

CY 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Proposed Rule Executive Summary

On August 4, 2020 the Centers for Medicare and Medicaid Services (CMS) released the Calendar Year (CY) 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS) proposed rule (CMS-1736-P). AAOS will be submitting formal comments to CMS, due on October 5, 2020. Below is a summary of key proposals:

OPPS Payment Update

-CMS is proposing to increase the payment rate under the OPPS by 2.6 percent

ASC Payment Update

-CMS is proposing to increase the ASC payment rates by 2.6 percent for ASCs that meet the quality reporting requirements under the ASCQR program

-CMS is proposing that the CY 2021 ASC weight scalar is 0.8494

-CMS is proposing that payment for office-based procedures would be the lesser of the proposed CY 2021 Medicare Physician Fee Schedule nonfacility Practice Expense (PE) RVU-based amount or the proposed CY 2021 ASC payment amount calculated according to the ASC standard ratesetting methodology

-CMS is proposing to continue to set the CY 2020 ASC payment rates and subsequent year payment rates for separately payable drugs and biologicals equal to the OPPS payment rates for CY 2021 and subsequent years

Proposed Changes to the Inpatient Only (IPO) List (pg. 376)

-CMS is proposing a three-year transition to the complete elimination of the IPO list, beginning with 266 musculoskeletal services being removed for CY 2021 (See Table 31) and complete elimination of all 1,740 services on the list by CY 2024.

-CMS believes that “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 otherwise applicable payment policies”

-CMS states that “developments in surgical technique and technological advances in the delivery of services may obviate the need for the IPO list”

-CMS believes that “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”

-CMS is seeking comment on whether procedures proposed for removal from the IPO for CY 2021 may meet the criteria to be added to the ASC Covered Procedure List.

-CMS is proposing to continue the 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” (otherwise known as site-of-service) for procedures removed from the IPO under the OPSS rule effective January 1, 2021.

-CMS states that the 2-midnight benchmark will remain an essential metric to guide when Part A payment for inpatient hospital admissions is appropriate.

Proposed Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A (pg. 416)

-CMS explains that “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”

-CMS states that the 2-midnight benchmark will remain an essential metric to guide when Part A payment for inpatient hospital admissions is appropriate

Changes to the ASC Covered Procedure List (CPL) (pg. 470)

-CMS is proposing to add 11 procedures to the ASC CPL, **including total hip arthroplasty** (CPT 27130) (See Table 40 for complete list of the procedures proposed to be added to the ASC CPL).

-CMS is proposing two options for updating the process for adding procedures to the ASC CPL:

- (1) CMS proposes to establish a nomination process beginning in CY 2021 for those procedures that would be added beginning the following calendar year in which external stakeholders, such as professional specialty societies, would operate under suggested parameters to nominate procedures where CMS would subsequently review and finalize through rulemaking.
 - For the OPSS/ASC rulemaking for a calendar year, CMS would request stakeholder nominations by March 1 of the previous calendar year
 - CMS would evaluate the nominated procedures based on the applicable statutory and regulatory requirements for the ASC CPL
 - CMS proposed 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”
 - CMS would then review public comments and finalize adding those procedures that meet the ASC CPL criteria
 - If CMS disagrees with any of the nominated procedures, they will provide specific feedback
 - CMS proposes to defer final determinations on nominated procedures to future rulemaking to provide more time for evaluation and decision-making

- (2) CMS proposes to revise the criteria for covered surgical procedures for the ASC payment system by keeping the general standards that presently require covered surgical procedures to be surgical procedures specified by the Secretary and published in the Federal Register, separately paid under the OPSS, not expected to pose a safety risk to a beneficiary when performed in the

ASC, and for which the beneficiary would not be expected to need active medical monitoring and care at midnight following the procedure.

