we propose to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2021. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2020 or beginning in CY 2021. The sum of the CY 2021 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2021 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending

For CY 2021, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2021, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2020 (83 FR 61336 through 61337).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2021, there are four active categories for CY 2021. The active categories are described by HCPCS codes C1734, C1824, C1982, and C2596. Based on the information from the device manufacturer, we estimate that C1824 will cost

$46 million in pass-through expenditures in CY 2021, C1982 will cost $116.3 million in pass-through expenditures in CY 2021, C2596 will cost $11.3 million in pass-through expenditures in CY 2021, and C1734 will cost $37.2 million in pass-through expenditures in CY 2021. Therefore, we propose an estimate for the first group of devices of $210.8 million.

In estimating our proposed CY 2021 pass-through spending for device categories in the second group, we included: device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2021; additional device categories that we estimated could be approved for pass-through status after the development of the proposed rule and before January 1, 2021; and contingent projections for new device categories established in the second through fourth quarters of CY 2021. For CY 2021, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. The proposed estimate of CY 2021 pass-through spending for this second group of device categories is $99 million.

There are 5 devices we are evaluating for potential pass-through payment status in the CY 2021 rulemaking cycle: Barostim NEO® System, Hemospray® Endoscopic Hemostat, EXALT™ Model D Single-Use Duodenoscope, The SpineJack® Expansion Kit, and Customflex® Artificial Iris. The manufacturers of these systems provided utilization and cost data that indicate the spending for the devices would be approximately $4 million for Barostim NEO® System, $40 million for Hemospray® Endoscopic Hemostat, $40 million for EXALT™ Model D Single-Use Duodenoscope, $14 million for SpineJack® Expansion Kit, and $600 thousand for Customflex® Artificial Iris. Therefore, we are finalizing an estimate of $99 million for this second group of devices for CY 2021.

To estimate proposed CY 2021 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and

continuing on pass-through payment status for at least one quarter in CY 2021, we propose to use the most recent Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2021 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2021, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, for which we generally currently pay ASP minus 22.5 percent but for which we propose to pay a net rate of ASP minus 28.7 percent. Therefore, the payment rate difference between the pass-through payment amount and the nonpass-through payment amount is $463.4 million for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we proposed to include in the CY 2021 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment, which we estimate

for CY 2021 for the first group of policy-packaged drugs to be $0 since there are currently no policy-packaged drugs that will be on pass-through in CY 2021.

To estimate proposed CY 2021 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible for pass-through payment in CY 2021, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2021 and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2021), we propose to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2021 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2021 pass-through payments for this second group of drugs, we calculate a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2021 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2021 would be approximately $783.2 million (approximately $309.8 million for device categories and approximately $473.4 million for drugs and biologicals) which represents 0.934 percent of total projected OPPS payments for CY 2021 (approximately $84 billion). Therefore, we estimate that pass-through spending in CY 2021 will not amount to 2.0 percent of total projected OPPS CY 2021 program spending.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2021, we propose to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2020. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In this proposed rule, we are seeking public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act by utilizing a Medicare Physician Fee Schedule (PFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments (PBDs). As discussed in section X.D of that proposed rule and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58818 through 59179), CY 2020 was the second year of the 2-year transition of this policy, and beginning in CY 2020, these departments are paid the site-specific PFS rate for the clinic visit service. We note that on September 1, 2019, the United States District Court for the District of Columbia (the district court) entered an order vacating the portion of the CY 2019 OPPS/ASC final rule with comment period that adopted the volume control method for clinic visit services furnished by nonexcepted off-campus PBDs and remanded the matter to the Secretary for further proceedings consistent with the district court's

opinion.[82] In the CY 2020 OPPS/ASC final rule with comment period, we acknowledged that the district court vacated the volume control policy for CY 2019 and we stated that we were working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order. We also stated that we did not believe it was appropriate at that time to make a change to the second year of the 2-year phase-in of the clinic visit policy. We explained that we still had appeal rights, and were evaluating the rulings and considering whether to appeal from the final judgment. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

VIII. Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization

[82] *American Hospital Ass'n, et al. v. Azar*, No. 1:18-cv-02841–RMC (D.D.C. Sept. 17, 2019).

services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011, (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base

the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a

portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352). We refer readers to section VIII.D. of this proposed rule for a discussion of the proposed updates and the applicability for CY 2021.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30th, 2020 interim final rule with comment (85 FR 27562-27566), effective as of March 1, 2020 and for the duration of the COVID-19 Public Health Emergency (PHE), hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID-19 PHE.

B. Proposed PHP APC Update for CY 2021

1. Proposed PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2021 and subsequent years, we propose to use the CY 2021 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost

floor equal to the per diem cost for CMHCs of $121.62 calculated last year for CY 2020 ratesetting (84 FR 61339 through 61344), as the basis for developing the CY 2021 CMHC APC per diem rate. For CY 2021 and subsequent years, we also propose to use the CY 2021 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for hospital-based providers of $222.76 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61345). Following this methodology, we propose to use the cost floor value of $121.62 for CMHCs as the basis for developing the CY 2021 CMHC APC per diem rate. We propose to use the CY 2021 hospital-based PHP geometric mean per diem cost of $243.94, calculated in accordance with our existing methodology for hospital-based PHPs, as the basis for developing the CY 2021 hospital-based APC per diem rate. We propose to use the most recent updated claims and cost data to determine CY 2021 geometric mean per diem costs in this proposed rule. The rationale behind this proposal is discussed in greater detail below.

Also, we propose to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)). These proposals are discussed in more detail below.

2. Development of the Proposed PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2021, we followed the PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to calculate the PHP APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period. As discussed in section VIII.B.1. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing three or more services.

Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing three or more services. The CMHC or hospital-based PHP APC per diem costs are the provider-type specific costs derived from the most recent claims and cost data. The CMHC or hospital-based PHP APC per diem payment rates are the national unadjusted payment rates calculated from the CMHC or hospital-based PHP APC geometric mean per diem costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this proposed rule.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2021 proposed rule, prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we are preparing the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 38 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2021 ratesetting, no CMHCs had geometric mean costs per day below the trim's lower limit of $18.89 or had geometric mean costs per day above the trim's upper limit of $572.65. Therefore, we do not exclude any CMHCs because of the ±2 standard deviation trim.

In accordance with our PHP ratesetting methodology, we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2021 proposed rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. In addition to our trims and data exclusions, before calculating the PHP APC geometric

mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR greater than one to the statewide hospital CCR (80 FR 70457). For this CY 2021 OPPS/ASC proposed rule ratesetting, there are no CMHCs that showed CCRs greater than one. Therefore, it is not necessary to default any CMHC to its statewide hospital CCR for ratesetting.

In summary, these data preparation steps did not adjust the CCR for any CMHCs with a CCR greater than one during our ratesetting process. We also do not exclude any CMHCs for other missing data or for failing the ±2 standard deviation trim, resulting in the inclusion of 38 CMHCs. There are 212 CMHC claims removed during data preparation steps because they either had no PHP-allowable codes or had zero payment days, leaving 9,369 CMHC claims in our CY 2021 proposed rule ratesetting modeling. After applying all of the previously listed trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691) to calculate a CMHC APC geometric mean per diem cost.[83] The calculated CY 2021 geometric mean per diem cost for all CMHCs for providing three or more services per day (CMHC APC 5853) is $104.00, a decrease from $121.62 calculated last year for CY 2020 ratesetting (84 FR 61347).

[83] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR from the OPSF (or statewide CCR, where the overall CCR was greater than 1) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have three or more services provided to be assigned to CMHC APC 5853. The final geometric mean per diem cost for CMHC APC 5853 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. CMHC service days with costs ±3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the final geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where three or more services were provided.

We investigated why the CY 2021 calculated CMHC APC geometric mean per diem cost had fallen below the cost floor established in the prior year (84 FR 61339 through 61344). We found that six providers, collectively representing 39.7 percent of all CMHC days, reported lower costs per day than those reported for the CY 2020 final rule ratesetting. These six providers heavily influenced the calculated geometric mean per diem cost for CY 2021. Because these providers had a high number of paid PHP days, and because the CMHC data set is so small (n=38), these providers had a significant influence on the calculated CY 2021 CMHC APC geometric mean per diem cost. In the case of PHPs provided by CMHCs, we have a low number of PHP providers in our ratesetting dataset (38 CMHCs compared to 363 hospital-based PHPs) that provide a small volume of services and, therefore, account for a limited amount of payments, relative to the rest of OPPS payments (total CY 2019 CMHC payments are estimated to be approximately 0.01 percent of all OPPS payments).

We are concerned that a CMHC APC geometric mean per diem cost of $104.00 would not support ongoing access to PHPs in CMHCs. This cost is roughly a 14.5 percent decrease from the final CY 2020 CMHC geometric mean per diem cost floor of $121.62. We believe access to partial hospitalization services and PHPs is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the CMHC APC 5853 is described as providing three or more partial hospitalization services per day (81 FR 79680), 85 percent of CMHC paid days in CY 2020 were for providing four or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP provider paid days are for providing four or more services per day (we refer readers to Table 30.—Percentage of PHP Days by Service Unit Frequency of the proposed rule). Therefore, the CMHC APC 5853 is actually heavily weighted to the cost of providing four or more services. The per diem costs for CMHC APC 5853 have been calculated as $124.92, $143.22, and

$121.62 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively. We do not believe it is likely that the actual cost of providing partial hospitalization services through a PHP by CMHCs has suddenly declined when costs generally increase over time. We are concerned by this fluctuation, which we believe is influenced by data from several high-utilization providers with low costs.

Therefore, rather than simply proposing the calculated CY 2021 CMHC APC geometric mean per diem cost of $104.00 for CY 2021 ratesetting, we are instead proposing to extend to CY 2021 and subsequent years the policy initially finalized only for CY 2020 (84 FR 61340 through 61341), to use the current year's CMHC APC geometric mean per diem cost (in this case, the CY 2021 CMHC APC geometric mean per diem cost), calculated in accordance with our existing methodology, but with a cost floor equal to $121.62 as established in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61345), as the basis for developing the proposed CY 2021 CMHC APC per diem rate. We believe using the CY 2020 CMHC geometric mean per diem cost floor as the floor for CY 2021 is appropriate because it is based on very recent CMHC PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for CMHC APC 5853. In this proposed rule, we used the most recent updated claims and cost data to calculate CY 2021 CMHC geometric mean per diem cost, which was $104.00. Because the CY 2021 CMHC calculated geometric mean per diem cost of $104.00 is less than the proposed cost floor (which equals the final CY 2020 CMHC APC geometric mean per diem cost of $121.62), the proposed CY 2021 CMHC geometric mean per diem cost is $121.62. Implementing the cost floor for CY 2021 would protect CMHCs since the CY 2021 calculated per diem cost of $104.00 results in an amount that is less than $121.62. We further propose that the established CMHC geometric mean per diem cost floor of $121.62 be extended to subsequent years and that if the calculated geometric mean per diem cost for a given year is below the floor, then the

geometric mean per diem cost that would be used for ratesetting in that year would be equal to the geometric mean per diem cost floor of $121.62. We believe proposing the CMHC cost floor amount of $121.62 as the proposed CMHC APC geometric mean per diem cost for CY 2021 and subsequent years allows us to use the most recent or very recent CMHC claims and cost reporting data while still protecting provider access.

We estimate the aggregate difference in the (prescaled) CMHC geometric mean per diem costs for CY 2021 from proposing the CMHC cost floor amount of $121.62 rather than the calculated CMHC geometric mean per diem cost of $104.00 to be $1.3 million. We refer readers to section XX of this proposed rule for payment impacts, which are budget neutral.

Because the proposed CY 2021 calculated CMHC geometric mean per diem cost of $104.00 is less than the cost floor amount of $121.62, the proposed CY 2021 CMHC geometric mean per diem cost is $121.62.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2021 proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. The CY 2019 PHP claims included data for 436 hospital-based PHP providers for our calculations in this CY 2021 OPPS/ASC proposed rule.

Consistent with our policies as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim. Applying this CCR greater than 5 trim removed affected service days from two hospital-based PHP providers from our proposed

ratesetting. However, 100 percent of the service days for these two hospital-based PHP provider had at least one service associated with a CCR greater than 5, so the trim removed these providers entirely from our proposed ratesetting. In addition, 68 hospital-based PHPs were removed for having no days with PHP payment. Two hospital-based PHPs were removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1717-P-2020-OPPS-Claims-Accounting.pdf

Overall, we removed 73 hospital-based PHP providers [(2 with all service days having a CCR greater than 5) + (68 with no PHP payment) + (2 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ± 3 SD limits)], resulting in 363 (436 total – 73 excluded) hospital-based PHP providers in the data used for calculating ratesetting.

After completing these data preparation steps, we calculated the proposed CY 2021 geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based partial hospitalization services by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 and 79691).[84] The calculated CY 2021 hospital-based PHP APC geometric mean per

[84] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have three or more services provided to be assigned to hospital-based PHP APC 5863. The final geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. Hospital-based PHP service days with costs ±3 standard deviations from the geometric

diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is $243.94, which is an increase of 4.5 percent from $233.52 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61348). We believe that a hospital-based PHP APC geometric mean per diem cost of $243.94 best supports ongoing access to hospital-based PHPs. This cost is nearly a 5 percent increase from the final CY 2020 hospital-based PHP geometric mean per diem cost.

We stated that we believe access is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the hospital-based PHP APC 5863 is described as providing payment for the cost of three or more services per day (81 FR 79680), 89.3 percent of hospital-based PHP paid service days in CY 2019 were for providing four or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP paid service days provide four or more services (we refer readers to Table 30.—Percentage of PHP Days by Service Unit Frequency in the proposed rule). Therefore, the hospital-based PHP APC 5863 is actually heavily weighted to the cost of providing four or more services. The per diem costs for hospital-based PHP APC 5863 have been calculated as $213.14, $208.09, and $222.76 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively.

As we noted for CMHCs above, we likewise do not believe that it is likely that the cost of providing hospital-based PHP services would suddenly decline when costs generally increase over time. In order to address concerns about potential fluctuations, which we believe could be influenced by data from a small number of providers with low service costs per day, we propose to use the CY 2021

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mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the final geometric mean per diem cost for hospital-based PHP APC 5863.

hospital-based PHP APC geometric mean per diem cost, calculated in accordance with our existing methodology, but with a cost floor equal to the floor for hospital-based providers of $222.76 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61345), as the basis for developing the CY 2021 hospital-based PHP APC per diem rate. As part of this proposal, we propose that we would use the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs, just as we did for CMHCs. We further propose that the established hospital-based geometric mean per diem cost floor of $222.76 be extended to CY 2021 and subsequent years and that if the calculated geometric mean per diem cost for a given year is below the floor, then the geometric mean per diem cost that would be used for ratesetting in that year would be equal to the geometric mean per diem cost floor of $222.76. We believe using the CY 2020 hospital-based PHP per diem cost floor as the floor for CY 2021 is appropriate because it is based on very recent hospital-based PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for hospital-based APC 5863.

While the cost floor would protect hospital-based PHPs if the CY 2021 calculated hospital-based PHP APC geometric mean per diem cost were less than $222.76, the calculated hospital-based PHP geometric mean per diem cost of $243.94 is greater than the floor, and therefore, we propose this calculated CY 2021 cost for hospital-based PHPs. As stated above, we believe this proposal allows us to use the most recent or very recent hospital-based PHP claims and cost reporting data while still protecting provider access.

Because the CY 2021 calculated hospital-based PHP geometric mean per diem cost of $243.94 is greater than the cost floor amount of $222.76, the proposed CY 2021 hospital-based PHP geometric mean per diem cost is $243.94. We refer readers to section XX. of this proposed rule for a discussion of payment impacts and the budget neutrality adjustment for OPPS rates.

c. Alternative Methodologies Considered

For this CY 2021 discussion of the proposed cost, we also considered proposing a 3-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the three most recent years, that is the final cost data from CY 2017 and CY 2018, along with the latest available cost data from CY 2019. The resulting 3-year collective PHP geometric mean per diem cost for CMHCs was $110.73, and the value was $243.31 for hospital-based PHP providers. While we believe that this option would support access to CMHCs better than the calculated geometric mean per diem cost of $104.00, it is significantly lower than the final CY 2020 CMHC geometric mean per diem cost of $121.62. As we discussed previously, we do not believe it is likely that the actual cost of providing partial hospitalization services through a PHP by CMHCs has suddenly declined when costs generally increase over time. We are concerned by this fluctuation, which we believe is influenced by data from several high-utilization providers with aberrantly low costs. We are further concerned that such an impact, though not observed for the CY 2021 proposed ratesetting, could affect hospital-based providers in the same way. Because each year's geometric mean per diem cost would be calculated from the prior 3 years, any similar fluctuations would therefore be reflected in the average for at least 3 years.

We also considered proposing a 4-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the four most recent years, which is the final cost data from CY 2016, CY 2017, and CY 2018, along with the latest available cost data from CY 2019. The resulting 4-year collective PHP geometric mean per diem cost for CMHCs was $119.68, and the value was $232.15 for hospital-based PHP providers. For CMHCs as well as hospital-based providers, these calculated 4-year geometric mean per diem cost values are slightly lower than the previous year's final geometric mean per diem costs ($121.62 and $233.52 respectively (84 FR 61347)). However, the value

for hospital-based providers would be substantially lower than the calculated CY 2021 geometric mean per diem cost of $243.94. Fundamentally, our concern with the 3-year collective geometric mean is applicable to the 4-year collective as well, as any fluctuations observed would be reflected in the average for at least 4 years.

We believe that it is important to support access to partial hospitalization services in both CMHCs and in hospital-based PHPs, and note that hospital-based PHPs provide 82 percent of all paid PHP service days. Therefore, we believe that it is most appropriate to propose to use the calculated CY 2021 CMHC geometric mean per diem cost and the calculated CY 2021 hospital-based PHP geometric mean per diem cost, each calculated in accordance with our existing methodology, but with a cost floor for each provider type equal to the cost floor established in the CY 2020 final rule (84 FR 61339 through 61347). Because the floors established for CY 2020 per diem costs are based on very recent CMHC and hospital-based PHP claims and cost data, are the easiest to understand, and would result in final geometric mean per diem costs which would help to protect provider access by preventing wide fluctuation in the per diem costs for both CMHCs and hospital-based PHPs, we propose to extend these two floors to CY 2021 and subsequent years.

In summary, for CY 2021, we propose to use the calculated CY 2021 CMHC geometric mean per diem cost and the calculated CY 2021 hospital-based PHP geometric mean per diem cost, each calculated in accordance with our existing methodology, but with a cost floor for each provider type equal to the cost floor established in the CY 2020 final rule (84 FR 61339 through 61347), that is $121.62 for CMHCs and $222.76 for hospital-based providers, as the basis for developing the CY 2021 PHP APC per diem rates. Because the CY 2021 calculated geometric mean per diem cost for CMHCs is less than the cost floor amount of $121.62, we propose a CY 2021 geometric mean per diem cost for CMHCs of $121.62. In addition, because the CY 2021 calculated hospital-based PHP geometric mean

per diem cost is greater than the hospital-based PHP cost floor amount of $222.76, we propose a CY 2021 hospital-based PHP geometric mean per diem cost of $243.94. In this proposed rule, we used the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs. The inclusion of a cost floor, which is based on very recent data, would protect CMHCs as their calculated per diem cost is less than the cost floor amount, but would not be relied upon for hospital-based PHPs for CY 2021.

These proposed CY 2021 PHP geometric mean per diem costs are shown in Table 28 and are used to derive the proposed CY 2021 PHP APC per diem rates for CMHCs and hospital-based PHPs. The proposed CY 2021 PHP APC per diem rates are included in Addendum A to this proposed rule (which is available on our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html).[85]

TABLE 28: CY 2020 PROPOSED PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2020 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	$121.62
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$243.94

[85] As discussed in section II.A. of this CY 2021 OPPS/ASC proposed rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for APC 5012 (Clinic Visits and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of this proposed rule for more information on scaling the weights, and for details on the final steps of the process that leads to final PHP APC per diem payment rates. The OPPS Claims Accounting narrative is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

3. PHP Service Utilization Updates

a. Provision of Individual Therapy

In the CY 2016 OPPS/ASC final rule with comment period (81 FR 79684 through 79685), we expressed concern over the low frequency of individual therapy provided to beneficiaries. The CY 2019 claims data used for this CY 2021 proposed rule revealed some changes in the provision of individual therapy compared to CY 2015, CY 2016, CY 2017, and CY 2018 claims data as shown in the Table 29.

TABLE 29: PROVISION OF INDIVIDUAL THERAPY, BY PROVIDER TYPE AND CLAIMS YEAR

	Percent of Individual Therapy on Days with 3 Services Only	**Percent of Individual Therapy on Days with Four or More Services**
CMHCs		
CY 2015 Claims	7.9%	4.4%
CY 2016 Claims	8.5%	5.0%
CY 2017 Claims	4.0%	4.3%
CY 2018 Claims	2.3%	4.5%
CY 2019 Claims	1.0%	4.6%
Hospital-based PHPs		
CY 2015 Claims	4.0%	6.2%
CY 2016 Claims	4.7%	5.8%
CY 2017 Claims	3.9%	5.1%
CY 2018 Claims	3.8%	5.7%
CY 2019 Claims	3.6%	5.6%

As shown in Table 29, the CY 2019 claims show that CMHCs have slightly increased the provision of individual therapy on days with four or more services, compared to CY 2018 claims. However, on CMHC days with three services, the provision of individual therapy decreased sharply from the prior year CY 2018. This appears to follow a downward trend which started in CY 2016 and has continued through CY 2019. In comparing CY 2018 to CY 2019, we see that for CMHCs the

provision of 3-service days also sharply increased (this increase is shown in Table 30 in subsection b below). The net effect of these two changes is that for all CMHC days with three or more services, the provision of individual therapy decreased from 4.4 percent in CY 2018 to 4.0 percent in CY 2019. We are concerned by this decrease in the provision of individual therapy among CMHCs from CY 2018, and will continue to monitor this trend. As we stated in the CY 2017 final rule with comment period (81 FR 79684 through 79685), the PHP is intensive in nature, and we believe that appropriate treatment for PHP patients includes individual therapy. We continue to encourage providers to examine their provision of individual therapy to PHP patients to ensure that patients are receiving all of the services that they may need.

For Hospital-based providers, the CY 2019 claims show that the provision of individual therapy has slightly decreased on days with only 3 services as well as days with four or more services. These very small decreases correspond with an overall decrease of less than one tenth of one percent in the provision of individual therapy on all days with three or more services, comparable with fluctuations in prior years.

b. Provision of 3-Service Days

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59378), we stated that we are aware that our single-tier payment policy may influence a change in service provision because providers are able to obtain payment that is heavily weighted to the cost of providing four or more services when they provide only 3 services. We indicated that we are interested in ensuring that providers furnish an appropriate number of services to beneficiaries enrolled in PHPs. Therefore, with the CY 2017 implementation of CMHC APC 5853 and hospital-based PHP APC 5863 for providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services.

For this CY 2021 OPPS/ASC proposed rule, we used the CY 2019 claims data. Table 30 shows the utilization findings based on the 2019 claims data.

TABLE 30: PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2016	CY 2017*	CY 2018*	CY 2019*
CMHCs:				
Percent of Days with three services	4.8%	5.6%	6.9%	15.2%
Percent of Days with four services	70.3%	74.0%	71.2%	61.1%
Percent of Days with five or more services	24.9%	20.5%	21.9%	23.6%
Hospital-based PHPs:				
Percent of Days with three services	10.9%	9.8%	12.0%	10.6%
Percent of Days with four services	64.9%	56.4%	64.0%	66.6%
Percent of Days with five or more services	24.1%	33.9%	24.0%	22.7%

*May not sum to 100 percent by provider type due to rounding.

As shown in Table 30, the CY 2019 claims data used for proposed rule show that for CMHCs, utilization of 3 service days is increasing compared to the 3 prior claim years, whereas it is decreasing for hospital-based providers. Compared to CY 2018, in CY 2019 hospital-based PHPs provided fewer days with three services only, more days with four services only, and fewer days with five or more services. Compared to CY 2018, in CY 2019 CMHCs provided substantially more days with three services, fewer days with four services, and more days with five or more services.

The CY 2017 data were the first year of claims data to reflect the change to the single-tier PHP APCs. Since that time, we have observed a steady increase in the percentage of CMHC days with three services only. We are concerned by this increase, because as noted below, the intent of the PHP is for three-service days to be the exception, rather than the norm. As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79685), we will continue to monitor the provision of days with

only three services, particularly now that the single-tier PHP APCs 5853 and 5863 are established for providing three or more services per day for CMHCs and hospital-based PHPs, respectively.

It is important to reiterate our expectation that days with only three services are meant to be an exception and not the typical PHP day. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68694), we clearly stated that we consider the acceptable minimum units of PHP services required in a PHP day to be 3 and explained that it was never our intention that three units of service represent the number of services to be provided in a typical PHP day. PHP is furnished in lieu of inpatient psychiatric hospitalization and is intended to be more intensive than a half-day program. We further indicated that a typical PHP day should generally consist of 5 to 6 units of service (73 FR 68689). We explained that days with only three units of services may be appropriate to bill in certain limited circumstances, such as when a patient might need to leave early for a medical appointment and, therefore, would be unable to complete a full day of PHP treatment. At that time, we noted that if a PHP were to only provide days with three services, it would be difficult for patients to meet the eligibility requirement in 42 CFR 410.43(c)(1) that patients must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care (73 FR 68689).

C. Proposed Outlier Policy for CMHCs

For CY 2021, we propose to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold according to previously established policies. These topics are discussed in more detail. We refer readers to section II.G. of this CY 2021 OPPS/ASC proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. This separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII. C. of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996). We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. We propose to continue to calculate the CMHC outlier

percentage according to previously established policies, and we do not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2021. To calculate the CMHC outlier percentage, we followed three steps:

- Step 1: We multiplied the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments:

(0.01 x Estimated Total OPPS Payments) = Estimated Total OPPS Outlier Payments.

- Step 2: We estimated CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3. of this proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceeded the threshold, we multiplied that excess by 50 percent, as described in section VIII.C.3. of this proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.C.5. of this proposed rule, so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we summed all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs - Each Provider's Estimated Multiplier Threshold) = A. If A is greater than 0, then (A x 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 x Provider's Total Estimated Per Diem Payments), then cap-adjusted B = (0.08 x Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- Step 3: We determined the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1:

(Estimated CMHC Outlier Payments / Total OPPS Outlier Payments).

In CY 2019, we designated approximately 0.01 percent of that estimated 1.0 percent hospital outpatient outlier threshold for CMHCs (83 FR 58996), based on this methodology. For CY 2021, we propose to continue to use the same methodology as CY 2020. Therefore, based on our CY 2021 payment estimates, CMHCs are projected to receive 0.01 percent of total hospital outpatient payments in CY 2021, excluding outlier payments. We propose to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid

under CMHC PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 x (CMHC Cost – (3.4 x APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351). For CY 2021, we propose to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. That is, for CY 2021, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [0.50 × (CMHC Cost - (3.4 × APC 5853 rate))].

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We propose to continue these policies for partial hospitalization services provided through PHPs for CY 2021. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing Internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf).

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years.

For CY 2021, we propose to continue to apply the 8 percent CMHC outlier payment cap to the CMHC's total per diem payments.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351). We propose to continue this policy for CY 2021.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our longstanding policies for identifying services that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, that will not be paid by Medicare under the OPPS, as well as the criteria we use to review the IPO list each year to determine whether or not any services should be removed from the list. The complete list of codes that describe services that will be paid by Medicare in CY 2021 as inpatient only services is

included as Addendum E to this CY 2021 OPPS/ASC proposed rule, which is available via the Internet on the CMS website.[86]

B. Proposed Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

Currently, there are approximately 1,740 services on the IPO list. Under our current policy, we annually review the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available. We have established five criteria to determine whether a procedure should be removed from the IPO list (65 FR 18455). As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we utilize these criteria when reviewing services to determine whether or not they should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We note that a procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria include the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

[86] Note, the IPO list is proposed to be eliminated beginning in CY 2021, with all services being removed from the list over the course of a three-year transition period. The CY 2020 IPO List can be found here: Hospital Outpatient PPS, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.

2. CY 2021 Proposal to Eliminate the IPO List

The IPO List was established with the implementation of the OPPS in the CY 2000 OPPS/ASC final rule with comment period (65 FR 18455). Using the authority under section 1833(t)(1)(B)(i) of the Act, the IPO List was created to identify services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient who would require the surgery and, therefore, the service would not be paid by Medicare under the OPPS. For example, the list includes certain surgically invasive services on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies.

Since the IPO list was established in 2000, we have stated that regardless of how a procedure is classified for purposes of payment, we expect that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests (65 FR 18456). We have reiterated this sentiment in rulemaking several times over the years, including in our discussion of the removal of total knee arthroplasty (TKA) from the IPO list in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59383) and most recently when we discussed removing total hip arthroplasty (THA) from the IPO List in the CY 2020 OPPS/ASC final rule with comment period, where we stated that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary (84 FR 61354).

In previous years, we received several comments from stakeholders who believe that we should eliminate the IPO list entirely and instead defer to the clinical judgment of physicians for decisions regarding site of service. For example, in the CY 2000 final rule with comment period, in response to the establishment of the IPO list, commenters stated that they believed CMS was making decisions, such

as the appropriate site of service for a particular medical procedure, that should be left to the discretion of surgeons and their patients (65 FR 18455, 18442). In the CY 2012 OPPS/ASC final rule with comment period, a number of commenters suggested that regulations should not supersede the physician's level of knowledge and assessment of the patient's condition, and that the physician can appropriately determine whether a procedure can be performed in a hospital outpatient setting (76 FR 74354). In the CY 2014 rulemaking, we again noted that some commenters requested that the IPO list be eliminated in its entirety (78 FR 75055). Stakeholders have also commented that the exclusion of services from payment under the OPPS is unnecessary and could have an adverse effect on advances in surgical care (65 FR 18442). Furthermore, some stakeholders have suggested that when a service is removed from the IPO list, it creates an expectation among hospitals that the service must be furnished in the outpatient setting, regardless of the clinical judgment of the physician or needs of the patient.

Other stakeholders have supported maintaining the IPO list and consider it an important tool to indicate which services are appropriate to furnish in the outpatient setting and to ensure that Medicare beneficiaries receive quality care. They have agreed that many of the procedures that we designated as ''inpatient only'' are currently performed appropriately and safely only in the inpatient setting (65 FR 18442). Commenters have expressed concerns that without the IPO list, patient safety and care quality could decline, and have noted the potential for surgical complications in response to allowing specific procedures to be paid under the OPPS when performed in the outpatient setting for the Medicare population, such as TKA and THA.

Stakeholders have also supported the use of the IPO list because services included on the IPO list are an exception to the 2-midnight rule and as such are considered appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay and therefore are not subject to medical review by Beneficiary and Family- Centered Care -Quality Improvement

Organizations (BFCC-QIOs) for "patient status" (that is, site-of-service). We note that in the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities for 2 calendar years following their removal from the IPO list. For CY 2021 and subsequent years, we propose to continue this 2-year exemption from site-of-service claim denials, BFCC-QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews for "patient status" for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We are also seeking comment on whether a 2-year exemption continues to be appropriate, or if a longer or shorter period may be more warranted. For more information on these policies please refer to section X.B of this proposed rule.

While we agreed with commenters in previous rulemakings that the IPO list was necessary, we stated there are many surgical procedures that cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting, and that it would be inappropriate for us to establish payment rates for those services under the OPPS (78 FR 75055), recently we have reconsidered the various stakeholder comments requesting that we eliminate the IPO list and reevaluated the need for CMS to restrict payment for certain procedures in the hospital outpatient setting. We have concluded that we no longer believe there is a need for the IPO list in order to identify services that require inpatient care. Instead, we agree with past commenters that the physician should use his or her clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary. We believe that this change will ensure maximum availability of services to beneficiaries in the outpatient setting.

We also believe that since the IPO list was established, there have been significant developments

in the practice of medicine that have allowed numerous services to be provided safely and effectively in the outpatient setting. We acknowledged in the CY 2000 OPPS/ASC final rule with comment period that we believed that emerging new technologies and innovative medical practice were blurring the difference between the need for inpatient care and the sufficiency of outpatient care for many services (65 FR 18456). We also stated in the CY 2001 OPPS/ASC interim final rule with comment period that, over time, given advances in technology and surgical technique, many of the procedures that were on the IPO list at the time may eventually be performed safely in a hospital outpatient setting and that we would continue to evaluate services to determine whether they should be removed from the IPO list (65 FR 67826). Specifically, we stated that insofar as advances in medical practice mitigate concerns about these services being furnished on an outpatient basis, we would be prepared to remove them from the IPO list and provide for payment under the OPPS (65 FR 67826). Since that time, there have been many new technologies and advances in surgical techniques and surgical care protocols, including the use of minimally invasive surgical procedures such as laparoscopy, improved perioperative anesthesia, expedited rehabilitation protocols, as well as significant enhancements to postoperative processes, such as improvements in pain management, that have reduced the inpatient length of stay and as well as the need for postoperative care following a surgical service. In consideration of these advancements, we have removed services from the IPO list that were previously considered to require inpatient care, including TKA in CY 2018 (82 FR 59385) and THA in CY 2020 (84 FR 61355). As medical practice continues to develop, we believe that the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. Therefore, we believe that the IPO list is no longer necessary to identify services that require inpatient care.

We acknowledge the seriousness of the concerns regarding patient safety and quality of care that various stakeholders have expressed regarding removing procedures from the IPO list or eliminating the

IPO list altogether. However, we believe that the evolving nature in of the practice of medicine, which has allowed more procedures to be performed on an outpatient basis with a shorter recovery time, in addition to physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list. In the past, we stated that although hospitals must meet minimum safety standards through accreditation or state survey and certification of compliance with the CoPs that ensure a hospital is generally safe and an appropriate environment for providing care, we were concerned that those measures did not determine whether a particular service could be safely provided in the outpatient setting to beneficiaries (76 FR 74355). However, the CoPs are regulations that are focused on protecting the health and safety of all patients receiving services from Medicare enrolled providers. The CoPs are the baseline health and safety requirements for Medicare certification. Accrediting organizations and states and localities, through their licensure authorities, may have more specific and stringent requirements. Often professional organizations or other nonprofit organizations give additional guidance to health care providers to improve patient safety and quality of care. We note that the CoPs already require hospitals to be in compliance with applicable Federal laws related to the health and safety of patients (42 CFR 482.11) Additionally, there are numerous provisions in the hospital CoPs at 42 CFR part 482 that provide extensive patient safeguards and that provide enough room and flexibility to ensure that hospitals can follow nationally recognized standards of practice and of care where they are applicable and can adapt if those standards change over time through innovative new practices. For example, the hospital CoPs require that hospitals must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs

(42 CFR 482.30). More specifically, the utilization review includes a review of the length of stay, medical necessity of admission and services rendered, and also looks to promote the most efficient use of available health facilities and services.

Additionally, as indicated in the 2020 Quality Strategy,[87] CMS has also continued to develop safety measures and tools, like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey and the CMS' case management system, to help determine the safety and quality of the performance of procedures in the outpatient setting, to address concerns about the safety and quality of more varied, complex procedures performed in the outpatient setting. We believe that the aforementioned federally established CoPs, the CMS Quality Strategy and state and local safety requirements help ensure important patient safeguards for all patients, including Medicare beneficiaries. Further, although we believe it is important to pause certain medical contractor reviews for patient status to allow providers time to adjust to the proposed changes to the IPO, we note that the BFCC-QIO program's beneficiary case review contractors routinely address, and will continue to address any beneficiary quality of care complaints that include concerns about treatment as a hospital inpatient or outpatient, not receiving expected services, early discharge, and discharge planning. CMS' case management system currently allows QIOs and CMS to monitor the frequency and status of beneficiary quality of care complaints and other beneficiary appeals by topic, provider type, and geographic area. These numbers are compiled by the BFCC-QIO national coordinating and oversight review contractor and reported to the QIOs and CMS leadership on a weekly basis for monitoring purposes. As previously noted, although we propose to continue a 2-year exemption from site-of-service claim denials, BFCC-QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews

[87] Speech: Remarks by CMS Administrator Seema Verma at the 2020 CMS Quality Conference, https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-2020-cms-quality-conference

for "patient status" for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021, BFCC-QIOs will continue to conduct initial medical reviews for both the medical necessity of the services, the medical necessity of the site of service, and will also continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable and medically necessary as noted in the CY 2020 OPPS/ASC final rule (84 FR 61365). Therefore, given CMS' increasing ability to measure the safety of procedures performed in the outpatient setting and to monitor the quality of care, in addition to the other safeguards detailed above, we now believe that quality of care is unlikely to be negatively affected by the elimination of the IPO list. However, we are also requesting that commenters submit evidence on what effect, if any, they believe eliminating the IPO list may have on the quality of care.

Furthermore, some stakeholders have shared concerns with us that removing procedures from the IPO list and allowing them to be paid under the OPPS when performed in the outpatient setting may result in an increased financial burden for beneficiaries for certain complex services. Under current law, the OPPS cost-sharing for a service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. However, this cap applies to individual services, so if a Medicare beneficiary receives multiple separately payable OPPS services, it is possible that the aggregate cost-sharing for a beneficiary may be higher for services provided in the outpatient setting than it would be had the services been furnished during an inpatient stay. We emphasize that services included on the IPO list tend to be surgical procedures that would typically be the focus of the hospital outpatient stay and would likely be assigned to a comprehensive APC (C-APC) when they are removed from the IPO list. As such, these services would likely be considered to be a single episode of care with one payment rate and one copayment amount instead of multiple copayments for each individual service. In most instances, we expect that beneficiaries will not be responsible for multiple copayments for individual

ancillary services associated with services removed from the IPO list, since because of their assignment to C-APCs, the inpatient deductible cap will apply to the entire hospital claim which is paid as a comprehensive service or procedure. In the event there are separately payable OPPS services included on a claim with a service assigned to a C-APC, our previously mentioned policy remains applicable, that is the OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. For further information regarding beneficiary copayments, please refer to section II.I.1. of this proposed rule.

After careful consideration of the need for the IPO list and taking into account the feedback that we have received since the OPPS was implemented, we believe that instead of maintaining a list of services that typically require inpatient care and are not paid under the OPPS, physicians should continue to use their clinical knowledge and judgment to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences, subject to the general coverage rules requiring that any procedure be reasonable and necessary, and that payment should be made pursuant to the otherwise applicable payment policies. We also believe that developments in surgical technique and technological advances in the delivery of services may obviate the need for the IPO list. Finally, we believe physician judgment, state and local regulations, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and other CMS quality and monitoring initiatives will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings in the absence of the IPO list. Therefore, we propose to eliminate the IPO list over a transitional period beginning in

CY 2021. While we believe that the list could be eliminated in its entirety at this point, as explained in further detail below, we propose a transitional period.

Given the significant number of services on the list and that they will be newly priced under the OPPS, we recognize that stakeholders may need time to adjust to the removal of procedures from the list. Providers may need time to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the inpatient prospective payment system or outpatient prospective payment system. Therefore, we propose to transition services off of the IPO list over a 3-year period, with the list completely eliminated by 2024. In accordance with this proposal, we propose to amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024.

For CY 2021, we propose that musculoskeletal services would be the first group of services that would be removed from the IPO list. We believe it is appropriate to remove this group of services first for several reasons. In recent years, due to new technologies and advances in surgical care protocols, expedited rehabilitation protocols, and significant enhancements to postoperative processes we have removed TKA and THA, which are both musculoskeletal services, from the IPO list. During the process of proposing and finalizing removing TKA and THA from the IPO list, stakeholders have continuously requested that CMS remove other musculoskeletal services from the IPO list as well, citing shortened length of stay times, advancements in technologies and surgical techniques, and improved postoperative processes. Additionally, we note that, more often than not, stakeholders' historical requests for removals were for musculoskeletal services. We also recognize that there is already a set of comprehensive APCs for musculoskeletal services for payment in the outpatient setting, which facilitates the removal of these types of services for CY 2021. Specifically, because we have previously

removed codes from the IPO list that are similar clinically and in terms of resource cost and assigned them to these comprehensive APCs, these APCs generally describe appropriate ranges and placements for these musculoskeletal codes being proposed for removal in CY 2021, which will allow for appropriate payment. We have identified 266 musculoskeletal services that we propose to remove from the IPO list for CY 2021.

3. Comment Solicitation on Order of Removal of Additional Clinical Families from the IPO List during the Transition to Complete Elimination of the IPO List

As stated above, we propose to eliminate the current IPO list of 1,740 services, starting with the 266 musculoskeletal-related services as provided in Table 31. We are requesting comments from the public on whether 3 years is an appropriate time frame for the transition, whether there are other services that would be ideal candidates for removal from the IPO list in the near term given known technological and other advances in care, and the order of removal of additional clinical families and/or specific services for each of the CY 2022 and CY 2023 rulemakings, until the IPO list is completely eliminated. Additionally, we seek comment on whether we should restructure or create any new APCs to allow for OPPS payment for services that are removed from the IPO list. We are also soliciting public comments on whether any of the musculoskeletal codes proposed for removal from the IPO list for CY 2021 may meet the criteria to be added to the ASC Covered Procedures List. We refer readers to section XIII.C.1.c. of this proposed rule for a complete discussion of the ASC Covered Procedures List.

The 266 services that we propose to remove from the IPO list for CY 2021 and subsequent years, including the CPT/HCPCS code, long descriptor, and the proposed CY 2021 payment indicators, are included in Table 31 of this proposed rule.

In summary, given the developments in surgical technique and technological advances in the practice of medicine as well as the various safeguards discussed above, we propose to eliminate the IPO

list over the course of the next 3 years, starting with the removal of 266 musculoskeletal-related services as provided in Table 31 in CY 2021. We propose to amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024. We believe that several safety mechanisms that will remain in place will ensure the safety of our beneficiaries and the quality of care, including, but not limited to, physician judgment, state and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives.

Table 31 lists the procedures we propose to remove from the IPO list for CY 2021. These services and their proposed status indicators and APC assignments (if applicable) are included in Addendum B to this proposed rule as well.

TABLE 31: PROPOSED MUSCULOSKELETAL-RELATED SERVICE REMOVALS FROM THE INPATIENT ONLY (IPO) LIST FOR CY 2021 (N=266)

CY 2020 CPT Code		CY 2020 Long Descriptor	Related Services	Proposed CY 2021 OPPS Status Indicator	Proposed CY 2021 OPPS APC Assignment
0095T		Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	22856	N/A	
0098T		Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	22858	N/A	
0163T		Total disc arthroplasty (artificial disc), anterior approach,	22858	N/A	

		including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (list separately in addition to code for primary procedure)			
0164T		Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	22856	N/A	
0165T		Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	22858	N/A	
0202T		Posterior vertebral joint(s) arthroplasty (for example, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	63030	J1	5115
0219T		Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	63040	J1	5115
0220T		Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	63046	J1	5115
20661		Application of halo, including removal; cranial	20660	Q1	5113
20664		Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (for example, pediatric patients,	20660	Q1	5113

		hydrocephalus, osteogenesis imperfecta)			
20802		Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	24545	J1	5116
20805		Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	24545	J1	5116
20808		Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	24545	J1	5116
20816		Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	24371	J1	5114
20824		Replantation, thumb (includes carpometacarpal joint to mp joint), complete amputation	24371	J1	5114
20827		Replantation, thumb (includes distal tip to mp joint), complete amputation	24371	J1	5114
20838		Replantation, foot, complete amputation	24371	J1	5116
20955		Bone graft with microvascular anastomosis; fibula	27634	J1	5114
20956		Bone graft with microvascular anastomosis; iliac crest	27634	J1	5114
20957		Bone graft with microvascular anastomosis; metatarsal	27634	J1	5114
20962		Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	27634	J1	5114
20969		Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	27634	J1	5114
20970		Free osteocutaneous flap with microvascular anastomosis; iliac crest	27634	J1	5114
21045		Excision of malignant tumor of mandible; radical resection	21044	J1	5165
21141		Reconstruction midface, lefort i; single piece, segment movement	21150	J1	5165

		in any direction (for example, for long face syndrome), without bone graft			
21142		Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	21150	J1	5165
21143		Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	21150	J1	5165
21145		Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	21150	J1	5165
21146		Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	21150	J1	5165
21147		Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	21150	J1	5165
21151		Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	21150	J1	5165
21154		Reconstruction of midface bones with bone graft Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	21150	J1	5165
21155		Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	21150	J1	5165
21159		Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring	21150	J1	5165

		bone grafts (includes obtaining autografts); without LeFort I			
21160		Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	21150	J1	5165
21179		Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	21175	J1	5165
21180		Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	21175	J1	5165
21182		Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	21175	J1	5165
21183		Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	21175	J1	5165
21184		Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	21175	J1	5165

21188		Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	21175	J1	5165
21194		Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	21175	J1	5165
21196		Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	21175	J1	5165
21247		Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (for example, for hemifacial microsomia)	21175	J1	5165
21255		Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	21175	J1	5165
21268		Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	21172	J1	5165
21343		Open treatment of depressed frontal sinus fracture	21346	J1	5165
21344		Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	21346	J1	5165
21347		Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	21346	J1	5165
21348		Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	21346	J1	5165
21366		Open treatment of complicated (for example, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	21365	J1	5165

21422		Open treatment of palatal or maxillary fracture (lefort i type);	21445	J1	5165
21423		Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	21445	J1	5165
21431		Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	21445	J1	5165
21432		Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	21445	J1	5165
21433		Open treatment of craniofacial separation (lefort iii type); complicated (for example, comminuted or involving cranial nerve foramina), multiple surgical approaches	21445	J1	5165
21435		Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (for example, head cap, halo device, and/or intermaxillary fixation)	21445	J1	5165
21436		Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	21445	J1	5165
21510		Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax	21502	J1	5114
21602		Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	21601	J1	5114
21603		Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	21601	J1	5114
21615		Excision first and/or cervical rib;	21601	J1	5114

21616		Excision first and/or cervical rib; with sympathectomy	21601	J1	5114
21620		Ostectomy of sternum, partial	21601	J1	5114
21627		Sternal debridement	21601	J1	5114
21630		Radical resection of sternum;	21601	J1	5114
21632		Radical resection of sternum; with mediastinal lymphadenectomy	21601	J1	5114
21705		Division of scalenus anticus; with resection of cervical rib	21700	J1	5114
21740		Reconstructive repair of pectus excavatum or carinatum; open	21601	J1	5114
21750		Closure of median sternotomy separation with or without debridement (separate procedure)	21601	J1	5114
21825		Open treatment of sternum fracture with or without skeletal fixation	21813	J1	5114
22010		Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	22100	J1	5114
22015		Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	22102	J1	5114
22110		Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	22100	J1	5114
22112		Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	22102	J1	5114
22114		Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	22102	J1	5114
22116		Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional	22100	N/A	N/A

		vertebral segment (list separately in addition to code for primary procedure)			
22206		Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); thoracic	22102	J1	5114
22207		Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); lumbar	22102	J1	5114
22208		Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	22103	N/A	
22210		Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	22100	J1	5114
22212		Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	22102	J1	5114
22214		Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	22102	J1	5114
22216		Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	22103	N/A	
22220		Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	22100	J1	5114
22222		Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	22102	J1	5114
22224		Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	22102	J1	5114

22226		Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	22103	N/A	
22318		Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	22551	J1	5115
22319		Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	22551	J1	5115
22325		Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	22554	J1	5115
22326		Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical	22554	J1	5115
22327		Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	22102	J1	5115
22328		Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	22103	N/A	
22532		Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace	22554	J1	5116

		(other than for decompression); thoracic			
22533		Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	22554	J1	5116
22534		Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	22103	N/A	
22548		Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	22551	J1	5116
22556		Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	22554	J1	5116
22558		Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	22554	J1	5116
22586		Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	22554	J1	5116
22590		Arthrodesis, posterior technique, craniocervical (occiput-c2)	22551	J1	5116
22595		Arthrodesis, posterior technique, atlas-axis (c1-c2)	22551	J1	5116
22600		Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	22551	J1	5116
22610		Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral	22612	J1	5116

		transverse technique, when performed)			
22630		Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	22612	J1	5116
22632		Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	22585	N/A	
22800		Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	22612	J1	5116
22802		Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	22612	J1	5116
22804		Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	22612	J1	5116
22808		Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	22612	J1	5116
22810		Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	22612	J1	5116
22812		Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	22612	J1	5116
22818		Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	22612	J1	5116
22819		Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	22612	J1	5116
22830		Exploration of spinal fusion	22612	J1	5115

22841		Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	22840	N/A	
22843		Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	22840	N/A	
22844		Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	22840	N/A	
22846		Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	22840	N/A	
22847		Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	22840	N/A	
22848		Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list separately in addition to code for primary procedure)	22840	N/A	
22849		Reinsertion of spinal fixation device	22612	J1	5116
22850		Removal of posterior nonsegmental instrumentation (for example, harrington rod)	22612	J1	5115
22852		Removal of posterior segmental instrumentation	22612	J1	5115
22855		Removal of anterior instrumentation	22612	J1	5115
22857		Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for	22856	J1	5116

		decompression), single interspace, lumbar			
22861		Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	22856	J1	5116
22862		Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	22856	J1	5116
22864		Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	22856	J1	5115
22865		Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	22856	J1	5115
23200		Radical resection of tumor; clavicle	23155	J1	5114
23210		Radical resection of tumor; scapula	23155	J1	5114
23220		Radical resection of tumor, proximal humerus	23155	J1	5114
23335		Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)	23334	J1	5073
23472		Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))	23470	J1	5115
23474		Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	23473	J1	5115
23900		Interthoracoscapular amputation (forequarter)	23680	J1	5115
23920		Disarticulation of shoulder;	23680	J1	5115
24900		Amputation, arm through humerus; with primary closure	23680	J1	5115

24920		Amputation, arm through humerus; open, circular (guillotine)	23680	J1	5115
24930		Amputation, arm through humerus; re-amputation	24925	J1	5114
24931		Amputation, arm through humerus; with implant	23680	J1	5115
24940		Cineplasty, upper extremity, complete procedure	23680	J1	5115
25900		Amputation, forearm, through radius and ulna;	27709	J1	5115
25905		Amputation, forearm, through radius and ulna; open, circular (guillotine)	27709	J1	5115
25915		Krukenberg procedure	27709	J1	5114
25920		Disarticulation through wrist;	25922	J1	5114
25924		Disarticulation through wrist; re-amputation	25922	J1	5114
25927		Transmetacarpal amputation;	25922	J1	5113
26551		Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	20973	J1	5114
26553		Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	20973	J1	5114
26554		Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	20973	J1	5114
26556		Transfer, free toe joint, with microvascular anastomosis	20973	J1	5114
26992		Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)	26990	J1	5114
27005		Tenotomy, hip flexor(s), open (separate procedure)	27006	J1	5114
27025		Fasciotomy, hip or thigh, any type	27027	J1	5114
27030		Arthrotomy, hip, with drainage (for example, infection)	27033	J1	5114
27036		Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor	27033	J1	5114

		fascia latae, rectus femoris, sartorius, iliopsoas)			
27054		Arthrotomy with synovectomy, hip joint	27052	J1	5113
27070		Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); superficial	27065	J1	5114
27071		Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	27065	J1	5114
27075		Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	27067	J1	5114
27076		Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	27067	J1	5114
27077		Radical resection of tumor; innominate bone, total	27067	J1	5115
27078		Radical resection of tumor; ischial tuberosity and greater trochanter of femur	27067	J1	5115
27090		Removal of hip prosthesis; (separate procedure)	20680	J1	5073
27091		Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	20680	J1	5073
27120		Acetabuloplasty; (for example, whitman, colonna, haygroves, or cup type)	27067	J1	5115
27122		Acetabuloplasty; resection, femoral head (for example, girdlestone procedure)	27067	J1	5115
27125		Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)	27130	J1	5115
27132		Conversion of previous hip surgery to total hip arthroplasty,	27130	J1	5115

		with or without autograft or allograft			
27134		Revision of total hip arthroplasty; both components, with or without autograft or allograft	27130	J1	5115
27137		Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	27130	J1	5115
27138		Revision of total hip arthroplasty; femoral component only, with or without allograft	27130	J1	5115
27140		Osteotomy and transfer of greater trochanter of femur (separate procedure)	27130	J1	5115
27146		Osteotomy, iliac, acetabular or innominate bone;	27179	J1	5114
27147		Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	27179	J1	5114
27151		Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	27179	J1	5114
27156		Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	27179	J1	5114
27158		Osteotomy, pelvis, bilateral (for example, congenital malformation)	27179	J1	5114
27161		Osteotomy, femoral neck (separate procedure)	27179	J1	5114
27165		Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	27179	J1	5114
27170		Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	27179	J1	5114
27175		Treatment of slipped femoral epiphysis; by traction, without reduction	27179	J1	5114
27176		Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	27179	J1	5115
27177		Open treatment of slipped femoral epiphysis; single or	27179	J1	5114

		multiple pinning or bone graft (includes obtaining graft)			
27178		Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	27179	J1	5114
27181		Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	27179	J1	5114
27185		Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	27179	J1	5114
27187		Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	27235	J1	5114
27222		Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	27220	J1	5111
27226		Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	27235	J1	5114
27227		Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	27235	J1	5114
27228		Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	27235	J1	5114
27232		Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	27238	J1	5112
27236		Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	27235	J1	5114

27240		Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	27238	J1	5112
27244		Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	27235	J1	5114
27245		Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	27235	J1	5114
27248		Open treatment of greater trochanteric fracture, includes internal fixation, when performed	27235	J1	5114
27253		Open treatment of hip dislocation, traumatic, without internal fixation	27235	J1	5113
27254		Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	27235	J1	5113
27258		Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	27235	J1	5113
27259		Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	27235	J1	5113
27268		Closed treatment of femoral fracture, proximal end, head; with manipulation	27238	J1	5113
27269		Open treatment of femoral fracture, proximal end, head,	27238	J1	5112

		includes internal fixation, when performed			
27280		Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	27279	J1	5116
27282		Arthrodesis, symphysis pubis (including obtaining graft)	28730	J1	5115
27284		Arthrodesis, hip joint (including obtaining graft);	27279	J1	5116
27286		Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	27279	J1	5116
27290		Interpelviabdominal amputation (hindquarter amputation)	27279	J1	5116
27295		Detachment of hip joint	27279	J1	5116
27303		Incision, deep, with opening of bone cortex, femur or knee (for example, osteomyelitis or bone abscess)	27305	J1	5114
27365		Radical resection of tumor, femur or knee	27364	J1	5114
27445		Arthroplasty, knee, hinge prosthesis (for example, walldius type)	27447	J1	5115
27448		Osteotomy, femur, shaft or supracondylar; without fixation	27485	J1	5114
27450		Osteotomy, femur, shaft or supracondylar; with fixation	27485	J1	5114
27454		Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (for example, sofield type procedure)	27485	J1	5114
27455		Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure	27485	J1	5114
27457		Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	27485	J1	5114

27465		Osteoplasty, femur; shortening (excluding 64876)	27485	J1	5114
27466		Osteoplasty, femur; lengthening	27485	J1	5114
27468		Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	27485	J1	5114
27470		Repair, nonunion or malunion, femur, distal to head and neck; without graft (for example, compression technique)	27485	J1	5114
27472		Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	27485	J1	5114
27486		Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	27477	J1	5115
27487		Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	27477	J1	5115
27488		Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	27485	J1	5114
27495		Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	27475	J1	5114
27506		Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	27509	J1	5114
27507		Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	27509	J1	5114
27511		Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	27509	J1	5114

27513		Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	27509	J1	5114
27514		Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	27509	J1	5114
27519		Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	27509	J1	5114
27535		Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	27532	J1	5114
27536		Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	27532	J1	5114
27540		Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	27532	J1	5114
27556		Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	27532	J1	5114
27557		Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	27532	J1	5114
27558		Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	27335	J1	5114
27580		Arthrodesis, knee, any technique	27594	J1	5115
27590		Amputation, thigh, through femur, any level;	27594	J1	5116
27591		Amputation, thigh, through femur, any level; immediate fitting technique including first cast	27594	J1	5116

27592		Amputation, thigh, through femur, any level; open, circular (guillotine)	27594	J1	5116
27596		Amputation, thigh, through femur, any level; re-amputation	27499	J1	5114
27598		Disarticulation at knee	27428	J1	5115
27645		Radical resection of tumor; tibia	27637	J1	5114
27646		Radical resection of tumor; fibula	27637	J1	5114
27702		Arthroplasty, ankle; with implant (total ankle)	27447	J1	5115
27703		Arthroplasty, ankle; revision, total ankle	27447	J1	5115
27712		Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)	27709	J1	5115
27715		Osteoplasty, tibia and fibula, lengthening or shortening	27709	J1	5115
27724		Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	27722	J1	5114
27725		Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	27722	J1	5114
27727		Repair of congenital pseudarthrosis, tibia	27722	J1	5114
27880		Amputation, leg, through tibia and fibula;	27884	J1	5116
27881		Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	27884	J1	5114
27882		Amputation, leg, through tibia and fibula; open, circular (guillotine)	27884	J1	5114
27886		Amputation, leg, through tibia and fibula; re-amputation	27884	J1	5114
27888		Amputation, ankle, through malleoli of tibia and fibula (for example, syme, pirogoff type procedures), with plastic closure and resection of nerves	27884	J1	5115
28800		Amputation, foot; midtarsal (for example, chopart type procedure)	28805	J1	5113

G0412		Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	27179	J1	5114
G0414		Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	27202	J1	5115
G0415		Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	27202	J1	5115

X. Proposed Nonrecurring Policy Changes

A. Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we implemented a policy for CY 2020 and subsequent years to change the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs. However, some groups of services were not subject to the change in the required supervision level and those services continue to have a minimum default level of supervision that is higher than general supervision.

