# CY 2021 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS

A side-by-side comparison of key provisions from the proposed and final rules for the CY 2021 OPPS and ASC Payment System

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## Overview

On December 2, 2020 the Centers for Medicare and Medicaid Services (CMS) released the Calendar Year (CY) 2021 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems final rule. Primarily, the final rule with comment period revises the Medicare OPPS and ASC payment system for Calendar Year (CY) 2021, as well as updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, the rule establishes and updates the Overall Hospital Quality Star Rating beginning with the CY 2021, adds two new service categories to the Hospital Outpatient Department (OPD) Prior Authorization Process, and revises the Clinical Laboratory Date of Service (DOS) policy. Finally, the rule establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking of COVID-19 therapeutic inventory and usage and for tracking of the incidence and impact of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) during the ongoing COVID-19 public health emergency (PHE).

Note that this rule also modifies the Radiation Oncology Model (RO Model) Model performance period for CY 2021, and these provisions are covered in a separate summary that the team at Hart Health Strategies Inc. has prepared.

**Given CMS' waiver of delay in effective date for this final rule, the finalized policies are effective beginning January 1, 2021.** Comments on the payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes are due January 4, 2021, while comments on the Reporting Requirements for Hospitals and CAHs to Report Acute Respiratory Illness During the PHE for COVID-19, instructions 21 and 23 amending §§ 482.42 and 485.640, are due February 2, 2021.

Hart Health Strategies Inc. has prepared the below "side-by-side" comparison of the proposed and final provisions for Medicare outpatient hospitals and ASCs, including regulatory impact and information collection requirements where pertinent, all with the goal of helping organizations better understand how CMS modified its proposals in response to stakeholder feedback. Page numbers and hyperlinks throughout the summary refer to the public display version of the final rule, which has been posted to our website. A table of contents is also provided to help you more easily navigate the summary. To go directly to a specific section of the rule, please click on the page number listed in the table of contents. To return to the table of contents, use the "Back to Table of Contents" link in the footer of each page.

| TOPIC | PROPOSED RULE | FINAL RULE |
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| **Payment and Policies for the Hospital Outpatient Department** | | |
| Ambulatory Payment Classification (APC) Payment Policies | **Recalibration of APC Relative Payment Weights.** CMS proposed to continue its policy of using hospital cost-to-charge ratios to estimate costs for rate setting purposes. | ***CMS finalized its proposal*** (p. 41). |
| | **Comprehensive APCs***:* For Comprehensive APCs, there is a single payment for the stay regardless of the length of the beneficiary's hospital outpatient stay. The packaging formula goes beyond what is typically packaged in an OPPS APC payment and includes payment for all services that are ancillary, supportive, dependent, and adjunctive to the primary service (to which CMS collectively refers as "adjunctive services"). CMS proposed continuing the Comprehensive APC payment methodology. | The finalized list of Comprehensive APCs for CY 2021 are listed in Table 3. |
| | Payment for Comprehensive APCs does not include payment non-OPPS charges or services that, because of statute, must be paid separately. These services include mammography and ambulance services; brachytherapy seeds; pass-through drugs and devices; and self-administered (non-Part B) drugs. CMS also excludes certain preventive services from the packaged payment. | CMS listed the C-APC excluded services on its website in Addendum J. |
| | • *Complexity Adjustments*. CMS allows for certain add-on codes (those that had previously been assigned to Device-dependent APCs) to qualify for a "complexity adjustment." For those primary service and add-on code combinations that are determined to be sufficiently frequent and sufficiently costly, CMS believes that a payment adjustment is warranted. CMS applies the complexity adjustment when the code pairing represents "a complex, costly form or version of the primary service" according to the following criteria: | |