- CMS would eliminate five of the general exclusion criteria but keep the remaining three (42 CFR 416.166(c)(6) through (c)(8))
- Under proposal 2, CMS estimates that 270 surgery or surgery-like codes would be added to the CPL that are not on the current IPO list (*See Table 41, pg. 489*)
- CMS is requesting comment on, if CMS finalized a proposal to allow more invasive surgical procedures in the ASC setting, whether the ASC Conditions for Coverage should be revised in the final rule and, if so, what those recommendations would be
 - For example, more prescriptive elements for risk evaluations and revisions to the quality measures under the ASCQR

Prior Authorization (pg. 658)

-CMS is proposing to add the following groups of services to the prior authorization list beginning on July 1, 2021: cervical fusion with disc removal and implanted spinal neurostimulators.

- This includes CPT codes 63685, 63688, 63650, 22551, and 22552

-CMS notes that the average annual increase for all outpatient department services is 2.8 percent

-CMS states that claims volume for insertion or replacement of spinal neurostimulator pulse generator or receiver (CPT code 63685) increased by 174.6 percent between 2007 and 2018, which shows a 10.2 percent average annual increase, that claims volume for revision or removal of implanted spinal neurostimulator pulse generator or received (CPT code 63688) increased by 149.7 percent between 2007 and 2018, which shows a 8.8 percent average annual increase, and that claims volume for implantation of spinal neurostimulator electrodes, accessed through the skin (CPT code 63650) increased by 77.9 percent between 2007 and 2018, which shows a 6.5 percent average annual increase

-CMS states that claims volume for the initial level of spinal fusion of the cervical spine with removal of the corresponding intervertebral disc (CPT code 22551) increased by 1,538.9 percent between 2012 and 2018, which shows a 124.9 percent average annual increase, and that claims volumes for add-on code (CPT code 22552) increased 3,779.6 percent between 2012 and 2018, which shows an average annual increase of 174.9 percent

Physician-Owned Hospitals (pg. 680)

-CMS is proposing the removal of unnecessary restrictions on high Medicaid facilities and the inclusion of beds in a physician-owned hospital's baseline consistent with State law.

-CMS defines high Medicaid facilities as those "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 which the hospital is located during the most recent 12-month period for which data are available", is not the only hospital in a county, and does not discriminate against beneficiaries of Federal health care programs.

-CMS is proposing to allow high Medicaid facilities to request an exception to the facility expansion prohibition more frequently than once every 2 years, however the facility may only submit one exception request at a time.

-CMS is proposing to lift 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 increasing beyond 200 percent of the hospital's baseline number of these rooms, as well as lifting the restriction on facility expansion only in facilities on the hospital's main campus.

-CMS is proposing to codify regulation text to reflect that a hospital bed is including in the hospital's baseline number of operating rooms, procedure rooms, and beds if the bed is considered licenses for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State

Changes to the Level of Supervision for Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals

-CMS is proposing 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

Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) Program

-CMS is proposing to keep all measures as is for both the OQR and ASCQR programs for CY 2021

Overall Hospital Quality Star Ratings (pg. 568)

-CMS is proposing to establish and update the methodology used to calculate Overall Hospital Quality Star Ratings beginning in CY 2021 by updating and simplifying how the ratings are calculated, reducing the total number of measure groups, and stratifying the Readmission measure group based on the proportion of dual-eligible patients.

-CMS acknowledges that usually the hospital inpatient measures are discussed in the Inpatient Prospective Payment System (IPPS) rule, but they are proposing the Overall Star Rating for both outpatient and inpatient in this rule

-CMS is proposing to continue to use publicly reported data on a CMS website from the following programs: Hospital VBP, Hospital IQR, Hospital OQR, HRRP, and HAC Reduction to calculate and publish the Overall Star Ratings

-CMS is proposing to include the Veterans Health Administration in the overall Star Rating beginning in CY 2023