On January 31, 2020, Health and Human Services Secretary Alex M. Azar II determined that a PHE exists retroactive to January 27, 2020[88] under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19), and on April 21, 2020, Secretary Azar renewed, effective April 26, 2020, and again effective July 25, 2020, the determination that a PHE exists.[89] On March 13, 2020, the President of the United States declared the COVID-19 outbreak in the United States constitutes a national emergency,[90] beginning March 1, 2020. On March 31, 2020, we issued an interim final rule with comment period (IFC) to give individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the COVID-19. The goal of the IFC issued on March 31, 2020, was to provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health (85 FR 19232).

In the IFC issued March 31, 2020, we adopted a policy to reduce, on an interim basis for the duration of the PHE, the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which we had previously required direct supervision. We also specified in the IFC issued March 31, 2020, that, for the duration of the PHE for the COVID-19 pandemic, the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence of the physician through audio/video

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[88] 7https://www.phe.gov/emergency/news/ healthactions/phe/Pages/2019-nCoV.aspx.
[89] https://www.phe.gov/emergency/news/ healthactions/phe/Pages/covid19-21apr2020.aspx.
[90] https://www.whitehouse.gov/presidentialactions/proclamation-declaring-nationalemergency-concerning-novel-coronavirus-diseasecovid-19-outbreak/.

real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

These policies were adopted on an interim final basis for the duration of the PHE. However, we believe that these policies are appropriate outside of the PHE and should apply permanently. Therefore, we propose to adopt these policies for CY 2021 and beyond as described in more detail below.

1. Proposal to Allow General Supervision of Outpatient Hospital Therapeutic Services Currently Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision

NSEDTS describe services that have a significant monitoring component that can extend for a lengthy period of time, that are not surgical, and that typically have a low risk of complications after the assessment at the beginning of the service. The minimum default supervision level of NSEDTS was established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72003 through 72013) as being direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner (§ 410.27(a)(1)(iv)(E)). In this case, initiation means the beginning portion of the NSEDTS which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision. We originally established general supervision as the appropriate level of supervision after the initiation of the service because it is challenging for hospitals to ensure direct supervision for services with an extended duration and a significant monitoring component, particularly for CAHs and small rural hospitals.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we changed the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs. We made

this change because we believe it is critical that hospitals have the most flexibility possible to provide the services Medicare beneficiaries need while minimizing provider burden. In the IFC issued March 31, 2020 (85 FR 19266), we assigned, on an interim basis, a minimum required supervision level of general supervision for NSEDTS services, including during the initiation portion of the service, during the PHE. Changing the minimum level of supervision to general supervision during the PHE gives providers additional flexibility to handle the burdens created by the PHE for the COVID-19 pandemic.

We believe changing the level of supervision for NSEDTS permanently for the duration of the service would be beneficial to patients and outpatient hospital providers as it would allow greater flexibility in providing these services and reduce provider burden, and thus, improve access to these services in cases where the direct supervision requirement may have otherwise prevented some services from being furnished due to lack of availability of the supervising physician or nonphysician practitioner. In addition, as we explained in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61360), our experience indicates that Medicare providers will provide a similar quality of hospital outpatient therapeutic services, including NSEDTS, regardless of whether the minimum level of supervision required under the Medicare program is direct or general. It is important to remember that the requirement for general supervision for an entire NSEDTS does not preclude these hospitals from providing direct supervision for any part of a NSEDTS when the practitioners administering the medical procedures decide that it is appropriate to do so. Many outpatient therapeutic services including NSEDTS may involve a level of complexity and risk such that direct supervision would be warranted even though only general supervision is required.

In addition, CAHs and hospitals in general continue to be subject to conditions of participation (CoPs) that complement the general supervision requirements for hospital outpatient therapeutic services, including NSEDTS, to ensure that the medical services Medicare patients receive are properly

supervised. CoPs for hospitals require Medicare patients to be under the care of a physician (42 CFR 482.12(c)(4)), and for the hospital to ‘‘have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital’’ (42 CFR 482.22). The CoPs for CAHs (42 CFR 485.631(b)(1)(i)) require physicians to provide medical direction for the CAHs' health care activities, consultation for, and medical supervision of the health care staff. The physicians' responsibilities in hospitals and CAHs include supervision of all services performed at those facilities. In addition, physicians must also follow state laws regarding scope of practice.

Therefore, we propose to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. This would be consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. General supervision, as defined in our regulation at § 410.32(b)(3)(i), means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure; and as provided under § 410.27(a)(1)(iv)(C), certain non-physician practitioners can provide the required supervision of services that they can personally furnish in accordance with state law and all other applicable requirements. Because we propose a minimum required level of general supervision for NSEDTS, including during the initiation of the service, we propose to delete subparagraph (E) from the regulations at § 410.27(a)(1)(iv). We are seeking public comments on this proposal.

2. Proposal to Allow Direct Supervision of Pulmonary Rehabilitation Services, Cardiac Rehabilitation Services, and Intensive Cardiac Rehabilitation Services using Interactive Telecommunications Technology

Direct physician supervision was the standard set forth in the April 7, 2000 OPPS final rule with comment period (68 FR 18524 through 18526) for supervision of hospital outpatient therapeutic services covered and paid by Medicare in hospitals and provider-based departments of hospitals, including for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services provided to hospital outpatients. As we explained in the CY 2011 OPPS/ASC final rule with comment period, the statutory language of sections 1861(eee)(2)(B) and (eee)(4)(A) and section 1861(fff)(1) of the Act (as added by section 144(a)(1) of Pub. L. 110–275) defines cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs as "physician supervised." More specifically, section 1861(eee)(2)(B) of the Act establishes that, for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs, "a physician is immediately available and accessible for consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed." As we explained in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, referencing the April 7, 2000 OPPS final rule (65 FR 18525)), the ''presumption'' or ''assumption'' of direct supervision means that direct physician supervision is the standard for all hospital outpatient therapeutic services. We have assumed this requirement is met on hospital premises because staff physicians would always be nearby in the hospital. In other words, the requirement is not negated by a presumption that the requirement is being met. Recently, some stakeholders suggested to us that we have the authority to change the default minimum level of supervision for pulmonary rehabilitation services, cardiac rehabilitation services, and intensive cardiac rehabilitation services to general supervision because of the policy we adopted in CY 2020 to change the generally applicable minimum required level of supervision for most other hospital outpatient therapeutic services from direct

supervision to general supervision (84 FR 61359 through 61363). For the reasons explained above, we disagree that we can change the default level of supervision for these services to general supervision under current law.

In the IFC issued March 31, 2020 (85 FR 19246), we implemented a policy for the duration of the PHE that allows the direct supervision requirement for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services to be met by the virtual presence of the supervising physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks to COVID-19 for the beneficiary or health care provider. While we adopted this policy to help improve the availability of rehabilitation services during the PHE and reduce the burden for providers, we also believe the policy to allow direct supervision provided by the virtual presence of the physician could continue to improve access for patients and reduce burden for providers after the end of the PHE. In some cases, depending upon the circumstances of individual patients and supervising physicians, we believe that telecommunications technology could be used in a manner that would facilitate the physician's immediate availability to furnish assistance and direction without necessarily requiring the physician's physical presence in the location where the service is being furnished. For example, use of real-time audio and video telecommunications technology could allow a supervising physician to observe the patient during treatment as they interact with or respond to the in-person clinical staff. Thus, the supervising physician's immediate availability to furnish assistance and direction during the service could be met virtually without requiring the physician's physical presence in that location.

Therefore for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, we propose to change our regulation at § 410.27(a)(1)(iv)(D) to specify that, beginning on or after January 1, 2021, direct supervision for these services includes virtual presence of

the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. We clarify that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure. We are seeking public comments on this proposal.

B. Proposed Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years

1. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Under this policy, we established a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not designated as an inpatient-only (IPO) procedure as described in 42 CFR 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed. With respect to services designated under the OPPS as IPO procedures, we explained that because of the intrinsic risks, recovery impacts, or complexities associated with such services, these procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. We also indicated that there might be further "rare and

unusual" exceptions to the application of the benchmark, which would be detailed in subregulatory guidance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we also finalized the 2-midnight presumption, which is related to the 2-midnight benchmark but is a separate medical review policy. The 2-midnight benchmark represents guidance to reviewers to identify when an inpatient admission is generally reasonable and necessary for purposes of Medicare Part A payment, while the 2-midnight presumption relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption. Thus, for purposes of the 2-midnight *presumption*, the "clock" starts at the point of admission as an inpatient.

With respect to the 2-midnight *benchmark*, however, the starting point is when the beneficiary begins receiving hospital care either as a registered outpatient or after inpatient admission. That is, for purposes of determining whether the 2-midnight benchmark is met and, therefore, whether an inpatient admission is appropriate for Medicare Part A payment, we consider the physician's expectation including the total time spent receiving hospital care—not only the expected duration of care after inpatient admission, but also any time the beneficiary has spent (before inpatient admission) receiving outpatient services, such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area. From the medical review perspective, while the time the beneficiary spent as an outpatient before the admission order is written is not considered inpatient time, it is considered during the medical review process for purposes of

determining whether the 2-midnight benchmark was met and, therefore, whether payment is appropriate under Medicare Part A. For beneficiaries who do not arrive through the emergency department or are directly receiving inpatient services (for example, inpatient admission order written prior to admission for an elective admission), the starting point for medical review purposes is when the beneficiary starts receiving medically responsive services following arrival at the hospital. For Medicare payment purposes, both the decision to keep the patient at the hospital and the expectation of needed duration of the stay must be supported by documentation in the medical record based on factors such as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event during hospitalization.

With respect to inpatient stays spanning less than 2 midnights after admission, we instructed contractors that, although such claims would not be subject to the presumption, the admission may still be appropriate for Medicare Part A payment because time spent as an outpatient should be considered in determining whether there was a reasonable expectation that the hospital care would span 2 or more midnights. In other words, even if an inpatient admission was for only 1 Medicare utilization day, medical reviewers are instructed to consider the total duration of hospital care, both pre- and post-inpatient admission, when making the determination of whether the inpatient stay was reasonable and necessary for purposes of Medicare Part A payment.

We continue to believe that use of the 2-midnight benchmark gives appropriate consideration to the medical judgment of physicians and also furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A. More specifically, as we described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the determination of whether an admission is

appropriately billed and paid under Medicare Part A or Part B is generally based upon the physician's medical judgment regarding the beneficiary's expected length of stay. We have not identified any circumstances where the 2-midnight benchmark restricts the physician to a specific pattern of care, because the 2-midnight benchmark does not prevent the physician from ordering or providing any service at any hospital, regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary's care is appropriate for coverage and payment under Medicare Part A as an inpatient, and when the beneficiary's care is reasonable and necessary for payment under Medicare Part B as an outpatient.

We also acknowledge that certain procedures may have intrinsic risks, recovery impacts, or complexities that would cause them to be appropriate for inpatient coverage under Medicare Part A regardless of the length of hospital time the admitting physician expects a particular patient to require.

2. Current Policy for Medical Review of Inpatient Hospital Admissions under Medicare Part A

As mentioned previously, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), we provided guidance for payment purposes that specified that, generally, a hospital inpatient admission is considered reasonable and necessary if a physician or other qualified practitioner (collectively, "physician") orders such admission based on the expectation that the beneficiary's length of stay will exceed 2 midnights or if the beneficiary requires a procedure specified as inpatient-only under § 419.22 of the regulations. We finalized at § 412.3(d)(1) of the regulations that services designated under the OPPS as inpatient only procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A. In addition, we finalized a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician

expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), we revisited the previous rare and unusual exceptions policy and finalized a proposal to allow for case-by-case exceptions to the 2-midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care.

We note that, in the CY 2016 OPPS/ASC final rule with comment period, we reiterated our position that the 2-midnight benchmark provides clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment. We stated that the following criteria will be relevant to determining whether an inpatient admission with an expected length of stay of less than 2 midnights is nonetheless appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

In other words, for purposes of Medicare payment, an inpatient admission is payable under Part A if the documentation in the medical record supports either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified previously that the patient nonetheless requires care on an inpatient basis. The exceptions for procedures on the IPO list and for "rare and unusual"

circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. For instance, for cases where the medical record does not support a reasonable expectation of the need for hospital care crossing at least 2 midnights, and for inpatient admissions not related to a surgical procedure specified by Medicare as an IPO procedure under 42 CFR 419.22(n) or for which there was not a national exception, payment of the claim under Medicare Part A is subject to the clinical judgment of the medical reviewer. The medical reviewer's clinical judgment involves the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS' policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides their decision to keep a beneficiary in the hospital and formulation of the expected length of stay.

In the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from eligibility for referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule within the 2-calendar years following their removal from the IPO list. We stated that these procedures will not be considered by the

Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for "patient status." We explained that during this 2-year period, BFCC-QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A.

3. Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years

As stated earlier in this section, services on the IPO list are not subject to the 2-midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, the 2-midnight rule is applicable once services have been removed from the IPO list. Services that are removed from the IPO list are subject to initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC-QIOs.

BFCC-QIOs may also refer providers to the RACs for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-midnight rule; or
- Failing to improve their performance after QIO educational intervention.

However, as finalized in the CY 2020 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list are exempt from eligibility for referral to RACs for noncompliance with the 2-midnight rule within the 2-calendar years following their removal from the IPO list.

As stated in section IX., we propose to eliminate the IPO list in CY 2021 with a transitional period of 3 years. For CY 2021, we propose to remove all musculoskeletal procedures from the IPO list. The elimination of the IPO list would mean that procedures currently on the IPO list would be subject to the 2-midnight rule (both the 2-midnight benchmark and 2-midnight presumption).

We believe that with the proposed elimination of the IPO list, the 2-midnight benchmark would remain an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. With more services available to be paid in the hospital outpatient setting, it would be increasingly important for physicians to exercise their clinical judgment in determining the generally appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. Importantly, removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the generally appropriate setting.

As stated previously, our current policy regarding IPO list procedures is that they are appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. With the proposed elimination of the IPO list, this policy would no longer be applicable. Instead, just as for services removed from the IPO list, the elimination of the IPO list would mean that any service that was once on the IPO list would be subject to the 2-midnight benchmark and 2-midnight presumption. This means that for services removed from the IPO list, under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after admission would be presumed to be appropriate for Medicare Part A payment and would not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption. Additionally, under the 2-midnight benchmark, services formerly on the IPO list would be generally considered appropriate for inpatient hospital

admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.

As finalized in the CY 2020 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list are not eligible for referral to RACs for noncompliance with the 2-midnight rule within the first 2 calendar years of their removal from the IPO list. These procedures are not considered by the BFCC-QIOs in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor are these procedures be reviewed by RACs for "patient status." During the 2-year period, BFCC-QIOs have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant are not denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the BFCC-QIO when reviewing procedures as they are newly removed from the IPO list can be used for educational purposes and does not result in a claim denial during the 2-year exemption period.

We continue to believe that in order to facilitate compliance with our payment policy for inpatient admissions, the 2-year exemption from certain medical review activities by the BFCC-QIOs for services removed from the IPO list under the OPPS in CY 2021 and subsequent years is appropriate. Accordingly, we propose to retain the existing 2-year exemption even in the event that we finalize the proposal to eliminate the IPO list. However, given that many more services would be removed from the IPO list during the proposed transition to elimination of the list, we seek comment on whether this 2-year period is appropriate or whether a longer or shorter period may be more appropriate in order for providers to gain experience with applying the 2-midnight rule to these services.

We also continue to believe that a 2-year exemption from BFCC-QIO referral to RACs and RAC "patient status" review of the setting for procedures removed from the IPO list under the OPPS and

performed in the inpatient setting would be an adequate amount of time to allow providers to gain experience with application of the 2-midnight rule to these procedures and the documentation necessary for Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting. Furthermore, it is our belief that the 2-year exemption from referrals to RACs, RAC patient status review, and claims denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures eligible to be paid under either the IPPS or the OPPS, while avoiding potential adverse site-of-service determinations. Nonetheless, we solicit public comments regarding the appropriate period of time for this exemption. Commenters may indicate whether and why they believe the 2-year period is appropriate, or whether they believe a longer or shorter exemption period would be more appropriate.

In summary, for CY 2021 and subsequent years, we propose to continue the 2-year exemption from site-of-service claim denials, BFCC-QIO referrals to RACs, and RAC reviews for "patient status" (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We encourage BFCC-QIOs to review these cases for medical necessity in order to educate themselves and the provider community on appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. We note that we will monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models. Finally, while we propose to retain the current 2-year exemption period, given that many more services will be removed from the IPO as part of the transition towards the elimination of the list, we are seeking comment on whether that time period continues to be appropriate, or if a longer or shorter period may be more warranted.

C. Comment Solicitation on OPPS Payment for Specimen Collection for COVID-19 Tests

In the interim final with comment period (IFC) (85 FR 27604 through 27605) entitled, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program", published on May 8, 2020, we created HCPCS code C9803 (*Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), and specimen source)*. This code was established in response to the significant increase in specimen collection and testing for COVID-19 in Hospital Outpatient Departments (HOPDs) during the COVID-19 Public Health Emergency (PHE). On January 31, 2020[91], HHS Secretary Alex M. Azar II determined that a PHE exists for the United States retroactive to January 27, 2020. On April 21, 2020 Secretary Azar renewed, effective April 26, 2020, the determination that a COVID-19 PHE exists[92]. On July 23, 2020, Secretary Azar again renewed the determination that a COVID-19 PHE exists, effective July 25, 2020.[93]

In our prior review of HCPCS codes for the May 8, 2020 IFC, we did not identify a code that described the standalone services of symptom assessment and specimen collection that HOPDs were undertaking to facilitate widespread testing for COVID-19. As stated in that IFC, we believed that HCPCS code C9803 was necessary to meet the resource requirements for HOPDs to provide extensive testing for the duration of the COVID-19 PHE. This code was created only to meet the need of the COVID-19 PHE and we stated that we expected to retire this code at the conclusion of the COVID-19 PHE (85 FR 27605).

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[91] https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx
[92] https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx
[93] https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx

As stated in the aforementioned IFC (85 FR 27604 through 27605), we assigned HCPCS code C9803 to APC 5731- Level 1 Minor Procedures effective March 1, 2020 for the duration of the COVID-19 PHE. In accordance with Section 1833(t)(2)(B) of the Act, APC 5731 - Level 1 Minor Procedures contains services similar to HCPCS code C9803. APC 5731 - Level 1 Minor Procedures has a payment rate of $22.98 for CY 2020. HCPCS code C9803 was also assigned a status indicator of "Q1." The Q1 status indicator indicates that the OPPS will package services billed under HCPCS code C9803 when billed with a separately payable primary service in the same encounter. When HCPCS code C9803 is billed without another separately payable primary service, we will make separate payment for the service under the OPPS. The OPPS also makes separate payment for HCPCS code C9803 when it is billed with a clinical diagnostic laboratory test with a status indicator of ''A'' on Addendum B of the OPPS.

As noted previously, the current determination of the existence of a COVID-19 PHE was recently renewed for another 90 day period, effective July 25, 2020. Given that the COVID-19 PHE is still active at this time and the possibility that it may need to be extended into 2021, for CY 2021 we propose to continue to assign HCPCS code C9803 to APC 5731 with a status indicator of "Q1", should the COVID-19 PHE continue to exist during CY 2021, with the presumption, as stated in the IFC that this code will be deleted when COVID-19 PHE ends. In this proposed rule, we are accepting public comments on the proposed APC and status indicator assignment for HCPCS code C9803 for CY 2021 (and remind commenters that the code is only active for the duration of the COVID-19 PHE under the IFC).

We are also soliciting public comments on whether we should keep HCPCS code C9803 active beyond the COVID-19 PHE and whether we should extend or make permanent the OPPS payment associated with specimen collection for COVID-19 tests after the COVID-19 PHE ends, including the

reasoning for continuing to provide OPPS payment for this service as well as the timeframe for extending payment for this code. In the event we keep HCPCS code C9803 active after the COVID-19 PHE concludes, we are seeking public input on whether we should continue to assign HCPCS code C9803 to APC 5731 - Level 1 Minor Procedures with a proposed status indicator of "Q1". In summary, we are requesting public comments on whether this code should continue to be payable under the OPPS to support COVID–19 testing beyond the conclusion of the COVID-19 PHE.

XI. Proposed CY 2021 OPPS Payment Status and Comment Indicators

A. Proposed CY 2021 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system, and also whether particular OPPS policies apply to the code.

For CY 2021, we are not proposing to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2020 OPPS/ASC final rule with comment period available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-P.html?DLPage=1&DLEntries=10&10DLSort=2DLSortDir=descending.

We are requesting public comments on the proposed definitions of the OPPS status indicators for CY 2021.

The complete list of the proposed payment status indicators and their definitions that would apply for CY 2021 is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

The proposed CY 2021 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

B. Proposed CY 2021 Comment Indicator Definitions

In this proposed rule, we propose to use four comment indicators for the CY 2021 OPPS. These comment indicators, "CH", "NC", "NI", and "NP", are in effect for CY 2020 and we propose to continue their use in CY 2021. The proposed CY 2021 OPPS comment indicators are as follows:

- "CH"—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.

- "NC"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.

- "NI"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

- "NP"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2021 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

We believe that the existing CY 2020 definitions of the OPPS comment indicators continue to be appropriate for CY 2021. Therefore, we propose to use those definitions without modification for CY 2021.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2020 report.

A. Proposed OPPS Payment Rates Update

The March 2020 MedPAC "Report to the Congress: Medicare Payment Policy," recommended that Congress update Medicare OPPS payment rates by 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the "Hospital Value Incentive Program (HVIP)." We refer readers to the March 2020 report for a complete discussion on these recommendations.[94] We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its March 2020 report, the Congress would need to change current law to enable us to implement its recommendations.

B. Proposed ASC Conversion Factor Update

[94] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, pp.94-95. Available at: http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0

In the March 2020 MedPAC "Report to the Congress: Medicare Payment Policy," MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[95] As a result, for CY 2021, MedPAC stated that payments to ASCs are adequate and recommended that in the absence of cost report data no payment update should be given for CY 2021 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the MFP-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the MFP-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in section XIII.G. of this proposed rule, we propose to apply a 2.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment amounts.

C. Proposed ASC Cost Data

In the March 2020 MedPAC "Report to the Congress: Medicare Payment Policy," MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or an ASC specific market basket should be developed. Further,

[95] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.147. Available at: http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0

MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program.[96]

We recognize that the submission of cost data could place additional administrative burden on most ASCs. We are interested in methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. We are not proposing any cost reporting requirements for ASCs in this CY 2021 OPPS/ASC proposed rule.

The full March 2020 MedPAC Report to Congress can be downloaded from MedPAC's website at: http://www.medpac.gov.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019 and 2020 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080, and 84 FR 61370 through 61410, respectively).

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[96] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services. Available at: http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure ("overnight stay"). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. Historically, we have defined surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment

period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of Current Procedural Terminology (CPT) codes for which separate payment is allowed under the OPPS when they are provided integral to an ASC covered surgical procedure. Covered ancillary services are specified in 42 CFR 416.164(b) and, as stated previously, are eligible for separate ASC payment. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (42 CFR 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services covered under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer

readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

3. Definition of ASC Covered Surgical Procedures

Since the implementation of the ASC prospective payment system, we have historically defined a "surgical" procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as "surgery" (CPT codes 10000 through 69999) (72 FR 42478). We also have included as "surgical," procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and that are separately paid under the OPPS (72 FR 42478).

As we noted in the August 7, 2007 final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, "surgery-like"

procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures.

However, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. We now define a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS.

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the

American Medical Association (AMA), and includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

● Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;

● Category III CPT codes, which describe new and emerging technologies, services, and procedures; and

● Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2021 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in this proposed rule (and respond to those comments in the CY 2021 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2021 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2022 OPPS/ASC final rule with comment period).

2. April 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2020 update, there were no new CPT codes, however, there were several new Level II HCPCS codes. In the April 2020 ASC quarterly update (Transmittal 10046, dated April 13, 2020, CR 11694), we added four new Level II HCPCS codes to the list of covered ancillary services. Table 32 lists the new Level II HCPCS codes that were implemented April 1, 2020, along with their proposed payment indicators for CY 2021. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2020 are assigned to comment indicator "NP" in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the Internet on the CMS website.

TABLE 32: NEW LEVEL II HCPCS CODES FOR ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
C9053*	Injection, crizanlizumab-tmca, 1 mg	CH	K2

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
C9056**	Injection, givosiran, 0.5 mg	CH	K2
C9057#	Injection, cetirizine hydrochloride, 1 mg	CH	K2
C9058##	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	CH	K2

*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.

**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.

#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.

##HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.

We are inviting public comments on these proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2020 through the quarterly update CRs, as listed in Table 32. We propose to finalize their payment indicators in the CY 2021 OPPS/ASC final rule with comment period.

3. July 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2020 ASC quarterly update (Transmittal 10188, Change Request 11842, dated June 19, 2020), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 33 lists the new HCPCS codes that are effective July 1, 2020. The proposed comment indicators, payment indicators and payment rates for these codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2020 are assigned to comment indicator "NP" in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and

definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the Internet on the CMS website.

TABLE 33: NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
C1748	Endoscope, single-use (that is, disposable), upper GI, imaging/illumination device (insertable)	NP	J7
C1849	Skin substitute, synthetic, resorbable, per square centimeter	NP	N1
C9059	Injection, meloxicam, 1 mg	NP	K2
C9061	Injection, teprotumumab-trbw, 10 mg	NP	K2
C9063	Injection, eptinezumab-jjmr, 1 mg	NP	K2
C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	NP	K2
C9759	Transcatheter intraoperative blood vessel microinfusion(s) (for example, intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	NP	N1
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	NP	Z2
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	NP	Z2
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	NP	G2
C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	NP	J8
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	G2
C9767	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	J8
G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (for	NP	J8

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
	example, transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed		
G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (for example, vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	NP	J8
J0223	Injection, givosiran, 0.5 mg	NP	K2
J0691	Injection, lefamulin, 1 mg	NP	K2
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	NP	K2
J0791	Injection, crizanlizumab-tmca, 5 mg	NP	K2
J0896	Injection, luspatercept-aamt, 0.25 mg	NP	K2
J1201	Injection, cetirizine hydrochloride, 0.5 mg	NP	K2
J1429	Injection, golodirsen, 10 mg	NP	K2
J1558	Injection, immune globulin (Xembify), 100 mg	NP	K2
J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	NP	K2
J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	NP	K2
J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	NP	N1
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	NP	K2
J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	NP	K2
J9246	Injection, melphalan (evomela), 1 mg	NP	K2
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	NP	K2
Q4227#	Amniocore, per square centimeter	NP	N1
Q4228#	BioNextPATCH, per square centimeter	NP	N1
Q4229#	Cogenex amniotic membrane, per square centimeter	NP	N1
Q4230#	Cogenex flowable amnion, per 0.5 cc	NP	N1
Q4231#	Corplex P, per cc.	NP	N1
Q4232#	Corplex, per square centimeter	NP	N1
Q4233#	Surfactor or Nudyn, per 0.5 cc	NP	N1
Q4234#	Xcellerate, per square centimeter	NP	N1

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
Q4235#	Amniorepair or altiply, per square centimeter	NP	N1
Q4236#	CarePATCH, per square centimeter	NP	N1
Q4237#	Cryo-cord, per square centimeter	NP	N1
Q4238#	Derm-maxx, per square centimeter	NP	N1
Q4239#	Amnio-maxx or Amnio-maxx lite, per square centimeter	NP	N1
Q4240#	Corecyte, for topical use only, per 0.5 cc	NP	N1
Q4241#	Polycyte, for topical use only, per 0.5 cc	NP	N1
Q4242#	Amniocyte plus, per 0.5 cc	NP	N1
Q4244#	Procenta, per 200 mg	NP	N1
Q4245#	Amniotext, per cc	NP	N1
Q4246#	Coretext or Protext, per cc	NP	N1
Q4247#	Amniotext patch, per square centimeter	NP	N1
Q4248#	Dermacyte Amniotic Membrane Allograft, per square centimeter	NP	N1
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	NP	K2
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	NP	K2
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	NP	J8
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	NP	R2
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	NP	R2
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	NP	J8
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	NP	J8
0614T	Removal and replacement of substernal implantable defibrillator pulse generator	NP	J8
0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	NP	J8

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	NP	J8
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	NP	J8
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	NP	J8

*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020.

**HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020.

#HCPCS codes Q4227 through Q4248: The availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR Part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR Part 1271.

In addition, through the July 2020 quarterly update CR, we are establishing ASC payment for two new Category III CPT codes as ASC covered ancillary services, effective July 1, 2020. These codes are listed in Table 34, along with the proposed comment indicator and payment indicator. The CY 2021 proposed payment rate for these new Category III CPT codes can be found in Addendum BB. As noted above, the list of payment indicators and comment indicators used under the ASC can be found in Addendum DD1 and DD2, respectively, of this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the Internet on the CMS website.

TABLE 34: NEW CATEGORY III CPT CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)	NP	Z2
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary procedure)	NP	N1

We are inviting public comments on the proposed payment indicators for the new CPT and Level II HCPCS codes newly recognized as ASC covered surgical procedures or covered ancillary services in July 2020 through the quarterly update CRs, as listed in Tables 32, 33, and 34. We propose to finalize the payment indicators in the CY 2021 OPPS/ASC final rule with comment period.

4. October 2020 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule with Comment Period

For CY 2021, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2020, would be flagged with comment indicator "NI" in Addendum BB to the CY 2021 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2021. We will invite public comments in the CY 2021 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

5. January 2021 HCPCS Codes

a. Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule with Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2021 OPPS/ASC final rule with comment period, January 2021 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2021, we will propose to continue our established policy of assigning comment indicator "NI" in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2021 to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2021 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For new and revised CPT codes effective January 1, 2021 that were received in time to be included in this proposed rule, we propose the appropriate payment indicator assignments, and soliciting public comments on the ASC payment indicators. We will accept comments and finalize the payment

indicators in the CY 2021 OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPS/ASC proposed rule, we may either make interim final assignments in the final rule with comment period or possibly use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle.

For the CY 2021 ASC update, the new and revised Category I and III CPT codes that will be effective on January 1, 2021 can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the Internet on the CMS website). The CPT codes are assigned to comment indicator "NP" to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we include the 5-digit placeholder codes and their long descriptors for the new and revised CY 2021 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled "CY 2021 OPPS/ASC Proposed Rule 5-Digit Placeholder Code." We intend to include the final CPT code numbers the CY 2021 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2021 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2021. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for

these codes (with their final CPT code numbers) in the CY 2021 OPPS/ASC final rule with comment period. The proposed payment indicator and comment indicator for these codes can be found in Addendum AA and BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new CPT codes that will be effective January 1, 2021 are assigned to comment indicator "NP" in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim ASC payment assignments. The list of comment indicators and definitions used under the ASC can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the Internet on the CMS website.

Finally, in Table 35, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC.

TABLE 35: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II codes)	April 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2021	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as "office-based" those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator "P2" (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); "P3" (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or "R2" (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization

data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or non office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2021 to Covered Surgical Procedures Designated as Office-Based

In developing this CY 2021 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment (described in detail in section XIII.C.1.d), including their potential designation as office-based. We reviewed the most recent claims volume and utilization data (CY 2019 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2020 of "G2" (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight), as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2", "P3", or "R2" in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61376 through 61380).

Our review of the CY 2019 volume and utilization data of covered surgical procedures currently assigned a payment indicator of "G2" (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.) resulted in our identification of seven covered surgical procedures that we believe meet the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we propose to permanently designate as office-based for CY 2021 are listed as Table 36.

TABLE 36: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2021

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
11760	Repair of nail bed	G2	P3*
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	J8	P3*
23077	Radical resection of tumor (eg, sarcoma), soft tissue of shoulder area; less than 5 cm	G2	P2*
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	G2	P2*
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	G2	P2*
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	G2	P3*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS proposed rule.

We also reviewed CY 2019 volume and utilization data and other information for 18 procedures designated as temporarily office-based and temporarily assigned one of the office-based payment indicators, specifically "P2," "P3" or "R2," as shown in Table 56 and Table 57 in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61380 through 61383). These procedures were surgical procedures that were designated as temporarily office-based in the CY 2019 OPPS/ASC final rule with comment period or were new CPT codes for CY 2020 that were designated as temporarily office-based. Of these 18 procedures, for each procedure, there were fewer than 50 claims in our data and no claims data for 11 of the 18 procedures described by CPT codes 64454, 64624, 65785, 67229, 0402T, 0512T, 0551T, 0566T, 0588T, 93985 and 93986. Therefore, we propose to continue to designate these procedures, shown in Table 37, as temporarily office-based for CY 2021. The procedures for which the proposed office-based designation for CY 2021 is temporary are indicated by

an asterisk in Addendum AA to this proposed rule with comment period (which is available via the internet on the CMS website).

TABLE 37: PROPOSED CY 2021 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2020 OPPS/ASC PROPOSED RULE

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2	R2*
0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

For the remaining seven procedures of the 18 procedures designated as temporarily office-based as shown in Table 56 and Table 57 in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61380 through 61383), we propose to permanently assign an office-based designation for five of the procedures, represented by CPT codes 10007, 10011, 11102, 11104, and 11106. After reviewing CY 2019 volume and utilization data for these five procedures, the claims data are sufficient to indicate that these covered surgical procedures are performed predominantly in physicians' offices (greater than 50 percent of the time) and, therefore, we propose to permanently assign one of the office-based payment indicators, specifically "P2," "P3" or "R2," – to these codes for CY 2021 as shown in Table 38. For the two remaining procedures that had temporary office-based designations for CY 2020, described by CPT codes 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and 10009 (Fine needle aspiration biopsy, including ct guidance; first lesion), utilization data are sufficient to indicate that these covered surgical procedures are not performed predominantly in physician's offices (performed in physician's offices less than 50 percent of the time) and, therefore, we propose to assign a non office-based payment indicator – "G2" – to these codes for CY 2021 as shown in Table 38.

TABLE 38: PROPOSED CY 2021 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3	G2
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3	P3*
10009	Fine needle aspiration biopsy, including ct guidance; first lesion	P2	G2
10011	Fine needle aspiration biopsy, including mr guidance; first lesion	R2	R2*
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3	P3*
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2	P3*
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3	P3*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

As discussed in the August 2, 2007 revised ASC payment system final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures temporarily as office-based until adequate claims data to assess their predominant sites of services, whereupon if we confirm their office-based nature, the procedures would be permanently assigned to the list of office-based procedures. In the absence of claims data, we stated we would use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

For CY 2021 we propose to designate 2 new CY 2021 CPT codes for ASC covered surgical procedures as temporarily office-based. After reviewing the clinical characteristics, utilization, and

volume of related procedure codes, we determined that the procedures in Table 39 would be predominantly performed in physicians' offices. We believe the procedures described by CPT codes 0596T (Temporary female intraurethral valve-pump (that is, voiding prosthesis); initial insertion, including urethral measurement) and 0597T (Temporary female intraurethral valve-pump (that is, voiding prosthesis); replacement) are similar to CPT code 55285 (Cystourethroscopy for treatment of the female urethral syndrome with any or all of the following: urethral meatotomy, urethral dilation, internal urethrotomy, lysis of urethrovaginal septal fibrosis, lateral incisions of the bladder neck, and fulguration of polyp(s) of urethra, bladder neck, and/or trigone) which is currently on the list of covered surgical procedures and assigned a proposed payment indicator "A2" – Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.– for CY 2021. While CPT code 52285 is not subject to office-based determinations as it is assigned an "A2" payment indicator, we note that this procedure is predominantly performed in a physician office setting (52 percent based on CY 2019 claims). As such, we propose to add CPT codes 0596T and 0597T in Table 39 to the list of temporarily office-based covered surgical procedures.

TABLE 39: PROPOSED CY 2021 PAYMENT INDICATORS FOR NEW CY 2021 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2021 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator**
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	R2**
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	R2**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

(3) Comment Solicitation on Office-Based Exemption for Dialysis Vascular Access Procedures

As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59036), the office-based utilization for CPT codes 36902 and 36905 (dialysis vascular access procedures) was greater than 50 percent. However, we did not designate CPT codes 36902 and 36905 as office-based procedures for CY 2019. These codes became effective January 1, 2017 and CY 2017 was the first year we had claims volume and utilization data for CPT codes 36902 and 36905. We shared commenters' concerns that the available data were not adequate to make a determination that these procedures should be office-based, and believed it was premature to assign office-based payment status to those procedures for CY 2019. For CY 2019, CPT codes 36902 and 36905 were assigned payment indicators of "G2" – Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative weight.

As we stated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61378), volume and utilization data for CPT code 36902 for CY 2018 showed the procedure was performed more than 50 percent of the time in physicians' offices. However, the office-based utilization for CPT code 36902 had fallen from 62 percent based on 2017 data to 52 percent based on 2018 data. In addition, there was a sizeable increase in claims for this service in ASCs – from approximately 14,000 in 2017 to 38,000 in 2018. In light of these changes in utilization and due to the high utilization of this procedure in all settings (over 125,000 claims in 2018), we believed it may have been premature to assign office-based payment status to CPT code 36902 for CY 2020. Therefore, for CY 2020, we finalized our proposal to not designate CPT code 36902 as an office-based procedure, but to continue to assign CPT code 36902 a payment indicator of "G2" – non office-based surgical procedure paid based on OPPS relative weights. Additionally, CY 2018 volume and utilization data for CPT code 36905 showed the procedure was not performed more than 50 percent of the time in physicians' offices and we finalized our proposal to retain

its payment indicator of "G2" – non office-based surgical procedure based on OPPS relative weights for CY 2020.

For this CY 2021 OPPS/ASC proposed rule, we reviewed CY 2019 volume and utilization data for CPT code 36902 and determined that this procedure was performed less than 50 percent of the time in physicians' offices. We note that the office-based utilization for CPT code 36902 has fallen from 52 percent in 2018 to 41 percent in 2019. Similarly, CY 2019 volume and utilization data for CPT code 36905 continues to show that this procedure was performed less than 50 percent of the time in physician's offices. Therefore, we are not proposing to designate CPT codes 36902 and 36905 as office-based procedures for CY 2021.

In past rulemaking, commenters have requested we permanently exempt dialysis vascular access procedures from office-based designations similar to our exemption for radiology services that involve certain nuclear medicine procedures and radiology services that involve contrast agents (42 CFR 416.171(d)(1) and (2)) (83 FR 59036). Commenters contended that an office-based designation for dialysis vascular access procedures (in particular CPT codes 36902 and 36905) would result in a lower ASC payment rate if frequently used additional services, which are often packaged under the ASC payment system but separately payable under the Physician Fee Schedule, are factored in to the analysis. Therefore, an office-based designation and payment at Physician Fee Schedule amounts under the ASC payment system may provide an inappropriate and lower global payment, after factoring in additional surgical procedures and/or ancillary items and services, when compared to the Physician Fee Schedule. Further, commenters have noted that ASCs are generally able to provide a wider array of dialysis vascular access procedures than a physician's office setting and at a lower Medicare payment rate than the hospital outpatient department setting. Providing an office-based ASC payment rate using PFS non facility PE RVUs for dialysis vascular access procedures may reduce the number of ASCs willing to

perform such services and, subsequently, reduce beneficiary access for dialysis vascular access procedures in an ASC setting. Such an outcome may inadvertently encourage migration of dialysis vascular access procedures related services to the more expensive hospital outpatient department setting.

While current volume and utilization data shows that dialysis vascular access procedures are not predominantly performed in a physician's office setting, future data for office-based designations may illustrate a different result. ASC rates established at PFS non facility PE RVU values may reduce the number of ASCs performing these procedures and inadvertently encourage greater utilization in the hospital outpatient department setting. While we are not currently proposing an exemption from payment at Physician Fee Schedule non facility PE RVU amounts, characterized by payment indicator "P3" for CY 2021, for dialysis vascular access procedures, we are contemplating implementing such an exemption in the future if necessary and are seeking comment on whether we might be justified in establishing a permanent exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d) in future rulemaking.

b. ASC Covered Surgical Procedures to Be Designated as Device-Intensive

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2021

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 590401 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we

modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

● All procedures must involve implantable devices assigned a CPT or HCPCS code;

● The required devices (including single-use devices) must be surgically inserted or implanted; and

● The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC involving the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

● Has received Food and Drug Administration (FDA) marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

● Is an integral part of the service furnished;

● Is used for one patient only;

● Comes in contact with human tissue;

● Is surgically implanted or inserted (either permanently or temporarily); and

● Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

Based on our modified device-intensive criteria, for CY 2021, we propose to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using the CY 2018 OPPS claims and cost report data available for the CY 2020 OPP/ASC proposed rule.

The ASC covered surgical procedures that we propose to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2021, are assigned payment indicator "J8" and are included in ASC Addendum AA to this proposed rule (which is available via the Internet on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2021 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply because the procedure is designated as device-intensive are also included in Addendum AA to the proposed rule (which is available via the Internet on the CMS website).

Under current policy, the payment rate under the ASC payment system for device-intensive procedures furnished with an implantable or inserted medical device are calculated by applying the

device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment based on the standard ratesetting methodology to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system. 82 FR 59409.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit, is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices.) Established ASC policy provides a reduction in ASC payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to

maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC covered device-intensive procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS "FB" modifier on the line in the claim with the procedure to implant or insert the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

Effective in CY 2019 (83 FR 59043 through 59044), for partial credit, we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS "FC" modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more

(but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our "FB"/"FC" modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY2019 and subsequent calendar years. Therefore, we propose to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2021 and subsequent calendar years. Specifically, for CY 2021 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by

one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. We are not proposing any other changes to our policies related to no/cost full credit or partial credit devices.

d. Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC-CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders

Under our current regulations at 42 CFR 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2008 are surgical procedures that meet the general standards specified in 42 CFR 416.166(b) and are not excluded under the general exclusion criteria specified in 42 CFR 416.166(c). Specifically, under 42 CFR 416.166(b), the general standards provide that covered surgical

procedures are surgical procedures specified by the Secretary and published in the Federal Register and/or via the Internet on the CMS Web site that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. 42 CFR 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under 42 CFR 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under 42 CFR 411.15.

For purposes of identifying procedures eligible to be added to the covered surgical procedure list, we define surgical procedures as those procedures described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category I and III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range (83 FR 59044 -59045), that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS. We propose to continue to apply the revised definition of "surgery" we adopted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), which includes certain "surgery-like" procedures that are assigned codes outside the CPT surgical range, for CY 2021 and subsequent years.

As discussed above, section 1833(i)(1) of the Act requires the Secretary to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately

performed on an inpatient basis in a hospital but that can be safely performed on an ambulatory basis in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. The report accompanying the legislation establishing section 1833(i)(1) of the Act explained that Congress intended procedures routinely performed on an ambulatory basis in a physician's office that do not generally require the more elaborate facilities of an ASC not to be included in the list of ASC covered procedures (H.R. Rep. No. 96–1167, at 390–91, reprinted in 1980 U.S.C.C.A.N. 5526, 5753–54).

In consideration of the statutory requirements and legislative history, in the implementing regulations of the current ASC system (effective in 2008), which we adopted in the August 2, 2007 final ASC rule (72 FR 42487), we excluded procedures that would otherwise pose a significant safety risk to the typical Medicare beneficiary if performed in the ASC setting. However, we agreed with stakeholders who have noted that ASCs are increasingly able to safely provide a greater range of services as medical practice continues to evolve and advance. We also believe that physicians play an important role and should be able to exercise their clinical judgment in making site-of-service determinations. Accordingly, CMS has continued to reexamine the process of how we determine which procedures are payable under Medicare when furnished in the ASC setting, keeping in mind the statutory requirement in section 1833(i)(1)(A) of the Act that the Secretary must specify those surgical procedures that are appropriately performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ASC, CAH or HOPD as part of reviewing and updating the list of procedures.

In the CY 2020 OPPS/ASC final rule with comment period, we added total knee arthroplasty and several coronary intervention procedures to the ASC-CPL (84 FR 61386 to 61397). Although the coronary intervention procedures involved blood vessels that could be considered major, based on our

policy to consider the involvement of major blood vessels in the context of the clinical characteristics of the individual procedures and to maintain logical and clinical consistency in excluding procedures from the ASC-CPL (72 FR 42481), as well as our review of the clinical characteristics of the procedures and their similarity to other procedures that were included on the ASC-CPL, we believed these procedures could be safely performed in the ASC setting for appropriate beneficiaries. In the CY 2019 OPPS/ASC final rule with comment period, we also noted that in light of our conditions of coverage for ASCs, including 42 CFR 416.42, which require surgical procedures to be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC, we believe that the CfCs provide further assurance that services furnished in the ASC setting are held to a high standard of safety. While we acknowledged in the CY 2019 OPPS/ASC final rule with comment period that it could be more appropriate for certain beneficiaries to receive the coronary intervention procedures we were adding to the ASC CPL in a hospital-level setting, which typically has a higher level of emergency staff and equipment available, including onsite cardiac surgery backup, when compared to an ASC setting, we also noted that many beneficiaries could be ideal candidates to receive these services in an ASC setting and that beneficiaries and their physicians should be able to choose an appropriate site of service for surgeries based on the clinical characteristics of the patient and other factors (83 FR 59046). We continue to believe that relatively healthy and less complex patients would benefit from the shorter length of stay and reduced cost-sharing that would be expected in an ASC setting.

In the August 2, 2007 final rule with comment period establishing the revised ASC payment system, we discussed criteria for excluding procedures from the ASC-CPL (72 FR 42478 to 42484). In that same final rule, we adopted the current general standards and general exclusion criteria described above. One of the general exclusion criteria we established for the revised ASC payment system, at §

416.166(c)(6), excludes any procedure on the OPPS Inpatient Only (IPO) list, which is a list of procedures for which we do not make payment under the OPPS and that are typically performed in the hospital inpatient setting because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, and the underlying physical condition of the patient (65 FR 18456). We also stated that we believed that any procedures for which we did not allow payment in the hospital outpatient setting due to safety concerns would not be safe to perform in an ASC (72 FR 42478). We stated that we were committed to revising the ASC-CPL so that it excludes only those surgical procedures that pose significant safety risks to beneficiaries or that are expected to require an overnight stay (72 FR 42479).

Also in the August 2, 2007 final rule with comment period, we discussed the exclusion of procedures involving major blood vessels, but we noted that it was important to maintain flexibility in our review of procedures for safe performance in the ASC setting, consistent with our past practice regarding this criterion (72 FR 42481). We discussed that there were some procedures already on the ASC list being safely performed in ASCs that involve blood vessels that would generally be defined as major. We did not agree with commenters that it would be logical or clinically consistent for us to adopt a specific definition of major blood vessels to evaluate procedures for exclusion from ASC payment (72 FR 42481). We noted the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures.

We noted that we proposed to exclude surgical procedures that were expected to involve major blood vessels, major or prolonged invasion of body cavities, extensive blood loss, or that are emergent or life-threatening in nature from ASC payment, based on evaluation by our medical advisors (72 FR 42478-42479). We also noted that most of the procedures that our medical advisors identified as involving any of the characteristics listed in 42 CFR 416.65(b)(3) also require overnight or inpatient

stays, reinforcing our belief that they should be excluded from ASC payment (72 FR 42478-42479). We also disagreed, at that time, that all procedures performed in HOPDs were appropriate for performance in ASCs. This was due in part to the fact that we believed that HOPDs were able to provide much higher acuity care, and because hospitals were subject to more stringent infection prevention, documentation, and patient assessment requirements than ASCs. As discussed in the August 2, 2007 final rule with comment period, ASCs were not required to meet patient safety standards consistent with those in place for hospitals (that is, hospital conditions of participation), and ASCs were not required, and are not currently required, to have the trained staff and equipment needed to provide the breadth and intensity of care that hospitals are required to maintain (72 FR 42479).

Many of these concerns have been addressed with the passage of time. We believe that our approach needs to evolve away from the criteria we established in 2008, in order to reflect the significant advances in medical practice and ASC capabilities over the last 12 years. In particular, we believe that significant advancements in medical practice, surgical techniques, medical technology, and other factors have allowed certain ASCs to safely perform procedures that were once too complex, including those involving major blood vessels and other general exclusion criteria. We acknowledge that ASCs and hospitals have different health and safety requirements. Despite this fact, ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals as well as meet Medicare conditions for coverage (see 42 CFR 416.40 through 416.54).

As mentioned above, in recent years, we have added procedures to the ASC-CPL that were largely considered hospital inpatient procedures in the past, such as TKA and certain coronary intervention procedures. As the practice of medicine has evolved, hospital lengths of stay have become shorter for many surgical procedures. Many services that used to be predominantly performed in the

hospital inpatient setting are now routinely performed in the hospital outpatient setting on an ambulatory basis. Further, many procedures that are currently only payable as hospital outpatient services under Medicare fee-for-service are safely performed in the ASC setting for other payors. While we recognize that non-Medicare patients tend to be younger and have fewer comorbidities than the Medicare population, we note that careful patient selection can identify Medicare beneficiaries who are suitable candidates for these services in the ASC setting. Further, Medicare Advantage plans are not obligated to adopt the ASC-CPL as it exists in Medicare fee-for-service and, based on Medicare Advantage encounter data, many MA enrollees have had services performed in the ASC setting that are not currently payable under Medicare fee-for-service.

In addition, the COVID-19 pandemic has highlighted the need for more healthcare access points throughout the country. Many ASCs temporarily closed or significantly scaled back their operations based on state and federal recommendations to delay elective procedures during the public health emergency associated with COVID-19; while, some ASCs opted to temporarily enroll as hospitals. Looking ahead to after the pandemic, it will be more important than ever to ensure that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible. Because the pandemic has forced many ASCs to close, thereby decreasing Medicare beneficiary access to care in that setting, we believe allowing greater flexibility for physicians and patients to choose ASCs as the site of care, particularly during the pandemic, would help to alleviate both access to care concerns for elective procedures as well as access to emergency care concerns for hospital outpatient departments.

(1) Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2021

Historically, we have reviewed the clinical characteristics of procedures and consulted with stakeholders and our clinical advisors to determine if those procedures would meet our existing regulatory criteria under 42 CFR 416.2 and 42 CFR 416.166. Our regulation at 416.166(b) specifies the

general standard criteria for covered surgical procedures, and requires that covered surgical procedures be surgical procedures: (1) that are separately paid under OPPS, (2) that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and (3) for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Additionally, 42 CFR 416.166(b) requires that a procedure not meet our exclusion criteria set forth in 42 CFR 416.166(c).

For CY 2021, we propose to continue to apply our current policies and criteria set forth in 42 CFR 416.2 and 42 CFR 416.166 for updating the ASC-CPL. In addition, we propose two alternative options for modifying our approach to adding surgical procedures to the ASC-CPL – (1) a nomination process for adding new procedures to the ASC-CPL, and (2) a broader approach under which we would revise our regulatory criteria at 42 CFR 416.166 to evaluate potential additions to the ASC-CPL. Under our first alternative proposal, a proposed nomination process along with modifications to certain regulatory criteria (as described later in this proposed rule), the effective date would be CY 2021 to accept and consider nominations and nominated procedures could be proposed to be added to the ASC-CPL beginning in the CY 2022 rulemaking. Under our second alternative proposal, we propose to revise our regulatory criteria by removing certain general exclusion criteria at 42 CFR 416.166(c) and under the revised criteria, we propose to add certain surgical procedures to the ASC-CPL beginning in CY 2021. We expect either of these options would have the effect of expanding the ASC-CPL, while maintaining the balance between safety and access for Medicare beneficiaries.

A. Standard ASC-CPL Review Process for CY 2021

For CY 2021, consistent with our current policy for reviewing the ASC-CPL, we conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC-CPL, and that meet the definition of surgery to determine if changes in technology and/or medical practice

affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, and as explained in more detail below, we propose to update the list of ASC covered surgical procedures by adding eleven procedures to the list for CY 2021 as shown in Table 40 of this proposed rule. Procedures that we propose to add to the ASC-CPL for CY 2021 include total hip arthroplasty (THA), vaginal colpopexy, transcervical uterine fibroid ablation, and intravascular lithotripsy procedures, among others. After reviewing the clinical characteristics of these eleven procedures and consulting with our clinical advisors, we determined that these procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. We have assessed each of the proposed procedures against the regulatory safety criteria in the regulation at 42 CFR 416.166(c) and believe that none of the procedures meet the general exclusion criteria.

Of the eleven procedures we propose to add, we believe that the THA procedure merits additional discussion in this proposed rule, given prior discussion of this procedure in past rulemaking, to explain our belief that the procedure meets existing safety criteria for purposes of adding this procedure to the ASC-CPL. In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on whether the THA procedure, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), met the criteria to be added to the ASC-CPL. In the CY 2018 OPPS/ASC final rule with comment period, we noted that some commenters argued many ASCs are equipped to perform this procedure and orthopedic surgeons in ASCs are increasingly performing this procedure safely and effectively on non-Medicare patients and appropriate Medicare patients (82 FR 59412). Commenters also stated that adding THA to the ASC-CPLwould allow for greater choices in care settings for Medicare patients, would provide a more

patient-centered approach to joint arthroplasty procedures, and that it may be safer in some cases to have joint arthroplasty procedures performed in an outpatient setting to prevent certain hospital-acquired infections (82 FR 59412).

However, other commenters recommended that ASCs obtain enhanced certification from a national accrediting organization that certifies an ASC meets higher quality standards and can safely perform joint arthroplasty procedures (82 FR 59412). Some commenters opposed adding THA to the ASC-CPL as they believed the vast majority of ASCs are not equipped to safely perform these procedures on patients and the vast majority of Medicare patients are not suitable candidates to receive "overnight" joint arthroplasty procedures in an ASC setting (82 FR 59412). For CY 2018, we did not finalize adding THA to the ASC-CPL, but noted that we would take commenters' suggestions and recommendations into consideration for future rulemaking.

In this CY 2021 OPPS/ASC proposed rule, we are seeking to continue to promote site neutrality, where possible, between the hospital outpatient department and ASC settings, and expanding the ASC-CPL to include as many procedures that can be performed in the HOPD as reasonably possible will advance that goal. Further, we believe that there are at least a subset of Medicare beneficiaries who may be suitable candidates to receive THA procedures in an ASC setting based on the beneficiaries' clinical characteristics. We believe physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for THA. We believe THA would meet our existing regulatory requirements established under 42 CFR 416.2 and 416.166(b) and (c) for covered surgical procedures in the ASC setting. In light of this information and the public comments submitted in support of adding THA to the ASC-CPL in response to our CY 2018 public comment solicitation, we propose to add THA to the ASC-CPL in CY 2021, as shown in Table 40.

We propose to add a total of eleven procedures, displayed in Table 40 with their HCPCS code long descriptors, to the list of ASC covered surgical procedures for CY 2021. We seek public comment on our proposal, including any medical evidence or literature to support the commenters' views on whether or not we should add any of these procedures to the ASC-CPL for CY 2021. In addition, we also seek comment on the two alternative proposals described below. Note that under both alternative proposals, we still propose to add the eleven procedures proposed under this section for CY 2021.

(1) Proposed changes to general exclusion criterion for procedures requiring inpatient care to conform to proposed changes to the underlying requirements under the OPPS

As described in section IX.B. of this proposed rule, CMS is proposing to eliminate the OPPS IPO list and amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024. We believe that retaining §416.166(c)(6) will ensure that procedures that are largely performed on an inpatient basis and cannot be safely performed on an ambulatory basis will not be added to the CPL prematurely. As a result, we propose to revise the regulatory language and modify this standard to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020.