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| | ○ Frequency of 25 or more claims reporting the code combination (frequency threshold); and<br>○ Violation of the 2 times rule in the originating Comprehensive APC (cost threshold). | |
| | If the criteria are met, CMS makes a "complexity adjustment" for the code combination by reassigning the primary services with the add-on code to the next higher cost Comprehensive APC within the same clinical family of Comprehensive APCs (unless the primary service is already assigned to the highest cost APC in the clinical family). The list of add-on codes eligible for the complexity adjustment can be found in Addendum J available on the CMS Web site. | The list of add-on codes eligible for the complexity adjustment can be found in Addendum J available on the CMS Web site. For additional information on comments submitted regarding Comprehensive APC complexity adjustments, see p. 68. ***CMS finalized its proposal to continue its complexity adjustment policy for CY 2021*** (p. 72). |
| | • *Comprehensive APC Exclusion of Procedures Assigned to New Technology APCs*: CMS stated that services that are assigned to New Technology APCs do not typically have sufficient claims history on which to set accurate payment. CMS noted, however, that when a procedure assigned to a New Technology APC is on a claim that *also* includes a primary procedure, the new technology service had typically been packaged into the payment for the primary procedure. Given that the new technology is not separately paid, the number of claims available for future price determination for the new technology is reduced, which is contrary to New Technology APC payment policy, "which is to gather sufficient claims data to enable [CMS] to assign the service to an appropriate clinical APC." Therefore, in CY 2019, CMS began exclude payment for any procedure from being packaged into a Comprehensive APC when that procedure is assigned to a New Technology APC (APCs 1491 – 1599; 1901 – 1908). | CMS revisited this policy on p. 72, but made no changes. |
| | • *Comprehensive APC Changes*: CMS proposed additional levels for the following Comprehensive APCs for CY 2021:<br>○ Urology & Related Services<br>○ Neurostimulator & Related Services | ***CMS finalized these changes as proposed*** (p. 77). |
| **Composite APCs***:* CMS has had a policy since 2008 for Composite APCs which provide a "single payment for groups of services that are typically | | |

| TOPIC | PROPOSED RULE | FINAL RULE |
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| | performed together during a single clinical encounter and that result in the provision of a complete service. | |
| | CMS proposed continuing its Composite APC policy for APC 8010 (*Mental Health Services*). | ***CMS finalized continuation of its policy*** (p. 79). |
| | CMS proposed to continue its Composite APC policy for APCs 8004, 8005, 8006, 8007, and 8008 (*Multiple Imagine Composite APCs)*. | ***CMS finalized continuation of its policy*** (p. 85). The imagine families and composite APC groupings can be found in Table 4. |
| | **Packaged Items and Services***:* CMS packages items or services when they are "integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code." CMS proposed to generally maintain its packaging policies. | **Packaged Items and Services*****: CMS finalized continuation of its general packaging policy*** (p. 92). CMS noted receipt of comments asking for the Agency to consider a more detailed approach to packaging proposals for products after which pass-through status expires and that it will take it into consideration for future rulemaking (p. 93). |
| | Non-Opioid Pain Management Treatments. CMS proposed to continue its policy to pay separately (average sales price (ASP) +6%) for non-opioid pain management drugs that function as surgical supplies in the ASC setting (but continue packaging in the OPPS setting). | ***CMS finalized its policy without modification*** (p. 108). CMS continues to believe that there is a lack of evidence to justify unpackaging Exparel under the OPPS (p. 101). CMS received requests under this policy to unpackage the following items, but declined to do so in all instances:<br>• Dexycu (HCPCS J1095): This drug already is already separate payable as it has pass-through status (p. 103).<br>• Omidria (CPT J1097): According to statute, this drug continues to have pass-through status (p. 105).<br>• Drug IV Acetaminophen (CPT J0131): (p. 105).<br>• Pain Block CPT Codes: CMS also noted that the CPT codes submitted do not represent payment for the products, but for the procedure to administer (p. 106).<br>• ERAS Protocols: (p. 107).<br>• Spinal Cord Stimulators (SCS): (p. 107) |
| | CMS made reference to The SUPPORT Act, passed in 2018, which includes Section 6082(a) which directs the Secretary to "*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, the statute states that the Secretary shall make changes beginning on or after January 1, 2020. In CY 2020 rulemaking, CMS stated that it did not believe that there are no | See more at CY 2021 ASC Packaging Policy for Non-Opioid Pain Management Treatments below.<br><br>CMS continues to state that it did not believe it needed to conduct an updated review in CY 2021 (p. 101). |