-CMS is proposing to make the following updates to the methodology: (1) regroup measures by combining the three process measure groups into one group names Timely and Effective Care within Step 2: Assignment of Measures to Groups (2) update the calculation of measure group scores to include the standardization of measure group scores using a simple average instead of latent variable modeling (3) stratify the Readmission measure group scores using the proportion of dual-eligible patients at each hospital within the Step 3: Calculation of Measure Group Scores (4) alter the reporting thresholds to receive a star rating to three measures within three measure groups, one of which is required to be Mortality or Safety of Care within Step 5: Application of Minimum Thresholds for Receiving a Star Rating (5) apply peer grouping of hospitals that provide acute inpatient and outpatient care based on the 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

- CMS is proposing to publish the Overall Star Rating once annually using data that is publicly available on Hospital Compare instead of using data from the same quarter or prior quarter
- CMS is proposing to consolidate all three process measure groups (Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging) into one new measure group named Timely and Effective Care

Evaluation and CY 2021 Payment for Non-Opioid Alternatives

-CMS is proposing to continue paying separately at ASP+6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgery when furnished in the ASC setting while continuing to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgery in the HOPD

OPPS Payment for Devices (pgs. 243, 258)

-CMS is requesting comment on whether the SpineJack Expansion Kit system meets the substantial clinical improvement criterion for establishment of a device category and the pass-through payment criteria.

- Stryker Inc. submitted this application and describes the systems as an implantable fracture reduction system which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs)
- It's intended to be used in combination with the Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement
- The implants are progressively expanded through actuation of an implant tube that pulls the two ends of the implant toward each other in situ to mechanically restore vertebral body height
- Stryker claimed the SpineJack Expansion Kit meets the device eligibility requirements of § 419.66(b) because it is not an instrument, apparatus, implement or item for which depreciation and financing expenses are recovered. It is also not a supply or material furnished incident to a service.

Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices (pg. 460)

-CMS is proposing to reduce the payment by one-half of the device offset amount that would be applied if the device was provided at no cost or with full credit for device-intensive procedures where the ASC receives partial credit, if the credit to the ASC is between 50 and 100 percent of the cost of the device

OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals (pg. 266)

-CMS is proposing to end pass-through payment status for 26 biologicals and drugs in the CY 2021 (See Table 22).

-CMS is proposing that for policy-packaged drugs (anesthesia, biologicals) the pass-through payment be equal to ASP+6 percent minus 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 the proposed rule.

Biosimilar Biologics (pg. 293)

-CMS is proposing to continue the standing policy to allow all biosimilar biological products to be eligible for pass-through payment and not “just the first biosimilar biological product for a reference product”

- For CY 2021, CMS proposes continuing average sales price (ASP)+6% as payment for pass-through drugs and biologics.

-CMS proposes continuing their current policy for paying for nonpass-through biosimilars acquired under the 340B program, except that they 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.

- CMS proposes for CY 2021 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent.

July 2020 HCPCS Codes CMS is Seeking Comment On (pg. 123)

-CMS is seeking comment on proposed APC and status indicator assignments for the codes implemented on July 1, 2020. This includes HCPCS code J7333, Hyaluronan or derivative, visco-3, for intraarticular injection per dose.

Proposed Musculoskeletal Procedures APCs for CY 2021 (pg. 176)

-CMS is proposing to remove musculoskeletal codes that were on the Inpatient Only List and instead assign them to clinical APCs. The Secretary will eliminate the list of services and procedures designated as requiring inpatient care over a 3-year transition period through January 1, 2024.

-The influx of new MSK codes in the APC series may have an impact on the geometric means of the APCs for these six levels of MSK procedures:

- APC 5111, Level 1 Musculoskeletal Procedures
- APC 5112, Level 2 Musculoskeletal Procedures
- APC 5113, Level 3 Musculoskeletal Procedures
- APC 5114, Level 4, Musculoskeletal Procedures
- APC 5115, Level 5, Musculoskeletal Procedures
- APC 5116, Level 6, Musculoskeletal Procedures

The complete rule can be found [here](#) and the tables can be found [here](#).

The AAOS high-level summary of this proposed rule can be found online [here](#).