(2) Alternative Proposals under Consideration for CY 2021

For CY 2021, we are continuing to build on our efforts to maximize patient and physician choice and access to care by exploring broader approaches to adding procedures to the ASC-CPL in order to further increase the availability of ASCs as an alternative site of care for Medicare beneficiaries, often at a lower cost than other options. In light of the current national Public Health Emergency related to COVID-19 and its anticipated lasting effects on the health care system, we also believe a broader approach for adding procedures to the ASC-CPL would allow for a more efficient use of healthcare

resources and infrastructure. An expansion of the ASC-CPL would maximize the ability of ASCs to divert patients that can be safely treated in an ASC setting away from the hospital setting, which would preserve the capacity of hospitals to treat more acute patients. Expanding the procedures placed on the ASC-CPL would also build on the policy changes we have made in recent years to further site neutrality between the HOPD and ASC settings. In light of these objectives, we propose two alternatives to our existing policy of adding procedures to the ASC-CPL, each of which would further support these goals.

a. Alternative Proposal One

Under the first approach, we propose and may finalize in the final rule a policy to adopt a nomination process for adding new procedures to the ASC-CPL. This process would involve soliciting recommendations from external stakeholders, like medical specialty societies and other members of the public, for procedures that may be suitable candidates to add to the ASC-CPL. As discussed in greater detail below, under this approach, we would provide parameters as guidelines that we would strongly encourage stakeholders to consider in nominating procedures for the ASC-CPL. CMS anticipates that stakeholders, such as specialty societies who specialize in and have a deep understanding of the complexities involved in providing certain procedures, would be able to provide valuable suggestions on which additional procedures may reasonably and safely be provided in an ASC context.

While members of the public may already suggest procedures to be added to the CPL through meetings with CMS or through public comments to the proposed rule, we believe it may be beneficial to adopt a streamlined process under which the public, particularly specialty societies who are very familiar with procedures in their specialty, can to nominate procedures based on the latest evidence available as well as input from their memberships. We believe that this revised process could increase transparency in how we are assessing procedures to add to the ASC list and also help ensure that we are assessing the list in a more streamlined fashion.

We propose that the nomination process would be conducted through annual notice and comment rulemaking and the final determinations regarding nominated procedures would be decided in the final rule. Specifically, for the OPPS/ASC rulemaking for a calendar year, we would request stakeholder nominations by March 1 of the previous calendar year, with all nominations received by that date considered in the next applicable rulemaking cycle, likely the rulemaking for the following calendar year. Any nominations received after that date, including those received through comments as part of the rulemaking cycle, would generally be addressed in rulemaking the following year. CMS would evaluate procedures nominated by stakeholders based on the applicable statutory and regulatory requirements for ASC covered surgical procedures and the additional parameters specified in detail below. We propose to establish the nomination process in the CY 2021 final rule to begin in CY 2021, for surgical procedures that could be added to the ASC-CPL beginning in CY 2022. We propose a process under which nominated procedures would be included in the proposed rule for that calendar year, along with a summary of the policy and factual justification for adding or not adding each procedure, which would allow members of the public to assess and provide comment on nominated procedures during the public comment period. After reviewing comments provided during the public comment period, CMS would finalize adding the procedures that meet the requisite criteria to the ASC-CPL in the final rule. In the event that CMS disagrees with any procedures nominated, we would provide a specific rationale in the final rule. In certain cases, CMS may need to defer a final determination regarding a nominated procedure to future rulemaking, in order to provide sufficient time to evaluate and make the most appropriate decision about the nominated procedure.

Under this alternative proposal, we would update the ASC-CPL by considering whether nominated procedures meet the requirements for covered surgical procedures under 42 CFR 416.166, as we propose to amend them. This would include 42 CFR 416.166(b), which sets out the general

standards for covered surgical procedures, requiring that surgical procedures be separately paid under the OPPS, not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. We also propose to eliminate the general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5) such that nominated procedures would not have to meet those criteria. Further, we propose to modify § 416.166(c)(6) to align the regulatory text with the proposed elimination of the IPO list. Finally, we propose that nominated procedures would need to meet the general exclusions at 42 CFR 416.166(c)(7) and (c)(8).

With respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, this alternative proposal would modify this standard since the IPO list is being proposed to be eliminated beginning in CY 2021, as described in section IX.B of this proposed rule. Therefore, we would propose to modify this criterion to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020. In other words, we would not accept any nominations for procedures to add to the ASC-CPL if the procedure is on the CY 2020 IPO list. We are retaining the criteria §§ 416.166(c)(6) through (8) and eliminating the five criteria currently at §§ 416.166(c)(1) through (5) because we believe that the general standards at 416.166(b) provide sufficient guardrails to ensure, along with appropriate patient selection and the complex medical judgment of the physician, that procedures can be performed safely on an ambulatory basis, including certain procedures that may involve these five characteristics. We believe that this alternative proposal could balance the goals of increasing physician and patient choice and expanding site neutral options with patient safety considerations.

As noted above, under this alternative proposal, stakeholders would nominate procedures to be added to the ASC-CPL by March 1 of a year to be considered for addition to the ASC-CPL for the next calendar year. As stated above, and similar to the second alternative described in the next section, we propose that nominated procedures must meet the general standards for covered surgical procedures under 42 CFR 416.166(b) and the general exclusions under 42 CFR 416.166(c)(6) through (8), subject to the modifications we propose for 42 CFR 416.166(c)(6), to reflect the proposed phase out of the IPO list under the OPPS, as discussed in section IX.B of this proposed rule. Specifically with respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, the alternative proposal would modify this standard because the IPO list is being proposed to be eliminated beginning in CY 2021, as described in section IX.B of this proposed rule. Therefore, we would propose to modify this criterion to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020. Under this alternative proposal, a nomination process would be added at 42 CFR 416.166(d), explaining the process that would be used to review and update the list of ASC procedures each year. We propose to remove the general exclusions under 42 CFR 416.166(c)(1) through (c)(5), as discussed above.

Additionally, we are also proposing to adopt the following parameters for stakeholders to consider and specifically address in nominating procedures to add to the ASC-CPL. These parameters are meant as general guidelines, not requirements, and we seek public comment on these suggested parameters including language changes, recommendations for additional parameters, potential unintended implications of the parameters we propose, and whether we should finalize these parameters if this alternative proposal is finalized in the CY 2021 final rule:

- Does the procedure involve a risk of life-threatening complications?

Example: Does the procedure involve high or low risk of life-threatening complications?

- If the procedure involves lower risk for life-threatening complications, it may be a reasonable candidate for consideration.
- If the procedure involves a higher risk, consider the next question.

- Is there a need for specialized resources, not generally available in an ASC, to mitigate the risk of one or more life-threatening complications?

  Example: Are specialized resources, not generally available in an ASC, needed to mitigate the risk of one or more life-threatening complications from the procedure?

  - If specialized resources are not needed for this procedure, it may be a reasonable candidate for consideration.
  - If specialized resources are needed to reduce the patient's risk of life-threatening complications, consider the next question.

- What is the average length of time for patients to be stabilized for transport to another facility?

  Example: If a complication occurs, can the patient generally be stabilized in transport for at least 90 minutes?

  - If a patient undergoing the procedure cannot be stabilized for 90 minutes, this would be a serious consideration regarding the appropriateness of performing the procedure for Medicare beneficiaries in the ASC setting.
  - If a patient undergoing this procedure can be stabilized for 90 minutes, please consider the next question.

- Are resources and providers required for intervention generally available at nearby facilities for intervention?

Example: If a patient is transferred to another institution, can a team be mobilized and prepared to intervene within a relatively short period from complication onset, inclusive of transport? Although the length of this time period may vary, it should be enough time to ensure the patient has a viable chance of rescue from the other facility.

- If a team cannot be mobilized and prepared to intervene within this period, then this procedure should not be considered for the ASC-CPL.
- If a team can be mobilized and prepared to intervene within this period, then this procedure could be a reasonable candidate for consideration.

We believe a nomination process will take time to develop and stakeholders will need time to consider and evaluate potential nominations. We propose to implement this process for CY 2021 in order to accept nominations for procedures to be added to the ASC CPL beginning in CY 2022.

b. Alternative Proposal Two

We also considered another alternative approach that would allow for more immediate changes to the ASC-CPL for CY 2021 and beyond. Specifically, under this alternative proposal, we propose, and may finalize in the CY 2021 final rule, to keep the existing general standards under 42 CFR 416.166(b) that currently require covered surgical procedures to be surgical procedures specified by the Secretary and published in the Federal Register and/or via the Internet on the CMS Web site, separately paid under the OPPS, not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. However, under this alternative proposal, we would eliminate five of the current general exclusion criteria at 42 CFR 416.166(c)(1) through (c)(5). We considered whether these five exclusionary criteria may no longer be necessary to determine what procedures can be safely added to the ASC-CPL because many

ASCs are currently able to safely provide services with these characteristics based on prior stakeholder feedback and public comments we have received.

We explored whether it is appropriate to remove the general exclusion criteria. This would allow physicians practicing in the ASC setting, who have the greatest familiarity and insight into the needs of individual beneficiaries, to use their complex medical judgment to determine whether they can safely perform a procedure in the ASC, given the entirety of the circumstances, including the clinical profile of the patient, the surgical back-up available at the ASC, and the ability to safely and timely respond to unexpected complications. Under this alternative proposal, we would keep the remaining three general exclusion criteria at 42 CFR 416.166(c)(6) through (c)(8), as the original reasons we adopted them in CY 2008 continue to exist, subject to the proposed modifications to 416.166(c)(6). These criteria would continue to prohibit the addition of certain procedures to the ASC CPL, namely those that are either designated as requiring inpatient care under 42 CFR 419.22(n) as of December 31, 2020, which can only be reported using a CPT unlisted surgical procedure code, and any procedures that are otherwise excluded under 42 CFR 411.15. We propose to retain these criteria and eliminate the previous five criteria because we believe that the general standards alone are sufficient guardrails to ensure, along with appropriate patient selection and complex medical judgment of the physician, that the procedure can be performed safely on an ambulatory basis, including procedures that involve these five characteristics.

With respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, the alternative proposal would modify this standard since the IPO list is being proposed to be eliminated beginning in CY 2021, as described in section IX.B of this proposed rule. Therefore, we would propose to modify this criterion to exclude procedures designated as requiring

inpatient care under 419.22(n) as of December 31, 2020. In other words, not all procedures on the current (that is, CY 2020) IPO list would necessarily meet the remaining revised criteria to be added to the ASC-CPL. However, because any procedure not on the IPO can be performed safely on an ambulatory basis in the hospital outpatient setting, we believe that the remaining criteria in 42 CFR 416.166, most notably the exclusion of services that are on the current IPO list, could sufficiently limit the expansion of the ASC-CPL to those services that can be safely performed on an ambulatory basis. As previously mentioned, we are proposing to retain the criteria in §§ 416.166(c)(6) through (8) and eliminate the five criteria currently at §§ 416.166(c)(1) through (5) because we believe that the general standards at 416.166(b) provide sufficient guardrails to ensure, along with appropriate patient selection and the complex medical judgment of the physician, that procedures can be performed safely on an ambulatory basis, including certain procedures that may involve these five characteristics. We believe that this alternative proposal could balance the goals of increasing physician and patient choice and expanding site neutral options with patient safety considerations.

We identified approximately 270 potential surgery or surgery-like codes that we believe would meet the proposed revised criteria for being added to the ASC-CPL under 42 CFR 416.166. That is, we reviewed these procedures and found that they would meet the proposed revised regulatory requirements that would be in effect if we were to adopt this alternative proposal. Specifically, the identified procedures under this alternative proposal were surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure, that have not been designated as requiring inpatient care under 419.22(n) as of

December 31, 2020, that can be reported without using a CPT unlisted surgical procedure code, and are not otherwise excluded under 42 CFR 411.15.

Additionally, while several of the identified procedures may typically require hospital care that lasts beyond midnight, we expect that appropriately selected patient population in the ASC setting would be healthier and less complex and would likely not require active monitoring or medical care past midnight beyond the procedure. We believe that these procedures are safe to perform in an ASC setting because all procedures identified are already payable in the HOPD setting and, therefore, are already safely performed on an ambulatory basis, consistent with the statutory requirement under section 1833(i)(1) of the Act. We would retain the general standard criteria, as we believe these criteria are sufficient to ensure that procedures meet the statutory requirements and can be safely performed in ASCs. We seek public comment on whether any of these procedures would typically require care after midnight, and, therefore, should not be added to the ASC-CPL.

We believe that this alternative proposal could have beneficial effects for Medicare beneficiaries and healthcare professionals. For beneficiaries, expansion of the ASC-CPL would increase access to procedures in ambulatory surgery settings, often at a lower cost. ASCs and healthcare professionals would also benefit from this proposal as this expansion would better utilize the potential of existing healthcare resources and expand the capacity of the healthcare system. Further, under this alternative, physicians would have greater flexibility to divert patients who can be safely treated in the ASC setting away from hospitals and preserve hospital capacity for more acute patients.

We acknowledge that this approach is a departure from the existing criteria that we established effective beginning in 2008. However, we believe that this approach would expand and build upon our 2008 policy intent. In the August 2, 2007 final rule with comment period, we discussed criteria for procedures excluded from the ASC-CPL under the revised ASC payment system (72 FR 42478 to

42484). However, although there are differences, much of the underlying rationale we used to develop the August 2, 2007 final rule revised criteria remains true under the broader CY 2021 proposal. For example, in the August 2, 2007 final rule with comment period, we indicated that we believed that any procedure for which we did not allow payment in the hospital outpatient setting due to safety concerns would not be safe to perform in an ASC (72 FR 42478). Much like we are considering now, we excluded from the ASC list any procedure on the IPO list, and committed to excluding surgical procedures that pose significant safety risks to beneficiaries or that are expected to require an overnight stay (72 FR 42478 to 42479). Although there are some differences when comparing our CY 2008 criteria and the proposed CY 2021 criteria, such as removing several of the original general exclusion criteria, permitting the addition of procedures to the ASC-CPL that would have been prohibited by those criteria, and the different accreditation requirements and conditions of participation requirements between HOPDS and ASCs, these concerns have largely been addressed by the progress in medical practice and ASC capabilities in the twelve years since the criteria were developed as previously noted. In particular, given advances in the practice of medicine and the evolving nature of ASCs, we believe ASCs are now better equipped to safely perform procedures that were once too complex or risky to be performed safely on Medicare beneficiaries in the ASC setting. As previously mentioned, although ASCs and hospitals have different health and safety requirements, many ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals. Each of these requirements provides additional safeguards for the health and safety of Medicare beneficiaries receiving surgical procedures in an ASC.

(c) Comment Solicitation on Potential Revisions to the ASC Conditions of Coverage if Alternative 2 is Adopted

Providers and suppliers participating in Medicare must comply with our regulations (variously called Conditions of Participation (CoPs), Conditions for Coverage (CfCs), Conditions of Certification, or Requirements) in order to begin and continue participating in the Medicare program. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. For ambulatory surgical centers (ASCs), the CfCs are located at 42 CFR Part 416.

Section 416.2 of our regulations defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following an admission. The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting.

The ASC CfCs were first published on August 5, 1982 (47 FR 34082), and have since been amended several times. The ASC CfCs currently contain 14 separate conditions that include requirements regarding compliance with State licensure law; governing body; surgical services; quality assessment and performance improvement; environment; medical staff; nursing services; medical records; pharmaceutical services; laboratory and radiologic services; patient rights; infection control; patient admission, assessment and discharge; and emergency preparedness.

As noted previously, CMS agrees with stakeholders that as medical practice continues to evolve and advance, ASCs are increasingly able to safely provide a greater range of services. The proposed expansion of the ASC-CPL would allow physicians to exercise their clinical judgment in making site-of-service determinations that are appropriate and also beneficial to the patient. In recent years, more complex surgical procedures that have been identified to be appropriate for certain Medicare patients have been added to the ASC-CPL. For example, effective CY 2020, the total knee arthroplasty (TKA) procedure was added to the ASC-CPL as part of the rulemaking process (84 FR 61385). CMS agreed

with public commenters that there is a small subset of Medicare beneficiaries who may be suitable candidates to receive TKA in an ASC setting based on their clinical characteristics. In addition, certain coronary intervention procedures were added even though these procedures involve blood vessels that could be considered major; it was appropriate to add these procedures in our view based upon our belief that the procedures should be considered in the context of proper patient selection and clinical characteristics.

The current ASC CfCs provide the baseline health and safety standards that accommodate the oversight of a broad spectrum of ASC facility types that include services such as orthopedics, ophthalmology, endoscopy, dental and other specialty practices. We believe the current ASC CfCs provide sufficient flexibility and protection to patients such that they would not need to be revised even if we were to adopt a significant expansion of the ASC-CPL as outlined under the second alternative proposal described in the above section. The current ASC CfCs require the ASC, governing body and the medical staff to be responsible for the policies and procedures that are reflective of the patients that are served in the ASC. The ASC is directly responsible for ensuring the ASC and medical staff evaluate their patient base and ensure appropriate precautions and services are in place for all surgical procedures performed in their facility.

The CfCs are one part of our coordinated requirements and expectations for ASCs, which also include reporting of quality measures under the ASCQR program. Both the CfCs and quality reporting program would remain in place to ensure patient safety during and after any changes to the ASC-CPL, but we request comments on whether the CfCs or quality metrics should also change in response to an expanded range of services that may be paid under Medicare in the ASC setting. We refer readers to section XV.B. of this proposed rule regarding ASCQR Program quality measures.

In the event that CMS were to finalize a proposal to allow more invasive and lengthy surgical procedures in ASCs, we are requesting comment on whether or not the ASC CfCs should be revised in the CY 2021 final rule to ensure that our health and safety standards are sufficiently updated to reflect the additional range of complex services that would be added to the ASC-CPL, and, if so, the recommended revisions. For example, the current surgical services CfC regulations under 42 CFR 416.42(a)(1)(I) require that a physician must examine the patient to evaluate the risk of the procedure to be performed while the regulations at 42 CFR 416.42(a)(1)(II) require a physician or anesthetist as defined at § 410.69(b) to examine the patient to evaluate the risk of anesthesia. We seek public comment on whether or not these risk evaluations should be expanded to be more prescriptive and require additional elements such as requiring the referring doctor to submit pertinent health information and attest that an individual patient can safely undergo the specified procedure(s) in an ASC and, if appropriate, may adopt such changes in the CY 2021 final rule.

In addition, current standards at 42 CFR 416.46(a) require a registered nurse be available for emergency treatment whenever there is a patient in the ASC. We are soliciting comment on whether we should add an additional CfC at § 416.46 to require that an adequate number of nurses be on duty in the ASC at all times that the ASC has patient(s), consistent with the standard required of hospitals under § 482.23(b) and the associated guidance in the Medicare State Operations Manual A-0392 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf). Similar to the hospital requirements, we anticipate that ASCs must take into account the specific types of services being furnished and the acuity of the patients in ensuring that there is adequate nursing staff available.

Further, standards under 42 CFR 416.44(e) also currently require personnel trained in the use of emergency equipment and cardiopulmonary resuscitation be available whenever there is a patient in the

ASC. Despite ASCs having access to local emergency services to transfer patients to the nearest appropriate hospital for continued care, we request comment on whether, in the final rule for CY 2021, we should change the requirements to increase the mandatory level of certification for personnel. For example, with respect to the current regulations at 42 CFR 416.44(e), we are interested in whether or not CMS should require the presence of staff certified to provide Advance Cardiac Life Support (ACLS) in the ASC to respond to any life threatening emergencies, and be capable of providing a full and complete medical resuscitation response in the ASC, to stabilize the patient before an emergency transfer to the closest hospital.

We also request comment on whether we should make specific requirements in the CfC regulations at 42 CFR 416.52(a) for particular patient conditions or more complex and invasive surgical procedures ASCs would need to meet and for any evidence that would support such recommendations. As mentioned previously, we also request comments on possible additions or revisions to the quality measures under ASCQR if additional procedures are added to the ASC-CPL.

We note the most useful comments are those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

In summary, in light of the possibility of significantly expanding the ASC-CPL for CY 2021, we are considering whether changes to the ASC CfCs may be appropriate. As noted above, the current ASC CfCs provide the baseline health and safety standards that accommodate the oversight of a broad spectrum of ASC facility types that include a variety of services. We believe the current ASC CfCs provide sufficient flexibility and protection to patients such that they would not need to be revised even if we were to adopt a significant expansion of the covered ASC-CPL, however, we seek comment on

whether certain revisions may be necessary and may adopt such revisions as final in the CY 2021 final rule.

(4) Summary of Proposals

For CY 2021, we propose to add eleven procedures using the standard ASC-CPL review process under our current regulations. In addition, we include two alternative proposals that we may finalize for CY 2021. One alternative is to establish a nomination process for CY 2021, which would allow us to propose to add nominated procedures beginning in CY 2022. Under this proposal, external stakeholders, such as professional specialty societies, would nominate procedures that can be safely performed in the ASC setting based on the requirements in the ASC regulations, revised as described in this proposed rule (that is, retaining the general standard criteria and eliminating five of the general exclusion criteria), along with suggested parameters and all other regulatory standards. CMS would review and finalize procedures through annual rulemaking.

Alternatively, we propose to revise the ASC-CPL criteria under 42 CFR 416.166, retaining the general standard criteria and eliminating five of the general exclusion criteria. Using these revised criteria, we propose to add approximately 270 potential surgery or surgery-like codes to the CPL that are not on the CY 2020 IPO list. We propose to finalize only one of these alternative proposals, and we welcome public comment as to which policy should be adopted in the final rule.

After consideration of priorities discussed above, we believe that these proposed policies strike an appropriate balance of between flexibility for physicians to exercise their complex medical judgment in factoring in patient safety considerations and flexibility for patients to choose from more settings of care in which to receive surgical procedures.

TABLE 40. — PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2021 UNDER STANDARD REVIEW PROCESS

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	G2
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	G2
21365	Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	G2
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27412	Autologous chondrocyte implantation, knee	G2
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	G2
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	G2
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	G2
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J8

TABLE 41. — PROPOSED ADDITIONS TO THE ASC-CPL UNDER SECOND ALTERNATIVE PROPOSAL CONSIDERED FOR CY 2021

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	G2
20100	Exploration of penetrating wound (separate procedure); neck	G2
20101	Exploration of penetrating wound (separate procedure); chest	G2
20102	Exploration of penetrating wound (separate procedure); abdomen/flank/back	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
20660	Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)	G2
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (eg, locally aggressive or destructive lesion[s])	G2
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)	G2
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)	G2
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	G2
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	J8
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)	G2
21261	Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach	G2
21263	Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement	G2
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation	G2
21365	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	G2
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)	G2
21386	Open treatment of orbital floor blowout fracture; periorbital approach	G2
21387	Open treatment of orbital floor blowout fracture; combined approach	G2
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	G2
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	G2
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	J8
21601	Excision of chest wall tumor including rib(s)	G2
21742	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), without thoracoscopy	G2
21743	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), with thoracoscopy	G2
22100	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
22101	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic	G2
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	J8
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	J8
24150	Radical resection of tumor, shaft or distal humerus	G2
24935	Stump elongation, upper extremity	G2
25170	Radical resection of tumor, radius or ulna	G2
25909	Amputation, forearm, through radius and ulna; re-amputation	G2
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	G2
27027	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle), unilateral	G2
27057	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral	G2
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (heyman type procedure)	G2
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	G2
27412	Autologous chondrocyte implantation, knee	G2
27477	Arrest, epiphyseal, any method (eg, epiphysiodesis); tibia and fibula, proximal	J8
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus)	G2
27722	Repair of nonunion or malunion, tibia; with sliding graft	J8
28360	Reconstruction, cleft foot	G2
28805	Amputation, foot; transmetatarsal	G2
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral	G2
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	G2
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	G2
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	G2
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	G2
31584	Laryngoplasty; with open reduction and fixation of (eg, plating) fracture, includes tracheostomy, if performed	G2
31587	Laryngoplasty, cricoid split, without graft placement	G2
31600	Tracheostomy, planned (separate procedure);	G2
31601	Tracheostomy, planned (separate procedure); younger than 2 years	G2
31610	Tracheostomy, fenestration procedure with skin flaps	G2
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J8
31785	Excision of tracheal tumor or carcinoma; cervical	G2
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	G2
32560	Instillation, via chest tube/catheter, agent for pleurodesis (eg, talc for recurrent or persistent pneumothorax)	G2
32561	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); initial day	G2
32562	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day	G2
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy	G2
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	G2
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy	G2
32607	Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral	G2
32608	Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral	G2
32609	Thoracoscopy; with biopsy(ies) of pleura	G2
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	G2
33272	Removal of subcutaneous implantable defibrillator electrode	G2
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision	G2
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision	G2
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision	G2
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision	G2
34421	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by leg incision	G2
34471	Thrombectomy, direct or with catheter; subclavian vein, by neck incision	G2
34501	Valvuloplasty, femoral vein	G2
34510	Venous valve transposition, any vein donor	G2
34520	Cross-over vein graft to venous system	G2
34530	Saphenopopliteal vein anastomosis	G2
35011	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm and associated occlusive disease, axillary-brachial artery, by arm incision	G2
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	G2
35180	Repair, congenital arteriovenous fistula; head and neck	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
35184	Repair, congenital arteriovenous fistula; extremities	G2
35190	Repair, acquired or traumatic arteriovenous fistula; extremities	G2
35201	Repair blood vessel, direct; neck	G2
35206	Repair blood vessel, direct; upper extremity	G2
35226	Repair blood vessel, direct; lower extremity	G2
35231	Repair blood vessel with vein graft; neck	G2
35236	Repair blood vessel with vein graft; upper extremity	G2
35256	Repair blood vessel with vein graft; lower extremity	G2
35261	Repair blood vessel with graft other than vein; neck	G2
35266	Repair blood vessel with graft other than vein; upper extremity	G2
35286	Repair blood vessel with graft other than vein; lower extremity	G2
35321	Thromboendarterectomy, including patch graft, if performed; axillary-brachial	G2
35860	Exploration for postoperative hemorrhage, thrombosis or infection; extremity	G2
35879	Revision, lower extremity arterial bypass, without thrombectomy, open; with vein patch angioplasty	G2
35881	Revision, lower extremity arterial bypass, without thrombectomy, open; with segmental vein interposition	G2
35883	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with nonautogenous patch graft (eg, dacron, eptfe, bovine pericardium)	G2
35884	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with autogenous vein patch graft	G2
35903	Excision of infected graft; extremity	G2
36460	Transfusion, intrauterine, fetal	G2
36838	Distal revascularization and interval ligation (dril), upper extremity hemodialysis access (steal syndrome)	G2
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	J8
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	G2
37195	Thrombolysis, cerebral, by intravenous infusion	G2
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy,	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
	including follow-up catheter contrast injection, position change, or exchange, when performed;	
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method	G2
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	J8
37565	Ligation, internal jugular vein	G2
37600	Ligation; external carotid artery	G2
37605	Ligation; internal or common carotid artery	G2
37606	Ligation; internal or common carotid artery, with gradual occlusion, as with selverstone or crutchfield clamp	G2
37615	Ligation, major artery (eg, post-traumatic, rupture); neck	G2
37619	Ligation of inferior vena cava	G2
38120	Laparoscopy, surgical, splenectomy	G2
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage	G2
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	G2
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor	G2
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	G2
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion	G2
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal	G2
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion	G2
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion	G2
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer	G2
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor	G2
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	G2
38720	Cervical lymphadenectomy (complete)	G2
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed	G2
39402	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging)	G2
42842	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; without closure	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (eg, tongue, buccal)	G2
43020	Esophagotomy, cervical approach, with removal of foreign body	G2
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, nissen, toupet procedures)	G2
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	G2
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	G2
43420	Closure of esophagostomy or fistula; cervical approach	G2
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (eg, celestin or mousseaux-barbin)	G2
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	J8
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	G2
43651	Laparoscopy, surgical; transection of vagus nerves, truncal	G2
43652	Laparoscopy, surgical; transection of vagus nerves, selective or highly selective	G2
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	J8
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	G2
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	G2
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	G2
43830	Gastrostomy, open; without construction of gastric tube (eg, stamm procedure) (separate procedure)	G2
43831	Gastrostomy, open; neonatal, for feeding	G2
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	G2
44186	Laparoscopy, surgical; jejunostomy (eg, for decompression or feeding)	G2
44950	Appendectomy;	G2
44955	Appendectomy; when done for indicated purpose at time of other major procedure (not as separate procedure) (list separately in addition to code for primary procedure)	N1
44970	Laparoscopy, surgical, appendectomy	G2
47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency	G2
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	G2
47490	Cholecystostomy, percutaneous, complete procedure, including imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation	G2
49185	Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
	study, imaging guidance (eg, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	
49323	Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity	G2
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	G2
49491	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; reducible	G2
49492	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated	G2
50020	Drainage of perirenal or renal abscess, open	G2
50541	Laparoscopy, surgical; ablation of renal cysts	G2
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	G2
50543	Laparoscopy, surgical; partial nephrectomy	G2
50544	Laparoscopy, surgical; pyeloplasty	G2
50945	Laparoscopy, surgical; ureterolithotomy	G2
51060	Transvesical ureterolithotomy	G2
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, stamey, raz, modified pereyra)	G2
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	G2
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	G2
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (eg, postsurgical obstruction, scarring)	G2
54332	1-stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54336	1-stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54535	Orchiectomy, radical, for tumor; with abdominal exploration	G2
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, fowler-stephens)	G2
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	G2
55970	Intersex surgery; male to female	G2
55980	Intersex surgery; female to male	G2
57106	Vaginectomy, partial removal of vaginal wall;	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	G2
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	G2
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	G2
57284	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach	G2
57285	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach	G2
57292	Construction of artificial vagina; with graft	G2
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	G2
57335	Vaginoplasty for intersex state	G2
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach	G2
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	G2
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	G2
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele	G2
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	G2
58290	Vaginal hysterectomy, for uterus greater than 250 g;	G2
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	G2
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	G2
58770	Salpingostomy (salpingoneostomy)	G2
58920	Wedge resection or bisection of ovary, unilateral or bilateral	G2
58925	Ovarian cystectomy, unilateral or bilateral	G2
59030	Fetal scalp blood sampling	G2
59409	Vaginal delivery only (with or without episiotomy and/or forceps);	G2
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	G2
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	G2
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	G2
60271	Thyroidectomy, including substernal thyroid; cervical approach	G2
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	G2
60512	Parathyroid autotransplantation (list separately in addition to code for primary procedure)	N1
60520	Thymectomy, partial or total; transcervical approach (separate procedure)	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	J8
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	J8
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus	G2
62000	Elevation of depressed skull fracture; simple, extradural	G2
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy	G2
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral	G2
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)	G2
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical	G2
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; thoracic	G2
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; lumbar	G2
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)	N1
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	G2
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (list separately in addition to code for primary procedure)	N1
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment,	N1

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
	cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)	N1
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; single segment	G2
63066	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; each additional segment (list separately in addition to code for primary procedure)	N1
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	J8
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)	N1
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneous, not requiring laminectomy	J8
64804	Sympathectomy, cervicothoracic	G2
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	G2
69725	Decompression facial nerve, intratemporal; including medial to geniculate ganglion	G2
69955	Total facial nerve decompression and/or repair (may include graft)	G2
69960	Decompression internal auditory canal	G2
69970	Removal of tumor, temporal bone	G2
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J8
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	J8
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	N1
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	N1
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	G2
C9758	Blinded procedure for nyha class iii/iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	G2
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, tems), including muscularis propria (ie, full thickness)	G2
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	G2
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	G2
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (egj), with implantation of pulse generator, includes programming	G2
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	G2
0453T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface	G2
0454T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode	G2
0457T	Removal of permanently implantable aortic counterpulsation ventricular assist system; mechano-electrical skin interface	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
0458T	Removal of permanently implantable aortic counterpulsation ventricular assist system; subcutaneous electrode	G2
0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode	G2
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	G2
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	J8
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	G2
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	J8
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only	J8
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	J8
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	G2
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode	J8

D. Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through

66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators "G2" and "A2". Payment indicator "A2" was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator "A2" is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator "A2" because it is used to identify procedures that are exempted from the application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator "J8") is structured so only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59028 through 59080), we updated the CY 2018 ASC payment rates for ASC covered surgical procedures with payment indicators of "A2", "G2", and "J8" using CY 2017 data, consistent with the CY 2019 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2019 OPPS device offset percentages calculated under the standard APC ratesetting methodology, as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators "P2", "P3", and "R2") are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2018 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators "P2", "P3", and "R2") using the most recent available MPFS and OPPS data. We compared the estimated CY 2018 rate for each of the office-based procedures, calculated according to the ASC standard rate setting

methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2018 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators "Q1" and "Q2") describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator "N1") under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal – conditionally packaged in the OPPS (status indicator "Q2") – we continued to provide separate payment since CY 2014 and assigned the current ASC payment indicators associated with these procedures.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2021

We propose to update ASC payment rates for CY 2021 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2021 OPPS/ASC proposed rule. Because the

proposed OPPS relative payment weights are generally based on geometric mean costs, the ASC system would generally use the geometric mean to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2".

We propose to calculate payment rates for office-based procedures (payment indicators "P2", "P3", and "R2") and device-intensive procedures (payment indicator "J8") according to our established policies and, for device-intensive procedures, using our modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2021 OPPS/ASC proposed rule. Therefore, we propose to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2021 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2021 MPFS nonfacility PE RVU-based amount or the proposed CY 2021 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2020, for CY 2021 we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2") would be assigned the current ASC payment indicators associated with those procedures and would continue to be paid separately under the ASC payment system.

c. Proposed Limit on ASC Payment Rates for Low Volume Device-Intensive Procedures

As stated in section XIII.D.1.b. of this CY 2021 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology. However, for low-

volume device-intensive procedures, the proposed relative payment weights are based on median costs, rather than geometric mean costs, as discussed in section IV.B.5. of this CY 2021 OPPS/ASC proposed rule.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61400), we finalized our policy to limit the ASC payment rate for low-volume device-intensive procedures to a payment rate equal to the OPPS payment rate for that procedure. Under our new policy, where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, we establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure. For CY 2020, this policy only affected HCPCS code 0308T, which had very low claims volume (7 claims from CY 2018 used for CY 2020 ratesetting in the OPPS). Additionally, we amended § 416.171(b) of the regulations to reflect the new limit on ASC payment rates for low-volume device-intensive procedures. CMS' existing regulation at § 416.171(b)(2) requires the payment of the device portion of a device-intensive procedure at an amount derived from the payment rate for the equivalent item under the OPPS using our standard ratesetting methodology. We added paragraph (b)(4) to § 416.171 to require that, notwithstanding paragraph (b)(2), low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device-intensive procedures would exceed the payment rate for the equivalent procedure set under the OPPS, the payment rate for the procedure under the ASC payment system would be equal to the payment rate for the same procedure under the OPPS.

Based on our review of CY 2019 claims using our standard ratesetting methodology, there are no low volume device-intensive procedures that would exceed the rate paid under the OPPS for the same procedure. However, there was a single claim containing CPT code 0308T that was unable to be used for the CY 2021 OPPS/ASC proposed rule ratesetting process as it was packaged into a comprehensive

APC. Because our claims accounting logic does not assign the costs of individual procedures provided as part of a comprehensive APC to the APC that would otherwise apply the costs for CPT code 0308T were not assigned to the APC for that procedure, APC 5495 (Level 5 Intraocular Procedures). As a result, there was no available cost data from CY 2019 claims data to construct relative payment weights for CPT code 0308T. As discussed in section III.D.2., under the OPPS, we propose to establish the payment weight for the CY 2021 OPPS for CPT code 0308T using the CY 2020 OPPS final rule median cost of $20,229.78 and relative payment weight as reflecting the most recent claims and cost data. Similarly, as there are no usable claims with CPT code 0308T from CY 2019, which we would normally use for this CY 2021 proposed rule under our standard ratesetting methodology, to establish an appropriate payment rate in CY 2021 for CPT code 0308T using the most recent claims and cost data, we propose to establish the payment rate under the ASC payment system for CY 2021 using CY 2020 final rule OPPS median cost of $20,229.78 and relative payment weight as reflecting the most recent available claims and cost data.

However, CPT code 0308T was designated as a low volume device-intensive procedure in CY 2020. For CY 2020, under the low-volume procedure payment policies in effect through CY 2019, the available claims data would have resulted in a payment rate of approximately $111,019.30 for CPT code 0308T when performed in the ASC setting, which would have been several times greater than the OPPS payment rate. Therefore, for CY 2020 we finalized our policy to limit the ASC payment rate for low-volume device intensive procedures to a payment rate equal to the OPPS payment rate for the procedures. This policy had the effect of limiting the ASC payment rate for CPT code 0308T to the applicable payment rate under the OPPS (which was $20,675.62 in CY 2020). Therefore, for this CY 2021 proposed rule, we propose to apply a payment rate under the ASC payment system equal to the OPPS payment rate for CPT code 0308T, which is $20, 994.57 in this proposed rule. Further, in the

absence of claims data for this proposed rule, we also propose in this CY 2021 OPPS/ASC proposed rule to continue the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T. We will continue to monitor the claims available for ratesetting as they become available in preparation for the CY 2021 OPPS/ASC final rule.

The proposed payment rate for covered surgical procedures for CY 2021, including CPT code 0308T, are listed in Addendum AA of this CY 2021 OPPS/ASC proposed rule (which is available via the Internet on the CMS website).

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators "N", "Q1", and "Q2") under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2"). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor "N1") under the ASC payment system (except for device removal procedures, as discussed in section IV. of this CY 2021 OPPS/ASC proposed rule). Thus, our policy

generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in section XIII.D.3. of this CY 2021 OPPS/ASC proposed rule, for CY 2019, we finalized a policy to unpackage and pay separately at ASP + 6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting, even though payment for these drugs continues to be packaged under the OPPS. We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount ("Z3"), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to "Z2" for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at

prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a "device offset" to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine

range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator "Z2" and revised the definition of payment indicator "Z2" to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator "Z3," and revised the definition of payment indicator "Z3" to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2021

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2021 OPPS and ASC payment rates and subsequent year payment rates. We also propose to continue to set the CY 2020 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2021 and subsequent year payment rates.

Based on our quarterly updates for April and July 2020, we propose to add CPT 0598T (Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)), CPT 0599T(Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary

procedure)), C9762 (Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging), and C7963(Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging) as covered ancillary services.

Covered ancillary services and their proposed payment indicators for CY 2021 are listed in Addendum BB of this CY 2021 OPPS/ASC proposed rule (which is available via the Internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard rate setting methodology and the PFS final rates, the proposed payment indicators and rates set forth in the proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS proposed rule, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

3. CY 2021 ASC Packaging Policy for Non-Opioid Pain Management Treatments

Section 6082 of the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act," also referred to as the "SUPPORT for Patients and Communities Act" (SUPPORT Act) (Pub. L. 115-271) was enacted on October 24, 2018. Section 6082(a) of the SUPPORT Act requires in part that the Secretary: "(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives; (ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and (iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered

OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management." Section 6082(b) of the SUPPORT Act requires that the Secretary conduct a similar type of review in ambulatory surgical centers.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59066 through 59072), we finalized the policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019. We also finalized conforming changes to § 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to package payment for drugs and biologicals for which separate payment is not allowed under the OPPS into the ASC payment for the covered surgical procedure. We added a new § 416.164(b)(6) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as covered ancillary services that are integral to a covered surgical procedure. Finally, we finalized a change to § 416.171(b)(1) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service set under the OPPS.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39424 through 39427), we reviewed payments under the ASC for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. We used available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives to determine whether our packaging policies reduced the use of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39426), we proposed to continue our policy to pay

separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61177), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, the only FDA-approved drug that meets these criteria is Exparel.

We conducted an evaluation to determine whether there are payment incentives for using opioids instead of non-opioid alternatives in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 to 61180). The results of our review and evaluation of our claims data did not provide evidence to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Our updated review of claims data for the CY 2020 proposed rule showed a continued decline in the utilization of Exparel® in the ASC setting, which supported our proposal to continue paying separately for Exparel® in the ASC setting.

(4) Evaluation and CY 2021 Proposal for Payment for Non-Opioid Alternatives

Over the last 2 years, we have conducted detailed evaluations of our payment policies regarding the use of opioids and non-opioid alternatives. We have reviewed multiple years of Medicare claims data, all public comments received on this topic, and studies and data from external stakeholders. Each of these reviews have led to the consistent conclusion that CMS's packaging policies are not discouraging the use of non-opioid alternatives or impeding access to these products, with the exception

of Exparel, the only non-opioid pain management drug that functions as a surgical supply when furnished in the ASC setting.

Section 6082(a) of the SUPPORT Act also provides that after an initial review, the Secretary can conduct subsequent reviews of covered payments as the Secretary deems appropriate. In light of the fact that CMS has conducted a thorough review of payments for opioids and evidence-based non-opioid alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, we do not believe that conducting a similar review for CY2021 would be a fruitful effort. After careful consideration, we believe we have fulfilled the statutory requirement to review payments for opioids and evidence-based non-opioid alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, as described in the CY 2020 OPPS/ASC rulemaking. We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. However, we do not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system.

Current claims data suggest that CMS' current policies are having a positive impact on the utilization of non-opioid alternatives, including Exparel. A preliminary claims analysis showed that the total units of Exparel have increased over the last year. From CY 2015 to CY 2018, we saw an annual decline in the total units of Exparel furnished in the ASC setting, with 244,756 total units provided in CY 2015 dropping to 60,125 total units provided in CY 2018. In CY 2019, ASCs furnished a total of 1,379,286 units of Exparel. Due to this positive trend that reflects the increased use of non-opioid treatment for pain, we do not believe that further changes are necessary under the ASC payment system for non-opioid pain management drugs that function as a surgical supply in the ASC setting. Therefore,

for CY 2021, we propose to continue our policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021.

E. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled "Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class" posted on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.

- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103-432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

● In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests to Establish New NTIOL Classes for CY 2021

We did not receive any requests for review to establish a new NTIOL class for CY 2021.3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2021.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule

with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator "NI" is used in the OPPS/ASC final rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator "NI" also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator "NP" is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator "NP" also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned

is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The "CH" comment indicator is used in Addenda AA and BB to the proposed rule (which are available via the Internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The "CH" comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. ASC Payment and Comment Indicators for CY 2021

For CY 2021, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Therefore, proposed Category I and III CPT codes that are new and revised for CY 2021 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 202a compared to the CY 2020 descriptors are included in ASC Addenda AA and BB to this proposed rule were labeled with proposed comment indicator "NP" to indicate that these CPT and Level II HCPCS codes were open for comment as part of the proposed rule. Proposed comment indicator "NP" meant a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year; and denoted that comments would be accepted on the proposed ASC payment indicator for the new code.

For the CY 2021 update, we propose to add ASC payment indicator ''K5'' – Items, Codes, and Services for which pricing information and claims data are not available. No payment made. –) to ASC Addendum DD1 to this proposed rule (which is available via the Internet on the CMS Web site). New

drug HCPCS codes that do not have claims data or payment rate information are currently assigned to OPPS status indicator "E2" – Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). These codes are categorized and included in the ASC payment system as nonpayable codes and are currently assigned an ASC payment indicator "Y5" – Non-surgical procedure/item not valid for Medicare purposes because of coverage, regulation and/or statute; no payment made – because that is the ASC payment indicator that currently best describes the status of these HCPCS codes. However, "Y5" assignments include both those drug codes that would not be integral to the performance of a surgical procedure and are therefore not payable in the ASC payment system and those codes that may become separately payable in the ASC payment system. Since there is not a separate payment indicator that describes the subset of drug codes that will become payable when claims data or payment information is available the existing ASC payment indicators cannot currently communicate the distinction between these two classes of drugs. Therefore, for CY2021 and subsequent calendar years, we propose to add ASC payment indicator "K5" – Items, Codes, and Services for which pricing information and claims data are not available. No payment made. – to ASC Addendum DD1 to this proposed rule (which is available via the Internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2021 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of this proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2020 update. Addenda DD1 and DD2 to this proposed rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2021.

G. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term "expenditures" in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this CY 2021 OPPS/ASC proposed rule), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for

geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d) (10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13-01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13-01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15-01, which provides updates to and supersedes OMB Bulletin No. 13-01 that was issued on February 28, 2013. OMB Bulletin

No. 15-01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf).

On August 15, 2017, OMB issued OMB Bulletin No. 17-01, which provided updates to and superseded OMB Bulletin No. 15-01 that was issued on July 15, 2015. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf).

For CY 2021, the proposed CY 2021 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 15-01 and 17-01).

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where "contiguous" is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the state (75 FR 72058 through 72059). (In other situations, where there are no IPPS hospitals located in a

relevant labor market area, we continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.)

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2021 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system equal to what would be the current expenditures based on the scaled ASC payment weights. In this way we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same

procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

Consistent with our established policy, we propose to scale the CY 2021 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2019, we propose to compare the total payment using the CY 2020 ASC relative payment weights with the total payment using the CY 2021 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2020 and CY 2021. We propose to use the ratio of CY 2020 to CY 2021 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2021. The proposed CY 2021 ASC weight scalar is 0.8494. Consistent with historical practice, we would scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, we have available 90 percent of CY 2019 ASC claims data.

To create an analytic file to support calculation of the weight scalar and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2019 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2019 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file is available to the public as a supporting data file for this proposed rule and is posted on the CMS website at: http:// http://www.cms.gov/Research-Statistics-Data-and- Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor.

Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2021, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2019 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2021 ASC wage indexes. Specifically, holding CY 2019 ASC utilization, service-mix, and the proposed CY 2021 national payment rates after application of the

weight scalar constant, we calculated the total adjusted payment using the CY 2020 ASC wage indexes and the total adjusted payment using the proposed CY 2021 ASC wage indexes. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2020 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2021 ASC wage indexes and applied the resulting ratio of 0.9999 (the proposed CY 2021 ASC wage index budget neutrality adjustment) to the CY 2020 ASC conversion factor to calculate the proposed CY 2021 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the MFP-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we will assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a MFP-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we finalized our proposal to revise our regulations

under § 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intend to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

The proposed hospital market basket update for CY 2021 is projected to be 3.0 percent, as published in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32738), based on IHS Global Inc.'s (IGI's) 2019 fourth quarter forecast with historical data through the third quarter of 2019.

We finalized the methodology for calculating the MFP adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed MFP adjustment for CY 2021 is projected to be 0.4 percentage point, as published in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32739) based on IGI's 2019 fourth quarter forecast.

For CY 2021, we propose to utilize the hospital market basket update of 3.0 percent minus the MFP adjustment of 0.4 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.6 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of this CY 2021 OPPS/ASC proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to

meet ASCQR Program requirements. We propose to utilize the hospital market basket update of 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.4 percentage point MFP adjustment. Therefore, we propose to apply a 0.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also propose that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or MFP adjustment), we would use such data, if appropriate, to determine the CY 2021 ASC update for the CY 2021 OPPS/ASC final rule with comment period.

For CY 2021, we propose to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the MFP-adjusted hospital market basket update of 2.6 percent discussed above, which results in a proposed CY 2021 ASC conversion factor of $48.984 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the quality reporting/MFP-adjusted hospital market basket update of 0.6 percent discussed above, which results in a proposed CY 2021 ASC conversion factor of $48.029.

3. Display of Proposed CY 2021 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2021 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the PFS rates that would be effective January 1, 2021. For a discussion of the

PFS rates, we refer readers to the CY 2021 PFS proposed rule that is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

The proposed payment rates included in addenda AA and BB to this proposed rule reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the proposed CY 2021 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "To be Subject to Multiple Procedure Discounting" indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator "CH" in the column titled "Comment Indicator" indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2021. Display of the comment indicator "NI" in the column titled "Comment Indicator" indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator "NP" in the column titled "Comment Indicator" indicates that the code is new (or substantially revised) and that comments will be accepted on the ASC payment indicator for the new code.

For CY 2021, we propose to add a new column to ASC Addendum BB titled "Drug Pass-Through Expiration during Calendar Year" where we would flag through the use of an asterisk each

drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled "Proposed CY 2021 Payment Weight" are the proposed relative payment weights for each of the listed services for CY 2021. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2021 payment rate displayed in the "Proposed CY 2021 Payment Rate" column, each ASC payment weight in the "Proposed CY 2021 Payment Weight" column was multiplied by the proposed CY 2021 conversion factor of $48.984. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment. The proposed CY 2021 ASC conversion factor uses the CY 2021 MFP-adjusted hospital market basket update factor of 2.6 percent (which is equal to the projected hospital market basket update of 3.0 percent minus a projected MFP adjustment of 0.4 percentage point).

In Addendum BB, there are no relative payment weights displayed in the "Proposed CY 2021 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "Proposed CY 2021 Payment" column displays the proposed CY 2021 national unadjusted ASC payment rates for all items and services. The proposed CY

2021 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in 2020.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2021.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Consistent with these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2019 OPPS/ASC final rules with comment period (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; 81 FR 79753 through 79797; 82 FR 59424 through 59445; 83 FR 59080 through 59110; and 84 FR 61410 through 61420) for the regulatory history

of the Hospital OQR Program. We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46.

4. Proposal to Codify Statutory Authority for Hospital OQR Program

The Hospital OQR Program regulations are codified at 42 CFR 419.46. We propose to update the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required to be submitted on measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual OPD fee schedule increase factor. We propose to redesignate the existing paragraphs (a) through (h) as paragraphs (b) through (i) and codify the Hospital OQR Program's statutory authority at new paragraph § 419.46(a). Because of the proposed redesignations, the cross-references throughout § 419.46 are also proposed to be updated.

Table 42 shows the correlation between the cross-references proposed to be removed and added if the proposed redesignations are finalized.

Table 42: CORRELATION BETWEEN THE CROSS-REFERENCES PROPOSED TO BE REMOVED AND ADDED IF THE PROPOSED REDESIGNATIONS ARE FINALIZED

Proposed Newly Redesignated Paragraphs	Proposed Cross-references to be Removed	Proposed Cross-references to be Added
(d)(3)(ii) and (iii)	(c)(2)	(d)(2)
(g)(2)(viii)	(e)(1)	(f)(1)
(i)(1)	(h)(2) and (3)	(i)(2) and (3)
(i)(3)	(h)(2)	(i)(2)
(i)(3)(ii)	(h)(3)(i)(A)	(i)(3)(i)(A)

We request public comment on this proposal.

We refer readers to section XIV.E. of the preamble of this proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2023 payment determination.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). For more information regarding this policy, we refer readers to that final rule with comment period. We codified this policy at 42 CFR 419.46(h)(1) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). We are not proposing any changes to these policies in this proposed rule.

3. Removal of Quality Measures from the Hospital OQR Program Measure Set

a. Immediate Removal

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635), we finalized a process for removal of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns.[97] We codified this policy at 42 CFR 419.46(h)(2) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). In the

[97] We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term "retirement" to "removal" in the Hospital OQR Program.

case of suspension or removal due to patient safety concerns, action would need to be taken quickly and may not coincide with rulemaking cycles (77 FR 68472). In this case, we would promptly remove the measure and notify hospitals of its removal, and confirm the removal of the measure in the next rulemaking cycle. We are not proposing any changes to these policies in this proposed rule.

b. Consideration Factors for Removing Measures

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60635), we finalized a process to use the regular rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns.[98] We codified this policy at 42 CFR 419.46(h)(3) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59083 through 59085), we clarified, finalized, and codified at 42 CFR 419.46(h)(3) an updated set of factors[99] and policies for determining whether to remove measures from the Hospital OQR Program. We refer readers to that final rule with comment period for a detailed discussion of our policies regarding measure removal factors. We are not proposing any changes to these policies in this proposed rule.

4. Summary of Hospital OQR Program Measure Set for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410 through 61420) for a summary of the previously finalized Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years.

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[98] We initially referred to this process as "retirement" of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to "removal" during final rulemaking.

[99] We note that we previously referred to these factors as "criteria" (for example, 77 FR 68472 through 68473); we now use the term "factors" in order to align the Hospital OQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

We are not proposing any changes to the previously finalized measure set. Table 43 summarizes the previously finalized Hospital OQR Program measure set for the CY 2023 payment determination and subsequent years.

TABLE 43: HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2023 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**
None	OP-37d: OAS CAHPS – Overall Rating of Facility**
None	OP-37e: OAS CAHPS – Recommendation of Facility**

† We note that NQF endorsement for this measure was removed.
* Measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).
** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

5. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 through 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and for subsequent years, such that we will release a manual once every 12 months and release addenda as necessary. We are not proposing any changes to these policies in this proposed rule.

6. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules with comment period (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures.

a. Codification

In the 2009 OPPS/ASC final rule with comment period (73 FR 68778), we finalized that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes. While we previously finalized this policy, it was not codified. In this proposed rule, we propose to codify this policy by adding language at the redesignated paragraph (d)(1). If finalized, the newly redesignated paragraph (d)(1) would specify that "Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes." We are soliciting public

comment on our proposal.

b. Overall Hospital Quality Star Rating

In this proposed rule, we propose a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). The Overall Star Rating would utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital OQR Program. We refer readers to section XVI. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years of this proposed rule for details.

C. Administrative Requirements

1. QualityNet Account and Security Administrator/Security Official

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). We codified these procedural requirements at 42 CFR 419.46(a) in that final rule with comment period.

In this proposed rule, we propose to use the term "security official" instead of "security administrator" to denote the exercise of authority invested in the role. The term "security official" would refer to "the individual(s)" who have responsibilities for security and account management requirements for a hospital's QualityNet account. To be clear, this proposed update in terminology would not change the individual's responsibilities or add burden. We propose to revise existing § 419.46(a)(2), proposed redesignated § 419.46(b)(2), by replacing the term "security administrator" with the term "security official." If finalized, the newly redesignated paragraph (b)(2) would read: "Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section." We invite public comment on our proposal to replace the term "security administrator" with "security official" and codify this change.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103 through 59104) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these procedural requirements regarding participation status at 42 CFR 419.46(a) and (b).

In this proposed rule, we propose to revise existing § 419.46(b) (proposed redesignated § 419.46(c)) by removing the phrase "submit a new participation form" to align with previously finalized policy; submission of this form was removed as a program requirement in the CY 2019 OPPS/ASC final rule (83 FR 59103 to 59104). We also propose to update internal cross-references as a result of the redesignations discussed under section XIV.A.4. of this proposed rule. If finalized as proposed, the newly redesignated § 419.46(c) would specify that "A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.46(i), and is required to renew participation as specified in § 419.46(b) in order to participate in any future year of the Hospital OQR Program." Our proposal also includes updated cross-referenced provisions in the newly redesignated § 419.46(c). We are soliciting public comment on our proposal.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules with comment period (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439) where we finalized our policies for data submission deadlines. We codified these submission requirements at 42 CFR 419.46(c). The submission deadlines for the CY 2023 payment determination and subsequent years are

illustrated in Table 44.

TABLE 44: CY 2023 Payment Determination and Subsequent Years

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2021 (April 1 - June 30)	11/1/2021
Q3 2021(July 1 – September 30)	2/1/2022
Q4 2021 (October 1 - December 31)	5/1/2022
Q1 2022 (January 1 - March 31)	8/1/2022

To align with statute, in this proposed rule, we propose one change to our submission deadlines. We propose that all deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), "Periods of Limitation Ending on Nonwork Days," beginning with the effective date of this rule. Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the Hospital OQR Program is administered. Under this proposal, all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order would be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order.

We propose to revise our policy regarding submission deadlines at existing § 419.46(c)(2), proposed redesignated § 419.46(d)(2). If finalized, the newly redesignated paragraph (d)(2) would specify that "All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order." We invite public comment on our proposal.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

The following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2022 payment determination and subsequent years:

- OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); and
- OP-23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

3. Claims-Based Measure Data Requirements for the CY 2023 Payment Determination and Subsequent Years

Currently, the following previously finalized Hospital OQR Program claims-based measures are required for the CY 2022 payment determination and subsequent years:

- OP-8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP-10: Abdomen CT – Use of Contrast Material;
- OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);

- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 through 59107), where we established a 3-year reporting period for OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years. In that final rule with comment period (83 FR 59136 through 59138), we established a similar policy under the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

4. Data Submission Requirements for the OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), where we finalized a policy to delay implementation of the OP-37a-e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking. We are not proposing any changes to the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures in this proposed rule.

5. Data Submission Requirements for Measures for Data Submitted via a Web-based Tool for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521), and the CMS QualityNet website (www.qualitynet.orgfor a discussion of the requirements for measure data submitted via the CMS QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) system secure portal) for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data submitted via the CDC NHSN website. We are not proposing any changes to these policies in this proposed rule.

The following previously finalized quality measures will require data to be submitted via a CMS web-based tool for the CY 2023 payment determination and subsequent years with the exception of OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) for which data submission remains voluntary:

- OP-22: Left Without Being Seen (NQF #0499) ;
- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) ; and
- OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

6. Population and Sampling Data Requirements for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through

74483) for discussions of our population and sampling requirements. We are not proposing any changes to these policies in this proposed rule.

7. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 and 67014) where we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. Per the previously finalized policy, the Hospital OQR Program implemented a 4-month review and corrections period for chart-abstracted measure data, which runs concurrently with the data submission period. During the review and corrections period for chart-abstracted data, hospitals can enter, review, and correct data submitted directly to CMS for the chart-abstracted measures.

b. Web-based Measures

In this proposed rule, we propose to expand our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years. Hospitals would have a review and corrections period for web-based measures, which would run concurrently with the data submission period. The review and corrections period for web-based measures is from the time the submission period opens to the submission deadline. During this review and corrections period, hospitals can enter, review, and correct data submitted directly to CMS. However, after the submission deadline, hospitals would not be allowed to change these data. The expansion of the existing policy for chart-abstracted measures to data submitted via the CMS web-based tool would accommodate a growing diversity of measure types in the Hospital OQR Program. We are soliciting public comment on our proposal.

c. Codification of the Review and Corrections Periods for Measure Data Submitted to the Hospital OQR Program

We note that the previously finalized policy relating to the review and corrections period for chart-abstracted measures has not yet been codified. Therefore, in this proposed rule, we propose to codify at 42 CFR 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool. Specifically, we propose to add a new paragraph (4) at existing § 419.46(c), proposed redesignated § 419.46(d). If finalized, the new paragraph (d)(4) would read: "*Review and Corrections Period*. For both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed." We are soliciting public comment on our proposal.

8. Hospital OQR Program Validation Requirements

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 through 72106), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and 42 CFR 419.46(e) for our policies regarding validation. In this proposed rule, while we are not proposing changes to our validation policies, we propose to codify certain previously finalized policies; these are discussed in more detail in section XIV.D.8.b.

a. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

(1) Background

In the CY 2018 final rule (82 FR 59441 through 59443), we finalized a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. Under the informal process, hospitals that were selected and received a score for validation may request an educational review to better understand the results. A hospital has 30 calendar days from the date the validation results are made available via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System) to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review (82 FR 59442). In response to a request, the VSC obtains and reviews medical records directly from the Clinical Data Abstraction Center (CDAC) and provides feedback (82 FR 59442). CMS, or its contractor, generally provides educational review results and responses via a secure file transfer to the hospital (82 FR 59442). In the CY 2018 final rule (82 FR 59441 through 59443), we (1) formalized this process; and (2) specified that if the results of an educational review indicate that we incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score would be used to compute the hospital's final validation score at the end of the calendar year. We are not proposing any changes to this finalized policy in this proposed rule.

(2) Proposed Codification of Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

The previously finalized policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction finalized in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59442), has not yet been codified at 42 CFR 419.46. In this proposed rule, we propose to codify those policies by adding a new paragraph (4) to existing § 419.46(e), proposed redesignated § 419.46(f). If finalized, the new paragraph (f)(4) would specify that "Hospitals that are selected and receive a score for validation of chart-abstracted

measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year." We invite public comment on this proposal.

9. Extraordinary Circumstances Exception (ECE) Process for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59444), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We are not proposing any changes to these policies in this proposed rule.

10. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), and 42 CFR 419.46(f) for our reconsideration and appeals procedures.

In alignment with our proposal to change submission deadlines in section XIV.D.1. of this proposed rule, we propose one change to our reconsideration deadlines. We propose that all deadlines

falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), "Periods of Limitation Ending on Nonwork Days," beginning with the effective date of this rule. Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the Hospital OQR Program is administered. Under this proposal, all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order would be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order. Specifically, we propose to remove "the first business day on or after" from existing § 419.46(f)(1), proposed redesignated § 419.46(g)(1), to ensure the language of the regulatory text regarding deadlines for reconsideration requests is consistent with 42 U.S.C. 416(j). If finalized, the newly redesignated paragraph (g)(1) would read: "A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in § 419.46(d)(2), of the affected payment year as determined using the date the request was mailed or submitted to CMS." We invite public comment on our proposal.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2021 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on

measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the Internet on the CMS website): "J1", "J2", "P", "Q1", "Q2", "Q3", "R", "S", "T", "V", or "U". In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator "Q4" because services and procedures coded with status indicator "Q4" are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements,

with the exception of services assigned to New Technology APCs with assigned status indicator "S" or "'T". We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the "reporting ratio" to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in

this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor – 0.02)

Reporting Ratio = Reduced Conversion Factor / Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor – 0.02) / (1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the

interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of the proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2021

We propose to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2021 annual payment update factor. For this CY 2021 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which when multiplied by the proposed full conversion factor of $83.697 equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $82.016. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For this CY 2021 OPPS/ASC proposed rule, we propose to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of "J1", "J2", "P", "Q1", "Q2", "Q3", "R", "S", "T", "V", and "U" (other than new technology APCs to which we have proposed status indicator assignment of "S" and "T"). We propose to continue to exclude services paid under New Technology APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting

requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2021, the proposed reporting ratio is 0.9805, which when multiplied by the final full conversion factor of 83.697 equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of 82.065. We note that the proposed reporting ratio can be applied to the full national unadjusted payment rates to determine reduced national unadjusted payment rates.

XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1. of the CY 2020 final rule (84 FR 61410) for a general overview of our quality reporting programs and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Initiative and our approach in evaluating quality program measures.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the CYs 2014 through 2020 OPPS/ASC final rules with comment period (78 FR 75122; 79 FR 66966 through 66987; 80 FR 70526 through 70538; 81 FR 79797 through 79826; 82 FR 59445 through 59476; 83 FR 59110 through 59139; and 84 FR 61420 through 61434, respectively) for an overview of the regulatory history of the ASCQR Program. We have codified certain requirements under the ASCQR Program at 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330). In this proposed rule, we propose to update certain currently codified program policies and propose a review and corrections period as well as other administrative changes. We discuss these proposals in more detail below in sections XV.C. and XV.D.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for the ASCQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Policies for Retention and Removal of Quality Measures from the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when such measures are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; and 79 FR 66967 through 66969). We are not proposing any changes to this policy in this proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115), we

clarified, finalized, and codified at 42 CFR 416.320 an updated set of factors[100] and the process for removing measures from the ASCQR Program. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115) for a detailed discussion of our process regarding measure removal. We are not proposing any changes to the measure removal factors in this proposed rule.

3. Summary of ASCQR Program Quality Measure Set Previously Finalized for the CY 2024 Payment Determination and for Subsequent Years

We are not proposing to remove any existing measures or to adopt any new measures for the CY 2023 payment determination. Table 45 summarizes the previously finalized ASCQR Program measure set for the CY 2024 payment determination and subsequent years.

TABLE 45: FINALIZED ASCQR PROGRAM MEASURE SET FOR THE CY 2024 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn*
ASC-2	0266†	Patient Fall*
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*
ASC-4	0265†	All-Cause Hospital Transfer/Admission*
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff***
ASC-15b	None	OAS CAHPS – Communication About Procedure***
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery***
ASC-15d	None	OAS CAHPS – Overall Rating of Facility***

[100] We note that we previously referred to these factors as "criteria" (for example, 79 FR 66967 through 66969); we now use the term "factors" in order to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

TABLE 45: FINALIZED ASCQR PROGRAM MEASURE SET FOR THE CY 2024 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC #	NQF #	Measure Name
ASC-15e	None	OAS CAHPS – Recommendation of Facility***
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers****

† NQF endorsement was removed.
* Measure finalized for suspension in reporting beginning with the CY 2021 payment determination (CY 2019 data collection) until further action in future rulemaking as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123).
** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
*** Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).
**** Measure will be added beginning with the CY 2024 payment determination as set forth in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61421 through 61428).

4. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CYs 2012 through 2016 OPPS/ASC final rules with comment period (76 FR 74513 through 74514; 77 FR 68496 through 68497; 78 FR 75131; 79 FR 66981; and 80 FR 70531, respectively) for detailed discussion of our policies regarding the maintenance of technical specifications for the ASCQR Program, which are codified at 42 CFR 416.325. We are not proposing any changes to these policies.

5. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017 and 2018 OPPS/ASC final rules with comment period (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified at 42 CFR 416.315 (80 FR 70533). We are not proposing any changes to these policies.

6. ASCQR Program Measures and Topics for Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the ASC setting. We also seek measures that

would facilitate meaningful comparisons between ASCs and hospitals. Therefore, we invite public comment on new measures for our consideration that address care quality in the ASC settings as well as on additional measures that could facilitate comparison of care provided in ASCs and hospitals.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding the maintenance of a QualityNet account and security administrator for the ASCQR Program at § 416.310(c)(1)(i).

In this proposed rule, we propose to use the term "security official" instead of "security administrator" to denote the exercise of authority invested in the role. The term "security official" refers to "the individual(s)" who have responsibilities for security and account management requirements for a facility's QualityNet account. To be clear, this proposed update in terminology would not change the individual's responsibilities or add burden. We also propose to revise § 416.310(c)(1)(i) by replacing the term "security administrator" with the term "security official". The new sentence would read: "A QualityNet security official is necessary to set up such an account for the purpose of submitting this information." We invite public comment on our proposals.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment

period (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. We are not proposing any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Update of Language Generally

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at 42 CFR 416.310. We currently use the phrases "data collection period" and "data collection time period" interchangeably in § 416.310(a) through (c). We believe that using one, consistent phrase will streamline and simplify the section and our policies to help avoid potential confusion. As such, we propose to remove the phrase "data collection time period" in all instances where it appears in § 416.310, and replace it with the phrase "data collection period" – specifically at § 416.310(a)(2), (b), (c)(1)(ii), and (c)(2), as well as replacing the phrase "time period" with "period" in § 416.310(c)(1)(ii) for language consistency. We invite comment on our proposal.

b. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2).

We are not proposing any changes to these requirements. We note that data submission for the following claims-based measures using QDCs was suspended in the CY 2019 OPPS/ASC final rule with

comment period (83 FR 59117 through 59123 and 83 FR 59134 through 59135) until further action in rulemaking:

- ASC-1: Patient Burn;
- ASC-2: Patient Fall;
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC-4: Hospital Transfer/Admission.

Furthermore, we note that the previously finalized data processing and collection period requirements will apply to any future claims-based -measures using QDCs adopted in the ASCQR Program.

c. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We are not proposing any changes to these policies.

As noted above, while data submission for certain claims-based measures using QDCs was suspended, our policies for minimum threshold, minimum case volume, and data completeness requirements will apply to any future claims-based -measures using QDCs adopted in the ASCQR Program.

d. Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138), for a complete summary of the data processing and collection requirements for the non-

QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program at 42 CFR 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously finalized measures:

- ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
- ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

We are not proposing any changes to the requirements for non-QDC based, claims-based measures.

e. Requirements for Data Submitted via an Online Data Submission Tool

(1). Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the CMS QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) secure portal) to host our CMS online data submission tool: https://www.qualitynet.org. We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at 42 CFR 416.310(c)(1)(i).

The following previously finalized measures require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

- ASC-11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery
- ASC-13: Normothermia Outcome
- ASC-14: Unplanned Anterior Vitrectomy

We are not proposing any changes to these policies for data submitted via a CMS online data submission tool.

(2). Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (that is, the CDC NHSN website). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2).

As we noted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59135), no measures submitted via a non-CMS online data submission tool remain in the ASCQR Program beginning with the CY 2020 payment determination. We are not proposing any changes to our non-CMS online data submission tool reporting requirements; these requirements would apply to any future non-CMS online data submission tool measures adopted in the ASCQR Program.

f. Requirements for Data Submission for ASC-15a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) for our previously finalized policies regarding survey administration and vendor requirements for the CY 2020 payment determination and subsequent years. In addition, we codified

these policies at 42 CFR 416.310(e). However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451), we delayed implementation of the ASC15a-e: OAS CAHPS -Survey-based -measures beginning with the CY 2020 payment determination (CY 2018 data submission) until further action in future rulemaking, and we refer readers to that discussion for more details. We are not proposing any changes to this policy.

g. ASCQR Program Data Submission Deadlines

While the ASCQR Program has established submission deadlines (42 CFR 416.310), there is no specified policy for deadlines falling on nonwork days. Therefore, we propose that all program deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), "Periods of Limitation Ending on Nonwork Days." Specifically, the Act indicates that all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day, all or part of which is declared to be a nonwork day for federal employees by statute or Executive order, shall be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order (42 U.S.C. 416(j)). Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the ASCQR Program is administered. As such, we propose to add this policy for the submission deadlines associated with the ASCQR Program beginning with the effective date of this rule. We also propose to codify this policy by adding a new paragraph (f) at § 416.310, which would read “All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.” We invite public comment on our proposals.

2. Proposed Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool in the ASCQR Program

Under the ASCQR Program, for measures submitted via a CMS online data submission tool, ASCs submit measure data to CMS from January 1 through May 15 during the calendar year subsequent to the current data collection period (84 FR 61432).[101] For example, ASCs collect measure data from January 1, 2019 through December 31, 2019 and submit these data to CMS from January 1, 2020 through May 15, 2020. ASCs may begin submitting data to CMS as early as January 1. ASCs are encouraged, but not required, to submit data early in the submission period so that they can identify errors and resubmit data before the established submission deadline.

In this proposed rule, we propose to formalize that process and create a review and corrections period similar to that being proposed for the Hospital OQR Program in section XIV.D.7 of this proposed rule. For the ASCQR Program, we propose to implement a review and corrections period which would run concurrently with the data submission period beginning with the effective date of this rule. During this review and corrections period, ASCs could enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs would not be allowed to change these data. We also propose to codify this review and corrections period at new paragraph (c)(1)(iii) in § 416.310, which would read "For measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed." We invite public comment on our proposals, including on the burden and benefits of such a review and corrections period.

[101] ASCQR Program Data Submission Deadlines. Available at: https://www.qualitynet.org/asc/data-submission#tab2

3. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We are not proposing any changes to this policy.

4. Extraordinary Circumstances Exception (ECE) Process for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's policies for extraordinary circumstance exceptions (ECE) requests. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475), we: (1) changed the name of this policy from "extraordinary circumstances extensions or exemption" to "extraordinary circumstances exceptions" for the ASCQR Program, beginning January 1, 2018; and (2) revised 42 CFR 416.310(d) of our regulations to reflect this change. We will strive to complete our review of each request within 90 days of receipt. We are not proposing any changes to these policies.

E. Proposed Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail to Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the

APC to which the service is assigned. For CY 2021, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the multifactor productivity (MFP)-adjusted hospital market basket update factor. The MFP adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available

via the Internet on the CMS website): "A2", "G2", "P2", "R2" and "Z2", as well as the service portion of device-intensive procedures identified by "J8" (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators "A2", "G2", "J8", "P2", "R2" and "Z2." These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated

according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2020 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We propose the continuation of these policies for CY 2021.

XVI. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years

A. Background

The Overall Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs, in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars. The Overall Star Rating was first introduced and reported on *Hospital Compare* in July 2016[102] and has been refreshed six times,[103] [104] [105] [106] two of which included minor methodology updates,[107] [108] over the past years. *Hospital Compare,* and any successor site, is a public website hosted by CMS with transparent information and data on over 100 quality measure for over 4,000 hospitals, nationwide in the United States, for consumers and researchers. In this rule, for the Overall Star Ratings, the term "publish"

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[102] Centers for Medicare & Medicaid Services. (2016, July 27). *First Release of the Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from www.cms.gov/newsroom: https://www.cms.gov/newsroom/fact-sheets/first-release-overall-hospital-quality-star-rating-hospital-compare

[103] Centers for Medicare & Medicaid Services. (2016, May). *Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.*

[104] Centers for Medicare & Medicaid Services. (2016, October). *Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.*

[105] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.*

[106] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2

[107] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2

[108] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources

refers to the public posting of the Overall Star Rating and "refresh" refers to the public posting quality measure and program data on *Hospital Compare* or its successor website.

During development of the Overall Star Rating, we established guiding principles to use methods that were scientifically valid, inclusive of hospitals and measure information, accounted for the heterogeneity of available measures and hospital reporting, and accommodated changes in the underlying measures.[109] In addition, we aimed to provide alignment with the information displayed on *Hospital Compare* and the measures and methods used within CMS programs, transparency of Overall Star Rating methods, and responsiveness to stakeholder input. After the launch of the Overall Star Rating in July 2016 and as the Overall Star Rating gained broader use by multiple stakeholders, we added new guiding principles to guide reevaluation of the methodology.[110]

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose a methodology which includes elements of the current methodology as well as updates (we refer readers to section E. Current and Proposed Overall Star Rating Methodology) that aim to increase simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals. We are also proposing to include Veterans Health Administration (VHA) hospitals (we refer readers to section C. Veterans Health Administration Hospitals in Overall Star Rating) and Critical Access Hospitals (CAHs) (we refer readers to B. Critical Access Hospitals in the Overall Star Rating) in the Overall Star Rating. In addition, we propose to establish the Overall Hospital Quality Star Rating and methodology at subpart J of part 412 (proposed § 412.190).

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[109] Centers for Medicare & Medicaid Services. (2017, December*). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1

[110] Ibid.

Because of our production timeline to calculate and distribute Overall Star Rating results in time for hospitals to preview the ratings in advance of public release, we are using this CY 2021 OPPS/ASC proposed rule to propose the methodology for the Overall Star Rating even though it includes not only hospital outpatient measures, but also hospital inpatient measures, which are generally discussed in the Inpatient Prospective Payment System (IPPS) rule. We plan to reference policies for the Overall Star Rating in the FY 2022 IPPS rule.

1. Purpose, Authority, and Applicable Hospital Quality Data

a. Purpose

In 2014, to inform the initial methodology for the Overall Star Rating, we conducted a review of the literature as well as a review of prior and current star rating efforts. This review supported the notion that patients care about information on hospital quality, but that patient use of this information is limited by low understanding of quality information. Additionally, we heard feedback that hospital quality information is often intimidating as displayed and is not user-friendly in comparison to other consumer ratings. The key findings of the review were consistent with consumer priorities to bring a wide variety of measures together into a single overall star rating. Therefore, we sought to help consumers understand hospital quality information through development of a summary measure, which combines publicly reported quality information in an easy-to-understand rating that is familiar to consumers.

The primary objective of the Overall Star Rating was to use an established, evidence-based statistical approach to summarize hospital quality measure results reported on *Hospital Compare* with the goal of assigning acute care hospitals and facilities that provide acute inpatient and outpatient care in

the U.S. to an overall rating between one and five whole stars.[111] The Overall Star Rating is meant to complement other hospital quality information publicly posted on *Hospital Compare* or its successor website, including the individual measure scores and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Star Rating.[112] The original guiding principles of the Overall Star Rating was to use scientifically valid methods that are inclusive of hospitals and measure information, able to account for different hospitals reporting on different measures, and able to accommodate changes in the underlying measures over time.[113] We also aimed to create alignment with *Hospital Compare* and CMS programs, transparency of the methods for calculating the Overall Star Rating, and responsiveness to stakeholder input through various and ongoing engagement activities.

The goal of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make more informed decisions about their healthcare. To this end, we propose that (1) the Overall Star Rating is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals, (2) the guiding principles of the Overall Star Rating are to use scientifically valid methods, inclusive of hospitals and measure information and able to accommodate measure changes; alignment with *Hospital Compare* or its successor website and CMS programs; provide transparency of the methods for calculating the Overall Star Ratings; and be responsive to stakeholder input; and (3) and to codify this at § 412.190.

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[111] Centers for Medicare and& Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1

[112] Centers for Medicare and& Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources

[113] Centers for Medicare and& Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1

b. Subsection (d) Hospitals

The Overall Star Rating includes measures that (1) capture quality of care at hospitals and facilities providing acute inpatient and outpatient care and (2) are publicly reported on *Hospital Compare* or its successor websites. CMS currently publicly reports information regarding the performance of individual hospitals in the following CMS quality programs: Hospital Inpatient Quality Reporting (IQR) Program, Hospital Readmission Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, Hospital Value-Based Purchasing (VBP) Program, and Hospital Outpatient Quality Reporting (OQR) Program. Such authority is granted under applicable sections 1833 and 1886 of the Act.[114]

Specifically, under sections 1886(b)(3)(B)(viii)(VII) and 1833(t)(17)(E) of the Act for the Hospital IQR and OQR Programs respectively, the Secretary is required to make quality information available to the public. Section 1886(b)(3)(B)(viii)(VII) of the Act states that "The Secretary shall establish procedures for making information regarding measures submitted under this clause available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to furnished in inpatient settings in on the Internet website of the Centers for Medicare & Medicaid Services." Section 1833(t)(17)(E) of the Act states that "The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that

[114] U.S Congress. (1934) *United States Code: Social Security Act, 18 U.S.C §§1833 and 1886.*

relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare and Medicaid Services." We believe that these requirements allow the agency to create the Overall Star Rating as a means to summarize existing publicly reported quality measure data from the Hospital IQR and OQR Programs, along with quality measure data from other hospitals, in a form and manner that improves accessibility of hospital quality information for the benefit of patients and consumers.

In addition, the HRRP (under section 1886(q)(6)(A) of the Act) and the HAC Reduction Program (under section 1886(p)(6)(A) of the Act) require that the Secretary must make information regarding readmission and hospital acquired condition rates for hospitals available to the public. Specifically, section 1886(q)(6)(A) of the Act states that "The Secretary shall make information available to the public regarding readmission rates of each subsection (d) hospital under the program" and section 1886(p)(6)(A) of the Act states that "The Secretary shall make information available to the public regarding hospital acquired conditions of each applicable hospital." Similar to Hospital IQR and OQR Programs, we believe that these requirements allow the agency to create and publicly release the Overall Star Rating as a means to summarize existing publicly reported quality measure data from the HRRP and HAC Reduction Program, along with quality measure data from other hospitals, in a form and manner that improves accessibility of hospital quality information for the benefit of patients and consumers.

Our use of data reported by hospitals under the Hospital VBP Program in the Overall Star Ratings is supported by section 1886(o)(10)(A)(i) of the Act. Specifically, section 1886(o)(10)(A) of the Act states that "The Secretary shall make information available to the public regarding the performance of individual hospitals under the Program, including (i) the performance of the hospital with respect to each measure that applies to the hospital; (ii) the performance of the hospital with respect

to each condition or procedure; and (iii) the hospital performance score assessing the total performance of the hospital." Hospitals that participate in the Hospital VBP Program report data on each Hospital VBP measure for a specified performance period that applies to the program year. Under our proposed star rating methodology, which we describe in detail below, we would use these Hospital VBP measure rates, in combination with measure rates reported by various hospitals under the Hospital IQR Program, Hospital OQR Program, HRRP, and HAC Reduction Program to calculate and make public a star rating that applies to the hospital for a corresponding star rating period, making that star reflective of the hospital's measured level of quality in all of these programs.

The Overall Star Ratings does not use data reported by hospitals under the Prospective Payment System-Exempt Cancer Hospitals Quality Reporting (PCHQR) Program, the Inpatient Psychiatric Facilities (IPF) Quality Reporting Program, or the Ambulatory Surgical Centers (ASC) Quality Reporting Program.

Beginning with publication of Overall Star Rating in CY 2021 and subsequent years, we propose to: (1) continue to use data publicly reported on a CMS website from the programs described above as a basis to calculate the Overall Star Ratings, and (2) codify this at §412.190. We invite public comment on our proposals.

B. Critical Access Hospitals in the Overall Star Rating

1. Current Critical Access Hospitals in the Overall Star Rating

The current Overall Star Rating is calculated based on certain data that is publicly reported on a CMS website and includes data from hospitals and facilitates that provide acute inpatient and outpatient care, including critical access hospitals (CAHs). Many CAHs currently voluntarily submit measure data consistent with certain CMS quality programs and elect to have their quality measure data publicly reported through their QualityNet account by selecting Optional Public Reporting Notice of

Participation. We note, however, that the Hospital OQR Program no longer uses a Notice of Participation form (83 FR 59103 through 59104). Submission of data through the Hospital OQR Program is considered participation specifically in that program. If a CAH elects to voluntarily submit data and have their quality measure data publicly reported, they are subsequently eligible to receive a star rating so long as they meet the specified reporting thresholds, discussed in detail in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating.

We note that many CAHs do not meet the minimum threshold to receive a star rating due to serving too few patients to report some of the underlying measures. To date, typically anywhere from 48 to 55 percent of CAHs report enough measures to receive a star rating.

2. Proposal to Continue to Include Critical Access Hospitals in the Overall Star Rating

In this proposed rule, the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue to include voluntary measure data from CAHs for the purpose of calculating Overall Star Rating through authority in section 1704 of the Public Health Service Act (PHSA)[115]. Section 1704 of the PHSA states that "The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters." We believe that this authority allows the agency to include CAHs in Overall Star Rating because the purpose of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make informed decisions about their healthcare. We have an existing contract mechanism through our current

[115] Public Health Service Act of 2019, Pub. L. 116–69, Page 133 STAT. 1134, codified as amended at 42 U.S.C. § 201.

Healthcare Quality Analytics and Reports (HCQAR) contract, which would continue under a future similar contract vehicle as appropriate, for the calculation of the Overall Star Rating for all hospitals that provide acute inpatient and outpatient care, including CAHs, and for the dissemination of reports to these hospitals prior to public release. Any hospital or facility providing acute inpatient and outpatient care, including CAHs, with measure or measure group scores reported on *Hospital Compare* or its successor website are given a confidential hospital-specific report (HSR) during the Overall Star Rating preview where they may review their measure, measure group, and star rating results prior to public release. The Overall Star Rating preview period and confidential hospital-specific reports are discussed in more detail in section F. Preview Period.

In addition, section 1851(d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[116] Many CAHs are located in remote areas that face unique challenges in resources and are often one of the only options for patients to seek care.[117] We believe it is important to include CAH data when available because it aligns with CMS goals of healthcare transparency, consumer choice, and the guiding principle of the Overall Star Rating, which is to include as much information as possible about hospital quality. The inclusion of CAHs in the Overall Star Rating has been supported by the Health Resources and Services Administration (HRSA) through their ongoing work with rural hospitals and facilities that provide acute inpatient and outpatient care, including CAHs. HRSA encourages CAHs to report quality measure data as part of quality improvement and public reporting and supports the inclusion of publicly reported measure scores for CAHs within the Overall Star Rating. Additionally, as part of ongoing stakeholder

[116] U.S Congress. (1934) United States Code: Social Security Act, 42 U.S.C §§1851.
[117] Centers for Medicare & Medicaid Services. (2013, April 9). *Critical Access Hospitals.* Retrieved from www.cms.gov: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs

engagement activities, we have heard from some CAHs that they are interested in receiving a star rating and that voluntary measure reporting places no additional burden on CAHs.

Therefore, we propose that CAHs that wish to be voluntarily included in the Overall Star Rating must have elected to both a.) voluntarily submit quality measures included in and as specified by CMS hospital programs and b.) publicly report their quality measure data on one of CMS' public websites. We propose to codify this at §412.190. CAHs that do not elect to participate or that elect to withhold their data from public reporting will not be included in the Overall Star Rating calculation. Since CAHs voluntarily report measures, CAHs may have their Overall Star Rating withheld from public release provided they submit a timely request, as described in more detail under section G. Overall Star Rating Suppressions.

Of note, the proposal to peer group hospitals by the number of measure groups, as outlined in section E.7. Proposed Approach to Peer Grouping Hospitals, is dependent on CAH participation in the Overall Star Rating since CAHs make up approximately half of the hospitals within the three measure peer group and excluding CAHs from the Overall Star Rating would not provide a sufficient amount of hospitals to make peer group comparisons.

We invite public comment on our proposals to include CAHs in the Overall Star Rating, the processes for CAHs to a.) voluntarily submit quality measures included in CMS hospital programs and b.) publicly report their quality measure data on one of CMS' public websites, and to codify this at §412.190. We note that for the purposes of the rest of this discussion, we will refer to both subsection (d) hospitals and CAHs as "hospitals."

C. Veterans Health Administration Hospitals in the Overall Star Rating

In this proposed rule, we propose to include quality measure data from Veterans Health Administration hospitals (VHA hospitals) for the purpose of calculating Overall Star Rating beginning

with the CY 2023. CMS has an existing contract mechanism with the Veterans Health Administration (VHA) through an Interagency Agreement to publish their hospitals' quality measure data on *Hospital Compare* [118] in accordance with section 206(c) of the Veterans Access, Choice, and Accountability Act (Choice Act) of 2014 (Pub. L. 113-146).[119]

Furthermore, section 1704 of the PHSA[120] allows the Secretary to make health information available to consumers of medical care through grant or contract mechanism including, but not limited to, the publication of health information. In addition, section 1851(d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options[121]. We believe this includes the publication of quality measure data and Overall Star Rating for VHA hospitals.

Therefore, in this proposed rule, we propose to include VHA hospitals in the Overall Star Rating beginning in CY 2023. Including VHA hospitals in the Overall Star Rating beginning in CY 2023 allows CMS to establish the methodology through this proposed rule and host confidential reporting of the Overall Star Rating for VHA hospitals prior to public release of VHA star ratings. In order to be eligible to receive a star rating, VHA data would be subject to the same reporting threshold as subsection (d) hospitals and CAHs included in the Overall Star Rating (proposed as three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each measure group as discussed in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating).

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[118] Centers for Medicare & Medicaid Services. (2016, October 19). *Veterans Health Administration Hospital Performance Data*. Retrieved July 6, 2020, from www.cms.gov; https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/VA-Data

[119] Veterans Access, Choice, and Accountability Act of 2014, Pub. L. 113-146, Page 128 STAT. 1754, codified as amended at 38 U.S.C. § section 1703C(b)(1).

[120] Public Health Service Act of 2019, Pub. L. 116–69, Page 133 STAT. 1134, codified as amended at 42 U.S.C. § section 201.

[121] U.S Congress. (1934) United States Code: Social Security Act, 42 U.S.C §§1851.

We anticipate that adding VHA hospital data to the Overall Star Rating calculation would influence national results due to several steps in the Overall Star Rating methodology that inherently assess quality measure performance in a relative manner, or by comparing hospitals to other hospitals. This influence is present in three places of the Overall Star Rating methodology: in the standardization of individual measure scores, in the standardization of measure group scores, and in the calculation of star ratings using k-means clustering. The addition of VHA hospitals has no direct influence on CMS-administered programs, however. CMS program impacts, including payment and burden, are assessed based on hospitals participating in CMS' programs and do not include VHA hospitals in those determinations. CMS intends to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule.

We invite public comment on our proposal to include VHA hospitals in the Overall Star Rating beginning with CY 2023.

D. History of the Overall Hospital Quality Star Rating

Prior to introduction of the Overall Star Rating on the *Hospital Compare* website in July 2016, we engaged stakeholders throughout development of the methodology. CMS' Overall Star Rating development contractor convened both a Technical Expert Panel (TEP), consisting of national statistical experts, providers, purchasers, and patient advocates, and a Patient & Advocate Work Group, as well as hosted two public input periods [122] [123] to gain stakeholder feedback on aspects of the methodology. Specifically, feedback was solicited on topics such as measure inclusion and groupings, statistical and non-statistical approaches to summarizing measures, weightings for individual measures and measure

[122] Centers for Medicare & Medicaid Services. (2015, January). *Hospital Compare Star Ratings Public Comment Report 1: Measure Selection for Hospital Star Ratings.*

[123] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

groups, and approaches to classifying hospitals to star ratings. In 2015, we hosted a confidential hospital dry run to provide all hospitals and facilities that provide acute inpatient and outpatient care with a private report on their measure performance, measure group scores, and star ratings results, which allowed hospitals to preview their preliminary results without public posting and to familiarize themselves with the methodology.[124] Concurrent with the July 2016 preview period, we also hosted a national provider call to present the final methodology and answer stakeholder questions.[125]

For the initial July 2016 and each subsequent release of the Overall Star Rating, including October 2016, December 2016, December 2017, February 2019, and January 2020, we have continuously provided resources to maintain transparency and facilitate understanding of the methods, including three National Provider Calls[126] [127] [128] as well as methodology reports,[129] hospital-specific reports,[130] and open access datasets with quality measure data used to calculate the Overall Star Rating (referred to as the public input file), and SAS programing code used to calculate the Overall Star Rating

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[124] Centers for Medicare & Medicaid Services. (2018, September 18). *Hospital Compare Overall Star Ratings Dry Run Q&A.* Retrieved from www.qualitynet.org: https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab4

[125] Centers for Medicare & Medicaid Services. (2015, August 13). *Centers for Medicare & Medicaid Services Hospital Compare Overall Star Ratings Methodology MLN Connects National Provider Call.* Retrieved from www.cms.gov: https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-08-13-Star-Ratings

[126] Ibid.

[127] Centers for Medicare & Medicaid Services. (2016, May 12). *Centers for Medicare & Medicaid Services Overall Hospital Quality Star Ratings on Hospital Compare National Provider Call.* Retrieved from: https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/hospital-inpatient-quality-reporting-iqr-program/archived-events/hiqr-event134/

[128] Centers for Medicare & Medicaid Services. (2017, November 30). *Centers for Medicare & Medicaid Services Hospital Quality Star Ratings on Hospital Compare December 2017 Methodology Enhancements National Provider Call.* Retrieved from: https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/hospital-inpatient-quality-reporting-iqr-program/archived-events/hiqr-event107/

[129] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from: https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf

[130] Centers for Medicare & Medicaid Services. *Hospital-Specific Reports.* Retrieved from: https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/reports

along with supporting documents to allow stakeholders to understand and replicate the Overall Star Rating results.

Since the introduction of the Overall Star Rating on the *Hospital Compare* website in July 2016, the Overall Star Rating development contractor has continued to engage stakeholders by convening two additional TEPs, maintaining the Patient & Advocate Work Group, convening a new Provider Leadership Work Group, consisting of hospital quality and medical staff, and hosting two additional public input periods.[131] [132] As a result of ongoing reevaluation and stakeholder engagement, we updated the methodology in December 2017 and February 2019. CMS also hosted a National Provider Call[133] to facilitate the December 2017 methodology enhancements and nine listening sessions to facilitate the February 2019 methodology enhancements. The current methodology includes enhancements made in December 2017[134] and February 2019[135].

1. Reevaluation of the Overall Hospital Quality Star Rating Methodology

The Overall Star Rating is a summary of certain existing hospital quality information, which is collected and reported as part of several CMS programs to improve and make transparent the quality of care provided at hospitals that provide acute inpatient and outpatient care. As the underlying measures reported on *Hospital Compare* have been added, updated, and removed, and as stakeholders have begun

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[131] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[132] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[133] Centers for Medicare & Medicaid Services. *Overall Hosptial Quality Star Ratings on Hospital Compare.* (2016, 12 May). Retrieved from www.qualityreportingcenter.com: https://www.qualityreportingcenter.com/globalassets/migrated-pdf/iqr_20160512_npc-overall-star-rating_vfinal5.9.16.508.pdf

[134] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources

[135] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2

using the methodology for purposes beyond consumer transparency, including provider quality improvement efforts, we propose refinements to the methodology of the Overall Star Rating. Since the first reporting of the Overall Star Rating in July 2016, we have maintained an active monitoring and re-evaluation process for the methodology, as well as engaged stakeholders for continuous feedback. Based on this ongoing reevaluation work, we have released multiple, iterative updates to the methodology in December 2017[136] and February 2019[137] that addressed stakeholder concerns revealed through previous stakeholder engagement by the TEP[138] [139] and during public input. We refer readers to section E.4.a.(2) Latent Variable Modeling Measure Loadings for an overview of the February 2019 methodology updates.

Between 2018 and 2019, CMS' Overall Star Rating development contractor received input on several potential methodology updates through two TEP meetings,[140] three Patient & Advocate Work Group meetings, two Provider Leadership Work Group meetings, nine public listening sessions,[141] and one public input period.[142] Through these reevaluation analyses and stakeholder engagement, we identified three aforementioned overarching areas of improvement for the Overall Star Rating

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[136] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources

[137] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2

[138] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[139] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[140] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[141] Centers for Medicare & Medicaid Services. (2019, November). *Overall Hospital Quality Star Rating Listening Session Meeting Summary Report.* Retrieved from https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report

[142] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

methodology – simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals that provide acute inpatient and outpatient care.[143] [144] Simplicity of the methodology means we aim to reduce the statistical complexity of the methodology, while maintaining a representative summary of hospital quality data, so that stakeholders can better understand how the Overall Star Rating is calculated. Predictability of measure emphasis within the methodology over time means we aim to create a methodology that assigns similar measure weight, or emphasis, to each measure to calculate measure group scores and Overall Star Rating over time (each Overall Star Rating publication). Comparability of ratings among hospitals means we aim to create a methodology that compares hospitals that are more similar to each other, such as the measures they report or services they provide, when calculating the Overall Star Rating.

Since the original introduction of the Overall Star Rating, stakeholders have requested a less complex, or simplified, methodology so that providers can better understand the methodology, interpret their star rating, and use the Overall Star Rating to identify areas for quality improvement.[145] We developed the current methodology under the original principles of the Overall Star Rating, which was to use a statistical approach to summarize quality measures for patients.[146] The current methodology aims to prioritize patient usability and employs data-driven statistical modeling approaches, including

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[143] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-U pdates-on-Previous-Comment-Periods#a0815

[144] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[145] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[146] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from: https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf

latent variable modeling[147] and k-means clustering,[148] to calculate measure group scores and to assign hospital summary scores to star ratings. In summary, the current methodology is designed to rely on data for several critical steps in the star ratings calculation. A couple of the proposed methodology updates aim to increase the simplicity of the methodology for health care providers seeking to replicate, better understand, or communicate an interpretation of the Overall Star Rating, -- including (1) regrouping measures into five measure groups, rather than seven, due to measure removals as a result of the Meaningful Measure Initiative discussed below in section E.3.b.(2) Proposed New Measure Group: Timely and Effective Care and (2) using a simple average of measure scores to calculate measure group scores discussed below in section E.4. Step 3: Calculation of Measure Group Scores.

Several proposed refinements aim to address the predictability of measure emphasis within the methodology over time. Between the December 2017 and the intended July 2018 publication of the Overall Star Rating, there were no Overall Star Rating methodology updates; however, there were several measure-level updates, including the introduction of two new measures (Severe Sepsis and Septic Shock: Early Management Bundle and Pneumonia Excess Days in Acute Care), the removal of one measure (Pneumonia 30-day Readmission), and updated specifications for the CMS Patient Safety Indicator Composite (CMS PSI-90) measure.[149] The updates to the underlying measures for the July 2018 confidential preview period resulted in differences in the emphasis of measure contributions to the star rating calculation from previous releases.[150] These observed changes in star ratings were similar to

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[147] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

[148] Illowsky, B., & Dean, S. (2013). *Introductary Statistics.* Houston, TX: 12th Media Services. Retrieved from: https://openstax.org/details/books/introductory-statistics.

[149] Centers for Medicare & Medicaid Services. *Hospital-Specific Reports.* Retrieved from: https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/reports

[150] Centers for Medicare & Medicaid Services. (2018, May). Quarterly Updates and Specifications Report: July 2018. Retrieved from: https://www.qualitynet.org/files/5d0d3abf764be766b0104a21?filename=StarRatingsJul18_UpdtSpecsRpt.pdf

star rating shifts observed between reporting periods for other CMS star rating programs, however greater than the shifts observed in prior Overall Star Rating publications. While some shifts in star ratings are expected as hospital performance worsens or improves relative to other hospitals in the nation and as measures are added, updated, and removed from the Overall Star Rating calculation, results from the July 2018 confidential preview period illuminated the extent of the sensitivity of a data-driven statistical model to underlying measure updates. As a result of this unexpected change in measure emphasis, we did not move forward with public release of the July 2018 Overall Star Rating and instead focused on potential improvements to the methodology and stakeholder engagement. Several of the proposed methodology updates, including (1) regrouping measures into five measure groups, rather than seven, due to measure removals as a result of the Meaningful Measure Initiative, discussed below in section E.3. Step 2: Assignment of Measures to Groups; (2) use of a simple average of measure scores to calculate measure group scores, discussed below in section E.4.b. Proposal to Use a Simple Average of Measure Scores to Calculate Measure Group Scores; and (3) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating discussed below in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating, aim to address concerns around the predictability of measure emphasis, and in turn star ratings, over time.

Comparability of the Overall Star Rating is a commonly expressed priority by stakeholders.[151] [152] Hospitals that provide acute inpatient and outpatient care differ in size or patient volume, geographical

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[151] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[152] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

location, urban or rural location, patient populations treated, and services offered. In turn, hospitals differ in the number and type of quality measures reported. All hospitals providing acute inpatient and outpatient care, regardless of differences in any of these characteristics, are included within the Overall Star Rating calculation and are eligible to receive a star rating. Stakeholders, primarily providers on the TEP, Provider Leadership Work Group, and during a public input period, have highly recommended that the Overall Star Rating account for differences in hospital case-mix or type to increase comparability of hospital star ratings.[153] [154] Several of the proposed methodology updates, including (1) stratifying the Readmission measure group according to proportion of dual-eligible patients at each hospital; (2) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating discussed below in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating; and (3) peer grouping hospitals by number of measure groups, discussed below in section E.7. Proposed Approach to Peer Grouping Hospitals, aim to increase the comparability of hospitals for patients and providers.

In 2019, we conducted extensive analyses and engaged multiple stakeholder groups to evaluate each of the proposed methodology updates outlined below. Most notably, CMS' Overall Star Rating development contractor recruited and convened a third TEP to provide technical input,[155] a second Provider Leadership Work Group to provide policy input, and a second Patient & Advocate Work Group

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[153] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[154] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[155] Ibid.

to provide input on usability, and we hosted a public listening session,[156] all to gain a range of new perspectives on the current methodology and potential methodology updates.

E. Current and Proposed Overall Star Rating Methodology

1. Overview

The current Overall Star Rating methodology can be outlined within six steps briefly described here and in more detail further below. In the first step, the measures are selected from among those reported on *Hospital Compare* to include as much information as possible while considering whether the measures are suitable for combination within the Overall Star Rating. In the first step, the measure scores are also standardized to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. In the second step, the measures are grouped into one of seven measure groups. Third, for each group, a statistical model, called a latent variable model (LVM), is used to determine a group score for each hospital reporting on measures in that group. In the fourth step, a weight is applied to each measure group score and all available measure groups are averaged to calculate the hospital summary score. In the fifth step, hospitals that provide acute inpatient and outpatient care reporting too few measures and measure groups are excluded. Finally, hospital summary scores are organized into five categories, representing the five star ratings, using an algorithm process called k-means clustering. K-means clustering is a method to cluster data so that observations within one cluster are more similar to each other than observations in another cluster.[157]

In this proposed rule, for public release of the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to both retain and update certain aspects of the current Overall Star Rating

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[156] Centers for Medicare & Medicaid Services. (2019, November). *Overall Hospital Quality Star Rating Listening Session Meeting Summary Report.* Retrieved from https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report

[157] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641

methodology, as outlined below within each of the six steps of the current methodology. Generally, we propose to retain the following aspects of the current Overall Star Rating methodology:

- An annual publication cycle using data posted on *Hospital Compare* or its successor site from data publicly reported within the prior year; for example, the Overall Star Ratings published in January 2020 used data publicly reported from the October 2019 refresh;
- Suppression policy for subsection (d) hospitals;
- Inclusion of measures publicly reported on *Hospital Compare* or its successor sites that meet specific inclusion and exclusion criteria and standardization of measure score within Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating;
- Publicly displaying measure group level information for measure groups for which a hospital has at least three measures, use of weighted average of measure group scores to calculate summary scores and measure group reweighting to account for measure group scores which are not reported within Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores; and
- Use of k-means clustering to assign hospitals that provide acute inpatient and outpatient care to one of five star ratings within Step 6: Application of Clustering Algorithm to Obtain a Star Rating.

We propose to make the following methodology updates:

- Regroup measures as a result of the Meaningful Measure Initiative (83 FR 41147 through 41148) by combining the three process measure groups into one group, Timely and Effective Care, within Step 2: Assignment of Measures to Groups;
- Update the calculation of measure group scores to include standardization of measure group scores and to use a simple average of measure scores, rather than latent variable modeling;
- Stratify the Readmission measure group scores using the proportion of dual-eligible patients at each hospital within Step 3: Calculation of Measure Group Scores;

- Change the reporting thresholds to receive a star rating to three measures within three measure groups, one of which must be Mortality or Safety of Care, within Step 5: Application of Minimum Thresholds for Receiving a Star Rating; and

- Apply peer grouping of hospitals that provide acute inpatient and outpatient care based on number of measure groups between Step 5: Application of Minimum Thresholds for Receiving a Star Rating and Step 6: Application of Clustering Algorithm to Obtain a Star Rating. These are discussed in more detail in section E.7. Proposed Approach to Peer Grouping Hospitals.

2. Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating

a. Timeframe

(1) Current Timeframe

Generally, for CMS quality programs, we update measure data results on the *Hospital Compare* or its successor website quarterly in January, April, July, and October of each year. In the past, the Overall Star Rating was published on *Hospital Compare* both quarterly and biannually. Beginning in February 2019, the Overall Star Rating was published annually. In January 2020, the Overall Star Rating continued the annual publication cycle with the additional approach of using data publicly posted on *Hospital Compare* in a quarter prior to the update to calculate star ratings. For example, we used October 2019 publicly reported measure data on *Hospital Compare* to calculate Overall Star Rating results for the January 2020 publication.[158] Note that the data collection period for each measure varies depending on measure specifications that set minimum case requirements to ensure individual measure reliability and meet the requirements of CMS quality programs, as detailed in each program's respective rules as well as on *Hospital Compare* or its successor website.

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[158] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2

(2) Proposal to Retain Current Timeframe With Modification

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to retain the current timeframe with modification, such that the Overall Star Rating would continue to be published once annually; however, instead of using data from the same quarter as or the quarter prior to the publication of the Overall Star Rating , we would use publicly available measure results on *Hospital Compare* or successor website from a quarter within the prior year. As mentioned above, for CMS quality programs, we generally update measure data results on the *Hospital Compare* or its successor website quarterly in January, April, July, and October of each year. Therefore, we would use publically reported data from one of those four *Hospital Compare* refreshes to calculate the Overall Star Rating. For example, for a January 2021 Overall Star Rating release, we could use data refreshed on *Hospital Compare* in , July or October of 2020. We propose to codify this timeframe at §412.190.

We believe publishing the Overall Star Rating once a year is appropriate because it may minimize period to period changes in hospital star ratings that may result from small changes in individual hospital and national performance for the underlying measures. Furthermore, publishing the Overall Star Ratings once a year would allow time for the star ratings to reflect improvements or updates in hospital performance on the underlying measures. It also is aligned with the current cycle of many underlying measures, particularly highly weighted outcome measures that are also refreshed annually. Also, using data publicly reported on *Hospital Compare* or its successor website within the prior year, rather than data publicly reported concurrent with the Overall Star Rating, would allow providers more time, beyond the standard 30 days, to review their star rating as well as the measure and measure group results that contribute to their star rating during the confidential preview period (we refer readers to section F. Preview Period). Hospitals that provide acute inpatient and outpatient care may use this

additional time to more thoroughly anticipate and understand their results as well as generate communication or improvement strategies.

We invite public comment on our proposals to: (1) publish the Overall Star Rating once annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year, and (2) codify this at §412.190.

b. Measure Inclusion

(1) Current Measure Inclusion

Generally, measures publicly reported on *Hospital Compare* or its successor site through CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, were used to calculate Overall Star Rating. We did not include publicly reported measures from any CMS programs not measuring acute inpatient or outpatient care or pertaining to specialty hospitals, such as cancer hospitals, and ambulatory surgical centers, such as the PPS-Exempt Cancer Hospitals Quality Reporting (PCHQR) Program, Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, or Ambulatory Surgical Centers Quality Reporting (ASCQR). The goal of Overall Star Rating is to summarize quality of care at hospitals providing acute inpatient and outpatient care and thus, only include measure scores representing quality of acute inpatient and outpatient care.

Any measures that were removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* or successor website were not included.

(2) Proposal to Retain Current Measure Inclusion

In this proposed rule, we propose to continue the same practice by incorporating measures summarizing quality of care at inpatient and outpatient care hospitals in the Overall Star Rating. Specifically, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to use

certain measures publicly reported on the *Hospital Compare* or successor website through certain CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, to calculate the Overall Star Rating. We also propose to codify this policy at §412.190.

We believe hospital inpatient and outpatient measures publicly reported on *Hospital Compare* or its successor website are appropriate for the Overall Star Rating because they capture the quality of care at hospitals providing acute inpatient and outpatient care and provide a snapshot of quality when combined together. We recognize that measures reported on *Hospital Compare* or its successor website undergo a rigorous development process which includes extensive measure testing, vetting by stakeholders, evaluation by the National Quality Forum, and undergo rulemaking for inclusion in CMS programs and public reporting. We have not and do not intend to make any changes to the underlying measures or measure scores specifically for the calculation of the Overall Star Rating. As such, the Overall Star Rating methodology uses the measures as specified under the CMS programs, and measure scores as reported on *Hospital Compare* or its successor website at the time of the Overall Star Rating calculation. As noted above, any measures that are removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* or successor website are not included. Additional measure exclusions are discussed in the next section. Also, we refer readers to sections B. Critical Access Hospitals in the Overall Star Rating and C. Veterans Health Administration Hospitals in Overall Star Rating for our discussions about CAHs and VHA hospitals.

We invite public comment on our proposals: (1) use measures publicly reported on *Hospital Compare* or its successor websites through certain CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Programs, for the Overall Star Rating in CY 2021 and subsequent years, and (2) codify this policy at §412.190.

c. Measure Exclusions

(1) Current Measure Exclusions

Of the measures publicly reported on the *Hospital Compare* website through the CMS quality programs listed in a previous section, in the past, we have excluded some measures from the Overall Star Rating methodology for various reasons. The measures excluded fall into the following categories:

1. Measures with no more than 100 hospitals reporting performance publicly, as these measures would not produce reliable measure group scores based on so few hospitals;

2. Structural measures not amenable to inclusion in a summary scoring calculation alongside process and outcome measures, as these measures cannot be as easily combined with other measures captured on a continuous scale with more granular data;

3. Non-directional measures (for which it is unclear whether a higher or lower score is better, such as payment measures), as these measures cannot be standardized to form an aggregate measure group score;

4. Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs, that is the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program and Hospital VBP Program, due to the purpose of Overall Star Rating being a summary of measure information as displayed on *Hospital Compare* or its successor websites;

5. Overlapping measures (for example, measures that are identical to another measure, measures with substantial overlap in cohort and/or outcome, and measures that are part of an already-included composite measure), in order to avoid duplicative measure results within the methodology; and

6. Measures with statistically significant negative loadings estimated by the LVM as described further in section E.4.a.(2) Latent Variable Model Measure Loadings.

In February 2019, we excluded measures for which the LVM estimates as statistically significant negative loading, which indicated the measure had an inverse relationship with other measures in the group.[159] LVM is the a statistical method for combining information that represents a latent trait, in this case measures within a measure group that represent an aspect of hospital quality, to estimate a numerical score, in this case measure group scores.[160] Measure loadings are the contribution, or emphasis, of each measure as assigned by the LVM.[161] Latent variable modeling and measure loadings are described in more detail under section E.4. Step 3: Calculation of Measure Group Scores below.

(2) Proposal to Retain and Update Select Measure Exclusions

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we intend to continue to exclude certain measures used to calculate the Overall Star Rating. We believe these measure exclusions remain appropriate moving forward because the Overall Star Rating is a summary of the existing publicly reported measures of hospital quality of care but not all measure scores can be reliably or appropriately combined with other measure scores. These are discussed in more detail below.

1. We propose to continue to exclude measures that only 100 hospitals or less publicly report. These measures would not produce reliable measure group scores based on too few hospitals.;

2. We propose to continue to exclude measures that are not able to be standardized and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome

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[159] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019)*. Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2

[160] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

[161] Ibid.

measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data.;

3. We propose to continue to exclude non-directional measures for which it is unclear whether a high or lower score is better. Without directional scores these measures cannot be standardized to be combined with other measures and form an aggregate measure group score as detailed in section E.2.d Measure Score Standardization.;

4. We propose to continue to exclude measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs.; and

5. We propose to continue to exclude measures that overlap with another measure in terms of cohort or outcome; this includes component measures that are part of an already-included composite measure. This exclusion criterion avoids duplicative measure results within the Overall Star Rating methodology. In general, we would determine which measures to include or exclude based on the level of information provided by the measure. For example, we would include a composite measure, such as PSI-90, over the component measures, such as PSI-03. As another example, we would include the excess days in acute care (EDAC) measures over the readmission measures, because while both measure sets have the same cohort, the EDAC measures capture a broader outcome inclusive of emergency department visits and observation stays in addition to the unplanned readmissions captured by both measures.

We also propose to codify these exclusions at §412.190. We note that we are not proposing to continue to exclude measures with statistically significant negative loadings estimated by the LVM. (Measure loadings are the contribution, or emphasis, of each measure as assigned by the LVM.[162] and are further discussed in section E.4.a.(2) Latent Variable Model Measure Loadings). This is because, in

[162] Ibid.

section E.4.b. of this proposed rule, we propose to calculate measure group scores using a simple average of measure scores, instead of latent variable modeling. Should that proposal be finalized, measure loadings would no longer be produced as a product of latent variable modeling and, therefore, the exclusion criteria of measures with statistically significant negative loadings would no longer be necessary. However, should that proposal not be finalized, we would continue using LVM to calculate measure group scores and exclude measures with statistically significant negative loadings as discussed in section E.4.a.(2) Latent Variable Modeling Measure Loadings. We invite public comment on our measure exclusion proposals.

d. Measure Score Standardization

(1) Current Measure Score Standardization

In the past, once the relevant measures were excluded, the remaining measures are standardized to a single, common scale to account for differences in measure score units, such as ratios or rates, and direction, specifically whether a higher or lower score indicates better quality.[163] It is necessary to standardize all measure scores to the same scale (that is, units and direction) for combination into and calculation of measure group scores. To standardize, we used a statistical technique to calculate Z-scores for each measure.[164] A Z-score is a standard deviation score, which relays the amount of variation in a dataset, or in this case, the variation in hospital measure scores. In the Overall Star Rating, Z-scores were produced by subtracting the national mean measure score from each hospital's measure score and dividing by the standard deviation[165] across hospitals. Standard deviation is a number that

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[163] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1

[164] DeVore, G.R. (2017, January 17). "Computing the Z score and centiles for cross-sectional analysis: a practical approach." Journal of Ultrasound in Medicine 36.3: 459-473.

[165] Illowsky, B., & Dean, S. (2013). *Introductary Statistics.* Houston, TX: 12th Media Services. Retrieved from: https://openstax.org/details/books/introductory-statistics.

measures how far data values are from their average.[166] See the measure score standardization example and table 46. In addition, we changed the direction of all measures that indicate better performance with a lower score so that they were reversed to uniformly indicate that a higher score indicates better performance for all the measures prior to combination with other measures to calculate measure group scores.

(2) Proposal to Retain Current Measure Score Standardization

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue to standardize measure scores as it allows for measures, which are different in units and direction, to be combined into aggregate measure group scores. Specifically, we propose that once applicable measures are excluded, we would standardize the remaining measures by calculating Z-scores for each measure prior to being combined in an aggregate measure group score so that all measures are on a single, common scale. That is, we would subtract the national mean measure score from each hospital's measure score and divide the difference by the measure standard deviation in order to standardize measures. We also propose to codify this at §412.190.

Example of Standardization of Measure Score

Standardized measures score (HAI-6) = - (0.470-0.694)/0.49 = 0.46

TABLE 46: EXAMPLE OF STANDARDIZATION OF MEASURE SCORES WITHIN SAFETY OF CARE MEASURE GROUP

Measure Name	Measure Score	Measure National Mean Score	Measure Standard Deviation	Standardized Measure Score
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	2.66%	0.005	-1.13

[166] Ibid.

HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	1.233	0.736	0.66	-0.75
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	0.747	0.806	0.64	0.09
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	0.000	0.826	0.68	1.21
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	0.000	0.867	0.89	0.97
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	0.166	0.843	0.69	0.98
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.694	0.49	0.46
PSI-90 Complication/Patient Safety for Selected Indicators	0.999	0.996	0.18	0.02

We invite public comment on our proposal to standardize measure scores and codify this policy at §412.190.

e. Measure Score Winsorization

(1) Current Measure Score Winsorization

In the past, to avoid extreme outlier performance that may be potentially inaccurate or pose technical challenges to statistical estimations, the standardized measure scores were Winsorized[167] at the 0.125th and 99.875th percentiles of a standard normal distribution so that all measure scores range from negative 3 to positive 3 (-3 to 3). Winsorization[168] is a common strategy used to set extreme outliers to a specified percentile of the data. This step was necessary in order to minimize the impact of extreme measure score outliers on the performance of the latent variable modeling (LVM) (we refer readers to section E.4.a.(1) Latent Variable Modeling Overview for details). We chose to Winsorize the 0.125th

[167] Kwak, S.K., & Kim, J.H. (2017, July 27)."Statistical data preparation: management of missing values and outliers." Korean journal of anesthesiology 70.4: 407.
[168] Ibid.

and 99.875th percentiles to minimize the number of scores requiring Winsorization, while also allowing the models to perform properly and produce results. This approach to measure inclusion and standardization within the Overall Star Rating has been vetted previously through the TEP,[169] [170] Patient & Advocate Work Group, and a public input period.[171]

(2) Elimination of Measure Score Winsorization Moving Forward

We refer readers to section E.4.b. Proposal to Use a Simple Average of Measure Scores to Calculate Measure Group Scores of this discussion in this proposed rule, where moving forward, we propose to calculate measure group scores using a simple average of measure scores for the Overall Star Rating beginning in CY 2021 and subsequent years, instead of latent variable modeling, as was used in the past. Because Winsorization was only necessary to minimize the impact of extreme outliers prior to statistical modeling to ensure model stability, the absence of LVM would eliminate the need for Winsorization. Eliminating Winsorization would be consistent with the proposal to replace the LVM with a simple average of measure scores, would support the goal of refinements to simplify the methodology, and would retain the original, observed performance of outlier hospitals within the calculations. However, should we not finalize our proposal to adopt the simple average of measure scores and retain LVM to calculate measure group scores, as discussed in section E.4.a. Current Approach to Calculating Measure Group Scores Using Latent Variable Modeling, we would continue to Winsorize measure scores to minimize the impact of extreme outliers.

