

Outpatient Prospective Payment System Proposed Rule 2020 **Summary**

Proposed Procedures and the Inpatient Only (IPO) List

The CY 2012 OPPTS/ASC Final Rule lists five criteria that are part of the methodology used to determine which procedures may be removed from the IPO list and assigned to an ambulatory payment classification (APC) group. The criteria are 1. Most outpatient departments are equipped to provide the services to the Medicare population; 2. The simplest procedure described by the code may be performed in most outpatient departments; 3. The procedure is related to codes that CMS has already removed from the IPO list; 4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis; 5. A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by CMS for addition to the ASC list.

Changes to the Inpatient Only List

One procedure is being proposed for removal from the IPO list, **CPT code 27130** (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft). CMS is proposing to remove THA from the IPO and assign it to C-APC 5115 with status indicator J1. CMS is seeking public comment on their conclusion that the THA procedure meets criteria 2 and 3 for removal and their suggestion to list it as C-APC 5115.

Updates to the Ambulatory Surgical Center (ASC) Payment System

Under the ASC payment system, a surgical procedure is defined as any procedure included within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as “surgery” (CPT codes 10000 through 69999) and 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 CMS has 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 by OPPTS.

ASC Treatment of New and Revised Codes

Payment for ASC procedures, services and items are based on HCPCS billing codes. HCPCS is divided into Level I (includes Categories I, II, and III CPT codes) and Level II (a CMS maintained, standardized coding system used to identify products, supplies, and services not included in CPT codes). New and revised codes have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. Comments will be sought on the April and July 2019 HCPCS ASC quarterly update in the CY 2020 proposed rule and finalized in the CY 2020 final rule with comment period. For HCPCS updates published in October 2019, comments will be sought for the CY 2020 final rule with comment period and finalized in the CY 2021 OPPTS/ASC final rule with comment period. CPT codes published in January 2020 will be available for comments in the CY 2020 OPPTS proposed rule and finalized in the CY 2020 OPPTS/ASC final rule with comment period. However, for Level II HCPCS codes published in January 2020, the comments will be accepted for the CY 2020 final rule with comment period and finalized in the CY 2021 OPPTS/ASC final rule.

Update to the List of ASC Covered Surgical Procedures

CMS annually reviews and updates the ASC CPL to include all covered surgical procedures eligible for payment in ASCs. Upon annual review of volume and utilization data, covered surgical procedures are identified as temporarily office-based (new procedure codes with limited or no utilization data that CMS has determined are clinically similar to other procedures which are permanently office-based), permanently office-based, or non-office based. Beginning in CY 2020, CMS proposed to apply the device-intensive procedure payment methodology under the ASC payment system only when the device-intensive procedure is furnished with a surgically implanted or inserted device. For those device-intensive procedures furnished without an implantable or inserted medical device, the payment rate would be calculated by applying the uniform ASC conversion factor to both the device portion and service portion of the OPPS relative payment weight for the device-intensive procedure and summing both portions to establish the ASC payment rate.

CMS is proposing to add TKA (CPT codes 27447, 29867) to the ASC CPL for CY 2020.

They are seeking public comment on the best approach to provide safeguards for Medicare beneficiaries who should not be eligible to receive TKA procedures in the ASC setting. CMS is also seeking comments on how these proposed additions of ASC covered surgical procedures will impact rural hospitals.

Short Inpatient Hospital Stays

The 2-midnight rule states that an inpatient admission is payable under Medicare 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 that the patient nonetheless requires care on an inpatient basis. Procedures removed from the IPO list are subject to the 2-midnight rule and initial medical reviews by BFCC-QIOs, along with subsequent referrals to RACs. **To ameliorate confusion surrounding the initial removal of THA from the IPO list, CMS is proposing to establish a 1-year exemption from RAC referrals for noncompliance with the 2-midnight rule. Additionally, THA would not be considered for persistent provider noncompliance with the 2-midnight rule by BFCC-QIOs in this 1-year period.** However, BFCC-QIOs would be allowed to review claims for provider education. Comments on the time period for the proposed exemption will be solicited by CMS.