| TOPIC | PROPOSED RULE | FINAL RULE |
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| | changes needed to its packaging policies under the OPPS for drugs that functions as a surgical supply, nerve blocks, surgical injections, and neuromodulation products at the time. CMS stated that it did not believe conducting a similar review in 2021 would provide significantly new evidence or changes in policy. | |
| | Clinical Diagnostic Laboratory Tests Packaging Policy. CMS proposed excluding cancer-related protein based Multianalyte Assays with Algorithmic Analyses (MAAAs) from the OPPS packaging policy and thus pay for them under the Clinical Laboratory Fee Schedule (CLFS). As part of its rationale, CMS stated that "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." CMS proposed assigning a status indicator "A" ("Not paid under the OPPS. Paid by Medicare Administrative Contractors (MACs) under a fee schedule or payment system other than OPPS") for the following codes:<br>• CPT 81500 (Onco (ovar) two proteins)<br>• CPT 81503 (Onco (ovar) five proteins)<br>• CPT 81535 (Oncology gynecologic)<br>• CPT 81536 (Oncology gynecologic)<br>• CPT 81539 (Oncology prostate prob score) | ***CMS finalized this policy plus added CPT 81490 (Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score).*** CMS noted that it will consider separate payment under the CLFS for the technical component of pathology tests in future rulemaking (p. 116). See more below in *Clinical Laboratory Fee Schedule: Revisions to the Laboratory Date of Service (DOS) Policy*. |
| | CMS also proposed applying the policy to codes for cancer-related protein-based MAAAs developed in the future. | ***CMS also finalized this policy*** (p. 121). |
| | **Payment Adjustment for Certain Cancer Hospitals**. In line with statutory provisions, CMS proposed providing additional payments to the 11 specified cancer hospitals so that each cancer hospital's final payment-to-cost ratio (PCR) is equal to the weighted average PCR/target PCR for the other OPPS hospitals using the most recent submitted or settled cost report data that are available reduced by 1 percentage point (but did not propose an additional reduction beyond the 1 percentage point). | CMS did not receive any comments on its proposal, and therefore, ***CMS finalized the policy without medication*** (p. 163). |
| | CMS proposed that the payment among associated with the cancer hospital payment adjustment is a proposed target PCR of 0.89 percent for each cancer hospital. | ***CMS finalized the target PCR of 0.89 for CY 2021*** (p. 164). CMS listed the percentage increase in OPPS payments to each cancer hospital for CY 2021 in Table 5. |