3. Step 2: Assignment of Measures to Groups

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[169] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[170] Centers for Medicare & Medicaid Services. (2014, December). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[171] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

a. Past Assignment of Measures to Groups

In the past, we have grouped measures into one of seven measure groups: Mortality, Safety of Care, Readmission, Patient Experience, Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging. Measures were grouped this way to align with the Hospital VBP Program[172] and the previous display of *Hospital Compare*,[173] to clinically reflect shared components of hospital quality, allow for measures to be added or removed as they are added or removed from public reporting, and to be useful to patients in making healthcare decisions as communicated by the Patient & Advocate Work Group. Grouping measures is also consistent with other CMS star rating initiatives, including Nursing Home Compare Star Ratings,[174] Medicare Plan Finder Star Ratings,[175] and Dialysis Facility Compare.[176]

b. Proposed New Measure Group and Continuation of Certain Groups

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to consolidate the three process measure groups – Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging – into one process measure group: Timely and Effective Care. We also propose to retain the current structure of the Mortality, Safety of Care, and Readmission, and the Patient Experience measure groups. These are discussed in more detail below.

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[172] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1

[173] Centers for Medicare & Medicaid Services. (2019) *Hospital Compare.* Retrieved from: www.medicare.gov/hospitalcompare: https://www.medicare.gov/hospitalcompare/search.html?

[174] Centers for Medicare and Medicaid Services (2019, October). Design for Nursing Home Compare. Retrieved from www.cms.gov: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/usersguide.pdf

[175] Centers for Medicare and Medicaid Services (2019, October 1). Medicare 2020 Part C & D Star Ratings Technical Notes. Retrieved from www.cms.gov: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Star-Ratings-Technical-Notes-Oct-10-2019.pdf

[176] Centers for Medicare and Medicaid Services (2016, June). Technical Notes on the Updated Dialysis Facility. Retrieved from dialysisdata.org: https://dialysisdata.org/sites/default/files/content/Methodology/UpdatedDFCStarRatingMethodology.pdf

(1) Continuation of the Mortality, Safety of Care, Readmission, and Patient Experience Measure Groups.

The Mortality, Safety of Care, Readmission, and Patient Experience measure groups were used in the past as noted above. The Mortality, Safety of Care, Readmission, and Patient Experience measure groups contain an adequate number of publicly reported measures to produce robust measure group scores, reflective of differences in hospital quality. These measure groups were not as affected as the process of care measure groups, discussed in the next section, by the Meaningful Measure Initiative (83 FR 41147 through 41148)[177]. In this proposed rule, for the Overall Star Rating beginning CY 2021 and subsequent years, we propose to continue to use these measure groups. We also propose to codify these measure groups at §412.190.

(2) Proposed New Measure Group: Timely and Effective Care

Since the first release of the Overall Star Rating, measures have been: (1) developed and adopted in CMS programs to address measurement gaps, and also (2) removed as a result of the Meaningful Measures Initiative (83 FR 41147 through 41148).[178] However, there has been a steady overall reduction in both the number of measures in CMS quality programs, as well as the number of measures publicly reported and available for inclusion in the Overall Star Rating– from 64 measures in the first publication of Overall Star Rating in 2016, to 51 measures for the most recent January 2020 publication.

[177] Ibid.

[178] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 Fed. Reg. 41147 (Aug 17, 2018) (to be codified at 42 C.F.R. parts 412, 413, 424 and 495)

More specifically, as finalized in the CY 2018[179] and CY 2019 OPPS/ASC[180] final rules, and the FY 2019 IPPS/ LTCH PPS final rule,[181] resulting from the Meaningful Measure Initiative (83 FR 41147 through 41148),[182] the following 12 process measures have been removed from the Hospital IQR and Hospital OQR Programs, and therefore, also from public reporting and the Overall Star Rating process measure groups between CY 2019 and CY 2021.

From the Effectiveness of Care measure group:

- Influenza Immunization (IMM-2) (83 FR 41151),
- Influenza Vaccination Coverage Among Healthcare Personnel (OP-27) (83 FR 37179 through 37186),
- Aspirin at Arrival (OP-4) (82 FR 59430),
- Colonoscopy Interval for Patients with a History of Adenomatous Polyps (OP-30) (83 FR 37179 through 37186), and
- Incidence of potentially preventable VTE (VTE-6) (83 FR 41151).

From the Timeliness of Care measure group:

- Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED-1b) (83 FR 41151),
- Median Time to ECG (OP-5) (83 FR 37179 through 37186),
- Door to Diagnosis Evaluation by a Qualified Medical Professional (OP-20) (82 FR 59430),
- Median Time to Pain Management for Long Bone Fracture (OP-21) (82 FR 59428), and

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[179] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 59216 (Dec 14, 2017) (to be codified at 42 CFR parts 414, 416, and 419)
[180] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 58818 (Nov 21, 2018) (to be codified at 42 CFR parts 416 and 419)
[181] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41151 (Aug 17, 2018) (to be codified at 42 C.F.R. parts 412, 413, 424 and 495)
[182] Ibid.

- Median Time to Fibrinolysis (OP-1) (83 FR 37179 through 37186).

From the Efficient Use of Medical Imaging group:

- Thorax CT—Use of Contrast Material (OP-11) (83 FR 37179 through 37186), and
- Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT) (OP-14) (83 FR 37179 through 37186).

The aforementioned measure removals from CMS quality programs and public reporting ultimately result in two of the previously used measure groups, Timeliness of Care and Efficient Use of Medical Imaging, being comprised each of only three measures, which would not produce robust or predictable measure group scores.

Therefore, in this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose combining three previously used measure groups – Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging – into one group entitled Timely and Effective Care. We also propose to codify this new group at §412.190. This new consolidated group would reflect the principles of measure reduction under the Meaningful Measures Initiative and align with the current display of measures on *Hospital Compare*.[183] This consolidation would be necessary to ensure that a sufficient number of measures exist in this group.[184] [185] [186] In general, the TEP supported

[183]Centers for Medicare & Medicaid Services. *Hospital Compare*. (2019). Retrieved from www.medicare.gov/hospitalcompare: https://www.medicare.gov/hospitalcompare/search.html?

[184] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41151 (Aug 17, 2018) (to be codified at 42 C.F.R. Parts 412, 413, 424 and 495)

[185] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 59216 (Dec 14, 2017) (to be codified at 42 CFR Parts 414, 416, and 419)

[186] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 58818 (Nov 21, 2018) (to be codified at 42 CFR Parts 416 and 419)

regrouping of measures into five measure groups with one process measure group (Timely and Effective Care) given the available measures and scheduled removal of measures in the upcoming years.[187]

In order to simulate the potential effects of these proposals, we used October 2019 publicly reported measure data on *Hospital Compare* to test the January 2020 Overall Star Rating to determine how many hospitals would be eligible to receive a star under the proposed measure grouping. Of the 4,576 hospitals that provide acute inpatient care, including CAHs, and reported measures on *Hospital Compare* in October 2019, 180 more hospitals (3,780 hospitals total) would have met the current reporting thresholds (that is, at least three measures in at least three measure groups, one of which must be an outcome group) to receive a star rating with the proposed five measure groups as compared to the original seven measure groups (3,600 hospitals). Additionally, the proposed new grouping would allow approximately 157 additional CAHs, beyond the 1,149 CAHs already receiving a star rating with the current methodology, to receive a star rating. To note, with the current methodology of seven measure groups, these 157 CAHs usually do not meet the minimum threshold to receive a star rating due to serving too few patients to report the underlying measures in each of the individual process groups. The minimum reporting threshold requirements are discussed in section E.6.b. Proposals to Update the Minimum Reporting Thresholds for Receiving a Star Rating of this proposed rule.

The above estimations of how many hospitals would receive a star rating are based on the measure regrouping methodology proposed in this rule; we note that other proposals may also influence hospitals meeting or not meeting reporting thresholds for star ratings. This measure regrouping proposal

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[187] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

aligns with the guiding principles of the Overall Star Rating,[188] which include being inclusive of hospitals and measure information, accommodating changes in the underlying measures, and accounting for the heterogeneity of available measures. We invite public comment on our proposed measure groupings and codification of those groupings.

4. Step 3: Calculation of Measure Group Scores

In the past, we have used latent variable modeling (LVM) to calculate measure group scores. In this proposed rule, we propose to replace LVM with a simple average of measure group scores to increase the simplicity of the methodology and predictability of measure weights within the methodology. LVM and the proposal to utilize a simple average of measure group scores is discussed in detail below.

a. Current Approach to Calculating Measure Group Scores Using Latent Variable Modeling

Latent Variable Modeling[189] (LVM) is a statistical approach used to combine or summarize multiple pieces of information, such as hospital quality measures, into a single number, such as measure group scores. LVM is described further within section E.4.a.(1) Latent Variable Modeling Overview below. Notably, LVM estimates loadings, or the contribution of each measure within each of the measure groups, using the data from hospitals that provide acute inpatient and outpatient care, as described in section E.4.a.(2) Latent Variable Modeling Measure Loadings. LVM also produces point estimates and standard errors for each hospitals' measure group score, allowing for the calculation of confidence intervals to assign hospitals with at least three measures in a measure group to "above,"

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[188] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from: https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf

[189] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

"same as," or "below the national average," as described in section E.4.a.(3) Measure Group Performance Categories.

(1) Latent Variable Modeling Overview

Latent Variable Modeling[190] (LVM) is a statistical approach used to combine or summarize multiple pieces of information and has been used to summarize information in a variety of settings ranging from education to healthcare.[191] [192] [193] The purpose for using LVM is to quantify the underlying quality trait, or an aspect of quality, as a number which best explains the correlation and variation of measures in a given group.

In the past, we have employed LVM to estimate measure group scores for each of the seven measure groups. In this context, LVM accounted for the relationship, or correlation, between measures for a given hospital so that measures that are more consistent with each other have a greater influence on the underlying aspect of quality calculated as a measure group score.[194] In addition, the LVM also accounted for differences in the size of each hospital's measure denominator so that measures with larger denominators also have more influence on the measure group score.[195]

When we developed the initial methodology for Overall Star Rating, we investigated multiple approaches to calculating measure group scores, including simple or weighted averages of measures, as well as more complex approaches such as LVM and factor analyses.[196] Both the simple and weighted

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[190] Ibid.

[191] Henderson CR. Best Linear Unbiased Estimation and Prediction under a Selection Model. Biometrics 1975;31:423-47.

[192] Shwartz M, Ren J, Pekoz EA, Wang X, Cohen AB, Restuccia JD. Estimating a composite measure of hospital quality from the Hospital Compare database: differences when using a Bayesian hierarchical latent variable model versus denominator-based weights. Med Care 2008;46:778-85.

[193] Landrum M, Bronskill S, Normand S-L. Analytic Methods for Constructing Cross-Sectional Profiles of Health Care Providers. Health Services and Outcomes Research Methodology 2000;1:23-47.

[194] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

[195] Ibid.

[196] Oh, J.H., et al. (2016, October 17). "A factor analysis approach for clustering patient reported outcomes." Methods of information in medicine 55.05: 431-439.

average approaches take the sum of measures, either with equal (that is, simple) or varying weights (that is, weighted), and divide by the number of measures a hospital reports in the measure group. Both LVM[197] and factor analysis[198] attempt to identify underlying traits, in this case quality of acute inpatient and outpatient care, within large datasets, such as hospital measure scores. Each approach was reviewed by the TEP and presented for public input prior to the launch of Overall Star Rating in 2016. We ultimately chose LVM to calculate measure group scores based on support from the TEP,[199] which favored the ability of LVM to utilize data to account for the relationship between measures, measures which are not reported, and sampling variation.[200]

Each LVM assumes that each measure in a measure group reflects information about an underlying aspect or domain of hospital quality as represented by each of the measure groups. For example, safety, mortality, or readmission are each aspects of quality represented by a distinct set of individual measures. Previously, we constructed a separate LVM for each of the seven measure groups. Each LVM estimated a quantitative value, or measure group score, for the group's underlying aspect of quality for each hospital that reports enough measures in each group.

LVM accounts for the correlation between measures by allowing measures that are more consistent with each other to have a greater influence on the measure group scores.[201] The LVM also accounts for differences in the size of each hospital's measure denominator so that measures with larger denominators have more influence on the measure group score, since their measure scores are

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[197] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

[198] Oh, J.H., et al. (2016, October 17). "A factor analysis approach for clustering patient reported outcomes." Methods of information in medicine 55.05: 431-439.

[199] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[200] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

[201] Ibid.

considered more precise.[202] A measure's influence on the measure group score, or loading, is derived by the LVM, ultimately by using the national performance of each measure, as well as the correlation between measures to find the best combination of measure emphasis for each measure group.[203] Measure loadings are further discussed below in section E.4.a.(2) Latent Variable Model Measure Loadings. The loading represents the measure's relationship to the underlying aspect of quality and therefore, the measure's contribution to the measure group score.[204] Measure loadings were re-estimated for each publication of the Overall Star Rating and were the same value for all hospitals that provide acute inpatient and outpatient care. In other words, LVM accounts for measures which are not reported by estimating and assigning the same measure loading values to all hospitals, regardless of differences in the number of measures hospitals report.

The LVM for each measure group can be explained using the below path diagram presented in Figure 1. In the sample path diagram, the ovals represent the measure group scores, calculated using LVM, and hospital summary scores, calculated by a weighted average of measure group scores. The measure group score is not directly observed but estimated from the LVM using the individual measures. The arrows between the measure group scores and each individual measure represent the relationship of that measure to the aspect of quality reflected by each measure with respect to the other measures in that group; each arrow has a different degree of association, also known as a "loading" or coefficient, which is explained in detail within section E.4.a.(2) Latent Variable Modeling Measure Loadings. The small circles on the left represent the residual error within each hospital for each of the measures included in the Overall Star Rating. The residual error (ε) is the variation which could not be explained by the measure group score (random effect).

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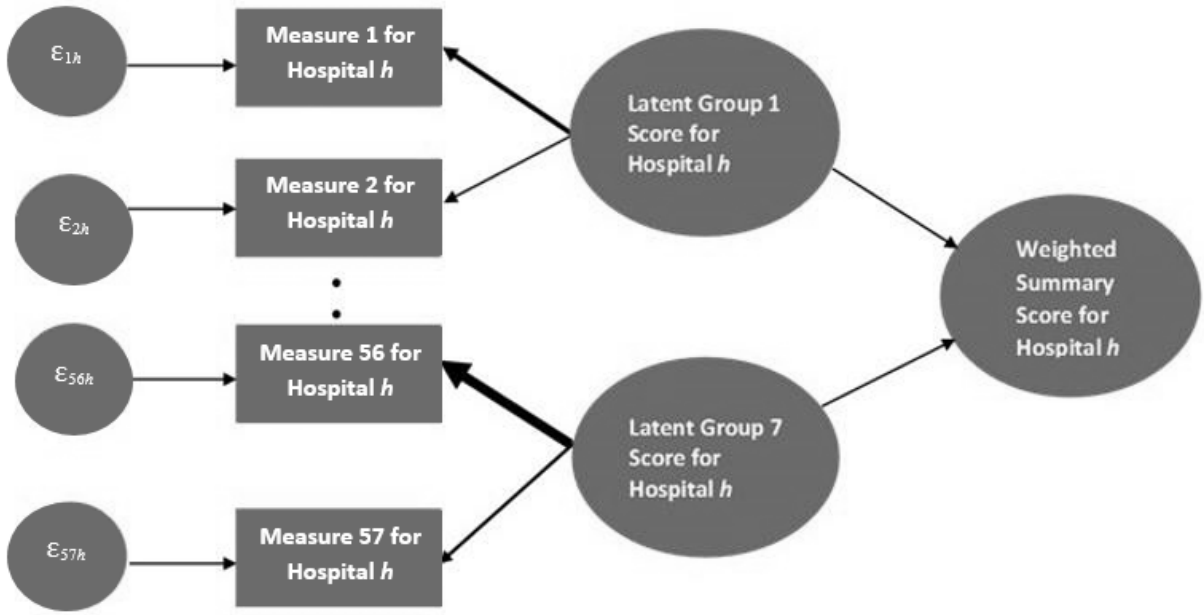
[202] Ibid.
[203] Ibid
[204] Ibid.

Figure 1. Sample Path Diagram of Group-Specific LVM



The LVM equation used to derive a hospital's measure group score is as follows:

$$Y_{khd} = \mu_{kd} + \gamma_{kd}\alpha_{hd} + \varepsilon_{khd},\ k=1,\ldots,N_d$$

$$\alpha_{hd} \sim N(0,1) \text{ and } \varepsilon_{khd} \sim N(0,\sigma_{kd}^2)$$

Let Y_{khd} denote the standardized score for hospital *h* and measure *k* in measure group *d*. α_{hd} is the hospital-specific group-level latent trait (random effect) for hospital *h* and measure group *d* and follows a normal distribution[205] with mean 0 and variance 1. The estimated value of α_{hd} will be used as a measure group score. γ_{kd} is the loading (regression coefficient of the latent variable) for measure *k*, which shows the relationship with the measure group score of measure group *d*. N_d is the total number of measures in measure group *d*. The assumption of unit variance here is an innocuous choice of units required to identify the parameter μ_{kd} and γ_{kd}. For detailed descriptions of the LVM model parameters

[205] Illowsky, B., & Dean, S. (2013). *Introductary Statistics*. Houston, TX: 12th Media Services. Retrieved from: https://openstax.org/details/books/introductory-statistics.

and equation, please see the Overall Hospital Quality Star Rating on *Hospital Compare* Methodology Report (v3.0)[206].

(2) Latent Variable Modeling Measure Loadings

In the past, the LVMs within the Overall Star Rating methodology estimate loadings for each measure within each of the measure groups. A measure's loading indicates its relative contribution to a hospital's measure group score, with higher loadings indicating measures with more influence.[207] A measure's loading is specific to the measure and the same for all hospitals reporting that measure.

A measure loading is a regression coefficient,[208] which is estimated through the LVM by using a statistical approach called maximum likelihood. Maximum likelihood[209] uses the observed data for each measure in a group, including the national performance on the measure and the measure's relationship to other measures in the group, to find the best combination of measure emphasis for the aspect of quality represented by the measure group. In other words, measure score variation nationally and the correlation between measures in a measure group influence measure loadings. Measures with more variation nationally and higher correlations with other measures in a measure group have higher measure loadings because such measures are assumed to convey more information about a given aspect of acute inpatient and outpatient quality of care than measures with limited variation or less correlation with other measures in the same group.

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[206] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0)*. Retrieved from www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1

[207] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

[208] Ibid.

[209] Cole, S.R., Chu, H., & Greenland, S. (2014, January 15) "Maximum likelihood, profile likelihood, and penalized likelihood: a primer." American journal of epidemiology 179.2: 252-260.

The LVM also accounts for sampling variation, or differences in the amount of information available for different hospitals to estimate loadings. For example, for each measure, some hospitals may report a score based on data from fewer cases while other hospitals report scores based on more cases, resulting in differing precision for each hospital's individual measure score. We accounted for these differences in case size by giving more weight to measures with larger denominators. Measure scores based on larger denominators are assumed to have more precise measure scores and therefore contribute more when estimating measure loadings. The weighted likelihood equation for accounting for sampling variation within each measure group is as follows:

$$L = \prod_{k=1}^{K} \prod_{h=1}^{H} (L(Y_{khd}))^{w_{khd}} \qquad w_{khd} = \frac{n_{khd}}{\sum_{h=1}^{N_{kd}} n_{khd}} \times N_{kd}$$

L is the likelihood function. N_{kd} is the total number of hospitals for measure k in measure group d and n_{khd} is the denominator for hospital h and measure k in measure group d. A hospital with a larger denominator will be weighted more in the LVM. The specified weighted likelihood is maximized with respect to all the parameters in the first LVM equation.

Measures with higher loadings have a greater association and impact on the measure group score than measures with lower loadings. Measures highly correlated with other measures in the measure group and the measure group score, measures with large denominators, and measures more commonly reported are likely to have higher loadings because they are generally expected to provide more information about a hospital's quality profile than other measures.

In February 2019, we made an update to remove measures with statistically significant negative loadings from the LVM calculations.[210] Measure loadings can be positive or negative. Measures with

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[210] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019)*. Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2

statistically significant negative loadings have an inverse relationship with other measures in the group. Although negative loadings rarely occur and are almost always statistically insignificant, some stakeholders, including those on the TEP, and during a public input period, expressed concern that measures with negative loadings could be perceived to promote lower quality with respect to measure group scores.[211] [212] [213] [214] [215] While internal analyses have not identified any substantial effect of measures with negative loadings on hospital star ratings, CMS understood the theoretical concern and decided to remove measures with statistically significant negative loadings, beginning in February 2019.[216]

Measure loadings were re-estimated for each publication of the Overall Star Rating and could change dynamically as the measure methodologies, hospitals' performance, and the relationship between measures evolved.

(3) Measure Group Performance Categories

We reported Overall Star Rating measure group performance categories to individual hospitals that provide acute inpatient and outpatient care and on *Hospital Compare* in order to provide context for measure group scores in comparison to all other hospitals in the nation. Performance categories were not calculated by the LVM, nor did they have influence on star ratings. Rather, they were assigned

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[211] Centers for Medicare & Medicaid Services. (2015, June 8). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[212] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[213] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[214] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[215] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[216] Centers for Medicare & Medicaid Services. (2018, November 30). *Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report.* Retrieved from qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2

categories of "above", "same as", or "below the national average" as additional public information on each of the measure groups a hospital reports by comparing a hospital's measure group score to the national average measure group score.

These measure group performance categories were assigned using information from the LVM, separate from measure loadings. For each measure group, LVM produced a point estimate[217] and standard error[218] for each hospital's measure group score that we used to construct a 95 percent confidence interval[219]. A point estimate is a statistic close to the exact value in a dataset, whereas the standard error is a measure of the variability, or how spread out individual points are around the average in the dataset, and both are used to construct a confidence interval, or a range of reasonable values in which we expect a value to fall.[220] We compared this 95 percent confidence interval to the national mean measure group score. Measure group scores with confidence intervals that fall entirely above the national average were considered "above the national average", confidence intervals that include the national average were considered "same as the national average", and confidence intervals that fall entirely below the national average were considered "below the national average".

b. Proposal to Use a Simple Average of Measure Scores to Calculate Measure Group Scores

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to eliminate use of the LVM and instead use a simple average of measure scores to calculate measure group scores beginning with the Overall Star Rating in CY 2021 and subsequent years.

We recognize that LVM may be challenging for stakeholders to understand and explain to others. Stakeholders, specifically providers, serving on the Provider Leadership Work Group and during

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[217] Illowsky, B., & Dean, S. (2013). Introductary Statistics. Houston, TX: 12th Media Services. Retrieved from: https://openstax.org/details/books/introductory-statistics.

[218] Ibid.

[219] Ibid.

[220] Ibid.

a public input period,[221] have requested a less complex methodology that can be easily understood by their organization, explained to their patients, and used to identify areas for quality improvement. In addition, LVM is a data-driven statistical approach that relies on underlying measure data to re-estimate measure loadings[222] for each release of the Overall Star Rating. Since the underlying measure data is refreshed variably based on the measure and CMS quality program requirements – either quarterly, biannually, or annually – the estimated measure loadings based on the underlying data for each annual publication of the Overall Star Ratings were unpredictable, further complicating understanding of the methodology and efforts to allocate resources for quality improvement.

Therefore, in this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to discontinue the use of the LVM, and instead, propose to adopt a simple average of measure scores to calculate measure group scores. This method would average the measure scores a hospital reports within a given measure group, which have been standardized, to calculate the measure group scores. In other words, we would take 100 percent divided by the number of measures reported to give us the percentage each measure would weigh; this measure weight would then be multiplied by the standardized measure score to calculate the measure's weighted score. Then, all of the individual measure weighted scores within a group would be added together to calculate the measure group score. We also propose to codify this policy at §412.190.

For example, if a hospital reports all eight measures in the Safety of Care measure group, the measure weights would be determined by calculating 100 percent divided by eight measures reported (100 percent / 8 reported measures = 12.5 percent) and each measure would be weighted 12.5 percent

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[221] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[222] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

within the group. The standardized measure scores for each of the eight measures would then be multiplied by the weight of 12.5 percent and summed to determine the Safety of Care measure group score. See Table 47 for an example of measure weights in which a hospital reports all eight measures within Safety of Care. For the Readmission measure group for example, a hospital's score on the Hospital-Wide, All-Cause Unplanned Readmission measure, which includes most patient admissions at a hospital, would have the same influence as their score on the condition specific Chronic Obstructive Pulmonary Disease (COPD) Readmission measures, which includes significantly fewer patients.

Example of Simple Average of Measure Scores to Calculate Measure Group Scores

Measure group score = [(-1.13*0.125) + (-0.75*0.125) + (0.09*0.125) + (1.21*0.125) + (0.97*0.125) + (0.98*0.125) + (0.46*0.125) + (0.02*0.125)] = 0.23

TABLE 47: EXAMPLE OF SIMPLE AVERAGE OF MEASURE SCORES TO CALCULATE OF SAFETY OF CARE MEASURE GROUP SCORE

Measure Name	Example Measure Score	Standardized Measure Score	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	-1.13	12.5%	-0.14	0.23
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	1.233	-0.75	12.5%	-0.09	
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	0.747	0.09	12.5%	0.01	
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	0.000	1.21	12.5%	0.15	
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	0.000	0.97	12.5%	0.12	

Measure Name	Example Measure Score	Standardized Measure Score	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	0.166	0.98	12.5%	0.12	
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.46	12.5%	0.06	
CMS PSI-90 Patient Safety and Adverse Events Composite	0.999	0.02	12.5%	0.003	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

Under certain circumstances, hospitals may not report all measures within a measure group. However, we note that the proposed minimum threshold is three measures within three measure groups, one of which must be Mortality or Safety of Care. Once this threshold is met, any additional measures or groups may contribute to a hospital's star rating. We refer readers to section E.6. Step 5 Application of Minimum Thresholds for Receiving a Star Rating where the proposed minimum threshold is discussed. As an example, if a hospital reports three measures in the Safety of Care measure group, the measure weights would be determined by calculating 100 percent divided by three measures reported (100 percent / 3 reported measures = 33.3 percent) and each measure would be weighted 33.3 percent within the group. The standardized measure scores for each of the three measures would then be multiplied by the weight of 33.3 percent and summed to determine the Safety of Care measure group score. See Table 48 for an example of measure weights in which a hospital reports three measures within Safety of Care.

Example of Simple Average of Measures Scores to Calculate Measure Group Scores When Measures Are Not Reported

Measure group score = [(-1.13*0.333) + (0.46*0.333) + (0.02*0.333)] = -0.22

TABLE 48: EXAMPLE OF SIMPLE AVERAGE OF MEASURE SCORES TO CALCULATE SAFETY OF CARE MEASURE GROUP SCORE WHEN MEASURES ARE NOT REPORTED

Measure Name	Example Measure Score	Standardized Measure Score*	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score*
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	-1.13	33.3 %	-0.38	-0.22
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	NA	NA	NA	NA	
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	NA	NA	NA	NA	
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	NA	NA	NA	NA	
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	NA	NA	NA	NA	
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	NA	NA	NA	NA	
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.46	33.3 %	0.15	
CMS PSI-90 Patient Safety and Adverse Events Composite	0.999	0.02	33.3 %	0.006	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

As previously noted, LVM accounted for measures which are not reported by uniformly assigning the same loading for a measure to hospitals that provide acute inpatient and outpatient care,[223] whereas use of a simple average of measure scores would result in hospitals having varying measure weights depending on differences in the number of measures reported. For example, if a hospital reports three of the eight measures in the Safety of Care measure group, each measure would be weighted at 33 percent within that group. On the other hand, a hospital that reports all eight measures in the Safety of Care measure group would have a different weighting of 12.5 percent for each measure within the measure group. We simulated the possible range of measure weights using the data used for January 2020 Overall Star Rating (October 2019 public reporting data), which included 51 measures. We simulated the results using the measure group weights proposed in section E.5.a.(2) Proposal to Continue Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores; outcome and patient experience measure groups were weighted 22 percent and the process group was weighted 12 percent. Taking into account the measure group weights applied later in the methodology, the minimum effective measure weight, or the percentage of the hospital summary score based on a single measure, would be 3 percent for a hospital reporting all 51 measures and the maximum effective measure weight would be 33 percent for another hospital reporting the minimum threshold number of nine measures (at least three measures in at least three groups). Hospitals with more measures will have lower measure weights for each measure, whereas hospitals with fewer measures will have higher measure weights for each measure. The number of measures included in the Overall Star Rating varies for each publication depending on measure removals from and additions for public reporting.

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[223] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002-0829.2012.02.010

Using a simple average of measure scores to calculate measure group scores would be responsive to stakeholder feedback that requested CMS increase the simplicity of the methods and the predictability of measure emphasis between publications. [224] [225] [226] [227] Using a simple average of measure scores would increase the predictability of measure emphasis by allowing hospitals to anticipate equal measure weights across the measures they report within a given group. While there may be differences in measure emphasis between hospitals that provide acute inpatient and outpatient care based on differences in measure reporting, a simple average of measure scores will be responsive to stakeholder feedback and make the methodology easier for stakeholders to understand, interpret, and explain to patients.

Since measure loadings are an artifact of the LVM approach, they would no longer be calculated under the proposed new method using a simple average of measure scores. In addition, since the point estimates and standard errors used to calculate 95 percent confidence intervals and assign hospital measure group performance to "above," "same as," or "below the national average" were products of the LVM approach, measure group performance categories will no longer be available under the proposed new method using a simple average of measure scores. However, we intend to continue to publicly display alternative summaries of hospital performance within measure groups for transparency and patient usability. Should the proposal to use a simple average of measure scores to calculate measure

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[224] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[225] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[226] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[227] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

group scores not be finalized, measure group performance categories would still be available in the same manner described above.

In crafting this proposal, we also considered continuing to utilize LVM as we have in the past and as discussed in the section above. Ultimately, we chose to propose to discontinue the use LVM because of the complexity associated with understanding how measure loadings are empirically assigned with the LVM and contribute to the measure group scores. We invite public comment on our proposals to use a simple average of measure scores to calculate measure group scores and to codify this policy at §412.190 as discussed.

c. Proposal to Standardize Measure Group Scores

Standardizing[228] scores is a way to make varying scores directly comparable by putting them on a common scale. While standardization is used in other parts of the methodology, particularly to standardize measure scores within the first step of methodology, it was previously not necessary to standardize measure group scores when using statistical modeling, such as LVM. In the absence of statistical modeling, under the use of the proposed simple average of measure scores as discussed in section E.4.b. Proposal to Use a Simple Average of Measure Scores to Calculate Measure Group Scores, the distributions and interpretations of measure group scores may differ. For example, a 0.5 measure group score in Safety of Care may not conceptually be similar to a 0.5 measure group score in Patient Experience, exaggerating the influence of some measure groups when calculating a weighted average of measure group scores.

Therefore, for the Overall Star Rating beginning with CY 2021 and subsequent years, we propose to standardize measure group scores. More specifically, we propose to standardize measure

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[228] Illowsky, B., & Dean, S. (2013). *Introductary Statistics*. Houston, TX: 12th Media Services. Retrieved from: https://openstax.org/details/books/introductory-statistics.

group scores by calculating Z-scores for each measure group. As mentioned in section E.2.d. Measure Score Standardization, a Z-score[229] is a standard deviation[230] score which relays the amount of variation in a dataset, or in this case, the variation in hospital measure scores. Z-scores would be calculated by subtracting the national average measure group scores from each hospital's measure group score and dividing by the standard deviation across hospitals. Standardization of measure group scores would occur prior to combining measure group scores through a weighted average to calculate summary scores, and would result in all measure group scores centered near zero with a standard deviation[231] of one. We also propose to codify this policy at §412.190.

See Table 49 for an example of how measures would be combined through a simple average of measure scores to calculate measure group scores and then how the measure group scores would be standardized. The standardization of measure group scores would not impact hospital performance within the measure group or the natural distribution of scores. As a result of standardization,[232] mean group scores and standard deviations would become more similar across measure groups. We simulated the potential effects of standardization using data from the January 2020 publication of Overall Star Rating and found that hospital summary scores with and without standardization of measure group scores are highly correlated with a Pearson correlation of 0.975, indicating that standardizing measure group scores does not substantially alter hospital performance assessment. We note that, should the proposal to use a simple average of measure scores to calculate measure group scores not be finalized, we would not need to standardize measure group scores.

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229 DeVore, G.R. (2017, January 17). "Computing the Z score and centiles for cross-sectional analysis: a practical approach." Journal of Ultrasound in Medicine 36.3: 459-473.

230 Illowsky, B., & Dean, S. (2013). *Introductary Statistics.* Houston, TX: 12th Media Services. Retrieved from: https://openstax.org/details/books/introductory-statistics.

231 Ibid.

232 Ibid.

We invite public comment on our proposal to standardize measure group scores and codify this policy at §412.190.

d. Proposal to Stratify Readmission Measure Group Scores

(1) Current Measure Group Scores Without Stratification

In the past, we have not stratified or adjusted any of the measures, measure groups, summary scores, or star ratings by social risk factor variables within the Overall Star Rating methodology, primarily based on the original guiding principles of the Overall Star Rating. The Overall Star Rating is meant to summarize the existing quality measure information that is publicly reported through CMS programs, including Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, on *Hospital Compare* or its successor websites. Individual measures undergo rigorous development and reevaluation processes under each program that include extensive analytic testing and stakeholder engagement. As such, individual measure methodologies as specified under each program, including approaches to risk adjustment, are included within the Overall Star Rating. As measure data and methodologies are updated under each of the programs, they are subsequently reflected within the Overall Star Rating methodology. CMS' Overall Star Rating development contractor has engaged stakeholders in discussion regarding the comparability of hospital star ratings for over five years throughout the development and reevaluation of the Overall Star Rating. Throughout that engagement, some stakeholders, primarily providers, requested incorporation of social risk factor adjustment within the Overall Star Rating, while other stakeholders expressed concerns regarding adjustment in general or the specific variables available for adjustment.[233] Specifically, some stakeholders have requested social risk factor adjustment of the readmission measures or the

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[233] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

Readmission measure group.[234] [235] Recently a HHS Report to Congress has set forth a broad range of recommendations regarding social risk factors and Medicare's value-based purchasing programs, which do not recommend adjusting quality measures for social risk for public reporting.[236] We seek comment on our proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients, and an alternative not to stratify the Readmission measure group based on the proportion of dual-eligible patients.

(2) Proposal to Stratify Only the Readmission Measure Group Scores

In this proposed rule, for Overall Star Rating beginning in CY 2021 and subsequent years, we propose to stratify only the Readmission measure group score by hospitals' proportion of dual-eligible patients and codify this at §412.190. We propose to specifically stratify only the Readmission measure group, and not other measure groups, based on hospitals' proportion of dual-eligible hospital discharges, to be responsive to select stakeholder concerns that some hospitals providing acute inpatient and outpatient care face unique challenges preventing readmissions among patients with complex social risk factors,[237] and to align with the payment adjustment recently implemented for HRRP payment determination (82 FR 38231 through 38237). We propose to utilize and repurpose the same peer group quintiles assigned by the HRRP annually. We propose to assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as

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[234] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx

[235] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[236] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf. Accessed July 2, 2020.

[237] National Quality Forum. (2014, August). Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors. Retrieved from: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=77474

they would not have already been assigned to a peer group through the HRRP. We also propose that in the event a hospital's proportion of dual-eligible patient data is missing, CMS would not adjust that hospital's Readmission measure group score and that hospital would retain its original, unadjusted Readmission measure group score, as calculated through a simple average of their measure scores.

The proposed stratification of the Overall Star Rating Readmission measure group score would use the same dual-eligible variable and a similar peer grouping approach as is used in the HRRP for payment determinations (82 FR 38231 through 38237). To be clear, the Overall Star Rating is not used to determine hospital payments. Dual-eligible[238] patients are those that are dually eligible for Medicare and full-benefit Medicaid among a hospital's total Medicare Fee-for-Service (FFS) and Medicare Advantage patient discharges (42 U.S. Code § 1315b(f)). Dual-eligible status is consistently captured for patients and available through enrollment files, which are updated annually, and does not require extrapolation from area of residence variables, such as census or community surveys.

In 2016, the 21st Century Cures Act mandated that CMS determine hospital penalties for readmissions that account for social risk factors through a transitional methodology that calculates excess readmissions ratios within hospital peer groups defined by the percentage of dual-eligible patients served by the hospital within the HRRP (Pub. L. 114-255). Section 15002 of the 21st Century Cures Act, adding a new section 1886(q)(3)(D) and (E) to the Act, also indicated this methodology could be characterized as a "transitional adjustment" and that the Secretary of Health and Human Services may revise the stratification methodology, taking into account recommendations made on risk-adjustment methodologies for HRRP based on the studies conducted under the IMPACT Act by the

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238 Centers for Medicare & Medicaid Services. (2018, May). *Dual Eligible Beneficiaries Under Medicare and Medicaid.* Retrieved from www.cms.gov: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf

Office of the Assistant Secretary for Planning and Evaluation (ASPE) on the role of socioeconomic status in Medicare's value-based purchasing program.

In the FY 2018 IPPS/LTCH PPS rule, we finalized our HRRP proposal to implement a methodology that categorizes participating hospitals that provide acute inpatient care into five peer groups by quintiles, based on the proportion of dual-eligible patients to total patients served by the hospital. The methodology uses the median excess readmission ratio of hospitals within each of the five peer groups as the threshold to assess hospital performance on each measure (82 FR 38231 through 38237). The excess readmission ratio measures a hospital's relative performance and is the ratio of predicted-to-expected readmissions.[239] This methodology was implemented within HRRP in FY 2019 as announced in the associated correction notice (82 FR 49837). The individual readmission measures included within HRRP and publicly reported on *Hospital Compare* or its successor website are not adjusted for social risk factors.

The proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients is intended to provide consistency between the current stratification method used for the HRRP and the Overall Star Rating methodology. It is not in any way intended to suggest a new policy direction for the more general question of whether CMS programs should employ social risk factor adjustment methods of any kind. The rationale for this proposal is based on alignment between the two CMS efforts. If changes are made in the future to the HRRP stratification approach, CMS may consider similar changes to the Overall Star Rating methodology through future rulemaking. Recently a HHS Report to Congress has set forth a broad range of recommendations regarding social risk factors and Medicare's value-based purchasing programs, which do not recommend adjusting quality measures for

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[239] Centers for Medicare & Medicaid Services. (2019, Novemebr 19). *Hospital Readmissions Reduction Program (HRRP)*. Retrieved from www.cms.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HRRP/Hospital-Readmission-Reduction-Program

social risk for public reporting.[240] The stratification approach in the HRRP has been recommended for removal based on HHS recommendations in a second Report to Congress, mandated by the IMPACT Act of 2014, titled *"Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs"* submitted by ASPE on June 29, 2020.[241] The report recommends not adjusting outcome measures for social risk factors in CMS programs and recommends that, eventually, stratification of hospitals by the proportion dual-eligible patients should be removed from the HRRP. CMS is currently reviewing the report recommendations and considering how to incorporate these recommendations within CMS programs.

The Overall Star Rating uses individual measure scores, as calculated under the quality programs and reported on *Hospital Compare* or its successor website, to calculate measure group scores. Individual measure methodologies, including current and future approaches to risk adjustment for each measure, as specified in the measures, are inherently included within the Overall Star Rating. Since the Overall Star Rating utilizes the individual measure scores as publicly reported, it is not appropriate to apply social risk factor adjustment to the individual measure scores for the purpose of the Overall Star Rating. In addition, stakeholders have agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections where the onset of adverse

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[240] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf. Accessed July 2, 2020.

[241] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf. Accessed July 2, 2020.

events occur in the hospital setting should not be influenced by a patient's socioeconomic status. [242] [243] The proposed stratification approach would stratify only the Readmission measure group scores based on a comparison to other hospitals with similar proportions of dual-eligible patients, as opposed to in comparison to all hospitals.

Since the Overall Star Rating is not used to determine hospital payment, we propose calculating the readmission measure group score within each dual-eligible peer group. In the formula below, α_h is the readmission group score for hospital *h*, $\bar{\alpha}$ is the national average of readmission group score, $\bar{\alpha}_{peer\ group\ j}$ is the average readmission group score for dual-eligible peer group *j* (*j* =1 ,2, …, 5).

$$\tilde{\alpha}_{h|peer\ group\ j} = \alpha_h * \left\{1 + \frac{\bar{\alpha}}{\alpha_h}\left(1 - \frac{\bar{\alpha}_{peer\ group\ j}}{\bar{\alpha}}\right)\right\}$$
$$= \alpha_h + \bar{\alpha} - \bar{\alpha}_{peer\ group\ j}$$

During public input periods,[244] CMS' contractor received feedback from stakeholders, specifically providers, encouraging alignment between Overall Star Rating and CMS programs, with specific mention of alignment with HRRP's approach to peer grouping by dual-eligibility. In response to stakeholder feedback to promote alignment between programs and provide consistent measurement standards for providers, we propose to utilize the same dual-eligible quintiles as HRRP for the Readmission measure group. Applying stratification to the Readmission measure group scores based on proportion of dual-eligible patients would align with HRRP (82 FR 38231 through 38237). Consistent

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[242] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx

[243] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[244] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

with HRRP, stratifying the Overall Star Rating Readmission measure group would assign hospitals to one of five peer groups based on the proportion of dual-eligible patients. For FY 2019, the range of proportion of dual-eligible patients within each of the hospital peer group quintiles for HRRP are as follows: 0 to 13.69 percent, 13.70 to 18.40 percent, 18.41 to 23.23 percent, 23.24 to 30.98 percent, 30.99 to 100 percent for peer groups one, two, three, four, five, respectively. We propose to utilize and repurpose the same peer group quintiles assigned by the HRRP, annually. Peer groups for the Overall Star Rating would not be exact quintiles, as a greater number of hospitals are included in Overall Star Rating than those participating in HRPP. The Overall Star Rating includes hospitals providing acute inpatient and outpatient care, including both subsection (d) hospitals and CAHs, whereas HRRP only includes subsection (d) hospitals. We refer readers to section A.1.b. Subsection (d) Hospitals and B. Critical Access Hospitals in the Overall Star Rating for more information on the hospitals included within the Overall Star Rating. For the 2020 Overall Star Rating release, 4,384 hospitals received a Readmission group score, while 3,077 hospitals participated in HRRP received a readmission score. Since the hospitals within the Overall Star Rating that do not participate in HRRP would not already be assigned to a peer group by the HRRP methodology, we propose to calculate their proportion of dual-eligible patients and assign them to one of the five peer groups based on the HRRP designated peer groups.

As stated above, we propose to assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP. This is necessary to maintain alignment with HRRP so that hospitals in HRRP are assigned to the same peer group within both HRRP and the Overall Star Ratings. As also stated above, we propose to not adjust a hospital's Readmission measure

group score if that hospital has missing dual-eligible patient data. This is necessary because we would not have the dual-eligible data necessary to produce an adjusted score.

(i) Other Methods Considered

In developing our proposal, we also considered recalculating the peer group quintiles based on all hospitals in the Overall Star Rating dataset, and not solely based on those participating in HRRP. Using all hospitals to calculate peer group quintiles would be more consistent with other aspects of the methodology that use all hospital data, such as the calculation of measure group scores and weighted average of measure groups scores to calculate summary scores. However, calculating quintiles based on all hospitals would create potential misalignment between quintiles, and therefore peer group assignment, for HRRP and the Overall Star Rating Readmission measure group. More specifically, if dual-eligible quintiles were recalculated based on all hospitals within the Overall Star Rating, some hospitals that are within both HRRP and the Overall Star Rating would be assigned to different peer groups in each of the two methodologies based on the different dual-eligible quintile cutoffs.

Using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*), we simulated calculation of quintiles based on all hospitals, 155 (5.04 percent) of the 3,174 HRRP hospitals would move down a peer group quintile; that is, they would move to a quintile with a lower proportion of patients that are dual-eligible, indicating their patient case mix has lower social risk. Under this simulation, specifically, 23 (3.67 percent) hospitals assigned dual-eligible quintiles in HRRP would move from peer group two to peer group one, with the lowest proportion of dual-eligible patients, 40 (6.46 percent) hospitals would move from peer group three to peer group two, 48 (7.74 percent) hospitals would move from peer group four to peer group three, and 44 (7.28 percent) hospitals would move from peer group five, with the highest proportion of dual-eligible patients, to peer group four.

For the January 2020 Overall Star Rating release, 4,384 hospitals received a Readmission group score, while 1,307 hospitals did not participate in HRRP. Similarly, using the same simulated calculation of quintiles based on all hospitals, 90 (6.89 percent) of the 1,307 non-HRRP hospitals would move down a peer group quintile if calculating based on all hospitals than they would have if using only HRRP hospitals. Specifically, 9 (0.69 percent) hospitals would move from peer group two to peer group one, with the lowest proportion of dual-eligible patients, 31 (2.37 percent) hospitals would move from peer group three to peer group two, 27 (2.07 percent) hospitals would move from peer group four to peer group three, and 23 (1.76 percent) hospitals would move from peer group five, with the highest proportion of dual-eligible patients, to peer group four.

After calculation, mean Readmission measure group scores would be the same for each hospital peer group, resulting in more similar measure group scores across hospital peer groups. While stratifying results in more comparable measure group scores across peer groups of proportions of dual-eligible patients, the effect on the Overall Star Rating Readmission measure group is modest; our simulations showed a 0.967 correlation between unadjusted and adjusted Readmission measure group scores using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*).

In developing our proposal, as discussed in section a. Alternatives Considered, we also considered not stratifying the Readmission measure group and retaining the current measure group without stratification based on proportion of dual-eligible patients within the calculation of the Overall Star Ratings. CMS' Overall Star Rating development contractor engaged stakeholders in discussion regarding the comparability of hospital star ratings for over five years throughout the development and reevaluation of the methodology. Throughout that engagement, some stakeholders expressed concerns regarding adjustment for social risk factors in general, adjustment for social risk factors within the

Overall Star Rating methodology, or use of specific social risk factor variables that are currently available for adjustment.[245] Most stakeholders agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections, and therefore, not appropriate to be applied at aggregated levels, such as the Overall Star Rating.[246] [247] Some stakeholders, including patients and patient advocates, expressed concern that stratifying the Readmission measure group by the proportion of dual-eligible patients would result in a misrepresentation of quality of care at hospitals, particularly for dual-eligible patients, and would be confusing to patients as consumers of the Overall Star Rating.[248] [249] [250] Furthermore, the effect of stratifying the Overall Star Rating Readmission measure group score is negligible, as shown through a 0.967 correlation between unadjusted and adjusted Readmission measure group scores using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*).

CMS is also considering recommendations on risk-adjustment recently submitted to Congress. On behalf of the Secretary for Health and Human Services (HHS), ASPE recently submitted a HHS Report to Congress on ***Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs*** that includes recommendations on risk-adjustment for CMS programs and quality efforts, including the Overall Star Rating. For publicly reported quality measures, recommendations are that

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[245] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[246] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx

[247] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[248] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[249] Centers for Medicare & Medicaid Services. (2019, October 24) Patient and Patient Advocate Work Group Minutes-October 2019.

[250] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx

"*Quality measures, resource use measures, and composite scores should not be adjusted for social risk factors for public reporting.*" Instead, recommendations are for quality and resource use measures to be reported separately for dual-eligible beneficiaries and other beneficiaries in order to monitor disparities and improvements over time. The report indicates for public reporting, it is also important to hold providers accountable for outcomes, regardless of social risk. Overall, the report lays out a comprehensive approach for CMS programs to move towards incentivizing providers and initiatives to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors. The report indicates proposed solutions that address only the measures or programs, without considering the broader delivery system and policy context, are unlikely to mitigate the full implications of the relationship between social risk factors and outcomes.

However, we are ultimately proposing to stratify the Readmission measure group based on the proportion of dual-eligible patients to align with HRRP and be responsive to stakeholder feedback, particularly form health care providers. However, considering inconsistent feedback received from stakeholders and HHS recommendations for CMS programs, we also seek comment on an alternative to retain the Readmission measure group calculation without stratification based on the proportion of dual-eligible patients.

We invite public comment on our proposals to: (1) stratify only the Readmission measure group score based on the proportion of dual-eligible patients by using peer groups annually designated by the HRRP, (2) assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP, (3) not adjust a hospital's Readmission measure group score if that hospital has missing dual-eligible patient data, and (4) codify this policy at §412.190. We

refer readers to section a. Alternatives Considered where we seek comment on the alternative to not stratify the Readmission measure group score based on the proportion of dual-eligible patients.

5. Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores

a. Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

(1) Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

In the past, we have calculated hospital summary scores as a weighted average of measure group scores. That is, each measure group score is multiplied by the assigned weight for that group, and then the weighted measure group scores are summed to calculate the hospital summary score. The measure group weights were determined based on CMS policy, stakeholder feedback, and similarities to that of the Hospital VBP Program[251] in that outcome measures are given more weight than process measures. Specifically, the Mortality, Safety of Care, Readmission, and Patient Experience measure groups are each weighted 22 percent and the Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging measure groups are each weighted 4 percent. In 2015, CMS' contracted development team engaged stakeholders for input on the measure group weights through the TEP,[252] the Patient & Advocate Work Group, and a public input period.[253] In general, stakeholders supported the current measure group weights and agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. The

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[251] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 80 Fed. Reg. 49567 (Aug 17, 2015) (to be codified at 42 C.F.R Parts 412)

[252] Centers for Medicare & Medicaid Services. (2015, February). Summary *of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[253] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

development contractor included this topic in several past public input periods,[254] [255] wherein some stakeholders suggested different measure group weightings; however, little consensus has been reached on an appropriate alternative weighting scheme.

(2) Proposal to Continue Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue to calculate hospital summary scores through a weighted average of measure group scores with a similar weighting scheme that continues to assign more weight to the outcome and patient experience measure groups and less weight to the process measure group. Specifically, for Overall Star Rating beginning in CY 2021 and subsequent years, we propose to weight each of the outcome and patient experience measure groups – Mortality, Safety of Care, Readmission, and Patient Experience – at 22 percent, and the proposed combined process measure group, Timely and Effective Care (we refer readers to section E.3.b. Proposed New Measure Group and Continuation of Certain Groups of this proposed rule), at 12 percent. We also propose that hospital summary scores would then be calculated by multiplying the standardized measure group scores by the assigned measure group weight and then summed. We refer readers to an example equation and Table 49. We also propose to codify the measure group weightings at §412.190 and summary score calculations at §412.190.

Example of Weighted Average of Measure Group Scores to Calculate Summary Scores

Summary score = [(-0.70*0.22) + (0.23*0.22) + (-0.76*0.22) + (-1.13*0.22) + (-0.25*0.12)] = -0.55

TABLE 49: EXAMPLE OF SUMMARY SCORE CALCULATION AND STAR RATING ASSIGNMENT

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[254] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[255] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

Measure Groups	Example Group Scores*	Standardized Example Group Scores*	Measure Group Weights	Weighted Standardized Example Group Scores*	Summary Score Calculation*
Mortality	-0.45	-0.70	22 %	-0.15	-0.55
Safety of Care	0.16	0.23	22 %	0.05	
Readmission	-0.35	-0.76	22 %	-0.17	
Patient Experience	-0.93	-1.13	22 %	-0.25	
Timely and Effective Care	-0.07	-0.25	12 %	-0.03	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

In developing our proposal, we also considered equal measure weights across all the measure groups, such that each measure group would be weighted 20 percent. We ultimately chose to propose to weight outcome measures more, because this was vetted and supported by stakeholders and is consistent with past and current stakeholder feedback that outcome measures capture important aspects of quality and are more important to patients.[256] [257]

We invite public comment on our proposals to: (1) continue to calculate hospital summary scores by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores; (2) continue to weight outcome and patient experience measure groups, (that is, Mortality, Safety of Care, Readmission, and Patient Experience groups) at 22 percent; (3) weight the proposed Timely and Effective Care process measure group at 12 percent; and (4) codify these policies at §412.190.

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[256] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[257] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

b. Reweighting Measure Group Scores to Calculate Summary Scores

(1) Current Reweighting Measure Group Scores to Calculate Summary Scores

In the past, if a hospital did not report or have sufficient measures for a given measure group under the Overall Star Rating methodology, the weights of those measure groups would be redistributed proportionally across the measure groups for which the hospital did report sufficient measures. Generally, the four outcome measure groups were weighted at 22 percent each, and the three process measure groups were weighted at 4 percent each. The approach to proportioning weights when a hospital did not report enough measures for one or more measure groups was similar to the Hospital VBP Program where the weighting of groups is redistributed where one or more groups are not reported,[258] and was vetted by stakeholders for the Overall Star Rating through TEP[259] engagement and a public input period[260].

(2) Proposal to Reweight Measure Group Scores to Calculate Summary Scores

Moving forward, we propose to continue to reweight measure group scores. Taking into consideration the proposed new measure grouping (we refer readers to section 5 E.3.b. Proposed New Measure Group and Continuation of Certain Groups) and the proposed Timely and Effective Care process measure group weighting of 12 percent (we refer readers to section E.5.a. Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores), for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to re-distribute measure group weights for measure groups which a hospital does not have sufficient measures within the Overall Star Rating

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[258] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 77 Fed. Reg. 53606 (August 31, 2012) (to be codified at 42 CFR Parts 412, 413, 424 and 476)

[259] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[260] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

methodology. Once a hospital meets the reporting threshold to receive a star rating, which is having at least three measure groups each with at least three measures, any additional measures and measure groups contribute to their star rating (we refer readers to section E.6.b. Proposals to Update the Minimum Reporting Thresholds for Receiving a Star Rating). In other words, once the reporting thresholds are met, a hospital would need to report at least one measure in each group and the weight of any measure group that does not have at least one measure will be re-distributed amongst the other measure groups. Specifically, we propose to re-distribute the weights for measure groups which are not reported proportionally across the remaining measure groups, to ensure the relative weight between groups is preserved. We would calculate this by subtracting the standard weight percentage of the group that does not meet the minimum threshold from 100 percent; the standard weight percentage of each of the remaining groups would then be divided by the resulting percentage giving new re-proportioned weights. If a hospital does not meet the threshold for two groups, then those two groups' standard weight percentages are added together before subtracting from 100 percent; the standard weight percentage of each of the remaining groups would then be divided by the resulting percentage giving new re-proportioned weights. We also propose to codify this at §412.190. These calculations are illustrated in the three examples below.

For example, if a hospital does not report at least one measure within the Timely and Effective Care measure group, the group's 12 percent weight would be subtracted from the total of 100 (100-12=88) and then each of the measure group weights for that hospital would be determined using the new total of 88 (Mortality weight: 22/88=25 percent, Safety of Care weight: 22/88=25 percent, Readmission weight: 22/88=25 percent, and Patient Experience weight: 22/88=25 percent). This example is illustrated in Table 50.

TABLE 50: EXAMPLE OF REWEIGHTING FOR A HOSPITAL WHICH DOES NOT REPORT TIMELY AND EFFECTIVE CARE MEASURE GROUP

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	25%
Safety of Care	22%	25%
Readmission	22%	25%
Patient Experience	22%	25%
Timely and Effective Care	12%	--

As another example, if a hospital does not report at least one measure within the Readmission measure group, the group's 22 percent weight would be subtracted from the total of 100 (100-22=78) and then each of the measure group weights for that hospital would be determined using the new total of 78 (Mortality weight: 22/78=28.2 percent, Safety of Care weight: 22/78=28.2 percent, Patient Experience weight: 22/78=28.2 percent, and Timely and Effective Care weight: 12/78=15.4 percent). This example is illustrated in Table 51.