Ambulatory Surgical Center Quality Reporting Program

The ASCQR program measures are designed to assess the quality of ASC services and make that information public to consumers. CMS is proposing the addition of one new quality measure for the CY 2024 payment determination and subsequent years. ASC-19: Facility-Level Seven-Day Hospital Visits after General Surgery Procedures Performed at ASCs (NQF #3357). The NQF developed this measure in conjunction with two others that have been adopted for the ASCQR program beginning in CY 2022. Together, measures ASC-17: Hospital Visits After Orthopaedic ASC Procedures, ASC-18: Hospital Visits After Urology ASC Procedures, and ASC-19 will assess patient outcomes for care in ASCs using a standardized risk-adjustment methodology. ASC-19 is a risk-standardized ratio that aligns with the Admissions and Readmissions to Hospitals and Preventable Healthcare Harm Meaningful Measure areas of CMS' Meaningful Measures Initiative.

Administrative Requirements

Continued submission of data through QualityNet. No updates to participation status requirements.

Form, Manner, and Timing of Data Submitted for the ASCQR Program

No proposed changes. Requesting comments on updating submission method for ASC-1, ASC-2, ASC-3, and ASC-4.

Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

No updates to policy.

Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

The CY 2018 OPPTS/ASC final rule stated that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals as well as in provider-based departments of hospitals. This rule also reinstated the enforcement instruction providing for the nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services in CAHs and small rural hospitals (less than 100 beds) through the end of CY 2019. CMS is proposing to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs. General supervision is defined by 42 CFR 410.32(b)(3)(i) as a procedure furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. However, the HOP Panel will continue to provide advice on the appropriate supervision levels for hospital outpatient services. CMS will continue to consider changes to the supervision levels of individual hospital outpatient therapeutic services to a level that is more intense through the notice and comment rulemaking process.

OPPS Payment for Devices

Currently, only one category of devices is eligible for transitional pass-through payments (HCPCS code C1822).

New Device Pass-Through Applications

A goal of this program is to "target pass-through payments for devices where cost considerations might be most likely to interfere with patient access." Similar to the proposal in the IPSS rule, an alternative pathway is proposed to the existing pass-through payment program where CMS would grant fast-track device pass-through payment for devices approved under the FDA Breakthrough Device Program for OPPTS device pass-through payment applications received on or after January 1, 2020. Eligibility requirements are outlined in 42 CFR 419.66(b)(1) through (3). Briefly, the device must have received FDA approval or clearance or have met exemption requirements (deemed safe and effective); pass-through payment application must be received within 3 years of the FDA approval or clearance; the device must be deemed reasonable and necessary; and the device is an integral part of the service furnished, used for one patient only, comes in contact with human tissue and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. CMS details the additional requirements related to the cost of the device the Agency uses to determine whether a new category of pass-through payment devices should be established. Finally, the device must demonstrate 'substantial clinical improvement', defined as substantial improvement in the diagnosis or treatment of an illness or injury or

improvement of the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other approved treatment.

Applications are accepted quarterly, with March 1 the cut off for consideration in the development of CY 2020 OPSS. Seven applications were received, none of which received approval during the quarterly review process. Of the seven, two devices are indicated for orthopaedic use. TracPath is a monitoring device to assess recovery following total knee replacement. The submitter claims the product is exempt from FDA regulation and therefore, the product fails to meet one of the criteria for eligibility. AUGMENT is a bone graft product indicated for use as an alternative to autograft in arthrodesis of the ankle and/or hindfoot where the need for supplemental graft material is required. CMS is accepting comments on these submissions, as well as feedback to provide greater understanding of CMS' approach to evaluating substantial clinical improvement. This solicitation was also included in the IPSS proposed rules.