TABLE 51: EXAMPLE REWEIGHTING FOR A HOSPITAL WHICH DOES NOT REPORT READMISSION MEASURE GROUP

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	28.2%
Safety of Care	22%	28.2%
Readmission	22%	--
Patient Experience	22%	28.2%
Timely and Effective Care	12%	15.4%

This same principle would apply if a hospital did not have at least one measure reported in two measure groups. We propose that a hospital must report at least three measure groups, each with at least three measures, one of which must be Mortality of Safety of Care, in order to receive a star rating; once both the minimum measure and measure group thresholds are met, any additional measures a hospital

reports would be included in the Overall Star Rating calculation, including measures groups with as few as one measure (we refer readers to section E.6.b. Proposals to Update the Minimum Reporting Thresholds for Receiving a Star Rating). If a hospital does not report at least one measure within both the Safety of Care and Timely and Effective Care measure groups, the groups' 22 and 12 percent weights would be subtracted from the total of 100 (100-22-12=66) and then each of the measure group weights would be determined using the new total of 66 (Mortality weight: 22/66=33.3 percent, Readmission weight: 22/66=33.3, and Patient Experience weight: 22/66=33.3 percent). This example is illustrated in Table 52.

TABLE 52: EXAMPLE REWEIGHTING FOR A HOSPITAL WHICH DOES NOT REPORT SAFETY OF CARE AND TIMELY AND EFFECTIVE CARE MEASURE GROUPS

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	33.3%
Safety of Care	22%	--
Readmission	22%	33.3%
Patient Experience	22%	33.3%
Timely and Effective Care	12%	--

We invite public comment on our proposals to reweight measure group scores and codify at §412.190.

6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating

a. Current Minimum Measure and Group Thresholds for Receiving a Star Rating

In the past, in order to receive a star rating, hospitals that provide acute inpatient and outpatient care had to publicly report sufficient measures to receive a star rating. Specifically, a minimum threshold was set to require at least three measure groups (one being an outcome group – that is, Mortality, Safety of Care, or Readmission), with at least three measures in each of the three groups.

Additionally, in the past, once a hospital met the minimum measure and measure group thresholds, any additional measures and groups, including groups with as few as one measure, the hospital reported were included in the calculation of their star rating. These reporting thresholds were applied based on the guiding principle of information inclusivity, in that it allowed as many hospitals as possible to receive a star rating while also maintaining face validity and reliability of the Overall Star Rating methodology, and were vetted through TEP and public comment stakeholder engagement.[261] [262]

In 2017, the CMS' Overall Star Rating development contractor vetted the minimum reporting thresholds through the TEP and public input.[263] In December 2017,[264] we updated the order of steps in the methodology for which minimum thresholds are applied; instead of applying minimum thresholds in step 6, after the assignment of hospitals to star ratings, we applied them in step 5, prior to the assignment of hospitals to star ratings so only hospitals meeting the threshold were included in the relative k-means clustering algorithm.[265] K-means clustering[266] is the algorithm used to assign hospital summary scores to one of five star ratings. An overview of k-means clustering is provided in section E.8. Step 6: Application of Clustering Algorithm to Obtain a Star Rating below.

b. Proposals to Update the Minimum Reporting Thresholds for Receiving a Star Rating

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[261] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[262] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[263] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[264] Centers for Medicare & Medicaid Services. (2017, December 20). Quarterly Updates and Specifications Report (v2.3). Retrieved from qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2

[265] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641

[266] Ibid.

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue a similar threshold as previously used, but with modification. We propose that hospitals must report at least three measures for three measures groups, however, one of the groups must specifically be the Mortality or Safety of Care outcome groups. We believe this would increase the comparability of hospitals through the requirement of specific measure groups to receive a star rating. We also believe that this would ensure that, in order to receive a star rating, hospitals have information available on important indicators of acute inpatient and outpatient quality of care – mortality and safety of care – that reflect survival and preventable complications or infections following care and are, therefore, important to patients in making healthcare decisions, as indicated by the Patient & Patient Advocate Work Group. We are also proposing to codify this minimum measure group threshold at §412.190.

However, we are aware that a requirement for at least three measures within the Mortality or Safety of Care groups would simultaneously limit the number of hospitals eligible to receive a star rating, particularly reducing the number of small, low volume hospitals with too few cases to report the individual measures. Furthermore, certain entities, such as CAHs, are not required to report safety measures (for example, healthcare-associated infections and PSI-90) as part of HAC Reduction Program (78 FR 50725 to 50728).[267] In January 2020, 125 hospitals did not report at least three measures in either the Mortality or Safety of Care groups. Of those 125 hospitals without at least three measures in either the Mortality or Safety of Care groups, 48 were safety-net hospitals, 68 were CAHs, and 16 were specialty hospitals. However, the TEP still recommended this change because Mortality and Safety of Care are aspects of quality that are most important to patients and reflective of performance under a

[267] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 50496 (Aug 19, 2013) (to be codified at 42 CFR Parts 412, 413, 414, 419, 424, 482, 485, and 489)

hospital's control.[268] Once both the minimum measure and measure group thresholds are met, any additional measures a hospital reports would be included in the star rating calculation.

We invite public comment on our proposals to require that hospitals must report at least three measures groups, one of which must specifically be the Mortality or Safety of Care outcome group, each with at least three measures. Once this reported threshold is met, any additional measures and measure groups would contribute to hospital star ratings. We also propose to codify these policies at §412.190.

7. Proposed Approach to Peer Grouping Hospitals

a. Background

We have not previously grouped hospitals by peers within the Overall Star Rating methodology. However, as part of our discussion with stakeholders about the comparability of the Overall Star Rating, peer grouping and potential peer grouping variables were discussed in two TEP meetings (March 2018[269], and November 2019[270]), two Provider Leadership Work Group meetings (February and November 2019), two Patient & Advocate Work Group meetings (December 2017 and October 2019), and presented during two public comment periods (August 2017[271] and March 2019[272]). Through stakeholder engagement activities, we presented data on peer grouping variables including number of measures or measure groups a hospital reports, teaching designation, specialty designation, critical

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[268] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[269] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[270] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[271] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[272] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

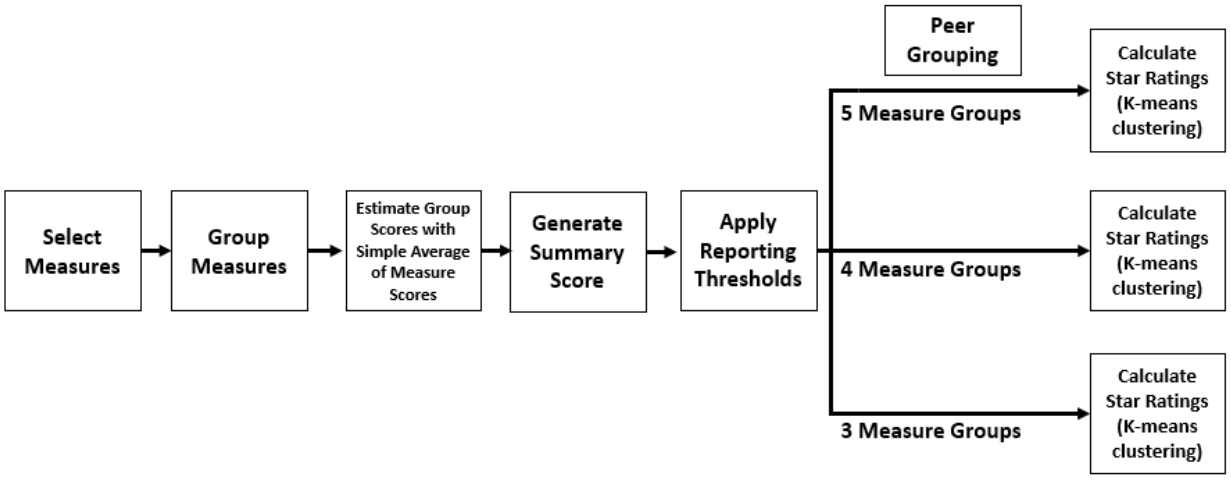
access designation, and number of beds at a hospital, among others. While there was no consensus among stakeholders regarding which hospital characteristic variable would be most appropriate for peer grouping,[273] CMS focused on the number of measure groups reported as a peer grouping variable based on analyses for many possible variables that assessed similarities among hospitals within peer groups and predictability of hospitals assignments to peer groups over time. Larger hospitals, for example, generally submit the most measures and smaller hospitals submit the fewest. Peer grouping by number of measure groups provides alignment with hospital size.

b. Proposed Peer Grouping

In this proposed rule, for Overall Star Rating beginning with CY 2021 and subsequent years, we propose to group hospitals that provide acute inpatient and outpatient care by the number of measure groups for which they have at least three measures as shown in Figure 2. Specifically, after the minimum reporting thresholds are applied, hospitals would be grouped into one of three peer groups based on the number of measure groups for which they report at least three measures – three measure groups, four measure groups, and five measure groups. Once grouped, k-means clustering would be applied within each peer group to assign hospital summary scores to star ratings. We also propose to codify this policy at §412.190.

Figure 2. Approach to Peer Grouping

[273] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815



Peer grouping hospitals based on the number of measure groups for which they report at least three measures is responsive to stakeholder concerns about the comparability of hospital star ratings and allows hospitals to be assigned to star ratings relative only to other similar hospitals in the same peer group.

We propose to group hospitals by measure group reporting to capture key differences that are important to stakeholders, such as differences in size, patient volume, case mix[274], and services provided (service mix[275]). For example, larger hospitals with more diverse case mix and service mix, such as large urban teaching hospitals, report a greater number of measures, and therefore measure groups, and would be grouped separately from smaller hospitals with less diverse patient cases and service mix, which tend to report fewer measures and measure groups.

Hospital summary scores would be placed into three peer groups after calculation of the weighted average of measure group scores and before the assignment of hospitals to star ratings using k-

[274] Centers for Medicare & Medicaid Services. (2019). *Frequently Asked Questions for the Risk-Standardized Outcome and Payment Measures.* Retrieved from qualitynet.org: https://www.qualitynet.org/files/5d0d374c764be766b010136d?filename=2019_IQR_CBMsrs_FAQs.pdf
[275] Ibid.

means clustering.[276] This proposal is dependent on a sufficient number of hospitals that provide acute inpatient and outpatient care reporting three, four, and five measure groups to form the three peer groups. We simulated effects of this policy based on January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*): 348 (10 percent) hospitals reported at least 3 measures in 3 groups, 583 (17 percent) reported 4 groups, and 2,509 (73 percent) reported all 5 groups. These group sizes were vetted with the TEP[277] and workgroups and considered adequately sized for clustering into peer grouped star ratings.

Of note, this proposal is contingent on the participation of CAHs, as outlined in section B.2. Proposal to Continue to Include Critical Access Hospitals in the Overall Star Rating, since CAHs make up approximately half of the hospitals in the three measure group peer group and their exclusion from the Overall Star Rating would not produce peer groups with a sufficient amount of hospitals for comparison. Because many CAHs currently report the minimum three measure groups required by the reporting threshold, as discussed in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating, and make up approximately half of the hospitals within the three measure group peer group, there would likely be an insufficient number of hospitals in the three measure group peer group to produce adequate variation through k-means clustering[278] if CAHs were not included in the calculation. If CAHs were not included, the difference in summary score between a two-star and three-star hospital may be modest and not truly reflective of differences in hospital quality.

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[276] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641

[277] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare*. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6

[278] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641

After peer grouping, we would then assign star ratings using k-means clustering[279] (discussed in section E.8. Step 6: Application of Clustering Algorithm to Obtain a Star Rating of this proposed rule) among hospitals within a single group, that is, relative only to hospitals in the same group. Specifically, hospitals would be grouped based on whether they have at least three measures for three measure groups, four measure groups, or five measure groups. The approach to peer grouping would retain the method used for assigning star ratings. Currently, the Overall Star Rating methodology uses a k-means clustering algorithm to assign hospitals to one of five star rating categories based on the distribution of hospital summary scores. This method aims to make hospital summary scores more similar within one star rating category and more different than hospital summary scores in other star rating categories. The proposed approach to peer grouping would be to also apply k-means clustering[280] to assign hospitals to one of five star ratings based only on hospitals in that peer group. For example, hospitals with three measure groups would be assigned to star ratings based on their summary score relative to other hospital summary scores with three measures groups, but not with respect to hospital summary scores among hospitals with four or five measure groups. Since hospitals in a peer group are being compared only to each other and k-means clustering is a comparative approach to assigning star ratings,[281] hospitals with the same summary score but different peer groups could receive different star ratings. In other words, a hospital with three measure groups could have the same summary score as a hospital with four measure groups; however, that summary score could fall within the four-star cluster for the three measure group peer group and the five-star cluster for the four measure group peer group. In addition, peer grouping hospitals would increase the comparability of star ratings within peer groups but decrease the

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[279] Ibid.

[280] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641

[281] Ibid.

comparability of star ratings across peer groups for patients. For example, once summary scores are calculated through the weighted average of measure group scores, a hospital within the three measure group peer group would not be assigned to a star rating relative to hospitals within the four or five measure group peer groups in the same geography or service line to whom that hospital is being compared by patients and consumers.

Applying peer grouping after the calculation of summary scores and before the assignment of hospitals to star ratings, allows: (1) hospital summary scores to be equivalent and comparable among all hospitals, regardless of peer grouping; (2) transparency and the ability for stakeholders to review measure group and summary score results comparable to all other hospitals in the nation for quality improvement efforts within their confidential hospital-specific reports during the 30-day confidential preview period or the *Hospital Compare* or its successor websites' downloadable database upon public release; (3) minimal sensitivity of measure-level differences between peer groups on star ratings; and (4) hospitals' final star ratings to only be in comparison to "like" hospitals that have a similar number of measure groups.

We have conducted several analyses to inform decision making regarding peer grouping. To determine whether peer grouping not only supports CMS efforts to improve the comparability of star ratings, but also the predictability of hospital assignments to peer groups, we simulated potential effects of this proposal and assessed the stability of peer groups over time. Hospitals tend to report the same number of measure groups over time and therefore are often assigned to the same peer group each reporting period. Using historical data over five previous years, hospitals would have been assigned to the same peer groups of three, four, or five measure groups 96 to 98 percent of the time, indicating a high level of consistency over time. Furthermore, peer grouping hospitals based on the number of measure groups for which they report at least three measures creates similar within peer group hospital

reporting profiles. Using January 2020 reporting data (from October 2019 publicly reported measure data on *Hospital Compare*), hospitals with three measure groups tend to almost always report at least three measures in the Mortality (86 percent), Readmission (86 percent), and Timely and Effective Care (96 percent) measure groups but tend to seldom report at least three measures in the Safety of Care (15 percent) and Patient Experience (17 percent) measures groups. Hospitals with four measure groups tend to always report at least three measures in the Readmission (100 percent) measure group, tend to almost always report at least three measures in the Mortality (92 percent), Patient Experience (98 percent), and Timely and Effective Care (99 percent) measure groups, and tend to seldom report at least three measures in the Safety of Care (11 percent) measure group. Hospitals with five measure groups report at least three measures in all five measure groups. Hospitals with three and four measure groups are more likely to be critical access hospitals (58 percent in the peer group with three measure groups and 52 percent in the peer group with four measure groups) while hospitals in the peer group with five measure groups tend to be safety-net (19 percent of the peer group) and teaching (56 percent of the peer group) hospitals. These results confirm that peer grouping results in the grouping of hospitals with similar reporting profiles and characteristics and may address stakeholder concerns about the comparability of hospital star ratings.

Peer grouping hospitals by the number of measure groups for which they report at least three measures for the assignment of hospital summary scores to star ratings addresses stakeholder concerns about the comparability of hospitals with fundamental differences, such as measure reporting, hospital size or volume, patient case mix, and service mix. However, we note that peer grouping hospitals would decrease the comparability of all hospitals for patients and change the historical, conceptual comparative nature of the Overall Star Rating.

In developing our proposal, we also considered not peer grouping and continuing to apply k-means clustering amongst all hospitals meeting the minimum reporting thresholds to assign hospitals to star ratings. However, we ultimately decided to propose to peer group hospitals based on the number of measure groups to be responsive to stakeholder feedback and increase comparability of hospital star ratings. Should we not finalize our proposal to include CAHs, we will not peer group the Overall Star Rating by number of measure groups.

We invite public comment on our proposal to peer group hospitals by number of measure groups and to codify this policy at §412.190.

8. Step 6: Application of Clustering Algorithm to Assign Star Rating

a. K-Means Clustering

(1) Current Application of K-Means Clustering

In the past, in order to assign hospitals to star ratings, we used an approach called k-means clustering to categorize hospitals' summary scores. K-means clustering is a clustering algorithm that groups entities, in this case hospitals, into a specified number of categories[282], in this case five star rating categories in which one star is the lowest and five stars is the highest, by grouping values, in this case hospital summary scores, so that they are more similar within groups and more different between groups. In other words, for each publication of the Overall Star Rating, k-means clustering establishes cutoffs, or a range of summary scores, for each of the star rating categories so that summary scores in one star rating category would be more similar to each other and less similar to summary scores in other star rating categories.

[282] Ibid.

We considered multiple approaches to assigning hospitals to star ratings, including percentiles, statistically significant cutoffs, and clustering algorithms. Each option was presented to the TEP[283] [284] and during a public input period[285] by the Overall Star Rating development contractor. While any approach to assigning hospitals to star ratings will result in some hospitals with summary scores near the cutoffs of two star rating categories, at that time, we chose to use k-means clustering because it applied a data-driven approach to specification of five categories, minimized the within-category differences and maximized the between-category differences in summary scores, and was similar to the clustering algorithm used to calculate the HCAHPS Star Rating.[286] Stakeholders have generally supported the use of k-means clustering to assign star ratings over arbitrary percentiles and statistically significant cutoffs.[287] [288] [289]

In December 2017, we applied a minor update to the application of k-means clustering by running the summary scores through the clustering algorithm multiple times, a statistical method called complete convergence,[290] to provide more reliable and stable star rating assignments. Prior to December 2017, we performed Winsorization[291] of hospital summary scores to limit the influence of extreme

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[283] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[284] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[285] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[286] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings* . Retrieved from www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf

[287] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[288] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[289] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[290] Hsu, P. L., & Robbins, H. (1947). Complete Convergence and the Law of Large Numbers. *Proceedings of the National Academy of Sciences of the United States of America*, *33*(2), 25–31. doi:10.1073/pnas.33.2.25

[291] Kwak, S.K., & Kim, J.H. (2017, July 27)."Statistical data preparation: management of missing values and outliers." Korean journal of anesthesiology 70.4: 407.

outliers. Winsorization is a common strategy used to set extreme outliers to a specified percentile of the data.[292] While k-means clustering has been used within the methodology since implementation in July 2016, the update to run k-means clustering to complete convergence results in a broader distribution of star ratings and negates the need for Winsorization of hospital summary scores.[293]

(2) Proposal to Continue K-Means Clustering

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue use k-means clustering with complete convergence without Winsorization of hospital summary scores, to group hospitals into five clusters to assign star ratings so that one star is the lowest and five stars is the highest. We also propose to codify this policy at §412.190. We believe use of k-means clustering is most appropriate because it aligns with the clustering algorithm used for the HCAHPS Star Rating[294] and maximizes the within star rating category similarities and between star rating category differences. We seek public comment on our proposal to continue to use k-means clustering to complete convergence to assign hospitals to star ratings, where one star is the lowest and five stars is the highest, and to codify this policy at §412.190

F. Preview Period

1. Background

In the past, similar to the process in place for multiple CMS quality programs prior to public reporting of measure scores, hospitals providing acute inpatient and outpatient care that are included in the Overall Star Rating had the opportunity to confidentially review their star rating as well as the

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[292] Ibid.

[293] Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1

[294] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings* . Retrieved from www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf

measures and measure group scores that contribute to their star rating during the confidential preview period a few months prior to the public release of the Overall Star Rating. We provided hospitals with a confidential report and at least 30 days to preview their results prior to releasing the Overall Star Rating. During the confidential preview period, hospitals received a confidential hospital-specific report (HSR), which detailed their measure performance and measure group scores with comparisons to the national average, as well as their summary score and star rating. The HSRs also provided information about how the measures' scores contribute to measure group scores, how measure group scores are weighted to calculate summary scores, and the range of summary scores for each star rating category. The Overall Star Rating preview period allowed hospitals to review, understand, and ask CMS questions about how the star rating was calculated.

2. Proposed Preview Period

In this proposed rule, for Overall Star Rating beginning with the CY 2021 and subsequent years, we propose to continue our current process regarding the preview period. Specifically, a few months prior to public release of the Overall Star Rating, we would issue a confidential HSR, which would detail measure and measure group scores as well as their summary score and star rating. The HSRs would also provide information about how the measures' scores contribute to measure group scores, how measure group scores are weighted to calculate summary scores, and the range of summary scores for each star rating category. During this preview period, hospitals would have at least 30 days to preview their results, and if necessary, reach out to CMS via the QualityNet Question and Answer tool, or additional contact information provided within preview period resources with questions about the methodology and their star ratings results. We also propose to codify this policy at §412.190. This proposal as well as the proposal to report Overall Star Rating annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year would allow hospitals

more time to review and understand the methodology and their results, as well as reach out with questions.

We invite public comment on our proposals to: (1) establish a 30-day confidential preview period, and (2) codify the confidential preview period at §412.190.

G. Overall Star Rating Suppressions

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose separate suppression policies for subsection (d) hospitals and CAHs given that subsection (d) hospitals are subject to CMS quality programs and CAHs voluntarily submit measure data.

1. Subsection (d) Hospitals

a. Background

In the past, we would have only suppressed Overall Star Rating for subsection (d) hospitals when there were errors within the Overall Star Ratings calculation or the calculation for individual measures, which would first need to be addressed through CMS programs prior to recalculating Star Ratings. Furthermore, there is currently no specific corrections process for the Overall Star Rating.

b. Proposed Suppression

In this proposed rule, we propose to continue to allow for suppression, but only in limited circumstances. Specifically, for the Overall Star Rating beginning with the CY 2021 and subsequent years, we propose to consider suppressing Overall Star Rating only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS or when CMS is at fault, including but not limited to when:

- There is an Overall Star Rating calculation error by CMS;
- There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation. For example, there is a CMS quality program level error for one or

more measures included within the Overall Star Rating due to incorrect data processing or measure calcualtions that affects a substantial number of hospitals reporting those measures. We note that we would strive to first correct systemic errors at the program level per program policies and then recalculate the Overall Star Rating, if possible; or

- A Public Health Emergency substantially affects the underlying measure data.

We also propose to codify this policy at §412.190.

As mentioned above, consistent with past practices, we propose that we would not suppress an individual hospital's Overall Star Rating because the hospital or one of its agents (for example, authorized vendors, representatives, or contractors) submitted inaccurate data to CMS, including inaccurate underlying measure data and claims records. We note that the Overall Star Rating is calculated using individual measures publicly reported on *Hospital Compare* or its successor site via CMS quality programs. Hospitals can utilize established processes under each program in order to review and correct individual measure scores. As policies are specific to each program, we refer readers to the respective hospital program's policies. We also refer readers to the QualityNet website: https://qualitynet.org/ for additional program-related information. We invite public comment on our proposals as discussed above.

(1) CAHs

(a) Background

As discussed in section B. Critical Access Hospitals in the Overall Star Rating of this proposed rule, CAHs voluntarily submit measure data consistent with certain CMS programs. These measure results are then publicly reported on *Hospital Compare* or its successor websites. In the past, since the Overall Star Rating summarizes available measure information on *Hospital Compare* or its successor

website, CAHs with publicly reported measures results on *Hospital Compare* that also met the reporting thresholds to receive a star rating were assigned a star rating.

CAHs that did not want their voluntarily submitted measure data publicly reported on *Hospital Compare* could submit a form ("Request Form for Withholding/Footnoting Data for Public Reporting" available on QualityNet) per the forms' instructions during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Ratings. We note that this preview period is distinct from the Overall Star Rating preview period. If the measure data itself was withheld on *Hospital Compare*, it subsequently could not be included in the Overall Star Rating. Generally, upon public release of the Overall Star Rating, we also provide a public input file containing aggregate hospital measure scores, measure group scores, and summary scores along with the Overall Star Rating SAS pack for transparency and to allow stakeholders the opportunity to replicate the calculation of star ratings. If a CAH withheld its data from *Hospital Compare* at this stage, that data was excluded from both the Overall Star Rating calculation and the public input file.

Furthermore, because CAHs voluntarily reported measures, CAHs that would otherwise receive an Overall Star Rating could request to withhold their star rating during the Overall Star Rating preview period. However, at this stage, individual measure scores were still included in the public input file due to time and process constraints.

(b) Proposed Withholding

In this proposed rule, for Overall Star Rating beginning in CY 2021 and subsequent years, we propose to 1) continue to allow CAHs to withhold their Overall Star Rating; and 2) to codify this at §412.190. These proposals, discussed in more detail below, align with the guiding principles of transparency and inclusivity of hospitals, as outlined within section A. Background, while allowing CAHs to voluntarily withhold their Overall Star Rating.

i. Withholding Star Ratings

Beginning with CY 2021 and for subsequent years, we propose that CAHs may request to withhold their Overall Star Rating from public release on *Hospital Compare* or its successor website so long as the request for withholding is made, at the latest, during the Overall Star Rating preview period as proposed in section F.2. Proposed Preview Period of this proposed rule. We also propose to codify this policy at §412.190. CAHs may make this request by submitting the "Request Form for Withholding/Footnoting Data for Public Reporting" form[295] available on QualityNet by midnight of the last day of the Overall Star Rating preview period. This is the same form used for withholding data from CMS programs. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital Compare* or its successor website through completion of this form, all of their measures scores will be withheld from the Overall Star Rating calculation. However, individual measure scores would still be included in the public input file. By the time the Overall Star Rating preview period begins, there would not be sufficient time for CMS to remove a CAH's data from the public input file and then recalculate the Overall Star Rating for all affected hospitals. As an example, for a January 2021 Overall Star Rating publication based on data publicly reported on *Hospital Compare* or its successor website using October 2020 data, CAHs would need to submit their withholding request during the Overall Star Rating preview period, which would occur a few months prior to the January 2021 publication, in order to withhold their Overall Star Rating (but their data would still remain in the Public Input File).

ii. Withholding Star Ratings and Public Input File Data

[295] The "Request Form for Withholding/Footnoting Data for Public Reporting" form is in the process of being updated for use in CY21.

In addition, we propose that CAHs may request to have their Overall Star Rating withheld from public release on *Hospital Compare* or its successor website, as well as their data from the public input file, which is posted upon the public release of the Overall Star Rating and used by stakeholders to replicate the calculation of star ratings, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Ratings. We also propose to codify this policy at §412.190. As an example, we refer readers to our discussion in the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608) for more information about this preview period in one of CMS' quality programs. CAHs may request that CMS withhold their measure and star rating results from public posting on *Hospital Compare* or its successor website and the Overall Star Rating public input file by submitting a form ("Request Form for Withholding/Footnoting Data for Public Reporting"[296] available on QualityNet) per the forms' instructions. This is the same form used for withholding from CMS programs. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital Compare* or its successor website through completion of this form during this stated timeframe, all of their measures scores would be withheld from the Overall Star Rating calculation and public input file.

As an example, for a January 2021 Overall Star Rating publication based on data publicly reported on *Hospital Compare* or its successor website using October 2020 data, CAHs would need to submit their withholding request during the CMS quality program-level 30-day confidential preview period, which would generally occur a few months prior to the October 2020 *Hospital Compare* refresh in order to withhold both their Overall Star Rating and data from the public input file.

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[296] The "Request Form for Withholding/Footnoting Data for Public Reporting" form is in the process of being updated for use in CY21.

We invite public comment on our proposals.

XVII. Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Social Security Act (the Act), which allows the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services" (84 FR 61142, November 12, 2019).[297] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In addition to codifying the basis and scope of subpart I, Prior Authorization for Outpatient Department Services, the regulations include definitions associated with the prior authorization process, provide that prior authorization must be obtained as a condition of payment for the listed service categories, and include the process by which hospitals must obtain prior authorization. Paragraph (a)(1) of § 419.83 lists the specific service categories for which prior authorization must be obtained, which are: (i) Blepharoplasty, (ii) Botulinum toxin injections, (iii) Panniculectomy, (iv) Rhinoplasty, and (v) Vein ablation. Paragraph (b) states that CMS will update this list through formal notice-and-comment rulemaking, paragraph (c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and paragraph (d) states that CMS may suspend the prior authorization process requirements generally or for a particular service at any time by issuing a notification on the CMS website.

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[297] See also Correction Notice issued January 3, 2020 (85 FR 224).

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Proposed Addition of Two New Service Categories

In accordance with § 419.83(b), we propose to require prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. We also propose to add those service categories to § 419.83(a). We propose that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. As explained more fully below, the proposed addition of these service categories is consistent with our authority under section 1833(t)(2)(F) and is based upon our determination that there has been an unnecessary increase in the volume of these services. Based on the different implementation dates for the original five service categories and the two proposed service categories, we propose to add a reference to the July 1, 2020 implementation date to the end of paragraph (a)(1) to reflect the implementation date for the original five service categories. Specifically, we propose that paragraph (a)(1) would read, "[t]he following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020." We also propose to add a new paragraph (a)(2), which would read: "[t]he following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021." We propose that the two proposed service categories would be added as new subparagraphs to new paragraph (a)(2) as follows: (i) Cervical Fusion with Disc Removal and (ii) Implanted Spinal Neurostimulators. We also propose that existing paragraph (a)(2) would be renumbered as paragraph (a)(3).

We propose that the list of covered OPD services that would require prior authorization are those identified by the CPT codes in Table 53. For ease of review, we are only including in Table 53 the CPT codes that fall into the two proposed service categories in proposed new § 419.83(a)(2)(i) and (ii). Note

that this is the same approach we took in establishing the initial five service categories in § 419.83(a)(1). For ease of reference, we have included the Final List of Outpatient Services that Require Prior Authorization for the five initial service categories in Table 54.[298] Again, the prior authorization process for the two proposed additional service categories would be effective for dates of service on or after July 1, 2021.

2. Basis for Proposing to Add Two New Service Categories

As part of our responsibility to protect the Medicare Trust Funds, we are continuing our routine analysis of data associated with all facets of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting.

As we noted in the CY 2020 OPPS/ASC proposed rule,[299] we recognize the need to establish baseline measures for comparison purposes, including, but not limited to, the yearly rate-of-increase in the number of OPD claims submitted and the average annual rate-of-increase in the Medicare allowed amounts. For this proposed rule, we updated the analyses undertaken for the CY 2020 OPPS/ASC proposed rule.[300] In proposing the addition of these two service categories, we reviewed over 1.2 billion claims related to OPD services during the 12-year period from 2007 through 2018.[301] We determined

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[298] The table appears on pages 61456 and 61457 of the Final Rule but contains certain technical errors. The table printed here is consistent with our January 3, 2020 correction notice. See 85 FR at 225.

[299] *See* Hospital Outpatient Prospective System/Ambulatory Surgical Center Payment System Proposed Rule, 84 FR 39398 at 39603 (August 9, 2019).

[300] 84 FR 39604.

[301] The data reviewed are maintained in the CMS Integrated Data Repository (IDR). The IDR is a high volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with

that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 2.8 percent. This equated to an increase from approximately 90 million OPD claims submitted for payment in 2007 to approximately 117 million claims submitted for payment in 2018. The 2.8 percent rate reflects a slight decrease when compared to the 3.2 percent rate identified in the CY 2020 OPPS proposed rule. Our analysis also showed an average annual rate-of-increase in the Medicare allowed amount (the amount that Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) of 7.8 percent. Again, this is a slight decrease when compared to the 8.2 percent rate identified in the CY 2020 OPPS/ASC proposed rule. We found that the total Medicare allowed amount for the OPD services claims processed in 2007 was approximately $31 billion and increased to $68 billion in 2018, while during this same 12-year period, the average annual increase in the number of Medicare beneficiaries per year was only 0.9 percent.

Below we describe what we believe are the unnecessary increases in volume for each of the categories of services for which we propose to require prior authorization.

- *Implanted Spinal Neurostimulators:* Our analysis of IDR data showed that, with regard to Implanted Spinal Neurostimulators, claims volume for insertion or replacement of spinal neurostimulator pulse generator or receiver, 63685, increased by 174.6 percent between 2007 and 2018, reflecting a 10.2 percent average annual increase, a significantly greater annual increase than the 2.8 percent average annual increase for all OPD services. From 2016 through 2018, the average annual increase in volume was 17 percent. For 63688, revision or removal of implanted spinal neurostimulator pulse generator or receiver, we observed an increase of 149.7 percent between 2007 and 2018, reflecting

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ancillary data such as contract information and risk scores. Additional information is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html*.

a 8.8 percent average annual increase, and for 63650, implantation of spinal neurostimulator electrodes, accessed through the skin, we observed an increase in volume of 77.9 percent between 2007 and 2018, which was an average annual increase of 6.5 percent, these average annual increases for both codes are higher than the 2.8 percent average annual increase for all OPD services over the same period. When analyzing these data, we fully accounted for changes that occurred in 2014 related to electrodes being incorporated into the 63650 code, which did not show a corresponding claims volume change that would explain the large increases noted over time when compared to the rates of change for all OPD services.

- *Cervical Fusion with Disc Removal*: When reviewing CMS data available through the Integrated Data Repository (IDR), we determined that claims volume for the initial level of spinal fusion of the cervical spine with removal of the corresponding intervertebral disc, CPT®[302] code 22551, had increased by 1,538.9 percent between 2012 and 2018, reflecting a 124.9 percent average annual increase, a substantially greater increase than the 2.8 percent average annual increase for all OPD services over the same period and the 2.1 percent average annual increase for all OPD services from 2007 through 2018. In fact, the increase between 2016 and 2018 for this code was 736 percent. The add-on code, 22552 (for additional levels), reflected claims volume increases of 3,779.6 percent between 2012 and 2018, reflecting a 174.9 percent average annual increase, again, far eclipsing the 2.8 percent average annual increase for all OPD services. Between 2016 and 2018 alone, the claims volume for this code increased 1,020 percent. These codes were first used in 2011 to better reflect the combination of the cervical fusion and the disc removal procedures. Accordingly, we use data from 2012 forward to allow for the start-up statistics to normalize. Nonetheless, the dramatic increases in volume that we have identified persisted well after the initial use of these codes.

[302] The Current Procedural Technology (CPT) coding system is a registered trademark of the American Medical Association.

A rate of increase higher than the expected rate is not always improper; however, when we considered the data, we believe the increases in the utilization rate for this service are unnecessary. CPT 22551 began being used in 2011. The use of the code almost tripled in 2012 and significantly increased each year thereafter. The increases became even more dramatic beginning in 2016, when the ambulatory payment classification (APC) for CPT 22551 was changed to a higher level. Effective January 1, 2016, the CY 2016 OPPS/ASC final rule[303] moved the APC for CPT 22551 from APC 0208 (Laminectomies and Laminotomies) to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis). APC 0425 has a higher payment than APC 0280, the group to which they were originally assigned. APC 0208 had a geometric mean cost of $4,267, but APC 0425 had a geometric mean cost of $10,606. This represents a 149 percent increase in allowed amount as a result of the move to APC 0425, which may have contributed to the unnecessary increase in volume. Again, this represents a 736 percent increase in claims volume between 2016 and 2018 when all outpatient department services demonstrated an 0.4 percent increase overall for the same time period. We believe that the change in the payment rate likely prompted the unnecessary volume increases and may have created a financial motivation to utilize these codes more than may be considered medically necessary. We believe prior authorization is an appropriate control method for the unnecessary increase in volume for this service.

Our conclusion that the increases in volume for both Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators are unnecessary is based not only on the data specific to each service category, but also on a comparison of the rate of increase for the service categories to the overall trends for all OPD services. We believe that comparing the utilization rate to the baseline growth rate is an appropriate method for identifying unnecessary increases in volume, particularly where there are no legitimate clinical or coding reasons for the changes. For both services categories, we researched

[303] 79 FR 66769 and 80 FR 70297

possible causes for the increases in volume that would indicate the services are increasingly necessary, but we did not find any explanations that would cause us to believe the increases were necessary. Moreover, other than the recent changes in the CPT code and APC assignments described above, CMS has not taken any action that would explain the significant increases identified. We also conducted reviews of clinical and industry-related literature and found no indication of changes that would justify the increases observed. After reviewing all available data, we found no evidence suggesting other plausible reasons for the increases, which we believe means financial motivation is the most likely cause. We believe utilizing codes because of financial motivations, as opposed to medical necessity reasons, has resulted in an unnecessary increase in volume. Therefore, comparing the utilization rate to the baseline growth rate is an appropriate method for identifying unnecessary increases in volume, and prior authorization is an appropriate method to control these volume increases.

We continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments, without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We request comments on the addition of these two service categories.

TABLE 53: 2021 PROPOSED LIST OF ADDITIONAL OUTPATIENT DEPARTMENT SERVICES THAT WOULD REQUIRE PRIOR AUTHORIZATION

	Beginning for service dates on or after July 1, 2021
Code	(i) Cervical Fusion with Disc Removal

22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck , anterior approach, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

TABLE 54: 2020 FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

	Beginning for service dates on or after July 1, 2020
Code	(i) Blepharoplasty, Eyelid Surgery, Brow Lift, and related services
15820	Removal of excessive skin of lower eyelid
15821	Removal of excessive skin of lower eyelid and fat around eye
15822	Removal of excessive skin of upper eyelid
15823	Removal of excessive skin and fat of upper eyelid
67900	Repair of brow paralysis
67901	Repair of upper eyelid muscle to correct drooping or paralysis
67902	Repair of upper eyelid muscle to correct drooping or paralysis
67903	Shortening or advancement of upper eyelid muscle to correct drooping or paralysis
67904	Repair of tendon of upper eyelid
67906	Suspension of upper eyelid muscle to correct drooping or paralysis
67908	Removal of tissue, muscle, and membrane to correct eyelid drooping or paralysis
67911	Correction of widely-opened upper eyelid
Code	(ii) Botulinum Toxin Injection
64612	Injection of chemical for destruction of nerve muscles on one side of face
64615	Injection of chemical for destruction of facial and neck nerve muscles on both sides of face
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services

15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (list separately in addition to code for primary procedure)
15877	Suction assisted removal of fat from trunk
Code	(iv) Rhinoplasty, and related services[304]
20912	Nasal cartilage graft
21210	Repair of nasal or cheek bone with bone graft
30400	Reshaping of tip of nose
30410	Reshaping of bone, cartilage, or tip of nose
30420	Reshaping of bony cartilage dividing nasal passages
30430	Revision to reshape nose or tip of nose after previous repair
30435	Revision to reshape nasal bones after previous repair
30450	Revision to reshape nasal bones and tip of nose after previous repair
30460	Repair of congenital nasal defect to lengthen tip of nose
30462	Repair of congenital nasal defect with lengthening of tip of nose
30465	Widening of nasal passage
30520	Reshaping of nasal cartilage
Code	(v) Vein Ablation, and related services
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin
36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance

[304] Code 21235, "Obtaining ear cartilage for grafting" was removed on June 10, 2020 in accordance with § 419.83(d). See CMS http://go.cms.gov/OPD_PA.

XVIII. Clinical Laboratory Fee Schedule: Proposed Revisions to the Laboratory Date of Service Policy

A. Background on the Medicare Part B Laboratory Date of Service Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. However, a laboratory service may take place over a period of time—the date the laboratory test is ordered, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date the laboratory performs the test, and the date results are produced may occur on different dates. In the final rule on coverage and administrative policies for clinical diagnostic laboratory services published in the **Federal Register** on November 23, 2001 (66 FR 58791 through 58792), we adopted a policy under which the DOS for clinical diagnostic laboratory services generally is the date the specimen is collected. In that final rule, we also established a policy that the DOS for laboratory tests that use an archived specimen is the date the specimen was obtained from storage (66 FR 58792).

In 2002, we issued Program Memorandum AB–02–134, which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered "archived." In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered "archived," in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the **Federal Register** on February 25, 2005 (70 FR 9357), we defined an "archived" specimen as a specimen that is stored for more than 30 calendar days before testing. Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected.

B. Medicare DOS Policy and the "14-Day Rule"

In the final rule with comment period entitled, in relevant part, "Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B" published in the **Federal Register** on December 1, 2006 (December 1, 2006 MPFS final rule) (71 FR 69705 through 69706), we added a new § 414.510 in title 42 of the CFR regarding the clinical laboratory DOS requirements and revised our DOS policy for stored specimens. We explained in that MPFS final rule that the DOS of a test may affect payment for the test, especially in situations in which a specimen that is collected while the patient is being treated in a hospital setting (for example, during a surgical procedure) is later used for testing after the patient has been discharged from the hospital. We noted that payment for the test is usually bundled with payment for the hospital service, even when the results of the test did not guide treatment during the hospital stay. To address concerns raised for tests related to cancer recurrence and therapeutic interventions, we finalized modifications to the DOS policy in § 414.510(b)(2)(i) for a test performed on a specimen stored less than or equal to 30 calendar days from the date it was collected (a non-archived specimen), so that the DOS is the date the test was performed (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

As we stated in the December 1, 2006 MPFS final rule, we established these five criteria, which we refer to as the "14-day rule," to distinguish laboratory tests performed as part of posthospital care from the care a beneficiary receives in the hospital. When the 14-day rule applies, laboratory tests are not bundled into the hospital stay, but are instead paid separately under Medicare Part B (as explained in more detail below).

We also revised the DOS requirements for a chemotherapy sensitivity test performed on live tissue. As discussed in the December 1, 2006 MPFS final rule (71 FR 69706), we agreed with commenters that these tests, which are primarily used to determine posthospital chemotherapy care for patients who also require hospital treatment for tumor removal or resection, appear to be unrelated to the hospital treatment in cases where it would be medically inappropriate to collect a test specimen other than at the time of surgery, especially when the specific drugs to be tested are ordered at least 14 days following hospital discharge. As a result, we revised the DOS policy for chemotherapy sensitivity tests, based on our understanding that the results of these tests, even if they were available immediately, would not typically affect the treatment regimen at the hospital. Specifically, we modified the DOS for chemotherapy sensitivity tests performed on live tissue in § 414.510(b)(3) so that the DOS is the date the test was performed if the following conditions are met:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

We explained in the December 1, 2006 MPFS final rule that, for chemotherapy sensitivity tests that meet this DOS policy, Medicare would allow separate payment under Medicare Part B; that is, separate from the payment for hospital services.

C. Billing and Payment for Laboratory Services Under the OPPS

As noted previously, the DOS requirements at 42 CFR 414.510 are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. Separate regulations at 42 CFR 410.42(a) and 411.15(m) generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined in 42 CFR 409.3) with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which we refer to as the "under arrangements" provisions in this discussion, require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

Under our current rules, if a test meets all DOS requirements in § 414.510(b)(2)(i), (b)(3), or (b)(5), the DOS is the date the test was performed. In this situation, the laboratory would bill Medicare directly for the test and would be paid under the Clinical Laboratory Fee Schedule (CLFS) directly by Medicare. However, if the test does not meet the DOS requirements in § 414.510(b)(2)(i), (b)(3), or (b)(5), the DOS would be the date the specimen was collected from the patient. In that case, the hospital would bill Medicare for the test and then would pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

In previous rulemakings, we have reviewed appropriate payment under the OPPS for certain diagnostic tests that are not commonly performed by hospitals. In CY 2014, we finalized a policy to package certain CDLTs under the OPPS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17) and

419.22(l)). In CYs 2016 and 2017, we made some modifications to this policy (80 FR 70348 through 70350 and 81 FR 79592 through 79594). Under our current policy, certain CDLTs that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Specifically, we package most CDLTs under the OPPS. However, when a CDLT is listed on the CLFS and meets one of the following four criteria, we do not pay for the test under the OPPS, but rather, we pay for it under the CLFS when it is: (1) the only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act (78 FR 74939 through 74942; 80 FR 70348 through 70350; and 81 FR 79592 through 79594). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70348 through 70350), we excluded all molecular pathology laboratory tests from packaging because we believed these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

For similar reasons, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592 through 79594), we extended the exclusion to also apply to all ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We stated that we will assign status indicator "A" (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. Laboratory tests that meet one of the four criteria above and that are listed on the CLFS are paid under the CLFS, rather than being packaged and paid for under the OPPS.

D. ADLTs under the New Private Payor Rate-Based CLFS

Section 1834A of the Act, as established by section 216(a) of Pub. L. 113-93, the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for

CDLTs under the CLFS. Section 216(a) of PAMA also established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. In the CLFS final rule published in the **Federal Register** on June 23, 2016, entitled "Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule" (81 FR 41036), we implemented the requirements of section 1834A of the Act.

As defined in § 414.502, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory, and cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays.

Or:

- *Criterion (B):* The test is cleared or approved by the Food and Drug Administration.

Generally, under the revised CLFS, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, updates to ADLT payment rates occur annually instead of every 3 years. The payment methodology for ADLTs is detailed in the June 23, 2016 CLFS final rule (81 FR 41076 through 41083). For additional information regarding ADLTs, we refer readers to the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html.

E. Additional Laboratory DOS Policy Exception for the Hospital Outpatient Setting

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59393 through 59400), we established an additional exception at § 414.510(b)(5) so that the DOS for molecular pathology tests and certain ADLTs that are excluded from the OPPS packaging policy is the date the test was performed (instead of the date of specimen collection) if certain conditions are met. Under the exception that we finalized at § 414.510(b)(5), in the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59397), we explained that we believed the laboratory DOS policy in effect prior to CY 2018 created administrative complexities for hospitals and laboratories with regard to molecular pathology tests and laboratory tests expected to be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We noted that under the laboratory DOS policy in effect prior to CY 2018, if the tests were ordered less than 14 days following a hospital outpatient's discharge from the hospital outpatient department, laboratories

generally could not bill Medicare directly for the molecular pathology test or ADLT. In those circumstances, the hospital had to bill Medicare for the test, and the laboratory had to seek payment from the hospital. We noted that commenters informed us that because ADLTs are performed by only a single laboratory and molecular pathology tests are often performed by only a few laboratories, and because hospitals may not have the technical ability to perform these complex tests, the hospital may be reluctant to bill Medicare for a test it would not typically (or never) perform. The commenters also stated that as a result, the hospital might delay ordering the test until at least 14 days after the patient is discharged from the hospital outpatient department, or even cancel the order to avoid the DOS policy, which may restrict a patient's timely access to these tests. In addition, we noted that we had heard from commenters that the laboratory DOS policy in effect prior to CY 2018 may have disproportionately limited access for Medicare beneficiaries under Medicare Parts A and B, because Medicare Advantage plans under Medicare Part C and other private payors allow laboratories to bill directly for tests they perform.

We also recognized that greater consistency between the laboratory DOS rules and the current OPPS packaging policy would be beneficial and would address some of the administrative and billing issues created by the DOS policy in effect prior to CY 2018. We noted that we exclude all molecular pathology tests and ADLTs under section 1834A(d)(5)(A) of the Act from the OPPS packaging policy because we believe these tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged, and we had already established exceptions to the DOS policy that permit the DOS to be the date of performance for certain tests that we believe are not related to the hospital treatment and are used to determine posthospital care. We stated that we believed a similar exception is justified for the molecular pathology tests and ADLTs excluded from the OPPS packaging

policy, which we understood are used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department. We noted that we believed that, like the other tests currently subject to DOS exceptions, these tests can legitimately be distinguished from the care the patient receives in the hospital, and thus we would not be unbundling services that are appropriately associated with hospital treatment. Moreover, we reiterated that these tests are already paid separately outside of the OPPS at CLFS payment rates. Therefore, we agreed with the commenters that the laboratory performing the test should be permitted to bill Medicare directly for these tests, instead of relying on the hospital to bill Medicare on behalf of the laboratory under arrangements.

Following publication of the CY 2018 OPPS/ASC final rule with comment period, we issued Change Request (CR) 10419, Transmittal 4000, the claims processing instruction implementing the laboratory DOS exception at § 414.510(b)(5), with an effective date of January 1, 2018 and an implementation date of July 2, 2018. After issuing CR 10419, we heard from stakeholders that many hospitals and laboratories were having administrative difficulties implementing the DOS exception set forth at § 414.510(b)(5). On July 3, 2018, we announced that, for a 6-month period, we would exercise enforcement discretion with respect to the laboratory DOS exception at § 414.510(b)(5). We explained that stakeholder feedback suggested many providers and suppliers would not be able to implement the laboratory DOS exception by the July 2, 2018 implementation date established by CR 10419, and that such entities required additional time to develop the systems changes necessary to enable the performing laboratory to bill for tests subject to the exception. We noted that this enforcement discretion would apply to all providers and suppliers with regard to ADLTs and molecular pathology tests subject to the laboratory DOS exception policy, and that during the enforcement discretion period, hospitals may continue to bill for these tests that would otherwise be subject to the laboratory DOS exception.

We then extended the enforcement discretion period for two additional, consecutive 6-month periods, after learning that there were still many entities needing additional time to come into compliance. The final enforcement discretion announcement as well as CR 10419, Transmittal 4000 is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html. The enforcement discretion period ended on January 2, 2020.

During the period of enforcement discretion, we continued to gage the industry's readiness to implement the laboratory DOS exception at § 414.510(b)(5). In particular, we heard from stakeholders that some entities performing molecular pathology testing subject to the laboratory DOS exception, such as blood banks and blood centers, may not be enrolled in the Medicare program and may not have established a mechanism to bill Medicare directly. In the CY 2020 OPPS/ASC proposed rule (84 FR 39603), we sought comments on excluding blood banks and blood centers from the laboratory DOS exception at § 414.510(b)(5). Based on concerns raised by stakeholders, we stated that we believe blood banks and centers perform molecular pathology testing for patients to enable hospitals to prevent adverse conditions associated with blood transfusions, rather than perform molecular pathology testing for diagnostic purposes. Given the different purpose of molecular pathology testing performed by the blood banks and centers, that is, blood compatibility testing, we questioned whether the molecular pathology testing performed by blood banks and centers is appropriately separable from the hospital stay, given that it typically informs the same patient's treatment during a future hospital stay. We stated that we were concerned that our current policy may unbundle molecular testing performed by a blood bank or center for a hospital patient.

For these reasons, and based on the support received from commenters, in the CY 2020 OPPS/ASC final rule (84 FR 61444), we finalized a revision to the laboratory DOS policy to exclude

molecular pathology tests when performed by laboratories that are blood banks or centers from the laboratory DOS exception at 42 CFR 414.510(b)(5). We also finalized a definition for "blood bank or center" at § 414.502 as an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

A list of the specific laboratory tests currently subject to the laboratory DOS exception at § 414.510(b)(5) is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html

F. Proposed Revision to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61438 through 61439), we explained that protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) that are not considered molecular pathology tests and are not designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, are packaged under the OPPS at this time. Though they do not currently qualify for the DOS exception at § 414.510(b)(5) solely because they are MAAAs, we noted that several stakeholders have suggested that they believe the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service.

In particular, stakeholders have suggested that certain protein-based MAAAs, specifically, those described by CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, are generally not performed in the HOPD setting and have similar clinical patterns of use as other tests that are not paid under the OPPS and are paid separately under the CLFS, and so should be treated similarly (82 FR 59299). Consequently, the stakeholders believed that protein-based MAAAs should be excluded from OPPS packaging and paid separately under the CLFS. Notably, with one exception (CPT code 81490), each of those tests described by the CPT codes identified by stakeholders is a cancer-related protein-based

MAAA. We did not establish an exception to the laboratory DOS policy for protein-based MAAAs in the CY 2020 OPPS/ASC final rule with comment period, but we did note that a protein-based MAAA that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be eligible for the DOS exception at § 414.510(b)(5). We indicated in that rule that we intended to consider policies regarding the application of the DOS policy to MAAAs for future rulemaking (84 FR 61439).

After further consideration of this issue, we now believe certain MAAAs, specifically, cancer-related protein-based MAAAs, which stakeholders identified, as discussed above, have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected because the results of these tests are typically used to determine posthospital care. As we explain below, we believe these tests are distinguishable from the care the patient receives in the hospital, similar to molecular pathology tests and tests designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, which are currently excluded from the OPPS packaging policy and subject to the laboratory DOS exception at § 414.510(b)(5). Therefore, we propose to exclude cancer-related protein-based MAAAs from the OPPS packaging policy, as discussed in section II.a.3. of this proposed rule, and create an exception to the laboratory DOS rule for them. These proposals, if finalized, would mean that Medicare would pay for cancer-related protein-based MAAAs under the CLFS instead of the OPPS and the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5).

We understand that, similar to molecular pathology tests and ADLTs under paragraph (1) of the definition of an ADLT in § 414.502, cancer-related protein-based MAAAs are typically used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department because the test results are used to determine potential future oncologic surgical and chemotherapeutic

interventions; they would almost never affect the treatment regimen during the same hospital outpatient service in which the specimen was collected, even if the results were available immediately. In other words, decisions as to particular therapies and/or surgical procedures, as guided by the results of the test, are not made during the same hospital outpatient encounter during which the specimen was collected.

For these reasons, we propose to add cancer-related protein-based MAAAs to our current laboratory DOS exception rule at § 414.510(b)(5). Under this proposed revision, the DOS for a cancer-related protein-based MAAA would be the date the test was performed if: (1) the test was performed following a hospital outpatient's discharge from the hospital outpatient department; (2) the specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2); (3) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) the test was reasonable and medically necessary for the treatment of an illness.

This proposed revision to our laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs, that are excluded from the OPPS packaging policy and meet the DOS requirements at § 414.510(b)(5), to bill Medicare directly for those tests instead of seeking payment from the hospital. Similar to molecular pathology tests and ADLTs under paragraph (1) of the definition of ADLT in § 414.502, we believe that cancer-related protein-based MAAAs are distinguishable from the care the patient receives during the primary hospital outpatient encounter because, as noted above, the results of the test would almost never affect the treatment regimen during the same hospital outpatient encounter in which the specimen was collected. Therefore, were we to finalize our proposal, we believe we would not be unbundling laboratory tests that are appropriately associated with the primary hospital outpatient service.

As discussed in section II.a.3. of this proposed rule, the AMA CPT 2020 manual describes a MAAA, in part, as "procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (for example, proteins, polypeptides, lipids, carbohydrates)." Further, the code descriptors of MAAAs include several specifics, including but not limited to disease type (for example, oncology, autoimmune, tissue rejection), and material(s) analyzed (for example, DNA, RNA, protein, antibody). As the AMA CPT 2020 manual describes a MAAA, and the code descriptor of each MAAA distinguishes MAAAs that are cancer-related assays from those that test for other disease types and provides information regarding the material(s) analyzed, the AMA CPT manual is a useful tool to identify cancer-related MAAAs that are "protein-based". Accordingly, using the AMA CPT 2020 manual criteria to identify a MAAA that is cancer-related, and, of those tests, identifying the ones whose analytes test proteins, we have determined there are currently six cancer-related protein-based MAAAs: CPT codes 81500, 81503, 81535, 81536, 81538 and 81539. We note that CPT code 81538 has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018, and therefore, is currently already subject to the laboratory DOS exception in § 414.510(b)(5). Therefore, the cancer-related protein-based MAAAs that would be excluded from the OPPS packaging policy and subject to an exception from the laboratory DOS policy under our proposals are CPT codes 81500, 81503, 81535, 81536 and 81539. These tests have not been designated by CMS as ADLTs under paragraph (1) of the definition of ADLT in § 414.502 and so are not currently subject to the laboratory DOS exception in § 414.510(b)(5). We would apply this policy to cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future.

XIX. Physician-owned Hospitals

A. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the "rural provider exception"). In order to qualify for the rural provider exception, the designated health services must be furnished in a rural area (as defined in section 1886(d)(2) of the Act), substantially all of the designated health services furnished by the entity must be furnished to individuals residing in a rural area, and, in the case where the entity is a hospital, the hospital meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the "whole hospital exception"). In order to qualify for the whole hospital exception, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the

hospital), and the hospital meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011.

B. Prohibition on Facility Expansion

Section 6001(a)(3) of the Affordable Care Act amended the rural provider and whole hospital exceptions to provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act, which required the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as an "applicable hospital." Section 1106 of the Health Care and Education Reconciliation Act of 2010 (HCERA) amended section 1877(i)(3)(A)(i) of the Act to require the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as either an "applicable hospital" or a "high Medicaid facility." These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act. The requirements for qualifying as an applicable hospital are set forth at § 411.362(c)(2) and the requirements for qualifying as a high Medicaid facility are set forth at § 411.362(c)(3). An applicable hospital means a hospital: (1) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census; (2) whose annual percent of total inpatient admissions under Medicaid is equal to or greater than the average percent with respect to such admissions for all hospitals in the county in hospital is located

during the most recent 12-month period for which data are available (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity); (3) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; (4) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and (v) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. CMS has identified in regulation at § 411.362(c)(2)(ii), (iv), and (v) acceptable data sources for determining whether a hospital qualifies as an applicable hospital. A "high Medicaid facility" means a hospital that: (1) is not the sole hospital in a county; (2) with respect to each of the 3 most recent 12-month periods for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. CMS has identified in regulation at § 411.362(c)(3)(ii) acceptable data sources for determining whether a hospital qualifies as a high Medicaid facility. In the CY 2012 OPPS/ASC final rule, we issued regulations setting forth the process for a hospital to request an exception from the prohibition on facility expansion (the exception process) and related definitions at § 411.362(c) and § 411.362(a), respectively (76 FR 74122).

Section 1877(i)(3)(B) of the Act provides that the exception process shall permit an applicable hospital to apply for an exception to the prohibition on expansion of facility capacity up to once every 2 years. In the CY 2012 OPPS/ASC final rule, we extended this provision to high Medicaid facilities using our authority under sections 1871 and 1877(i)(3)(A)(1) of the Act (76 FR 74525). We stated that, although the statute provides that an applicable hospital may request an exception up to once every 2

years, we believe that providing a high Medicaid facility the opportunity to request an exception once every 2 years (while also limiting its total growth) balances the Congress' intent to prohibit expansion of physician-owned hospitals with the purpose of the exception to the prohibition on expansion of facility capacity (76 FR 74524). We did not receive any public comments regarding the frequency of exception requests. Under current § 411.362(c)(1), both applicable hospitals and high Medicaid facilities may request an exception to the prohibition on expansion of facility capacity up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we adopted a parallel limit in the increase in the number of operating rooms, procedure rooms, and beds for which a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity (76 FR 74524). There, we noted that, in response to our request for comment on whether the 200 percent limit would be sufficient to balance the intent of the general prohibition on facility expansion with the purpose of the exception process, which is to provide the opportunity to expand in areas where a sufficient need for access to high Medicaid facilities is demonstrated, commenters supported our proposal regarding the amount of permitted increase and at least one commenter specifically supported the parallel treatment of high Medicaid facilities (76 FR 74524). Under current § 411.362(c)(6)(i), a 200 percent limitation applies to both applicable hospitals and high Medicaid facilities.

Section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed may occur only in facilities on the main campus of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we extended this limitation on the location of expanded facility capacity to high Medicaid facilities, explaining that we believe that applying the same limitation to applicable hospitals and high Medicaid facilities will result in an efficient and consistent process (76 FR 74524). We did not receive any public comments regarding the location of the permitted increase. Under current § 411.362(c)(6)(ii), expanded facility capacity may occur only in facilities on the hospital's main campus.

In 2017, CMS launched the Patients over Paperwork initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. This effort emphasizes a commitment to removing regulatory obstacles to providers spending time with patients. As part of this initiative, we reviewed the regulations at § 411.362(c) as they apply to high Medicaid facilities. Certain of the statutory provisions regarding expansion of facility capacity apply only to applicable hospitals and their extension to high Medicaid facilities was effectuated using the Secretary's authority under sections 1871 and 1877(i)(3)(A)(i) of the Act. We continue to believe that our current regulations, for which the Secretary appropriately used his authority and which treat high Medicaid facilities the same as applicable hospitals, are consistent with the Congress' intent to prohibit expansion of physician-owned hospitals generally. Nevertheless, the Congress did not mandate this treatment of high Medicaid facilities and, in light of the Patients over Paperwork initiative, we have reconsidered our policies. We believe that our current regulations impose unnecessary burden on high Medicaid facilities which, by definition, serve significant numbers of Medicaid patients relative to other hospitals in the counties in which they are

located. Because the statute does not apply to high Medicaid facilities those requirements related to the frequency of permitted requests for exceptions to the prohibition on expansion of facility capacity, the total amount of permitted expansion of facility capacity, or the location of permitted expanded facility capacity, using the Secretary's authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we propose to remove certain regulatory requirements for high Medicaid facilities that are not included in the statute.

We propose to revise § 411.362(c)(1) to permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. To preserve CMS resources and to continue to maintain an orderly and efficient exception process, we propose that a high Medicaid facility may submit only one exception request at a time. Under proposed § 411.362(c)(1), a high Medicaid facility could request an exception to the prohibition on expansion of facility capacity at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion for which CMS has not issued a decision. We also propose to revise § 411.362(c)(6) with respect to high Medicaid facilities only to remove the restriction that permitted expansion of facility capacity may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds and the restriction that permitted expanded facility capacity must occur only in facilities on the hospital's main campus. Under proposed § 411.362(c)(6), these restrictions would apply only to applicable hospitals. We seek comment regarding our proposals.

Section 1877(i)(3)(A)(ii) requires CMS to provide an opportunity for community input when an applicable hospital applies for an exception to the prohibition on expansion of facility capacity. Through regulation, we made the community input opportunity applicable to facility expansion requests submitted by high Medicaid facilities (76 FR 74523). However, the statute does not expressly require

CMS to furnish an opportunity for community input when a high Medicaid facility has applied for such an exception. Therefore, we are considering whether we should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities. We are specifically interested in comments regarding the importance of community input, which allows for confirmation of (or disagreement with) the data provided by a high Medicaid facility seeking an exception to the prohibition on expansion of facility capacity. We are interested in comments regarding how CMS could obtain independent confirmation of the data provided by a high Medicaid facility in the absence of the community input opportunity (see 76 FR 74523). We note that obtaining independent confirmation of the data furnished by a high Medicaid facility could delay or add complexity to the review process. We solicit comments regarding whether the additional delay and complexity caused by the elimination of the community input opportunity for requests by high Medicaid facilities would result in greater burden or cause greater harm to high Medicaid facilities than continuing to permit community input on the expansion exception requests submitted by these hospitals.

C. Deference to State Law for Purposes of Determining the Number of Beds for which a Hospital is Licensed

In order to qualify for the rural provider or whole hospital exception to the physician self-referral law, a hospital may not increase the aggregate number of operating rooms, procedure rooms, and beds above that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but did have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless the Secretary has granted an exception to the prohibition on expansion of facility capacity under section 1877(i)(3) of the Act and § 411.362(c). The statute and our regulations refer to this number as the hospital's "baseline number of operating rooms, procedure rooms, and beds." Thus, at the time a hospital wishes to qualify for the rural

provider or whole hospital exception, it may not have an aggregate number of operating rooms, procedure rooms, and beds that exceeds its baseline number of operating rooms, procedure rooms, and beds (unless the Secretary has granted an exception).

Because the availability of the rural provider and whole hospital exceptions turns on whether a hospital has exceeded its baseline number of operating rooms, procedure rooms, and beds at the time of a physician's referral, a clear understanding of how to calculate the hospital's baseline number of operating rooms, procedure rooms, and beds is critical. Stakeholders have asked what CMS would consider the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement) under various State licensure schemes. We responded to formal advisory opinion requests in August 2019 (https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2019-01-Redacted.pdf) and March 2020 (https://www.cms.gov/files/document/cms-ao-2020-01.pdf) regarding the inclusion of certain operating rooms, procedure rooms, and beds in a hospital's baseline number of operating rooms, procedure rooms, and beds. In March 2020, we also published a Frequently Asked Question addressing stakeholder inquiries regarding the determination of the number of beds for which a hospital was licensed on March 23, 2010 (https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf). The March 2020 Frequently Asked Question states:

Q: If a state's hospital licensure laws and regulations provide that a hospital may increase its licensed bed complement by a certain amount without prior approval of the state's licensing agency, what would CMS consider the number of beds for which the hospital was licensed on

March 23, 2010 for purposes of section 1877(i)(1)(B) of the Social Security Act (the "Act") and 42 CFR 411.362(b)(2)?

A: As a general matter, neither section 1877 of the Act nor the physician self-referral regulations (42 CFR 411.350 through 411.389) preempt state licensure laws and regulations. In interpreting and applying the physician self-referral law, CMS defers to state law with respect to the determination of whether a bed is licensed as of a certain date. If the state would consider a bed to be "licensed" or within a hospital's "bed complement" on March 23, 2010, CMS would also consider the bed to be "licensed" or within a hospital's "bed complement" as of that date, regardless of the exact number printed on the hospital's physical license. To illustrate, assume that a state does not require prior approval from its licensing agency for a hospital to increase its bed complement by not more than ten beds or 10 percent of the total bed capacity, whichever is less, during a period of a license. However, the state requires notification of the change and that the hospital must at all times meet the physical plant, staffing, and all other requirements set forth in state law and regulations if additional beds are added. The license issued to the hospital on January 1, 2009 indicated that the hospital's bed complement was 100 beds. If the hospital increased its bed complement by 9 beds (to 109 beds) on January 1, 2010 and made no further changes to its bed complement prior to March 23, 2010, its baseline number of licensed beds on March 23, 2010 would be 109 for purposes of section 1877(i)(1)(B) of the Act and 42 CFR 411.362(b)(2), provided that the hospital made the appropriate notification to the state and the hospital at all times met the physical plant, staffing, and all other requirements set forth in state law and regulations after increasing its bed complement. The same would apply to any beds that a state considered to be licensed under its specific licensure scheme on March 23, 2010. Section 1877(i)(1)(B) of the Act limits the expansion of facility capacity of a hospital that wishes to

qualify for the rural provider or hospital exceptions to the law's ownership or investment prohibition. (See section 1877(d)(2) and (3); 42 CFR 411.356(c)(1) and (3).) Specifically, section 1877(i)(1)(B) of the Act states that, among other things, to qualify for the rural provider or hospital exceptions, the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after March 23, 2010 is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010. For purposes of applying this provision of the physician self-referral law, we refer to the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 as the hospital's "baseline." As stated above, CMS defers to state law with respect to the determination of whether a bed is licensed as of a certain date. However, in extraordinary circumstances, CMS may include additional beds when determining a hospital's "baseline" for purposes of section 1877 of the Act. See, for example, CMS-AO-2020-01 (https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions).

In order to ensure stakeholders' awareness of our interpretation regarding the determination of the number of beds for which a hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), we propose to revise the definition of "baseline number of operating rooms, procedure rooms, and beds" at § 411.362(a) to include a statement that, for purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State. We seek comment on our proposal to include this language in regulation text at § 411.362(a) generally, and specifically whether the inclusion of this language is necessary or could be

perceived as inadvertently limiting the definition of "baseline number of operating rooms, procedure rooms, and beds."

XX. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available via the Internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C, by adding a column entitled "Copayment Capped at the Inpatient Deductible of $1,364.00" where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). For CY 2021, we are retaining these columns, updated to reflect the amount of the 2021 inpatient deductible. For CY 2021, we propose to add a new column to the OPPS Addenda, A, B, and C, entitled "Drug Pass-Through Expiration during Calendar Year" where we would flag through the use of an asterisk, each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31).

To view the Addenda to this proposed rule pertaining to proposed CY 2021 payments under the OPPS, we refer readers to the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html; select "CMS-1736-P" from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled "2021 NPRM OPPS Addenda" at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2021 payments under the ASC payment system, we refer readers to the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html; select "CMS-1736-P" from the list of

regulations. The ASC Addenda to this proposed rule are contained in a zipped folder entitled "Addendum AA, BB, DD1, DD2, and EE."

XXI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

B. ICRs for the Hospital OQR Program

1. Background

The Hospital OQR Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital IQR Program. We refer readers to the CY 2011 through CY 2020 OPPS/ASC final rules with comment periods (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through

67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156; and 84 FR 61468 through 61469, respectively) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938-1109 which expires on March 31, 2023.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59477), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data (May 2019) from the BLS reflects a median hourly wage of $19.40 per hour for a Medical Records and Health Information Technician professional.[305] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 59477). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. Summary

[305] Occupational Employment and Wages, May 2019. Available at: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm. Accessed March 30, 2020.

In this proposed rule, we propose to: (1) codify the statutory authority for the Hospital OQR Program; (2) revise and codify the previously finalized public display of measure data policy that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes; (3) revise existing § 419.46(a)(2) by replacing the term "security administrator" with the term "security official" and codify this language; (4) move all deadlines falling on nonwork days forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), "Periods of Limitation Ending on Nonwork Days," beginning with the effective date of this rule; (5) revise our policy regarding submission deadlines at existing § 419.46(c)(2) to reflect the proposed deadlines policy consistent with section 216(j) of the Act, 42 U.S.C. 416(j); (6) expand the existing review and corrections policy for chart-abstracted data to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years; (7) codify at 42 CFR 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool; (8) codify the previously finalized Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures; (9) revise existing § 419.46(b) (proposed redesignated § 419.46(c)) by removing the phrase "submit a new participation form" to align with previously finalized policy; and (10) update internal cross-references as a result of the redesignations discussed in the proposed rule.

We note that if finalized as proposed, our proposals for the CY 2021 OPPS/ASC proposed rule will not yield a change in burden for the hospitals participating in the Hospital OQR Program as our proposals seek only to refine existing regulatory text for current processes or to codify existing processes. As such, we note that the burden hours for the CY 2023 payment determination will be

consistent with the previously finalized burden for the CY 2022 payment determination. We refer readers to the information collection request that has been approved by OMB 0938-1109 (Expiration date March 31, 2023).[306]

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, CY 2019, and CY 2020 OPPS/ASC final rules with comment period (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; and 84 FR 61469, respectively) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized. The information collection requirements associated with the ASCQR Program are currently approved under OMB control number 0938-1270 which expires on December 31, 2022.

2. Summary

In this proposed rule, we propose to: (1) use the term "security official" instead of "security administrator" and revise § 416.310(c)(1)(i) by replacing the term “security administrator” with the term “security official;” (2) remove the phrase “data collection time period” in all instances where it appears in § 416.310, replace it with the phrase “data collection period”; (3) move forward all program deadlines falling on a nonwork day consistent with section 216(j) of the Act, 42 U.S.C. 416(j) and codify this policy; and (4) formalize the process by which ASCs identify errors and resubmit data before the

[306] CY 2020 Final Rule Hospital OQR Program “Supporting Statement-A”. Available at: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-015

established submission deadline by creating a review and corrections period in alignment with the Hospital OQR Program as proposed in section XIV.D.7. that runs concurrent with the existing data submission period and codify this policy. We note that if finalized as proposed, our proposals for the CY 2021 OPPS/ASC proposed rule will not yield a change in burden for the facilities participating in the ASCQR Program as our proposals seek only to refine existing regulatory text for current processes or to codify existing processes. As such, we note that the burden hours for the CY 2023 payment determination will be consistent with the previously finalized burden for the CY 2022 payment determination. We refer readers to the currently approved information collection request.[307]

D. ICRs for Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services. See 84 FR 61142 (November 12, 2019).[308] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with paragraph (b) of 42 CFR 419.83, we propose to add two new service categories to § 419.83(a): Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding,

[307] CY 2020 Final Rule Hospital OQR Program "Supporting Statement-A". Available at: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-016

[308] See also Correction Notice issued January 3, 2020 (85 FR 224).

and payment rules and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the two new proposed categories, Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators, would be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information would generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task would be 30 minutes, which is equivalent to that for normal prepayment or post payment medical review. We anticipate that most prior authorization requests would be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to the proposed July 1, 2021 start date, the first year of the prior authorization for the two new service categories would only include 6 months. Based on CY 2018 data, we estimate that for those first 6 months at a minimum there would be 6,808 initial requests mailed during the year. In addition, we estimate there would be 2,234 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $45,210 (9,042 mailed requests x $5). Based on CY 2018 data for the two new proposed service categories, we estimate that annually at a minimum there would be 13,615 initial requests mailed during a year. In addition, we estimate there would be 4,468 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $90,415 (18,083 mailed requests x $5). We also estimate that an

additional 3 hours would be required for attending educational meetings and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS information, we estimate an average clerical hourly rate of $16.63 with a loaded rate of $33.26. The proposed prior authorization program for these two service categories would not create any new documentation or administrative requirements. Instead, it would just require the currently needed documents to be submitted earlier in the claim process. Therefore, the estimate uses the clerical rate since we do not believe that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the proposed prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. We estimate that the total number of submissions for the first year (6 months) would be 30,140 (21,098 submissions through fax or electronic means + 9,042 mailed submissions). Therefore, we estimate that the total burden for the first year (6 months) for the two new service categories, allotted across all providers, would be 24,820 hours (.5 hours x 30,140 submissions plus 3 hours x 3,250 providers for education). The burden cost for the first year (6 months) is $870,723 (24,820 hours x $33.26 plus $45,210 for mailing costs). In addition, we estimate that the total annual number of submissions would be 60,277 (42,194 submissions through fax or electronic means + 18,083 mailed submissions). The annual burden hours for the two new service categories, allotted across all providers, would be 39,889 hours (.5 hours x 60,277 submissions plus 3 hours x 3,250 providers for education). The annual burden cost would be $1,417,107 (39,889 hours x $33.26 plus $90,416 for mailing costs). For the total burden and associated costs for the two new service categories, we estimate the annualized burden to be 34,866 hours and $1,234,979 million. The annualized burden is based on an average of

3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden. The ICR approved under OMB control number 0938-XXXX will be revised and submitted to OMB for approval.

E. ICRs for the Overall Hospital Quality Star Rating

The Overall Star Rating uses measures that are publicly reported on Hospital Compare or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. We believe the burden associated with measures included in the Overall Star Rating, including requesting withholding of measures from public reporting, is already captured in the respective hospital programs' ICRs and represents no increased information collection burden to hospitals.

F. ICRs for Physician-owned Hospitals

As discussed in section XIX. of this proposed rule, we propose to modify the physician-owned hospital expansion exception process under the rural provider and hospital ownership exceptions to the physician self-referral law. Specifically, we proposed to modify the frequency of submission such that a high Medicaid facility could request an exception to the prohibition on expansion of facility capacity at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion to CMS for which CMS has not issued a decision. We do not believe this proposal would result in any changes in burden under the PRA. First, we do not anticipate any changes in the annual number of respondents. Although a high Medicaid facility would be permitted to request an expansion exception more frequently than under current regulations, we believe that removing the cap on the size of an expansion would make more frequent expansion exception requests unlikely. Also, we are not changing the information being collected.

Based on our experience with the expansion exception process to date, we estimate that approximately one physician-owned hospital per year will request an expansion exception on the

grounds that it is a high Medicaid facility. We estimate that it takes approximately 6 hours and 45 minutes to prepare an expansion exception request and that a request is prepared by a lawyer. To estimate the cost to prepare a request, we use a 2019 wage rate of $69.86 for lawyers from the Bureau of Labor Statistics,[309] and we double that wage to account for overhead and benefits. The total estimated annual cost is $943.11. We seek comments on these estimates.

Summary of All Burden in This Final Rule

Below is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Overall Star Rating[4]	0.0	0.0
Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process	+34,866	+$1.2 million

* Numbers rounded.

[1] Burden changes for the Hospital IQR Program reflect total changes over a four-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination.

[2] Because the FY 2022 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this final rule.

[3] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for service- claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

[4] Because the Overall Star Rating uses measure data already collected and reported by other programs, the burden is captured in the respective programs and represents no increased burden.

If you comment on these information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the ADDRESSES section of this proposed rule.

[309] U.S. Department of Labor, Bureau of Labor Statistics, May 2019 National Occupational Employment and Wage Estimates United States, https://www.bls.gov/oes/current/oes_nat.htm

Comments must be received on/by [**INSERT DATE 60-DAYS AFTER THE DATE OF DISPLAY IN THE FEDERAL REGISTER**].

XXII. Waiver of the 60-day Delayed Effective Date for the Final Rule

We are committed to ensuring that we fulfill our statutory obligation to update the OPPS as required by law and are working diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accord with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, section 808(2) of the CRA provides that, if an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines.

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named "SARS-CoV-2" and the disease it causes has been named "coronavirus disease 2019" (abbreviated "COVID-19").

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a "Public Health Emergency of international concern" (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID-19. On March 11, 2020, the WHO publicly characterized COVID-19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID-19 outbreak a national emergency.

Due to CMS prioritizing efforts in support of containing and combatting the COVID-19 PHE, and devoting significant resources to that end, the work needed on the OPPS payment rule will not be completed in accordance with our usual schedule for this rulemaking, which aims for a publication date

of at least 60 days before the start of the fiscal year to which it applies. Up to an additional 30 days may be needed to complete the work needed on this payment rule. The OPPS payment rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the fiscal year to which they are intended to apply. Therefore, due to CMS prioritizing efforts in support of containing and combatting the COVID-19 PHE, and devoting significant resources to that end, we are hereby waiving the 60-day delay in the effective date of the OPPS final rule; it would be contrary to the public interest for CMS to do otherwise. However, we do expect to provide a 30-day delay in the effective date of the final rule in accord with section 5 U.S.C. 553(d) of the Administrative Procedure Act, which ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**, and section 1871(e)(1)(B)(i) of the Act, which generally prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date of its public availability.

XXIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXIV. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2021. We are required under section 1833(t)(3)(C)(ii) of the Act to update

annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2019, through and including December 31, 2019, and processed through December 31, 2019, and updated cost report information.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2021, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2021. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI-U for CY 2019 through 2023. We believe that this policy will help stabilize the differential between OPPS payments and ASC payments, given that the CPI-U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

B. Overall Impact for Provisions of this Proposed Rule

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving

Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This section of this proposed rule contains the impact and other economic analyses for the provisions we propose for CY 2021.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the provisions of this proposed rule. We are soliciting public comments on the regulatory impact analysis in the proposed rule, and we address any public comments we received in this proposed rule, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2021, compared to CY 2020, due only to the changes to the OPPS in this proposed rule, would be approximately $1.61 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2021, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2021 would be approximately $83.9 billion, which is approximately $7.5 billion higher than

estimated OPPS expenditures in CY 2020. Because the provisions of the OPPS are part of a proposed rule that is economically significant, as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 55 of this proposed rule displays the distributional impact of the CY 2021 changes in OPPS payment to various groups of hospitals and for CMHCs.

Under our CY 2021 policy, drugs and biologicals that are acquired under the 340B Program are proposed to be paid at ASP minus 28.7 percent, WAC minus 28.7 percent, or WAC minus 31.7 percent based on our policy described in V.B.2.b., or 63.90 percent of AWP, as applicable. We note that in the impact table as displayed in this impact analysis, we have modeled current and prospective payments as if separately payable drugs acquired under the 340B program from hospitals not excepted from the policy are paid in CY 2021 under the OPPS at ASP minus 28.7 percent. We also propose in the alternative that the agency could continue the current Medicare payment policy for CY 2021.

We estimate that the proposed update to the conversion factor, the CY 2021 frontier wage index adjustment, and other adjustments (not including the effects of outlier payments, the pass-through payment estimates) would increase total OPPS payments by 2.8 percent in CY 2021. The proposed changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, the proposed changes to separately payable drugs acquired under the 340B program, and the payment adjustment for cancer hospitals would not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2020 and CY 2021, considering all proposed budget neutral payment adjustments, changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule

increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 2.5 percent.

We estimate the total increase (from changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2021 compared to CY 2020, to be approximately $130 million. Because the provisions for the ASC payment system are part of a proposed rule that is economically significant, as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this proposed rule. Tables 56 and 57 of this proposed rule display the redistributive impact of the CY 2021 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in this Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2021 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2021 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. At the website, select "regulations and notices" from the left side of the page and then select "CMS-1736-P" from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in

Table 57. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of Proposal to Update the 340B Program Payment Policy

In section X.C. of this proposed rule with comment period, we discuss our proposal to update the payment percentage for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. We propose that rural SCHs, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from this payment policy in CY 2021. Specifically, in this proposed rule for CY 2021, for hospitals paid under the OPPS (other than those that are excepted for CY 2021), we propose to pay for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 28.7 percent. The difference in total OPPS Part B drug payment for 340B Program drugs at ASP minus 28.7 percent, relative to our current policy of paying ASP minus 22.5 percent, is a decrease of $427 million, which we propose to redistribute through a budget neutral adjustment to the OPPS conversion factor. We also propose in the alternative that the agency could continue the current Medicare payment policy for CY 2021, in which case the 340B policy would not require a change to the budget neutrality adjustment.

To develop an estimated impact of this proposal, we began with CY 2019 outpatient claims data used in ratesetting for the CY 2021 OPPS. We then flagged all claim lines that contained modifier ‘‘JG’’ because the presence of this modifier indicates that such claims were subject to the payment adjustment for separately payable non-pass through drugs acquired through the 340B Program in the claims year. We also flagged pass-through drug claim lines with modifier “TB” for drugs with pass-through status that will expire by CY 2021. We further subset this population by separating all providers that would be excepted from the policy and then identifying the payment differential between payment at ASP minus 22.5 percent and payment at ASP minus 28.7 percent, which results in a $427 million redistribution, or 0.85 percent increase, to the OPPS conversion factor. This estimate does not include adjustments for beneficiary enrollment, case-mix, or potential offsetting behaviors. We note that the estimated effect of the proposed policy could change in this final rule with comment period based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule.

c. Estimated Effects of OPPS Changes on Hospitals

Table 55 shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children’s hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 55, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2021, we propose to continue to pay CMHCs for partial

hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2021 is 3.0 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.4 percentage point for FY 2021 (which is also the MFP adjustment for FY 2021 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 32739)), resulting in the OPD fee schedule increase factor of 2.6 percent. We are using the OPD fee schedule increase factor of 2.6 percent in the calculation of the CY 2021 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2020 estimates in Table 55 of this proposed rule.

To illustrate the impact of the CY 2021 changes, our analysis begins with a baseline simulation model that uses the CY 2020 relative payment weights, the FY 2020 final IPPS wage indexes that include reclassifications, and the final CY 2020 conversion factor. Table 55 shows the estimated redistribution of the increase or decrease in payments for CY 2021 over CY 2020 payments to hospitals

and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2020 and CY 2021 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.6 percent OPD fee schedule increase factor update to the conversion factor (Column 5); the estimated impact taking into account all payments for CY 2021 relative to all payments for CY 2020, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2021. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2021 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2020 and CY 2021 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2021 will increase Medicare OPPS payments by an estimated 2.5 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 2.6 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 55 shows the total number of facilities (3,628), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2019 hospital outpatient and CMHC claims data to model CY 2020 and CY 2021 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2020 or CY 2021 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,523), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 38 CMHCs at the bottom of the impact table (Table 55) and discuss that impact separately below.

Column 2: APC Recalibration – All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban

hospitals will experience no change, with the impact ranging from a decrease of 0.3 percent to an increase of 0.3 depending on the number of beds. Rural hospitals will increase 0.1 percent overall. Major teaching hospitals will see an expected decrease of 0.4 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2021 IPPS post-reclassification wage indexes; the rural adjustment; the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2020 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the proposed updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2021 proposed changes in wage index policy discussed in section II.C. of this CY 2021 OPPS/ASC proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2021, as described in section II.E. of this proposed rule. We also did not model a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2021 is 0.89, the same as the ratio that was reported for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61191). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we propose to apply in section II.F. of this proposed rule.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2021 scaled weights and a CY 2020 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2020 and CY 2021.

Column 4: Effect of the Reduced Payment for 340B Drugs

Column 4 demonstrates the total payment effect of the proposed reduction in payment for drugs purchased under the 340B Program from ASP minus 22.5 percent to ASP minus 28.7 percent. This column includes both the reduced payment for 340B-acquired drugs and the increase to the conversion factor for budget neutrality purposes, which would increase payment for all non-drug items and services. For rural sole community hospitals, this column shows a 0.7 percent increase, reflecting a 0.0 percent decrease for drugs (because we propose that these providers would continue to be exempt from these reductions) and a 0.85 percent increase for non-drug services.

Column 5: All Budget Neutrality Changes Combined with the Market Basket Update

Column 5 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 2.6 percent. Overall, these changes will increase payments to urban hospitals by 2.8 percent and to rural hospitals by 3.6 percent. The increase for classes of rural hospitals will vary with sole community hospitals receiving a 4.0 percent increase and other rural hospitals receiving an increase of 2.9 percent.

Column 6: All Proposed Changes for CY 2021

Column 6 depicts the full impact of the proposed CY 2021 policies on each hospital group by including the effect of all changes for CY 2021 and comparing them to all estimated payments in CY 2020. Column 6 shows the combined budget neutral effects of Columns 2 through 4; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this

proposed rule; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV. of this proposed rule); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2020 update (and assumed, for modeling purposes, to be the same number for CY 2021), we included 21 hospitals in our model because they had both CY 2019 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2021 will increase payments to all facilities by 2.5 percent for CY 2021. We modeled the independent effect of all changes in Column 6 using the final relative payment weights for CY 2020 and the proposed relative payment weights for CY 2021. We used the final conversion factor for CY 2020 of $80.793 and the proposed CY 2021 conversion factor of $83.697 discussed in section II.B. of this proposed rule.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2021 IPPS/LTCH PPS proposed rule (84 FR 42629) of 6.3 percent (1.06353) to increase individual costs on the CY 2019 claims, and we used the most recent overall CCR in the April 2020 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2020. Using the CY 2019 claims and a 6.3 percent charge inflation factor, we currently estimate that outlier payments for CY 2020, using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,075, will be approximately 1.01 percent of total payments. The estimated current outlier payments of 1.01 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 13.1 percent (1.131096) and the CCRs in the April 2020 OPSF, with an adjustment of 0.97527, to reflect relative changes in cost and charge inflation between CY 2019 and CY 2021, to model the final CY 2020 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and

a fixed-dollar threshold of $5,300. The charge inflation and CCR inflation factors are discussed in detail in the FY 2021 IPPS/LTCH PPS proposed rule (84 FR 42629).

Overall, we estimate that facilities will experience an increase of 2.5 percent under this proposed rule in CY 2021 relative to total spending in CY 2020. This projected increase (shown in Column 6) of Table 55 reflects the 2.6 percent OPD fee schedule increase factor, minus 0.05 percent for the change in the pass-through payment estimate between CY 2020 and CY 2021, minus the difference in estimated outlier payments between CY 2020 (1.01 percent) and CY 2021 (1.00 percent). We estimate that the combined effect of all proposed changes for CY 2021 will increase payments to urban hospitals by 2.5 percent. Overall, we estimate that rural hospitals will experience a 3.2 percent increase as a result of the combined effects of all the proposed changes for CY 2021.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.4 percent for major teaching hospitals and an increase of 3.2 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 2.8 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 2.4 percent, proprietary hospitals will experience an increase of 4.1 percent, and governmental hospitals will experience an increase of 2.2 percent.

TABLE 55—ESTIMATED IMPACT OF THE PROPOSED CY 2021 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market**	**All Changes**

						Basket Update	
ALL PROVIDERS *		3,628	0.0	0.2	0.0	2.8	2.5
ALL HOSPITALS		3,523	0.1	0.2	0.0	2.9	2.6
	(excludes hospitals held harmless and CMHCs)						
URBAN HOSPITALS		2,772	0.0	0.2	-0.1	2.8	2.5
	LARGE URBAN	1,431	0.1	0.2	-0.1	2.8	2.5
	(GT 1 MILL.)						
	OTHER URBAN	1,341	0.0	0.2	-0.1	2.8	2.4
	(LE 1 MILL.)						
RURAL HOSPITALS		751	0.1	0.4	0.4	3.6	3.2
	SOLE COMMUNITY	368	0.1	0.5	0.7	4.0	3.5
	OTHER RURAL	383	0.1	0.2	0.0	2.9	2.7
BEDS (URBAN)							
	0 - 99 BEDS	927	0.3	0.3	0.5	3.7	3.4
	100-199 BEDS	789	0.3	0.2	0.3	3.4	3.1
	200-299 BEDS	449	0.2	0.2	0.1	3.2	2.9
	300-499 BEDS	383	0.1	0.3	0.0	2.9	2.6
	500 + BEDS	224	-0.3	0.0	-0.6	1.7	1.6
BEDS (RURAL)							
	0 - 49 BEDS	324	0.3	0.5	0.5	3.9	3.5
	50- 100 BEDS	262	0.3	0.5	0.5	3.9	3.4
	101- 149 BEDS	88	0.0	0.3	0.3	3.2	2.8
	150- 199 BEDS	38	0.0	0.4	0.1	3.1	2.9
	200 + BEDS	39	-0.1	0.3	0.3	3.1	3.0
REGION (URBAN)							
	NEW ENGLAND	133	-0.1	0.7	-0.2	3.0	2.0
	MIDDLE ATLANTIC	325	-0.2	0.0	-0.1	2.3	2.2
	SOUTH ATLANTIC	452	0.1	0.1	-0.1	2.7	2.7
	EAST NORTH CENT.	436	0.0	-0.1	0.0	2.5	2.4
	EAST SOUTH CENT.	162	-0.1	0.0	-0.3	2.2	2.1
	WEST NORTH CENT.	183	-0.1	0.7	-0.2	2.9	1.9
	WEST SOUTH CENT.	461	0.3	0.2	0.2	3.4	3.3
	MOUNTAIN	204	0.2	0.2	-0.1	3.0	2.3
	PACIFIC	367	0.2	0.2	-0.1	2.9	2.8
	PUERTO RICO	49	0.7	-0.3	0.8	3.7	3.7

REGION (RURAL)						
NEW ENGLAND	20	0.0	-0.1	0.3	2.8	2.7
MIDDLE ATLANTIC	50	0.0	0.3	0.4	3.2	3.2
SOUTH ATLANTIC	114	0.1	0.0	0.2	2.9	2.8
EAST NORTH CENT.	120	0.1	0.7	0.5	4.0	3.8
EAST SOUTH CENT.	146	0.2	0.0	0.0	2.9	2.8
WEST NORTH CENT.	91	0.0	1.0	0.6	4.3	3.1
WEST SOUTH CENT.	139	0.3	0.1	0.6	3.7	3.6
MOUNTAIN	48	0.0	2.0	0.6	5.2	3.1
PACIFIC	23	0.2	-0.3	0.3	2.8	2.7
TEACHING STATUS						
NON-TEACHING	2,367	0.3	0.2	0.3	3.5	3.2
MINOR	779	0.2	0.4	0.1	3.2	2.8
MAJOR	377	-0.4	0.0	-0.6	1.6	1.4
DSH PATIENT PERCENT						
0	11	0.5	-0.1	0.8	3.8	3.7
GT 0 - 0.10	268	0.5	0.2	0.8	4.1	3.8
0.10 - 0.16	241	0.3	0.0	0.7	3.7	3.4
0.16 - 0.23	591	0.4	0.2	0.7	4.0	3.7
0.23 - 0.35	1,081	0.0	0.3	-0.1	2.7	2.4
GE 0.35	906	-0.2	0.2	-0.6	2.0	1.8
DSH NOT AVAILABLE **	425	-1.0	0.2	0.7	2.5	2.3
URBAN TEACHING/DSH						
TEACHING & DSH	1,041	-0.1	0.2	-0.3	2.4	2.1
NO TEACHING/DSH	1,313	0.4	0.1	0.3	3.4	3.2
NO TEACHING/NO DSH	11	0.5	-0.1	0.8	3.8	3.7
DSH NOT AVAILABLE2	407	-0.9	0.2	0.7	2.6	2.4
TYPE OF OWNERSHIP						
VOLUNTARY	1,971	0.0	0.2	-0.1	2.7	2.4
PROPRIETARY	1,099	0.7	0.3	0.8	4.4	4.1
GOVERNMENT	453	-0.1	0.1	-0.3	-0.3	2.2
CMHCs	38	-2.0	0.1	0.9	1.5	1.3

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2021 OPPS policies and compares those to the CY 2020 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2021 hospital inpatient wage index and the non-budget neutral frontier adjustment. The proposed rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because in CY 2021 the proposed target payment-to-cost ratio is the same as that of CY 2020 (0.90 and reduced to 0.89 in accordance with the 21st Century Cures Act)

Column (4) shows the impact of the proposed CY 2021 OPPS changes to 340B drug payment and the corresponding budget neutrality adjustment.
Column (5) shows the impact of all budget neutrality adjustments and the addition of the 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage point for the productivity adjustment).
Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.
These 3,628 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 55 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2020, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2019 claims used for ratesetting in the proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 1.3 percent increase in payments from CY 2020 (shown in Column 6). We note that this includes the trimming methodology as well as the proposed CY 2021 floor on geometric mean costs used for developing the PHP payment rates described in section VIII.B. of this proposed rule. The CY 2021 proposal to establish a floor based on geometric mean costs, rather than based on a predetermined payment rate, makes the OPPS budget neutrality adjustments for both the weight scalar and the conversion factor applicable.

Column 3 shows that the estimated impact of adopting the proposed FY 2021 wage index values will result in an increase of 0.1 percent to CMHCs. Column 5 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2021 and the proposed FY 2021 wage index updates, will result in an estimated increase of 1.5 percent. Column 6 shows that

adding the proposed changes in outlier and pass-through payments will result in a total 1.3 percent increase in payment for CMHCs. This reflects all proposed changes for CMHCs for CY 2021.

e. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this CY 2021 OPPS/ASC proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 18.1 percent for all services paid under the OPPS in CY 2020. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the final CY 2020 comprehensive APC payment policy discussed in section II.A.2.b. of this final rule.

f. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of the final rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the final changes in the final rule.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $1.61 billion in program payments for OPPS services furnished in CY 2021. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the proposed changes in the proposed rule would increase

these Medicaid beneficiary payments by approximately $115 million in CY 2021. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately thirty percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking thirty percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated $115 million Medicaid increase, approximately $65 million will be from the Federal Government and $50 million would be from State government.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout the final rule.

- Alternatives Considered for the Payment Adjustment for Separately Paid Drugs Acquired through the 340B Program

We refer readers to section V.B.6. of this CY 2021 OPPS/ASC proposed rule for a discussion of our proposed policy to apply a payment adjustment of ASP minus 28.7 percent for separately paid non-pass through drugs acquired the 340B Program. We also propose in the alternative to maintain the same payment adjustment percentage of ASP minus 22.5 percent as initially established under the CY 2018 OPPS policy (82 FR 59350 through 59369). We note that effects of the proposal and its corresponding budget neutrality adjustment compared to the alternative considered are provided in Column 4 of table 55.

2. Estimated Effects of CY 2021 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we are setting the CY 2021 ASC relative payment weights by scaling the proposed CY 2021 OPPS relative payment weights

by the proposed ASC scalar of 0.8494. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 56 and 57 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, we propose that the CY 2021 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which we propose would be the hospital market basket for CY 2021. We calculated the CY 2021 ASC conversion factor by adjusting the CY 2020 ASC conversion factor by 0.9999 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2020 and CY 2021 and by applying the CY 2021 MFP-adjusted hospital market basket update factor of 2.6 percent (which is equal to the projected hospital market basket update of 3.0 percent minus an MFP adjustment of 0.4 percentage point). The proposed CY 2021 ASC conversion factor is $48.984 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2021 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2019 and CY 2021 with precision. We believe the net effect on Medicare expenditures

resulting from the proposed CY 2021 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2021 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2021 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2019 claims data. Table 57 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2020 payments to estimated proposed CY 2021 payments, and Table 56 shows a comparison of estimated CY 2020 payments to estimated proposed CY 2021 payments for procedures that we estimate will receive the most Medicare payment in CY 2020.

In Table 57, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are

sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 57.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

- Column 2—Estimated CY 2020 ASC Payments were calculated using CY 2019 ASC utilization data (the most recent full year of ASC utilization) and CY 2020 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2020 ASC payments.

- Column 3—Estimated CY 2021 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to proposed updates to ASC payment rates for CY 2021 compared to CY 2020.

As shown in Table 56, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2021 will result in a 3-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 2-percent increase in aggregate payment amounts for nervous system procedures, 4-percent increase in aggregate payment amounts for digestive system procedures, a 4-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 3-percent increase in aggregate payment amounts for cardiovascular system procedures, and a 5-percent increase in aggregate payment amounts for

genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.6 percent proposed payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.6-percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 4-percent increase in proposed aggregate gastrointestinal procedure payments due to an increase in hospital reported costs for Level 1 and Level 2 upper and lower gastrointestinal payment categories under the OPPS. The increases in payment weights for gastrointestinal procedure payments is further increased by the proposed 2.6 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 57 provided later in this section.

TABLE 56: ESTIMATED IMPACT OF THE PROPOSED CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2021 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP [310]

Surgical Specialty Group (1)	Estimated CY 2020 ASC Payments (in Millions) (2)	Estimated CY 2021 Percent Change (3)
Total	$5,446	3

[310] Projected impacts are the same under all proposals for the ASC Covered Procedures List, given the lack of prior ASC utilization data for the procedures being added.

Surgical Specialty Group (1)	Estimated CY 2020 ASC Payments (in Millions) (2)	Estimated CY 2021 Percent Change (3)
Eye and ocular adnexa	$1,811	3
Nervous system	$1,178	3
Digestive system	$908	4
Musculoskeletal system	$693	4
Cardiovascular system	$270	3
Genitourinary system	$201	5

Table 57 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2021. The table displays 30 of the procedures receiving the greatest estimated CY 2020 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2020 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2020 ASC Payments were calculated using CY 2019 ASC utilization (the most recent full year of ASC utilization) and the CY 2020 ASC payment rates. The estimated CY 2020 payments are expressed in millions of dollars.
- Column 4–Estimated CY 2021 Percent Change reflects the percent differences between the estimated ASC payment for CY 2020 and the estimated payment for CY 2021 based on the proposed update.

TABLE 57: ESTIMATED IMPACT OF THE FINAL CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2020 ASC Payment (in millions) (3)	Estimated CY 2021 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,259	3

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2020 ASC Payment (in millions) (3)	Estimated CY 2021 Percent Change (4)
63685	Insrt/redo spine n generator	$295	4
45380	Colonoscopy and biopsy	$247	3
63650	Implant neuroelectrodes	$189	2
43239	Egd biopsy single/multiple	$185	3
45385	Colonoscopy w/lesion removal	$184	3
0191T	Insert ant segment drain int	$125	4
64483	Njx aa&/strd tfrm epi l/s 1	$120	1
66982	Xcapsl ctrc rmvl cplx wo ecp	$92	3
64635	Destroy lumb/sac facet jnt	$86	1
64493	Inj paravert f jnt l/s 1 lev	$78	1
36902	Intro cath dialysis circuit	$78	1
29827	Arthroscop rotator cuff repr	$76	4
66821	After cataract laser surgery	$67	-1
64590	Insrt/redo pn/gastr stimul	$63	6
C9740	Cysto impl 4 or more	$58	4
22869	Insj stablj dev w/o dcmprn	$55	6
62323	Njx interlaminar lmbr/sac	$55	1
G0105	Colorectal scrn; hi risk ind	$53	4
15823	Revision of upper eyelid	$40	5
G0121	Colon ca scrn not hi rsk ind	$39	4
45378	Diagnostic colonoscopy	$39	4
64721	Carpal tunnel surgery	$37	1
63655	Implant neuroelectrodes	$33	8
65820	Relieve inner eye pressure	$29	1
62362	Implant spine infusion pump	$28	4
64561	Implant neuroelectrodes	$28	0
67042	Vit for macular hole	$28	1
29881	Knee arthroscopy/surgery	$28	4
64490	Inj paravert f jnt c/t 1 lev	$27	1

c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2021 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures we propose to add to the ASC list of covered surgical procedures and for those we propose to designate as office-based for CY 2021. For example, using 2019 utilization data and proposed CY 2021 OPPS and ASC payment rates, we estimate that if 10 percent of colpopexy procedures migrate from the hospital outpatient setting to the ASC setting as a result of this proposed policy, Medicare payments will be

reduced by approximately $6 million in CY 2021 and total beneficiary copayments will decline by approximately $1.2 million in CY 2021. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense based amount payable under the PFS. For those additional procedures that we propose to designate as office-based in CY 2021, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the

coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

3. Accounting Statements and Tables

As required by OMB Circular A-4 (available on the Office of Management and Budget website at: https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 58, illustrates the classification of expenditures for the CY 2021 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2021 OPD fee schedule increase. The second accounting statement, Table 59, illustrates the classification of expenditures associated with the 2.6 percent CY 2021 update to the ASC payment system, based on the provisions of the final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. The estimated costs of ICR Burden and Regulatory Familiarization are included in Table 60.

TABLE 58: ACCOUNTING STATEMENT: CY 2021 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2020 TO CY 2021 ASSOCIATED WITH THE FINAL CY 2020 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1,610 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$1,610 million

TABLE 59: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2020 TO CY 2021 AS A RESULT OF THE FINAL CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$110 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers

Category	Transfers
Total	$110 million

TABLE 60: ESTIMATED COSTS IN CY 2021

CATEGORY	Costs
ICR Burden	$1.58 million*
Regulatory Familiarization	$3.37 million**

*The annual estimates are in 2018 year dollars which includes the impact of hospital outpatient QRP and prior authorization process and requirements for certain OPD services.
** Regulatory familiarization costs occur upfront only.

4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59492 through 59494), for the previously estimated effects of changes to the Hospital OQR Program for the CY 2018, CY 2019, and CY 2020 payment determinations. Of the 3,144 hospitals that met eligibility requirements for the CY 2020 payment determination, we determined that 78 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. We do not propose to add any quality measures to the Hospital OQR Program measure set for the CY 2022 or CY 2023 payment determinations.

b. Impact of CY 2021 Proposals

We do not anticipate that any of the CY 2021 Hospital OQR program proposals will impact the number of facilities that will receive payment reductions. In this proposed rule, we propose to: (1) codify the statutory authority for the Hospital OQR Program; (2) revise and codify the previously finalized public display of measure data policy that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes; (3) revise existing § 419.46(a)(2) by replacing the term “security administrator” with the term

“security official” and codify this language; (4) move all deadlines falling on nonwork days forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j) "Periods of Limitation Ending on Nonwork Days," beginning with the effective date of this rule; (5) revise our policy regarding submission deadlines at existing § 419.46(c)(2) to reflect the proposed deadlines policy consistent with section 216(j) of the Act, 42 U.S.C. 416(j); (6) expand the existing review and corrections policy for chart-abstracted data to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years; (7) codify at 42 CFR 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool; (8) codify the previously finalized Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures; (9) revise existing § 419.46(b) (proposed redesignated § 419.46(c)) by removing the phrase “submit a new participation form” to align with previously finalized policy”; and (10) update internal cross-references as a result of the redesignations discussed in the proposed rule.”

We do not anticipate that the proposals affecting the Hospital OQR program in this proposed rule will impact the number of hospitals that will receive payment reductions.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XV.B. of this proposed rule, we discuss our finalized policies affecting the ASCQR Program. For the CY 2020 payment determination, of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 195 ASCs did not meet the requirements to receive the full annual payment update. We do not propose to add or remove any quality measures to the ASCQR Program measure set for future calendar year payment determinations.

b. Impact of CY 2021 Proposals

In sections XV.C. and XV.D. of this proposed rule, we propose to: (1) use the term "security official" instead of "security administrator" and revise § 416.310(c)(1)(i) by replacing the term “security administrator” with the term “security official;” (2) remove the phrase “data collection time period” in all instances where it appears in § 416.310, replace it with the phrase “data collection period,” and use the phrase “data collection period” wherever the phrase “data collection time period” is found in the preamble of this proposed rule; (3) move forward all program deadlines falling on a nonwork day consistent with the section 216(j) of the Act, 42 U.S.C. 416(j) and codify this policy; and (4) formalize the process by which ASCs identify errors and resubmit data before the established submission deadline by creating a review and corrections period similar to that in the Hospital OQR Program in section XIV.D.7. that runs concurrent with the existing data submission period from January 1 through May 15 and codify this policy.

We do not anticipate that the proposals affecting the ASCQR program in this proposed rule will impact the number of ASCs that will receive payment reductions.

6. Effects of Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop “a method for controlling unnecessary increases in the volume of covered OPD services” (84 FR 61142, November 12, 2019).[311] The regulations governing the prior

[311] See also Correction Notice issued January 3, 2020 (85 FR 224).

authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to require prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. We also propose to add those service categories to § 419.83(a). We propose that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. The proposed addition of these service categories is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the health care sector of this proposal to require prior authorization for two additional service categories is dependent on the number of claims affected. Table 61, Overall Economic Impact to the Health Sector, lists an estimate for the overall economic impact to the health sector for the two new service categories combined. The values populating this table were obtained from the cost reflected in Table 62, Annual Private Sector Costs, and Table 63, Estimated Annual Administrative Costs to CMS. Together, Tables 62 and 63 combine to convey the overall economic impact to the health sector for the two new service categories, which is illustrated in Table 61. It should be noted that due to the proposed July start date for prior authorization for these two new service categories, year one would include only 6 months of prior authorization requests.

Based on the estimate, the overall economic cost impact of this proposal is approximately $2.9 million in the first year based on 6 months for the two new service categories. The 5-year impact is approximately $22.9 million, and the 10-year impact is approximately $47.9 million. The 5- and 10-year impacts account for year one including only 6 months. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create

the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of $31,844,388. We believe there are likely to be other benefits that result from the proposed prior authorization requirement for the two new service categories, though many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We are soliciting public comments on the potential increased costs and benefits associated with this proposed provision for the two new service categories.

TABLE 61: OVERALL ECONOMIC COST IMPACT TO THE HEALTH SECTOR

	Year 1	**5 Years**	**10 Years**
Private Sector Costs	$870,723	$6,539,151	$13,624,686
Administrative Costs to CMS	$2,017,317	$16,349,353	$34,264,398
Total Economic Impact to Health Sector	$2,888,040	$22,888,504	$47,889,084

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of $10 million or less in any 1 year. While the economic costs and benefits of this proposal are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations will be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant; if finalized, the proposal will change the billing practices of those providers. We believe that the purpose of the statute and this proposal is to avoid unnecessary utilization of OPD services.

Therefore, we do not view decreased revenues from the two additional OPD services categories subject to unnecessary utilization by providers to be a condition that we must mitigate. We believe that the effect will be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. This proposal will offer an additional protection to a provider's cash flow as the provider will know in advance if the Medicare requirements are met.

b. Anticipated Specific Cost Effects

(1) Private Sector Costs

We do not believe that this proposal will significantly affect the number of legitimate claims submitted for these new service categories. However, we do expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the two proposed additional service categories is equivalent to that of submitting documentation and clerical activities associated for prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

TABLE 62: Year 1 (6 Month) Private Sector Costs

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests-Initial Submissions	15,884	0.5	7,942	$264,158
Fax and Electronic Submitted Requests-Resubmissions	5,214	0.5	2,607	$86,702

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Mailed in Requests-Initial Submissions	6,808	0.5	3,404	$113,210
Mailed in Requests-Resubmissions	2,234	0.5	1,117	$37,158
Mailing Costs	9,042	$5	NA	$45,210
Provider Demonstration-Education	3,250	3	9,750	$324,285
Total			24,820	$870,723

(2) Administrative Costs to CMS

CMS will incur additional costs associated with processing the proposed prior authorization requests for the two new service categories. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $50, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education and outreach, and system changes.

TABLE 63: Year 1 (6 Month) Estimated Administrative Costs to CMS

Cervical Fusion with Disc Removal	Implanted Spinal Neurostimulators	Combined
$489,916	$1,077,401	$2,017,317

(3) Estimated Beneficiary Costs

We expect a reduction in the utilization of the two new Medicare OPD service categories when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden. Although the proposal is designed to permit utilization that is medically necessary, OPD services that are not medically necessary may still provide

convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

c. Estimated Benefits

There will be quantifiable benefits for this proposal because we expect a reduction in the unnecessary utilization of those two new Medicare OPD service categories subject to prior authorization. It is difficult to project the exact decrease in unnecessary utilization; however, based on other prior authorization programs, we estimate our savings based on a 50 percent reduction in improper payments, using a 10 percent improper payment rate. We estimate that for the first six months, there would be savings of $15,922,194 overall. Annually, we estimate an overall gross savings of $31,844,388. This savings represents a Medicare benefit from a more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We will closely monitor utilization and billing practices. The expected benefits would also include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the two proposed additional OPD services categories would ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine his or her condition and what services are needed and medically necessary. This would require the facility to collaborate closely with the practitioner early on in the process to ensure the services are truly necessary and meet all requirements and the documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient or the patient does not meet the Medicare requirements would likely be reduced

by the requirement that a provider submit clinical documentation created as part of its prior authorization request.

7. Effects of Proposed Revision to the Laboratory Date of Service Policy

In section XVIII. of this proposed rule, we discuss our proposal to add cancer-related protein-based MAAAs to the laboratory date of service (DOS) provisions at § 414.510(b)(5). We also propose to exclude these tests from the OPPS packaging policy, which is discussed in section II.a.3 of this proposed rule. These proposals, if finalized, would mean that Medicare would pay for cancer-related protein-based MAAAs under the CLFS instead of the OPPS and the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5). While there may be some impact under the hospital OPPS resulting from additional testing being excluded from OPPS packaging policy and paid at the CLFS rate instead of the OPPS bundled rate, we expect this change to be budget neutral for scoring purposes. Accordingly, the discussion in sections II.a.3. and XVIII. of this proposed rule is not reflected in Table 55 in the regulatory impact analysis under section XXIV of this proposed rule.

8. Effects of Requirements for the Overall Hospital Quality Star Ratings

In section E. Current and Proposed Overall Star Rating Methodology of the preamble of this proposed rule, we discuss our proposal as it relates to the Overall Star Rating methodology. The Overall Star Rating uses measures that are publicly reported on *Hospital Compare* or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. The burden associated with measures included in the Overall Star Rating, including forms used to request withholding of publicly reported measure data and the Overall Star Rating (for CAHs), is already captured in the respective hospital programs' burden estimates and represents no increased information collection burden to hospitals.

In this proposed rule, however, we propose that hospitals have the opportunity to review confidential reports containing their measure, measure group, and Overall Star Rating results for at least 30 days prior to publication of the Overall Star Rating. We believe that reviewing the Overall Star Rating in confidential reports prior to public reporting represents additional burden to hospitals.

In this CY 2021 OPPS/ASC proposed rule, we are using the most recent data from the Bureau of Labor Statistics, which reflects a median hourly wage of $19.40[312] per hour for a Medical Records and Health Information Technician professional. We calculate the cost of overhead, including fringe benefits, at 100 percent of the hourly wage estimate, consistent with the previous year. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $38.80 per hour.

We estimate that the non-information collection burden associated with all non-VHA hospitals reviewing their Overall Star Rating preview report prior to public reporting to be 2 hours per hospital, which includes time to review the report and ask any questions about the calculation necessary to increase comprehension. Estimating that 4,500 hospitals that will receive an Overall Star Rating hospital specific report (HSR), regardless if they meet the reporting thresholds to be assigned a star rating, we estimate the overall non-information collection burden to be $397,710 annually [$38.80 x 2 hours per preview report x once per year x 4,500 hospitals]. For CAHs specifically, which are included in the estimate above, we estimate that half of CAHs will be eligible for an Overall Star Rating (using an

[312] Bureau of Labor Statistics. (2019, September 4). *Occupational Outlook Handbook: Medical Records and Health Information Technicians*. Retrieved from www.bls.gov: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.

estimate of 1,300 total CAHs in the United States), which represents a burden of $100,890 annually [650 CAHs x 2 hours per preview report x once per year x $38.80].

To simulate the impact of the combined methodology updates, we used January 2020 Overall Star Rating publication data (using October 2019 publicly reported measure data on *Hospital Compare)* to conduct analyses that describe the overall distribution of star ratings, reclassification of star ratings, and distribution of star ratings across different types of hospitals. We conducted these analyses following three proposals (referred to as combined methodology proposals): (1) grouping measures into five, rather than seven, measure groups; (2) using a simple average of measure scores to calculate measure group scores; and (3) updating the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group to receive a star rating. We also conducted these analyses separately with the combined methodology proposals and the additional proposal of peer grouping hospitals by number of measure groups for which the hospital reports at least three measures, with the combined methodology proposal and the additional proposal of Readmission measure group stratification by dual-eligible peer groups, and with the combined methodology proposals and the additional proposals of both peer grouping by number of measure groups and Readmission measure group stratification by dual-eligible peer groups to specifically solicit further comment on these proposals. Please note that the ultimate star ratings distribution and reclassification with the proposed methodology updates in CY 2021 will differ depending on measure additions and removals from CMS quality programs, and therefore public reporting, and changes in hospital measure performance.

The combined methodology proposals of (1) grouping measures into five measure groups, (2) using a simple average of measure scores to calculate measure group scores, and (3) updating the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety

of Care, with at least three measures in each group to receive a star rating, would result in a similar percent of hospitals that would and would not receive a star rating, regardless of peer grouping by number of measure groups or Readmission measure group stratification by dual-eligibility groups. However, slightly fewer safety-net and critical access hospitals (CAHs), would receive a star rating with the new methodology due to the proposal to update the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group. Specifically, approximately 30 percent of specialty, 90 percent of teaching, 60 percent of safety-net, and 40 percent of CAHs meet the proposed reporting thresholds of three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group.

The combined methodology proposals of grouping measures into five, rather than seven, measure groups, using a simple average of measure scores to calculate measure group scores, and updating the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group to receive a star rating results in the below distribution of star ratings, reclassification of star ratings, and distribution of star ratings across hospital characteristics:

- With the combined methodology proposals, there would be a similar distribution of star ratings with more three (23 percent) and four (23 percent) star ratings and fewer one (4 percent), two (13 percent), and five (13 percent) star ratings (Table 64).