Alternative Pathway to the OPSS Device Pass-Through Substantial Clinical Improvement Criterion for Transformative New Devices

CMS acknowledges the rationale employed by device manufacturers that devices that receive marketing authorization and are part of an FDA expedited program be deemed as representing a substantial clinical improvement for purposes of OPSS device pass-through status. They cite the administrative efficiencies that such an approach would provide and its alignment with concepts in the President's budget related to increased transparency and consistency in Medicare's coverage and payment policies for innovative technology. Therefore, the rule proposes language changes such that OPSS device pass-through payment applicants approved under the FDA Breakthrough Devices Program **would not be evaluated** in terms of the current substantial clinical improvement criterion for the purposes of determining device pass-through payment status but would continue to need to meet the other requirements for pass-through payment status in the regulation. Devices approved under the Breakthrough Devices Program that are approved for OPSS device transitional pass-through payment can be approved through the quarterly process and would be announced through that process. Finally, the rule includes proposals regarding these devices and whether pass-through payment status should continue to apply in the next applicable OPSS rulemaking cycle.

Proposed Device-Intensive Procedures

No changes proposed for CY 2020.

Device-Edit Policy

No changes proposed for CY 2020.

Adjustment to OPSS Payment for No Cost/Full Credit and Partial Credit Devices

No changes proposed for CY 2020.

Proposed Payment Policy for Low-Volume Device-Intensive Procedures

For CY 2020, proposed continuance of current policy which establishes 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. Applies to CPT code 0308T, proposing assignment to APC 5495 in CY 2020 – intraocular procedures. No orthopaedic procedures impacted in this draft.

OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

Defines “biological product” or “biologic” as outlined under section 351 of the PHS Act but does not limit the term to only those products. Stem cells and many of the other biologics currently in the spotlight for their use in orthopaedics are defined under section 361 of the PHS Act and may be considered by CMS given their parenthetical comment about not limiting the definition.

Given that many orthopaedic biologics are currently exempt from FDA regulation and given Medicare’s somewhat broad definition of biologic, it is possible that these therapies may be covered. There is an opening here to encourage Medicare to narrow their definition to limit biologics to those products regulated by FDA or as outlined under 351.

Three-Year Transitional Pass-Through Payment Period for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

No change for CY 2020.

Proposed Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2019

No orthopaedic-specific products or surgical products listed.

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2020

Proposing to continue pass-through payment status in CY 2020 for 61 drugs and biologicals. Includes hyaluronan or derivative for intra-articular injection.

Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141)

For CY 2020, proposing to continue pass-through payment status for the drugs and biologicals through September 30, 2020. PuraPly Antimicrobial wound dressing included.

Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

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 2020 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2020 is approximately \$268.8 million (approximately \$10.6 million for device categories and approximately \$258.2 million for drugs and biologicals) which represents 0.34 percent of total projected OPPS payments for CY 2020 (approximately \$80 billion). Therefore, CMS estimates that pass-through spending in CY 2020 would not amount to 2.0 percent of total projected OPPS CY 2020 program spending.

Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

In an effort to move toward site-neutral payments as a way to control for increases in spending, the CY 2019 OPPS/ASC final rule removed the payment differential for outpatient department services. CMS applied an amount equal to the site-specific Medicare Physician Fee Schedule payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when

provided at an off-campus PBD excepted from departments that bill the modifier “PO” on claim lines. The payment reduction is to be phased in over 2 years, with a PFS-equivalent rate reduction of 60 percent implemented incrementally as a 30 percent reduction in 2019 and a 60 percent reduction in 2020.

MedPAC Recommendations

OPPS Payment Rates Update

MedPAC’s March 2019 report to congress suggested a 2 percent increase in the OPPS payment rate. The difference between this and the update amount specified in current law would be used to increase payments in the newly suggested Medicare Hospital Value Incentive Program (HVIP). This update cannot be made until Congress changes current law to enable CMS to implement the recommendation.

ASC Conversion Factor Update

MedPAC recommended that there should be no payment update for ASCs. The 0 percent update factor is based on analysis of payment adequacy, increased number of Medicare-certified ASCs, increased beneficiary use of ASCs, and adequate ASC access to capital. However, in the CY 2019 OPPS/ASC final rule, a policy to apply the hospital market basket update to ASC payment system rates for an interim period of 5 years was codified. As such, CMS is proposing to apply a 2.7 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor.

ASC Cost Data

MedPAC suggested that Congress require ASCs to report cost data so that they could analyze the growth of ASC cost trends and examine Medicare payments relative to the costs of efficient providers. CMS could use the ASC cost data to determine whether or not an ASC-specific market basket should be developed. CMS is interested in methods that would allow data collection for appropriate ASC cost determination while mitigating the administrative burden of reporting measures.

Requirements for Hospitals to Make Public a List of Their Standard Charges

The Public Health Service Act requires each hospital operating in the US to annually establish or update, and make public, a list of the hospital’s standard charges for items and services provided by the hospital inclusive of those in diagnosis-related groups. GAO research and historical examples from state-level models suggest that increased price transparency in provider charge information and hospital services will lower costs and increase market competition. **Per the President’s executive order on price transparency, CMS is proposing an expansion of hospital charge display requirements to include charges and information based on negotiated rates for common shoppable services and items in a consumer-friendly format.**

Definition of “Hospital” and Proposed Special Requirements That Would Apply to Certain Types of Hospitals

“An institution in any State in which State or applicable local law provides for the licensing of hospital, (1) is licensed as a hospital pursuant to such law or (2) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing.” However, the definition does not include ASCs. CMS is proposing to deem

federally-owned or operated hospitals that only treat the general public for emergent situations and whose rates are not subject to negotiation as exempt from the new requirements as long as their hospital charges are posted to patients in advance on the Federal Register or elsewhere.

Definition of “Items and Services” Provided by Hospitals

“All items and services, including individual items and services and service packages that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge.” CMS is proposing to include in this definition “the services furnished by physicians and non-physician practitioners who are employed by the hospital.”

Surprise Billing (direct quote): “We also considered including in our proposed definition of items and services the services provided by physicians and non-physician practitioners who are not employed by the hospitals, but who provide services at a hospital location. For example, a procedure performed in a hospital setting may involve anesthesiology services provided by a non-employed physician who has established his or her own charge for the service he or she is providing at a hospital location...Often, health care consumers are not expecting an additional charge or are otherwise surprised when they receive bills from entities other than the hospital or when charges for non-employed physicians and non-physician practitioners are higher than expected (for example, when a non-employed physician is out-of-network and the consumer’s third party payer declines payment for those services for that reason). We believe that the provision of such additional charge information would be exceptionally valuable to give consumers a more complete picture of the total amount they might be charged in connection with an inpatient admission or an outpatient department visit at a hospital location, potentially helping to address the widely recognized surprise billing issue. However, because physicians and non-physician practitioners who are not employed by the hospital are practicing independently, establish their own charges for services, and receive the payment for their services, we do not believe their charges for their services fall within the scope of section 2718(e) as they are not services “provided by the hospital.” We welcome comment on these proposals.”

Definitions for Types of “Standard Charges”

“The regular rate established by the hospital for the items and services provided to a specific group of paying patients.” CMS believes that standard charges can be further defined as either “gross” or “payer-specific.” A gross charge would be the charge for an individual item or service that is reflected on a hospital’s chargemaster, absent any discounts. The payer-specific definition would be the charge that the hospital has negotiated with a third-party payer for an item or service. A third-party payer would be a recognized entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service. CMS is seeking comments on the unintended consequences of releasing specific charge information and alternative methods for increasing out-of-pocket cost transparency.

Requirements for Public Disclosure of All Hospital Standard Charges for All Items and Services

CMS is proposing that hospitals will display their payer-specific negotiated charges for the primary shoppable service side-by-side with payer-specific negotiated charges for all ancillary items and services the hospital customarily provides as part of, or in conjunction with, the

primary service. The hospital would disclose standard charges for all items and services online in a single file that is machine-readable. For uniformity, each hospital would make public the description of each item or service, the corresponding gross charge (including for inpatient or outpatient setting), the corresponding payer-specific negotiated charge with the name of the third party payer, corresponding billing codes (CPT, HCPCS, DRG, NDC), and the revenue code. CMS is seeking comments on whether or not hospitals should be required to make standard charge data for all items and services available as an .XML file only, and on the use of application programming interface (API) standards that could be used to facilitate public access to real-time hospital charge information in an “openly published” API. CMS is proposing to ensure that a hospital would have discretion to choose the internet location it uses to post the standard charges as long as the data file is displayed on a publicly-accessible webpage, with prominent and clear identification of the hospital location for which the charges are associated, is easily accessible, without barriers, and that the data can be easily searched. The charges should be updated at least once per year, at any point during that 12-month period. The file with the charges listed should include the date on which the file was last updated. Each hospital operating under a single or consolidated State license will be required to make public a separate identifiable list of standard charges.