- Given the substantial change in the proposed methods, particularly using a simple average of measure scores to calculate measure groups scores, we would expect there to be considerable changes in hospital star ratings from the current methodology to the proposed methodology. With the combined proposed methodology, 1,796 (53 percent) hospitals would receive the same star rating, 1,468 (43 percent) hospitals would shift up or down one star, 135 (4 percent) hospitals would shift up or down two

stars, 9 (0.3 percent) hospitals would shift up or down three stars, and 1 (0.03 percent) hospital would shift up or down four stars (Table 65).

- With the combined methodology proposals, most hospital characteristics have a similar distribution of star ratings to that of all hospitals. A few notable differences in the distribution of star ratings across hospital characteristics compared to all hospitals are listed in Table 72.

  - More specialty hospitals with three (4 percent), four (7 percent), and five (19 percent) stars than one (0 percent) or two (0 percent) stars.

  - More DSH hospitals with one (6 percent), two (19 percent), and three (31 percent) stars and fewer DSH hospitals with five stars (11 percent). Also, there would be more DSH hospitals with one (3 percent for DSH quintiles 1 and 2 to 17 percent for DSH quintile 5) and two stars (14 percent for DSH quintile 1 to 25 percent for DSH quintile 5) and fewer DSH hospitals with four (36 percent for DSH quintile 1 to 16 percent for DSH quintile 5) and five (18 percent for DSH quintile 1 to 5 percent for DSH quintile 5) stars with increasing DSH quintile.

  - More CAHs with five (13 percent) and four (14 percent) stars than one (1 percent), two (3 percent), and three (8 percent) stars.

  - More hospitals with one (2 percent for hospitals with 1-99 beds to 9 percent for hospitals with 400 or more beds) and two stars (9 percent for hospitals with 1-99 beds to 26 percent for hospitals with 300-399 beds and 24 percent for hospitals with 400 or more beds) with increasing bed size.

  - Slightly larger urban hospitals with one (8 percent) and two (19 percent) stars than other urban hospitals with one (4 percent) and two (17 percent) stars or rural hospitals with one (3 percent) and two (15 percent) stars. There would also be slightly fewer large urban hospitals with four (24 percent) stars than other urban hospitals with four (27 percent) stars or rural hospitals with four (30 percent) stars.

The combined methodology proposals with the additional proposal of peer grouping by number of measure groups would result in the below distribution of star ratings, reclassification of star ratings, and distribution of star ratings across hospital characteristics. With the combined methodology proposals and the additional proposal of peer grouping:

- There would be a similar distribution of star ratings with more three (22 percent) and four (23 percent) star ratings and fewer one (4 percent), two (14 percent), and five (12 percent) star ratings (Table 64).

- Approximately 2,676 (78 percent), 1,692 (50 percent) hospitals would receive the same star rating, 1,482 (43 percent) hospitals would shift up or down one star, 184 (5 percent) hospitals would shift up or down two stars, 10 (0.3 percent) hospitals would shift up or down three stars, and one (0.03 percent) hospital would shift up or down four stars (Table 66).

- Most hospital characteristics have a similar distribution of star ratings to that of all hospitals. A few notable differences in the distribution of star ratings across hospital characteristics compared to all hospitals are listed below (Table 73).

  - More specialty hospitals with three (5 percent), four (7 percent), and five (17 percent) stars than one (0 percent) and two (1 percent) stars.

  - More DSH hospitals with two stars (13 percent for DSH quintile 1 to 25 percent for DSH quintile 5) and fewer DSH hospitals with four (34 percent for DSH quintile 1 to 18 percent for DSH quintile 5) and five (23 percent for DSH quintile 1 to 5 percent for DSH quintile 5) stars with increased DSH quintiles.

  - Slightly larger urban hospitals with one star (8 percent) than other urban hospitals with one star (4 percent) or rural hospitals with one star (3 percent). There would also be slightly fewer large

urban hospitals with four stars (24 percent) than other urban hospitals with four stars (29 percent) or rural hospitals with four stars (29 percent).

The combined methodology proposal with the addition of stratifying Readmission measure group scores by dual-eligibility peer groups, using peer group quintiles assigned by the HRRP annually, would result in the below distribution of star ratings, reclassification of star ratings, and distribution of star ratings across hospital characteristics. With the combined methodology proposals and the additional proposal of Readmission stratification by dual-eligibility groups:

- There is a similar distribution of star ratings with more three (24 percent) and four (24 percent) star ratings and fewer one (3 percent), two (12 percent), and five (13 percent) star ratings (Table 64).
- Approximately 1,715 (50 percent) hospitals would receive the same star rating, 1,523 (45 percent) hospitals would shift up or down one star, 163 (5 percent) hospitals would shift up or down two stars, 7 (0.2 percent) hospitals would shift up or down three stars, and 1 (0.03 percent) hospitals would shift up or down four stars (Table 67).
- Most hospital characteristics have a similar distribution of star rating to that of the all hospitals. A few notable differences in the distribution of star ratings across hospital characteristics compared to all hospitals are listed in Table 74.
    - More specialty hospitals with four (7 percent) and five (20 percent) stars compared to one (0 percent) or two (1 percent) stars.
    - Similar star rating distribution for safety-net and non-safety-net hospitals, with more three (18 percent safety-net; 26 percent non-safety-net) and four (18 percent safety-net; 27 percent non-safety-net) stars and fewer one (4 percent safety-net; 2 percent non-safety-net), two (12 percent safety-net; 13 percent non-safety-net), or five (9 percent safety-net; 14 percent non-safety-net) stars.

- More DSH Quintile 5 hospitals with one (10 percent) and two (24 percent) stars than DSH Quintile 1 hospitals with one (2 percent) and two (13 percent) stars. Also, there would be fewer hospitals with four (37 percent for DSH quintile 1 to 20 percent for DSH quintile 5) and five stars (17 percent for DSH quintile 1 to 7 percent for DSH quintile 5) with increasing DSH quintiles.
- More CAHs receiving a star rating with four (14 percent) and five (14 percent) stars than one (1 percent) or two (3 percent) stars.
- More hospitals with one (1 percent for hospitals with 1 to 99 beds to 7 percent for hospitals with 300-399 beds and 5 percent for hospitals with 400 or more beds) and two stars (7 percent for hospitals with 1 to 99 beds to 26 percent for hospitals with 300-399 beds and 23 percent for hospitals with 400 or more beds) with increasing bed size.

In further support of our additional proposals to peer group hospitals by the number of measure groups and stratify the Readmission measure group by dual-eligibility groups, we also conducted analyses examining the distribution of star ratings, reclassification of star ratings, and distribution of star ratings across hospital characteristic analyses on the combined methodology proposals with the additional proposals of peer grouping and Readmission stratification. With the combined methodology proposals and the additional proposals of both peer grouping by number of measure groups and Readmission stratification by dual-eligibility groups:

- There would be a similar distribution of star ratings with more three (24 percent) and four (24 percent) star ratings and fewer one (3 percent), two (12 percent), and five (12 percent) star ratings (Table 64).
- Approximately 1,743 (51 percent) hospitals would receive the same star rating, 1,477 (43 percent) hospitals would shift up or down one star, 180 (5 percent) hospitals would shift up or

down two stars, 8 (0.2 percent) hospitals would shift up or down three stars, and 1 (0.03 percent) hospitals would shift up or down four stars (Table 68).

- Most hospital characteristics have a similar distribution of star rating to that of the all hospitals. A few notable differences in the distribution of star ratings across hospital characteristics compared to all hospitals are listed in Table 75.
  - More specialty hospitals with four (10 percent) and five (15 percent) stars compared to one (0 percent) or two (1 percent) stars.
  - More DSH hospitals with one (5 percent), two (17 percent), and three (30 percent) stars and fewer DSH hospitals with five stars (14 percent). Also, there would be more hospitals with one (3 percent for quintile 1 to 11 percent for quintile 5) and two (13 percent for quintile 1 to 24 percent for quintile 5) stars and fewer hospitals five stars (21 percent for quintile 1 to 7 percent for quintile 5) with increasing DSH quintiles.
  - More CAHs with four (15 percent) and five (6 percent) stars than one (1 percent) or two (5 percent) stars.
  - More hospitals with one (1 percent for hospitals with 1 to 99 beds to 8 percent for hospitals with 300 to 399 beds and 6 percent for hospitals with 400 or more beds) and two stars with increasing bed size.

To isolate the effects of our additional proposals to peer group hospitals by the number of measure groups and stratify the Readmission measure group by dual-eligibility groups, we also conducted reclassification analyses comparing the two additional proposals.

- When comparing the combined methodology proposals with the additional proposals of peer grouping by the number of measure groups and stratifying the Readmission measure group by dual-eligibility peer groups to the combined methodology proposals with the additional proposal to stratify

the Readmission measure group by dual-eligibility peer groups but without the proposal to peer group by number of measure groups, 2,676 (78 percent) hospitals would receive the same star rating, and 764 (22 percent) hospitals would shift up or down one star. No hospitals would move more than one star (Table 69).

- When comparing the combined methodology proposals with the additional proposals to peer group hospitals by the number of measure groups and stratifying the Readmission measure group by dual-eligibility peer groups to the combined methodology proposals with our proposal to peer group by the number of measure groups but without the proposal to stratify the Readmission measure group by dual-eligibility peer groups, 3,093 (90 percent) hospitals would receive the same star rating, and 347 (10 percent) hospitals would shift up or down one star. No hospitals would move more than one star (Table 70).

TABLE 64: OVERALL STAR RATING DISTRIBUTION BY CURRENT METHODOLOGY, COMBINED METHODOLOGY PROPOSALS, COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING, COMBINED METHODOLOGY PROPOSALS WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS, AND COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING AND READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating	Current Methodology	Combined Methodology Proposals	Combined Methodology Proposals, Peer Grouping	Combined Methodology Proposals, Readmission Stratification	Combined Methodology Proposals, Peer Grouping, Readmission Stratification
1	228 (4.97%)	197 (4.30%)	184 (4.01%)	122 (2.66%)	145 (3.16%)
2	710 (15.48%)	597 (13.02%)	620 (13.52%)	555 (12.10%)	567 (12.36%)
3	1,119 (24.4%)	1,037 (22.61%)	1,026 (22.37%)	1,078 (23.51%)	1,087 (23.70%)
4	1,136 (24.77%)	1,033 (22.53%)	1,051 (22.92%)	1,101 (24.01%)	1,093 (23.83%)
5	407 (8.87%)	576 (12.56%)	559 (12.19%)	584 (12.73%)	548 (11.95%)
N/A	986 (21.5%)	1,146 (24.99%)	1,146 (24.99%)	1,146 (24.99%)	1,146 (24.99%)

TABLE 65: STAR RATING RECLASSIFICATION, CURRENT METHODOLOGY VS COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Current Methodology)	Star Rating (Combined Methodology Proposals, No Peer Grouping, No Readmission Stratification)					
	1	2	3	4	5	Total
1	113	96	17	0	0	226
	50.0%	42.5%	7.5%	0%	0%	
2	65	345	253	38	2	703
	9.3%	49.1%	36.0%	5.4%	0.3%	
3	8	130	528	340	40	1,046
	0.8%	12.4%	50.5%	32.5%	3.8%	
4	5	19	218	543	256	1,041
	0.5%	1.8%	20.9%	52.2%	24.6%	
5	1	2	13	110	267	393
	0.3%	0.5%	3.3%	28.0%	67.9%	
Total	192	592	1,029	1,031	565	3,409

TABLE 66: STAR RATING RECLASSIFICATION, CURRENT METHODOLOGY VS COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING AND WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Current Methodology)	Star Rating (Combined Methodology Proposals, Peer Grouping, No Readmission Stratification)					
	1	2	3	4	5	Total
1	107	94	25	0	0	226
	47.4%	41.6%	11.1%	0%	0%	
2	58	318	265	60	2	703
	8.3%	45.2%	37.7%	8.5%	0.3%	
3	7	163	488	345	43	1,046
	0.7%	15.6%	46.7%	33.0%	4.1%	

4	7	37	228	541	228	1,041
	0.7%	3.6%	21.9%	52.0%	21.9%	
5	1	1	12	101	278	393
	0.3%	0.3%	3.1%	25.7%	70.7%	
Total	180	613	1,018	1,047	551	3,409

TABLE 67: STAR RATING RECLASSIFICATION, CURRENT METHODOLOGY VS COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Current Methodology)	Star Rating (Combined Methodology Proposals, No Peer Grouping, Readmission Stratification)					
	1	2	3	4	5	Total
1	76	126	24	0	0	226
	33.6%	55.6%	10.6%	0%	0%	
2	34	306	305	56	2	703
	4.8%	43.5%	43.4%	8.0%	0.3%	
3	3	100	522	370	51	1,046
	0.3%	9.6%	50.0%	35.4%	4.9%	
4	4	17	207	552	261	1,041
	0.4%	1.6%	19.9%	53.0%	25.1%	
5	1	1	12	120	259	393
	0.3%	0.3%	3.1%	30.5%	65.9%	
Total	118	550	1,070	1,098	573	3,409

TABLE 68: STAR RATING RECLASSIFICATION, CURRENT METHODOLOGY VS COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Current Methodology)	Star Rating (Combined Methodology Proposals, Peer Grouping, Readmission Stratification)					
	1	2	3	4	5	Total
1	86	111	29	0	0	226

	38.1%	49.1%	12.8%	0%	0%	
2	42	305	290	65	1	703
	6.0%	43.4%	41.3%	9.3%	0.1%	
3	6	122	518	351	49	1,046
	0.6%	11.7%	49.5%	33.6%	4.7%	
4	6	20	232	563	220	1,041
	0.6%	1.9%	22.3%	54.1%	21.1%	
5	1	1	11	109	271	393
	0.3%	0.3%	2.8%	27.7%	69.0%	
Total	141	559	1,080	1,088	541	3,409

TABLE 69: STAR RATING RECLASSIFICATION, COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS VS COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Combined Methodology Proposals, Peer Grouping, Readmission Stratification)	Star Rating (Combined Methodology Proposals, No Peer Grouping, Readmission Stratification)					
	1	2	3	4	5	Total
1	120	25	0	0	0	145
	82.8%	17.2%	0%	0%	0%	
2	2	492	73	0	0	567
	0.4%	86.8%	12.9%	0%	0%	
3	0	38	880	169	0	1,087
	0%	3.5%	90.0%	15.6%	0%	
4	0	0	125	784	184	1,093
	0%	0%	11.4%	71.7%	16.8%	
5	0	0	0	148	400	548
	0%	0%	0%	27.0%	73.0%	
Total	122	555	1,078	1,101	584	3,440

TABLE 70: STAR RATING RECLASSIFICATION, COMBINED METHODOLOGY PROPOSALS, PEER GROUPING, READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS VS COMBINED METHODOLOGY PROPOSALS, PEER GROUPING WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Combined Methodology Proposals, Peer Grouping, Readmission Stratification)	Star Rating (Combined Methodology Proposals, Peer Grouping, No Readmission Stratification)					
	1	2	3	4	5	Total
1	145	0	0	0	0	145
	100%	0%	0%	0%	0%	
2	39	517	11	0	0	567
	6.9%	91.2%	1.9%	0%	0%	
3	0	103	934	50	0	1,087
	0%	9.5%	85.9%	4.6%	0%	
4	0	0	81	975	37	1,093
	0%	0%	7.4%	89.2%	3.4%	
5	0	0	0	26	522	548
	0%	0%	0%	4.7%	95.3%	
Total	184	620	1,026	1,051	559	3,440

TABLE 71: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, CURRENT METHODOLOGY

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	228 (4.97%)	710 (15.48%)	1119 (24.40%)	1136 (24.77%)	407 (8.87%)	986 (21.50%)
Specialty	0 (0%)	0 (0%)	3 (2.48%)	9 (7.44%)	21 (17.36%)	88 (72.73%)
Non-Specialty	228 (5.24%)	705 (16.20%)	1102 (25.33%)	1100 (25.28%)	380 (8.73%)	836 (19.21%)
N/A	0 (0%)	5 (4.39%)	14 (12.28%)	27 (23.68%)	6 (5.26%)	62 (54.39%)
Major Teaching	45 (18.67%)	55 (22.82%)	67 (27.80%)	50 (20.75%)	23 (9.54%)	1 (0.41%)

Hospital Characteristic	1	2	3	4	5	N/A
Minor Teaching	112 (7.80%)	307 (21.39%)	375 (26.13%)	358 (24.95%)	181 (12.61%)	102 (7.11%)
Non-Teaching	71 (2.54%)	343 (12.27%)	663 (23.71%)	701 (25.07%)	197 (7.05%)	821 (29.36%)
N/A	0 (0%)	5 (4.39%)	14 (12.28%)	27 (23.68%)	6 (5.26%)	62 (54.39%)
Safety-Net	76 (5.74%)	170 (12.83%)	310 (23.40%)	276 (20.83%)	63 (4.75%)	430 (32.45%)
Non-Safety-Net	150 (4.81%)	529 (16.98%)	783 (25.13%)	826 (26.51%)	337 (10.82%)	491 (15.76%)
N/A	2 (1.38%)	11 (7.59%)	26 (17.93%)	34 (23.45%)	7 (4.83%)	65 (44.83%)
Non-DSH	8 (1.64%)	31 (6.34%)	91 (18.61%)	126 (25.77%)	90 (18.40%)	143 (29.24%)
DSH	219 (7.98%)	641 (23.36%)	802 (29.23%)	681 (24.82%)	262 (9.55%)	139 (5.07%)
Quintile 1	20 (3.65%)	90 (16.42%)	138 (25.18%)	183 (33.39%)	90 (16.42%)	27 (4.93%)
Quintile 2	21 (3.82%)	113 (20.55%)	154 (28.00%)	168 (30.55%)	73 (13.27%)	21 (3.82%)
Quintile 3	35 (6.39%)	143 (26.09%)	168 (30.66%)	146 (26.64%)	37 (6.75%)	19 (3.47%)
Quintile 4	46 (8.36%)	141 (25.64%)	185 (33.64%)	107 (19.45%)	41 (7.45%)	30 (5.45%)
Quintile 5	97 (17.70%)	154 (28.10%)	157 (28.65%)	77 (14.05%)	21 (3.83%)	42 (7.66%)
N/A	1 (0.07%)	38 (2.81%)	226 (16.70%)	329 (24.32%)	55 (4.07%)	704 (52.03%)
CAH	1 (0.08%)	37 (2.80%)	225 (17.02%)	328 (24.81%)	55 (4.16%)	676 (51.13%)
Non-CAH	227 (6.95%)	673 (20.62%)	894 (27.39%)	808 (24.75%)	352 (10.78%)	310 (9.50%)
1-99 beds	16 (1.34%)	133 (11.17%)	320 (26.87%)	340 (28.55%)	142 (11.92%)	240 (20.15%)
100-199 beds	52 (5.71%)	232 (25.49%)	284 (31.21%)	222 (24.40%)	84 (9.23%)	36 (3.96%)

Hospital Characteristic	1	2	3	4	5	N/A
200-299 beds	63 (13.24%)	131 (27.52%)	120 (25.21%)	106 (22.27%)	50 (10.50%)	6 (1.26%)
300-399 beds	37 (12.85%)	85 (29.51%)	70 (24.31%)	60 (20.83%)	36 (12.50%)	0 (0%)
400 or more beds	59 (16.03%)	91 (24.73%)	99 (26.90%)	79 (21.47%)	40 (10.87%)	0 (0%)
N/A	1 (0.07%)	38 (2.81%)	226 (16.70%)	329 (24.32%)	55 (4.07%)	704 (52.03%)
Large Urban	115 (8.86%)	294 (22.65%)	320 (24.65%)	289 (22.27%)	150 (11.56%)	130 (10.02%)
Other Urban	89 (7.64%)	245 (21.03%)	306 (26.27%)	290 (24.89%)	139 (11.93%)	96 (8.24%)
Rural	23 (2.99%)	133 (17.27%)	267 (34.68%)	228 (29.61%)	63 (8.18%)	56 (7.27%)
N/A	1 (0.07%)	38 (2.81%)	226 (16.70%)	329 (24.32%)	55 (4.07%)	704 (52.03%)

TABLE 72: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	197 (4.30%)	597 (13.02%)	1037 (22.61%)	1033 (22.53%)	576 (12.56%)	1146 (24.99%)
Specialty	0 (0%)	0 (0%)	5 (4.13%)	8 (6.61%)	23 (19.01%)	85 (70.25%)
Non-Specialty	197 (4.53%)	593 (13.63%)	1022 (23.49%)	1008 (23.17%)	537 (12.34%)	994 (22.85%)
N/A	0 (0%)	4 (3.51%)	10 (8.77%)	17 (14.91%)	16 (14.04%)	67 (58.77%)
Major Teaching	27 (11.20%)	54 (22.41%)	74 (30.71%)	58 (24.07%)	27 (11.20%)	1 (0.41%)
Minor Teaching	94 (6.55%)	259 (18.05%)	409 (28.50%)	386 (26.90%)	174 (12.13%)	113 (7.87%)

Hospital Characteristic	1	2	3	4	5	N/A
Non-Teaching	76 (2.72%)	280 (10.01%)	544 (19.46%)	572 (20.46%)	359 (12.84%)	965 (34.51%)
N/A	0 (0%)	4 (3.51%)	10 (8.77%)	17 (14.91%)	16 (14.04%)	67 (58.77%)
Safety-Net	79 (5.96%)	159 (12.00%)	234 (17.66%)	222 (16.75%)	116 (8.75%)	515 (38.87%)
Non-Safety-Net	118 (3.79%)	430 (13.80%)	782 (25.10%)	783 (25.13%)	442 (14.18%)	561 (18.00%)
N/A	0 (0%)	8 (5.52%)	21 (14.48%)	28 (19.31%)	18 (12.41%)	70 (48.28%)
Non-DSH	5 (1.02%)	25 (5.11%)	81 (16.56%)	124 (25.36%)	105 (21.47%)	149 (30.47%)
DSH	171 (6.23%)	527 (19.21%)	848 (30.90%)	725 (26.42%)	298 (10.86%)	175 (6.38%)
Quintile 1	17 (3.10%)	74 (13.50%)	129 (23.54%)	198 (36.13%)	96 (17.52%)	34 (6.20%)
Quintile 2	15 (2.73%)	91 (16.55%)	167 (30.36%)	174 (31.64%)	77 (14.00%)	26 (4.73%)
Quintile 3	23 (4.20%)	106 (19.34%)	201 (36.68%)	139 (25.36%)	55 (10.04%)	24 (4.38%)
Quintile 4	25 (4.55%)	121 (22.00%)	197 (35.82%)	127 (23.09%)	42 (7.64%)	38 (6.91%)
Quintile 5	91 (16.61%)	135 (24.64%)	154 (28.10%)	87 (15.88%)	28 (5.11%)	53 (9.67%)
N/A	21 (1.55%)	45 (3.33%)	108 (7.98%)	184 (13.60%)	173 (12.79%)	822 (60.75%)
CAH	19 (1.44%)	44 (3.33%)	108 (8.17%)	184 (13.92%)	173 (13.09%)	794 (60.06%)
Non-CAH	178 (5.45%)	553 (16.94%)	929 (28.46%)	849 (26.01%)	403 (12.35%)	352 (10.78%)
1-99 beds	19 (1.60%)	105 (8.82%)	261 (21.91%)	318 (26.70%)	205 (17.21%)	283 (23.76%)
100-199 beds	44 (4.84%)	180 (19.78%)	310 (34.07%)	251 (27.58%)	90 (9.89%)	35 (3.85%)
200-299 beds	50 (10.50%)	105 (22.06%)	144 (30.25%)	120 (25.21%)	51 (10.71%)	6 (1.26%)

Hospital Characteristic	1	2	3	4	5	N/A
300-399 beds	30 (10.42%)	74 (25.69%)	90 (31.25%)	75 (26.04%)	19 (6.60%)	0 (0%)
400 or more beds	33 (8.97%)	88 (23.91%)	124 (33.70%)	85 (23.10%)	38 (10.33%)	0 (0%)
N/A	21 (1.55%)	45 (3.33%)	108 (7.98%)	184 (13.60%)	173 (12.79%)	822 (60.75%)
Large Urban	107 (8.24%)	242 (18.64%)	349 (26.89%)	309 (23.81%)	156 (12.02%)	135 (10.40%)
Other Urban	48 (4.12%)	197 (16.91%)	361 (30.99%)	313 (26.87%)	140 (12.02%)	106 (9.10%)
Rural	21 (2.73%)	113 (14.68%)	219 (28.44%)	227 (29.48%)	107 (13.90%)	83 (10.78%)
N/A	21 (1.55%)	45 (3.33%)	108 (7.98%)	184 (13.60%)	173 (12.79%)	822 (60.75%)

TABLE 73: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING & WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	184 (4.01%)	620 (13.52%)	1026 (22.37%)	1051 (22.92%)	559 (12.19%)	1146 (24.99%)
Specialty	0 (0%)	1 (0.83%)	6 (4.96%)	9 (7.44%)	20 (16.53%)	85 (70.25%)
Non-Specialty	184 (4.23%)	612 (14.07%)	1006 (23.12%)	1029 (23.65%)	526 (12.09%)	994 (22.85%)
N/A	0 (0%)	7 (6.14%)	14 (12.28%)	13 (11.40%)	13 (11.40%)	67 (58.77%)
Major Teaching	24 (9.96%)	45 (18.67%)	72 (29.88%)	64 (26.56%)	35 (14.52%)	1 (0.41%)
Minor Teaching	86 (5.99%)	249 (17.35%)	380 (26.48%)	386 (26.90%)	221 (15.40%)	113 (7.87%)
Non-Teaching	74 (2.65%)	319 (11.41%)	560 (20.03%)	588 (21.03%)	290 (10.37%)	965 (34.51%)

Hospital Characteristic	1	2	3	4	5	N/A
N/A	0 (0%)	7 (6.14%)	14 (12.28%)	13 (11.40%)	13 (11.40%)	67 (58.77%)
Safety-Net	73 (5.51%)	188 (14.19%)	236 (17.81%)	229 (17.28%)	84 (6.34%)	515 (38.87%)
Non-Safety-Net	111 (3.56%)	421 (13.51%)	767 (24.61%)	798 (25.61%)	458 (14.70%)	561 (18.00%)
N/A	0 (0%)	11 (7.59%)	23 (15.86%)	24 (16.55%)	17 (11.72%)	70 (48.28%)
Non-DSH	5 (1.02%)	28 (5.73%)	87 (17.79%)	111 (22.70%)	109 (22.29%)	149 (30.47%)
DSH	161 (5.87%)	500 (18.22%)	775 (28.24%)	757 (27.59%)	376 (13.70%)	175 (6.38%)
Quintile 1	17 (3.10%)	72 (13.14%)	117 (21.35%)	185 (33.76%)	123 (22.45%)	34 (6.20%)
Quintile 2	12 (2.18%)	86 (15.64%)	150 (27.27%)	180 (32.73%)	96 (17.45%)	26 (4.73%)
Quintile 3	21 (3.83%)	96 (17.52%)	180 (32.85%)	149 (27.19%)	78 (14.23%)	24 (4.38%)
Quintile 4	26 (4.73%)	111 (20.18%)	180 (32.73%)	145 (26.36%)	50 (9.09%)	38 (6.91%)
Quintile 5	85 (15.51%)	135 (24.64%)	148 (27.01%)	98 (17.88%)	29 (5.29%)	53 (9.67%)
N/A	18 (1.33%)	92 (6.80%)	164 (12.12%)	183 (13.53%)	74 (5.47%)	822 (60.75%)
CAH	16 (1.21%)	91 (6.88%)	164 (12.41%)	183 (13.84%)	74 (5.60%)	794 (60.06%)
Non-CAH	168 (5.15%)	529 (16.21%)	862 (26.41%)	868 (26.59%)	485 (14.86%)	352 (10.78%)
1-99 beds	23 (1.93%)	131 (11.00%)	257 (21.58%)	298 (25.02%)	199 (16.71%)	283 (23.76%)
100-199 beds	42 (4.62%)	154 (16.92%)	277 (30.44%)	274 (30.11%)	128 (14.07%)	35 (3.85%)
200-299 beds	47 (9.87%)	96 (20.17%)	133 (27.94%)	121 (25.42%)	73 (15.34%)	6 (1.26%)
300-399 beds	27 (9.38%)	70 (24.31%)	83 (28.82%)	75 (26.04%)	33 (11.46%)	0 (0%)

Hospital Characteristic	1	2	3	4	5	N/A
400 or more beds	27 (7.34%)	77 (20.92%)	112 (30.43%)	100 (27.17%)	52 (14.13%)	0 (0%)
N/A	18 (1.33%)	92 (6.80%)	164 (12.12%)	183 (13.53%)	74 (5.47%)	822 (60.75%)
Large Urban	101 (7.78%)	220 (16.95%)	332 (25.58%)	305 (23.50%)	205 (15.79%)	135 (10.40%)
Other Urban	42 (3.61%)	185 (15.88%)	318 (27.30%)	343 (29.44%)	171 (14.68%)	106 (9.10%)
Rural	23 (2.99%)	123 (15.97%)	212 (27.53%)	220 (28.57%)	109 (14.16%)	83 (10.78%)

TABLE 74: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	122 (2.66%)	555 (12.10%)	1078 (23.51%)	1101 (24.01%)	584 (12.73%)	1146 (24.99%)
Specialty	0 (0%)	1 (0.83%)	3 (2.48%)	8 (6.61%)	24 (19.83%)	85 (70.25%)
Non-Specialty	122 (2.80%)	551 (12.66%)	1064 (24.45%)	1077 (24.75%)	543 (12.48%)	994 (22.85%)
N/A	0 (0%)	3 (2.63%)	11 (9.65%)	16 (14.04%)	17 (14.91%)	67 (58.77%)
Major Teaching	15 (6.22%)	52 (21.58%)	83 (34.44%)	64 (26.56%)	26 (10.79%)	1 (0.41%)
Minor Teaching	60 (4.18%)	245 (17.07%)	434 (30.24%)	412 (28.71%)	171 (11.92%)	113 (7.87%)
Non-Teaching	47 (1.68%)	255 (9.12%)	550 (19.67%)	609 (21.78%)	370 (13.23%)	965 (34.51%)
N/A	0 (0%)	3 (2.63%)	11 (9.65%)	16 (14.04%)	17 (14.91%)	67 (58.77%)
Safety-Net	51 (3.85%)	157 (11.85%)	236 (17.81%)	245 (18.49%)	121 (9.13%)	515 (38.87%)
Non-Safety-Net	71 (2.28%)	392 (12.58%)	820 (26.32%)	828 (26.57%)	444 (14.25%)	561 (18.00%)

N/A	0 (0%)	6 (4.14%)	22 (15.17%)	28 (19.31%)	19 (13.10%)	70 (48.28%)
Non-DSH	5 (1.02%)	23 (4.70%)	85 (17.38%)	133 (27.20%)	94 (19.22%)	149 (30.47%)
DSH	104 (3.79%)	485 (17.67%)	891 (32.47%)	785 (28.61%)	304 (11.08%)	175 (6.38%)
Quintile 1	12 (2.19%)	70 (12.77%)	136 (24.82%)	203 (37.04%)	93 (16.97%)	34 (6.20%)
Quintile 2	10 (1.82%)	76 (13.82%)	182 (33.09%)	181 (32.91%)	75 (13.64%)	26 (4.73%)
Quintile 3	15 (2.74%)	95 (17.34%)	209 (38.14%)	150 (27.37%)	55 (10.04%)	24 (4.38%)
Quintile 4	12 (2.18%)	113 (20.55%)	203 (36.91%)	141 (25.64%)	43 (7.82%)	38 (6.91%)
Quintile 5	55 (10.04%)	131 (23.91%)	161 (29.38%)	110 (20.07%)	38 (6.93%)	53 (9.67%)
N/A	13 (0.96%)	47 (3.47%)	102 (7.54%)	183 (13.53%)	186 (13.75%)	822 (60.75%)
CAH	11 (0.83%)	46 (3.48%)	102 (7.72%)	183 (13.84%)	186 (14.07%)	794 (60.06%)
Non-CAH	111 (3.40%)	509 (15.59%)	976 (29.90%)	918 (28.13%)	398 (12.19%)	352 (10.78%)
1-99 beds	12 (1.01%)	80 (6.72%)	270 (22.67%)	335 (28.13%)	211 (17.72%)	283 (23.76%)
100-199 beds	26 (2.86%)	159 (17.47%)	327 (35.93%)	279 (30.66%)	84 (9.23%)	35 (3.85%)
200-299 beds	31 (6.51%)	109 (22.90%)	153 (32.14%)	126 (26.47%)	51 (10.71%)	6 (1.26%)
300-399 beds	21 (7.29%)	75 (26.04%)	91 (31.60%)	84 (29.17%)	17 (5.90%)	0 (0%)
400 or more beds	19 (5.16%)	85 (23.10%)	135 (36.68%)	94 (25.54%)	35 (9.51%)	0 (0%)
N/A	13 (0.96%)	47 (3.47%)	102 (7.54%)	183 (13.53%)	186 (13.75%)	822 (60.75%)
Large Urban	68 (5.24%)	227 (17.49%)	384 (29.58%)	332 (25.58%)	152 (11.71%)	135 (10.40%)
Other Urban	27 (2.32%)	188 (16.14%)	372 (31.93%)	335 (28.76%)	137 (11.76%)	106 (9.10%)

Rural	14 (1.82%)	93 (12.08%)	220 (28.57%)	251 (32.60%)	109 (14.16%)	83 (10.78%)
N/A	13 (0.96%)	47 (3.47%)	102 (7.54%)	183 (13.53%)	186 (13.75%)	822 (60.75%)

TABLE 75: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	145 (3.16%)	567 (12.36%)	1087 (23.70%)	1093 (23.83%)	548 (11.95%)	1146 (24.99%)
Specialty	0 (0%)	1 (0.83%)	5 (4.13%)	12 (9.92%)	18 (14.88%)	85 (70.25%)
Non-Specialty	145 (3.33%)	560 (12.87%)	1069 (24.57%)	1067 (24.52%)	516 (11.86%)	994 (22.85%)
N/A	0 (0%)	6 (5.26%)	13 (11.40%)	14 (12.28%)	14 (12.28%)	67 (58.77%)
Major Teaching	17 (7.05%)	45 (18.67%)	77 (31.95%)	64 (26.56%)	37 (15.35%)	1 (0.41%)
Minor Teaching	72 (5.02%)	236 (16.45%)	405 (28.22%)	401 (27.94%)	208 (14.49%)	113 (7.87%)
Non-Teaching	56 (2.00%)	280 (10.01%)	592 (21.17%)	614 (21.96%)	289 (10.34%)	965 (34.51%)
N/A	0 (0%)	6 (5.26%)	13 (11.40%)	14 (12.28%)	14 (12.28%)	67 (58.77%)
Safety-Net	57 (4.30%)	161 (12.15%)	268 (20.23%)	243 (18.34%)	81 (6.11%)	515 (38.87%)
Non-Safety-Net	88 (2.82%)	397 (12.74%)	796 (25.55%)	825 (26.48%)	449 (14.41%)	561 (18.00%)
N/A	0 (0%)	9 (6.21%)	23 (15.86%)	25 (17.24%)	18 (12.41%)	70 (48.28%)
Non-DSH	5 (1.02%)	29 (5.93%)	91 (18.61%)	115 (23.52%)	100 (20.45%)	149 (30.47%)
DSH	124 (4.52%)	468 (17.06%)	829 (30.21%)	774 (28.21%)	374 (13.63%)	175 (6.38%)
Quintile 1	15 (2.74%)	69 (12.59%)	127 (23.18%)	190 (34.67%)	113 (20.62%)	34 (6.20%)
Quintile 2	12 (2.18%)	75 (13.64%)	161 (29.27%)	181 (32.91%)	95 (17.27%)	26 (4.73%)

Hospital Characteristic	1	2	3	4	5	N/A
Quintile 3	19 (3.47%)	87 (15.88%)	195 (35.58%)	147 (26.82%)	76 (13.87%)	24 (4.38%)
Quintile 4	16 (2.91%)	108 (19.64%)	188 (34.18%)	148 (26.91%)	52 (9.45%)	38 (6.91%)
Quintile 5	62 (11.31%)	129 (23.54%)	158 (28.83%)	108 (19.71%)	38 (6.93%)	53 (9.67%)
N/A	16 (1.18%)	70 (5.17%)	167 (12.34%)	204 (5.08%)	74 (5.47%)	822 (60.75%)
CAH	14 (1.06%)	69 (5.22%)	167 (12.63%)	204 (15.43%)	74 (5.60%)	794 (60.06%)
Non-CAH	131 (4.01%)	498 (15.26%)	920 (28.19%)	889 (27.24%)	474 (14.52%)	352 (10.78%)
1-99 beds	17 (1.43%)	99 (8.31%)	285 (23.93%)	312 (26.20%)	195 (16.37%)	283 (23.76%)
100-199 beds	31 (3.41%)	153 (16.81%)	292 (32.09%)	272 (29.89%)	127 (13.96%)	35 (3.85%)
200-299 beds	35 (7.35%)	102 (21.43%)	141 (29.62%)	119 (25.00%)	73 (15.34%)	6 (1.26%)
300-399 beds	23 (7.99%)	69 (23.96%)	80 (27.78%)	84 (29.17%)	32 (11.11%)	0 (0%)
400 or more beds	23 (6.25%)	74 (20.11%)	122 (33.15%)	102 (27.72%)	47 (12.77%)	0 (0%)
N/A	16 (1.18%)	70 (5.17%)	167 (12.34%)	204 (15.08%)	74 (5.47%)	822 (60.75%)
Large Urban	78 (6.01%)	213 (16.41%)	364 (28.04%)	313 (24.11%)	195 (15.02%)	135 (10.40%)
Other Urban	32 (2.75%)	181 (15.54%)	332 (28.50%)	344 (29.53%)	170 (14.59%)	106 (9.10%)
Rural	19 (2.47%)	103 (13.38%)	224 (29.09%)	232 (30.13%)	109 (14.16%)	83 (10.78%)
N/A	16 (1.18%)	70 (.17%)	167 (12.34%)	204 (15.08%)	74 (5.47%)	822 (60.75%)

a. Alternatives Considered

Overall Hospital Quality Star Rating

We considered a number of alternatives to our proposals discussed in section XVI. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years of the preamble of this proposed rule. As described more fully in section E. Current and Proposed Overall Star Rating Methodology, we considered alternatives to measure group weighting, calculation of measure group scores, stratifying the Readmission group based on proportion of dual-eligible patients, and peer grouping by number of measures.

We considered an alternative to equally weight the five measure groups instead of the proposal to weight the four outcome and patient experience measure groups at 22 percent (Morality, Safety of Care, Readmission, and Patient Experience) and the newly proposed Timely and Effective Care process group at 12 percent. Because past stakeholder comments have recommended that outcome groups receive the most weight, we are recommending our proposal but are seeking comment on the alternative presented.

We considered keeping the Latent Variable Model (LVM) as an alternative to the proposed simple average of measure group scores since it is a data driven model where the measure loadings, or measure contribution to the measure group score, are empirically derived and is able to account for sampling variation and missing data. Because past stakeholder comments have indicated that the use of LVM is difficult to understand and the weights of measures and their subsequent impact on the group score changes depending on the underlying data, we proposed to use a simple average of measure group scores but are seeking comment on the alternative presented.

We also considered not stratifying the Readmission measure group based on dual-eligibility peer groups and retaining the current approach, without stratification. This consideration was based on the premise that, although select stakeholders have requested social risk factor adjustment of the

Readmission measure group in alignment with HRRP,[313] other stakeholder groups expressed concern that social risk factor adjustment would be confusing to patients and consumers, resulting in misrepresentation of quality of care at hospitals providing acute inpatient and outpatient care, specifically for dual-eligible patients, while others were concerned that the dual-eligibility variable would not adequately account for social risk in the Overall Star Rating. [314] [315] [316] Furthermore, this consideration was in response to a HHS report titled ***"Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs,"*** submitted to Congress by ASPE, that sets forth new recommendations regarding social risk factors, wherein ASPE does not recommend adjusting quality measure for social risk in public reporting. [317] Due to these considerations, CMS is seeking comment on the alternative to not stratify the Readmission measure group by proportion of dual-eligible patients.

Within the proposal to stratify the Readmission measure group scores based on dual-eligibility peer groups, we also considered recalculating the peer group quintiles based on all hospitals in the Overall Star Rating, and not solely based on those participating in HRRP. However, calculating quintiles based on all hospitals would create potential misalignment between HRRP quintiles and Overall Star Rating quintiles, and therefore peer group assignment. Because of this potential misalignment, we propose to recalculate peer group quintiles based on those in the HRRP but we are seeking public

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[313] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815

[314] Ibid.

[315] Centers for Medicare & Medicaid Services. (2019, October 24) Patient and Patient Advocate Work Group Minutes-October 2019.

[316] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx

[317] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf. Accessed July 2, 2020.

comment on our proposal and alternative to recalculate the quintiles based on all hospitals included in the Overall Star Rating.

Finally, we considered not peer grouping by number of measures. Because past stakeholder feedback suggested that CMS consider some type of peer grouping to enable more similar comparisons among hospital types, we proposed to peer group by number of measure groups to achieve this aim. This would enable more similar comparisons among hospitals where smaller hospitals that submit the fewest number of measures are more likely to be in the three measure group peer group and larger hospitals that submit the most measures are more likely to be in the five measure group peer group. We also stated that if we do not finalize our proposal to include CAHs in the Overall Star Ratings, we would not be able to peer group since CAHs make up the majority of the three measure group peer group. Ultimately, we decided to propose peer grouping but are seeking public comment on our proposal as well as the alterative considered to not peer group. We are seeking comment on our alternative considered to not peer group even if we finalize our proposal to include CAHs.

9. Effects of Requirements for the Physician-Owned Hospitals

The physician-owned hospital provisions are discussed in section XIX. of this proposed rule. We propose regulatory updates to the process under which a physician-owned hospital that qualifies as a high Medicaid facility can request an exception to the prohibition on facility expansion. Specifically, we would permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. We would also remove the restriction that permitted expansion of facility capacity may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds and the restriction that permitted expanded facility capacity must occur only in facilities on the hospital’s main campus. We expect these proposals

would reduce burden on high Medicaid facilities and give them additional flexibility to expand. Finally, we propose to codify in regulations the policy in an existing frequently asked question that explains CMS' deference to State law for purposes of determining the number of beds for which a hospital is licensed. This proposal reflects current policy, so we do not anticipate that it would have an impact.

D. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review a rule, we assumed that the number of commenters on this CY 2020 OPPS/ASC proposed rule (3,400) will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing proposed rule. It is possible that not all commenters will review proposed rule in detail, and it is also possible that some reviewers will choose not to comment on proposed rule. Nonetheless, we believed that the number of commenters on the CY 2020 OPPS/ASC proposed rule would be a fair estimate of the number of reviewers of proposed rule. We welcome any comments on the approach in estimating the number of entities that will review the proposed rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule and the final rule with comment period, and, therefore, for the purposes of our estimate, we assumed that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the 2019 BLS for medical and health service managers (Code 11-9111), we estimated that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of proposed rule. For each facility that reviewed proposed rule, the estimated cost is $885.92 (8 hours x $110.74). Therefore, we

estimated that the total cost of reviewing proposed rule is $3,413,450 ($885.92 x 3,853 reviewers on the CY 2020 proposed rule).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's "Table of Size Standards" at http://www.sba.gov/content/table-small-business-size-standards. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. As a result, the Secretary has determined that this proposed rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule will increase payments to small rural hospitals by approximately 3 percent; therefore, it should not have a significant impact on approximately 586 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or

payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $156 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. It has been determined that this proposed rule, will be a regulatory action for the purposes of Executive Order 13771. We estimate that this proposed rule will generate $2.5 million in annualized cost at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

H. Conclusion

The changes we are making in this proposed rule will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2021. Table 67 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 2.5 percent increase in payments for all services paid under the OPPS in CY 2021, after considering all of the changes to APC reconfiguration and

recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, the finalized off-campus provider-based department clinic visits payment policy, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS will experience more significant gains or losses in OPPS payments in CY 2021.

The updates we propose to the ASC payment system for CY 2020 would affect each of the approximately 5,600 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 68 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted hospital market basket update factor of 2.6 percent for CY 2020.

XXV. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 67 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 2.2 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that

it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

2. Section 410.27 is amended by revising paragraph (a)(1)(iv)(D) and removing paragraph (a)(1)(iv)(E).

The revision reads as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(D) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively and may be provided by the physician remotely using audio/video real-time communications technology.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

3. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

4. Section 411.362 is amended—

a. In paragraph (a), by revising the definition of "Baseline number of operating rooms, procedure rooms, and beds";

b. By revising paragraphs (c)(1) and (c)(6) introductory text.

The revisions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State.

* * * * *

(c) * * *

(1) *General*. An applicable hospital may request an exception from the prohibition on facility expansion up to once every 2 years from the date of a CMS decision on the hospital's most recent request. A high Medicaid facility may request an exception from the prohibition on facility expansion at

any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion for which CMS has not issued a decision.

* * *

(6) *Permitted increase in facility capacity*. With respect to an applicable hospital only, a permitted increase under this section—

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

5. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

6. Section 412.190 is added to subpart I to read as follows:

§ 412.190 Overall Hospital Quality Star Rating.

(a) *Purpose.* (1) The Overall Hospital Quality Star Rating (Overall Star Rating) is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals.

(2) The guiding principles of the Overall Star Rating are as follows. In developing and maintaining the Overall Star Ratings, we strive to:

(i) Use scientifically valid methods that are inclusive of hospitals and measure information and able to accommodate underlying measure changes;

(ii) Align with *Hospital Compare* or its successor website and CMS programs;

(iii) Provide transparency of the methods for calculating the Overall Star Rating; and

(iv) be responsive to stakeholder input.

(b) *Data included in Overall Star Rating*—(1) *Source of data.* The Overall Star Rating is calculated based on measure data collected and publicly reported on *Hospital Compare* or its successor site under the following CMS hospital inpatient and outpatient programs:

(i) Hospital Inpatient Quality Reporting (IQR) Program - section 1886(b)(3)(B)(viii)(VII) of the Act.

(ii) Hospital-Acquired Condition Reduction Program - section 1886(p)(6)(A) of the Act.

(iii) Hospital Value-based Purchasing Program - section 1886(o)(10)(A) of the Act.

(iv) Hospital Readmissions Reduction Program - section 1886(q)(6)(A) of the Act.

(v) Hospital Outpatient Quality Reporting (OQR) Program - section 1833(t)(17)(e) of the Act.

(2) *Hospitals included in Overall Star Rating.* Subsection (d) hospitals subject to the CMS quality programs specified in paragraph (b)(1) of this section that also have their data publicly reported on one of CMS' websites are included in the Overall Star Rating.

(3) *Critical Access Hospitals.* Critical Access Hospitals (CAHs) that wish to be voluntarily included in the Overall Star Rating must have elected to --

(i) Voluntarily submit quality measures included in and as specified under CMS hospital programs; and

(ii) Publicly report their quality measure data on *Hospital Compare* or its successor site.

(c) *Frequency of publication and data used*. The Overall Star Rating are published once annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year.

(d) *Methodology*—(1) *Selection of measures*. Measures are selected from those publicly reported on *Hospital Compare* or its successor website through certain CMS quality programs under paragraph (b)(1) of this section.

(i) From this group of measures, measures falling into one or more of the below listed exclusions will be removed from consideration:

(A) Measures that 100 hospitals or less publicly report. These measures would not produce reliable measure group scores based on too few hospitals.

(B) Measures that cannot be standardized (as defined in section E.2.d. Measure Score Standardization) and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data.

(C) Non-directional measures for which it is unclear whether a high or lower score is better. These measures cannot be standardized to be combined with other measures and form an aggregate measure group score.

(D) Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs; or

(E) Measures that overlap with another measure in terms of cohort or outcome, including component measures that are part of an already-included composite measure.

(ii) [Reserved]

(2) *Measure Score Standardization*. All measure scores are standardized by calculating Z-scores so that all measures are on a single, common scale to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. This is calculated by subtracting the national mean measure score from each hospital's measure score and dividing the difference by the measure standard deviation in order to standardize measures.

(3) *Grouping measures*. Measures are grouped into one of the five clinical groups as follows:

(i) Mortality.

(ii) Safety of Care.

(iii) Readmission.

(iv) Patient Experience.

(v) Timely and Effective Care.

(4) *Calculate measure group scores*. A score is calculated for each measure group for which a hospital has measure data using a simple average of measure scores, as follows:

(i) Each measure group score is standardized by calculating Z-scores for each measure group so that all measure group scores are centered near zero with a standard deviation of one.

(ii) We then take 100 percent divided by the number of measures reported in a measure group to determine the percentage of each measure's weight;

(iii) The measure weight is then multiplied by the standardized measure score to calculate the measure's weighted score;

(iv) Then, all of the individual measure weighted scores within a measure group are added together to calculate the standardized measure group score.

(v) Applicable to the Readmission group only, CMS will stratify hospitals into peer groups based on the proportion of dual-eligible patients at each hospital, using peer groups annually designated by the Hospital Readmissions Reduction Program (HRRP), to calculate the hospitals' Readmission measure group score. Hospitals that do not participate in HRRP would be assigned to one of the peer groups based on their proportion of dual-eligible patients, as they would not have already been assigned to a peer group through the HRRP. If the proportion of dual-eligible patients at each hospital is missing or unavailable, CMS will not assign the hospital to a peer group or adjust their measure group score.

(5) *Reporting thresholds*. In order to receive an Overall Star Rating, a hospital must report at least three measures within at least three measure groups, one of which must specifically be the Mortality or Safety of Care outcome group.

(6) *Hospital Summary Score*. A summary score is calculated by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores.

(i) *Standard Measure Group Weighting*. (A) Each of the Mortality, Safety of Care, Readmission, and Patient Experience groups are weighted 22 percent; and

(B) The Timely and Effective Care group is weighted 12 percent.

(ii) *Reweighting*. (A) Hospitals may have too few cases to report particular measures and, in those cases, may not report enough measures in one or more measure groups.

(B) When a hospital does not have enough measures in one or more measure groups due to too few cases CMS may re-distribute one or more of the missing measure group's weight proportionally across the remaining measure groups by subtracting the standard weight percentage of the group or groups with insufficient measures from 100 percent; and then dividing the resulting percentage across the remaining measure groups, giving new re-proportioned weights.

(7) *Peer grouping*. Hospitals are assigned to one of three peer groups based on the number of measure groups for which they report at least three measures: three, four, or five measure groups.

(8) *Star ratings assignment*. Hospitals in each peer group are then assigned between one and five stars where one star is the lowest and five stars is the highest using k-means clustering to complete convergence.

(e) *Preview period prior to publication.* CMS provides hospitals the opportunity to preview their Overall Star Rating prior to publication. Hospitals have at least 30 days to preview their results, and if necessary, can reach out to CMS with questions.

(f) *Suppression of Overall Star Rating*—(1) *Subsection (d) hospitals*. CMS may consider suppressing Overall Star Rating for subsection (d) hospitals only under extenuating circumstances that

affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS, or when CMS is at fault, including but not limited to when:

(i) There is an Overall Star Rating calculation error by CMS;

(ii) There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation; or

(iii) If a Public Health Emergency substantially affects the underlying measure data.

(2) *CAHs*. (i) CAHs may request to withhold their Overall Star Rating from publication on *Hospital Compare* or its successor website so long as the request for withholding is made, at the latest, during the Overall Star Rating preview period.

(ii) CAHs may request to have their Overall Star Rating withheld from publication on *Hospital Compare* or its successor website, as well as their data from the public input file, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh data used to calculate the Overall Star Ratings.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

7. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

8. Section 414.510 is amended by revising paragraph (b)(5) introductory text to read as follows:

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

* * * * *

(b) * * *

(5) In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in §414.502, or a test that is a cancer-related protein-based Multianalyte

Assays with Algorithmic Analyses, the date of service of the test must be the date the test was performed only if—

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

9. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

10. Section 416.166 is amended by revising paragraph (c)(6) to read as follows:

§ 416.166 Covered surgical procedures.

* * * * *

(c) * * *

(6) Are designated as requiring inpatient care under § 419.22(n) of this chapter as of December 31, 2020;

* * * * *

11. Section 416.310 is amended –

a. In paragraphs (a)(2) and (b), by removing the phrase "data collection time period" and adding in its place "data collection period";

b. By revising paragraph (c)(1)(i);

c. In paragraph (c)(1)(ii), by removing the phrase "data collection time period" and adding in its place "data collection period" and removing the phrase "time period" and adding in its place "period";

d. By adding paragraph (c)(1)(iii);

e. In paragraph (c)(2), by removing the phrase "data collection time period" and adding in its place "data collection period"; and

f. By adding paragraph (f).

The revision and additions read as follows:

§ 416.310 Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(i) *QualityNet account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain a QualityNet account in order to submit quality measure data to the QualityNet Web site for all web-based measures submitted via a CMS online data submission tool. A QualityNet security official is necessary to set up such an account for the purpose of submitting this information.

* * * * *

(iii) *Review and corrections period.* For measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed.

* * * * *

(f) *Data submission deadlines.* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

12. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

13. Section 419.22 is amended by revising paragraph (n) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(n) Services and procedures that the Secretary designates as requiring inpatient care. Effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024.

* * * * *

14. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*11*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*11)* For calendar year 2020 and subsequent years, a multifactor productivity adjustment (as determined by CMS).

* * * * *

15. Section 419.45 is amended by revising paragraphs (b)(1) and (2) to read as follows:

§ 419.45 Payment and copayment reduction for devices replaced without cost or when full or

partial credit is received.

* * * * *

(b) * * *

(1) The amount of the reduction to the APC payment made under paragraphs (a)(1) and (2) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(2) of this section.

(2) The amount of the reduction to the APC payment made under paragraph (a)(3) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(3) of this section.

* * * * *

16. Section 419.46 is amended --

a. By redesignating paragraphs (a) through (h) as paragraphs (b) through (i), respectively;

b. By adding a new paragraph (a);

c. By revising newly redesignated paragraphs (b)(2), (c), and (d)(1) and (2);

d. In newly redesignated paragraphs (d)(3)(ii) and (iii), by removing the cross-reference to "paragraph (c)(2)" and adding in its place "paragraph (d)(2)";

e. By adding paragraphs (d)(4) and (f)(4);

f. By revising newly redesignated paragraph (g)(1);

g. In newly redesignated paragraph (g)(2)(viii), by removing the cross-reference to "paragraph (e)(1)" and adding in its place "paragraph (f)(1)";

h. In newly redesignated paragraph (i)(1), by removing the cross-reference "paragraphs (h)(2)

and (3)" and adding in its place "paragraphs (i)(2) and (3)";

i. In newly redesignated paragraph (i)(3), by removing the cross-reference "paragraph (h)(2)" and adding in its place "paragraph (i)(2)"; and

j. In newly redesignated paragraph (i)(3)(ii) introductory text, by removing the cross-reference "paragraph (h)(3)(i)(A)" and adding in its place "paragraph (i)(3)(i)(A)".

The additions and revisions read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Statutory authority*. Section 1833(t)(17) of the Act authorizes the Secretary to implement a quality reporting program in a manner so as to provide for a 2.0 percentage point reduction in the OPD fee schedule increase factor for a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit data required to be submitted on measures in accordance with the Secretary's requirements.

(b) * * *

(2) Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section; and

* * * * *

(c) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet website. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.46(i), and is required to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the Hospital OQR Program.

(d) * * *

(1) *General rule.* Except as provided in paragraph (e) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(t)(17)(C) of the Act in a form and manner, and at a time, specified by CMS. Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the QualityNet website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

* * * * *

(4) *Review and corrections period*. For both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed.

* * * * *

(f) * * *

(4) Hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored,

the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) * * *

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet Website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in § 419.46(d)(2), of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

17. Section 419.66 is amended by revising paragraph (c)(2)(i) and (ii) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(c) * * *

(2) * * *

(i) The device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or

(ii) For devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to paragraph (c)(2)(i) of this section, a new medical device is part of the Food and Drug Administration's (FDA's) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

* * * * *

18. Section 419.83 is amended by revising paragraph (a) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* (1) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020:

(i) Blepharoplasty.

(ii) Botulinum toxin injections.

(iii) Panniculectomy.

(iv) Rhinoplasty.

(v) Vein ablation.

(2) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021:

(i) Cervical Fusion with Disc Removal.

(ii) Implanted Spinal Neurostimulators.

(3) Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.

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Dated: July 23, 2020.

Seema Verma,

Administrator,

Centers for Medicare and Medicaid

Services.

Dated: July 31, 2020.

Alex M Azar II,

Secretary,

Department of Health and Human Services.

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