Requirements for Consumer-Friendly Display of the Payer-Specific Negotiated Charges for Selected Shoppable Services

CMS is proposing to define “shoppable services” as a service package that can be scheduled in advance and is typically provided in non-urgent situations that do not require immediate action or attention. The charges for shoppable services should be displayed as a grouping of related services and ancillary items the hospital typically provides along with, or in addition to, the primary shoppable service. Ancillary services would be defined as “an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service. These may include labs, radiology, drugs, operating room, therapy services, hospital fees, room and board charges, and charges for employed professional services. Outpatient procedures may include anesthesia, imaging, labs, and pre/post-op follow up. **CMS is proposing that at least 300 shoppable services be displayed in a consumer-friendly format, including at least 70 CMS-selected shoppable services. If a hospital does not provide all 70 of those, then the hospital may choose additional services until they reach 300. These CMS-selected procedures include major joint replacement, spinal fusion, and removal of one knee cartilage using an endoscope.** The corresponding data elements to be made public with these charges include a plain-language description of the service, payer-specific negotiated charges, a list of the associated ancillary items, the location at which each service is provided, and any primary code used by the hospital for billing. To ensure access for consumers who do not have access to the information online, hospitals may be required to provide a paper copy of the information within 72 hours of a consumer request. There would be the same accessibility and update requirements as with standard charge files. Compliance monitoring methods may include CMS evaluation of complaints made to CMS, and CMS review of individual or entity analysis of noncompliance. Hospitals that do not comply with public standard charge requirements may be subject to a Corrective Action Plan and a publicly-viewable Civil Monetary Penalty of a maximum total sum of \$300 per day.

Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

A CMS analysis revealed that the rate of OPD claims submitted to Medicare increased by 3.2 percent annually. From 2007-2017, the rate of Medicare spending outpaced the average increase in overall healthcare spending. A majority of the OPD services with higher than expected volume increases come from five categories of service (blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation). To limit the cost of these primarily cosmetic procedures, CMS is proposing to impose prior-authorization requirements as a condition of payment.

Prior Authorization Process for Certain OPD Services

Prior-authorization will be defined as “a process through which a request for provisional coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted” and provisional affirmation will be defined as “a preliminary finding that a future claim for the service will meet Medicare’s coverage, coding, and payment rules.” **CMS is proposing that claims submitted for prior-authorization that did not receive a provisional affirmation of coverage from CMS or its contractors would be denied along with the denial of any claims associated with the service, including anesthesiology and physician services.** For non-expedited requests, CMS would issue a decision within 10 business days. For expedited requests, CMS is proposing to issue a provisional affirmation or non-affirmation within 2 business days. A prior-authorization request that is non-affirmed is not an initial determination on a claim for payment for services provided and thus is not appealable. The provider will still be able to resubmit a prior-authorization request provided the claim has not yet been submitted and denied. **A claim denial is considered an initial determination and a redetermination request may be submitted. A contractor is not required to request medical documentation from the provider who billed the associated claims before making such a denial.** CMS is proposing that they may elect to exempt a provider from the prior-authorization process upon a provider’s demonstration of compliance with Medicare coverage, coding and payment rules, and that this exemption would remain in effect until CMS elects to withdraw the exemption. CMS proposes to exempt providers that achieve a prior-authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. The exemption may take 90 days to go into effect. If the rate of non-payable claims submitted increases above 10 percent during a biannual assessment, CMS may consider withdrawing the exemption.

List of Outpatient Department Services Requiring Prior Authorization

The services requiring prior-authorization are widely considered cosmetic and rarely covered by Medicare, with the exception of certain circumstances. The categories of proposed outpatient services that would require prior-authorization are blepharoplasty, eyelid surgery, brow lift, and related services; botulinum toxin injection; panniculectomy, excision of excess skin and subcutaneous tissue (including lipectomy), and related services; rhinoplasty and related services; and vein ablation and related services.