| TOPIC | PROPOSED RULE | FINAL RULE |
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| | **Hospital Outpatient Outlier Payments.** CMS proposed continuing its policy of estimating aggregate outlier payments at 1 percent of total payments under the OPPS. | ***CMS finalized this policy without modification*** (p. 169). |
| | CMS proposed maintaining the percentage threshold for outlier payments at 1.75 times the APC payment amount. | ***CMS finalized this policy without modification*** (p. 169). |
| | CMS proposed to increase the dollar amount threshold to $5,300. | CMS repeated its estimated dollar amount outlier payment threshold of $5,300, but does not appear to formally finalize this as the CY 2021 dollar amount threshold (or there is language missing from the final rule). *See*, p. 170. |
| APC Group Policies | **New CPT and Level II HCPCS Codes.** CMS sought comment on the APC assignments and status indicators for new HCPCS Codes. | CMS again illustrates the timeline for APC and status indicator assignments for new codes, here in Table 8.<br><br>CMS assignments for the April 2020 update can be found in in Table 6.<br><br>New HCPCS Codes Implemented and finalized assignments for July 2020 update codes can be found in Table 7.<br><br>CMS finalized that new HCPCS Codes effective on October 1, 2020 were assigned an interim payment status of "NI," listed in Addendum B (p. 197).<br><br>New and Revised HCPCS Codes Effective January 1, 2021: The codes are available for review in Addendum B with interim OPPS payment status for CY 2021 (p. 198) |
| | **Variations Within APCs.** According to statute, the services within an APC cannot be considered "comparable" if the highest cost service in the APC is more than 2 times greater than the lowest costs for an item or service within the same APC ("2 Times Rule").<br>• When reassignments are necessary, in some cases, CMS proposed to change the status indicators for some procedure codes, rename existing APCs, or create new clinical APCs to reflect the new APCs due to the reassignments.<br>• CMS listed the reassignments to avoid violation of this rule on its Web site in Addendum B with the "CH" comment indicator.<br><br>CMS often makes exceptions when the 2 Times Rule has been violated, typically in cases of low-volume items or services (although the statute | |

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| | prohibits the Secretary from making an exception for orphan drugs). CMS identified 18 violations of the 2 times rule for CY 2021, and CMS determined that all 18 violations qualified for an exception. | ***CMS finalized its exceptions to the 2 Times Rule, plus an addition five APCs*** (p. 207). CMS listed the final 23 APCs where it finalized exceptions to the 2 times rule for CY 2021 in Table 9. |
| | **New Technology APCs.**<br>*Establishing Payment Rates for Low-Volume New Technology Services:* CMS proposed to continue the policy adopted in CY 2019 under which it will utilize its equitable adjustment authority 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. | ***CMS finalized this proposal without modification.*** (p. 211) |
| | *Procedures Assigned to New Technology APC Groups for CY 2021:* CMS proposed to retain services within New Technology APC groups until the agency obtains sufficient claims data to justify reassignment of the service to a clinically appropriate APC. | ***CMS finalized this proposal without modification.*** (p. 215) |
| | *Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1575, 5114, and 5414):* Currently, there are four CPT/HCPCS codes that describe MRgFUS procedures, three of which CMS proposed to continue to assign to standard APCs:<br>• CPT code 0071T: procedures for the treatment of uterine fibroids<br>• CPT code 0072T: procedures for the treatment of uterine fibroids<br>• HCPCS code C9734: procedures for pain palliation for metastatic bone cancer<br><br>The fourth MRgFUS-related code is CPT code 0398T. Given the significant difference in the payment rate between APC 5462 and 5463, CMS proposed to create an additional payment level between the two existing levels. 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. CMS proposed 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. | ***CMS finalized its proposal for CPT code 0071T, CPT code 0072T, and HCPCS code C9734.*** (p. 216)<br><br>***CMS also finalized its proposal to assign CPT code 0398T to APC 5463 for CY 2021.*** The final rule data shows the payment rate for the new APC 5463 (Level 3 Neurostimulator and Related Procedures) is $11,236.21. While this payment rate is lower than what was calculated for the proposed rule, CMS continues to believe APC 5463 is an appropriate placement for CPT code 0398T. (p. 216) |
| | *Retinal Prosthesis Implant Procedure*: CMS proposed 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. | ***CMS finalized this policy without modification.*** (p. 218) |
| | *Administration of Subretinal Therapies Requiring Vitrectomy*. CMS proposed to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of | ***CMS finalized its proposal to create C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of*** |

| TOPIC | PROPOSED RULE | FINAL RULE |
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| | pharmacologic/biologic agent) to describe this process. For CY 2021, CMS proposed to assign C97X1 to APC 1561 – New Technology – Level 24 ($3001-$3500). | ***pharmacologic/biologic agent) and assign this code to APC 1561 (New Technology – Level 24 ($3001-$3500)).*** (p. 225) |
| | *Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy*: CMS proposed 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. | For CY 2021, ***CMS finalized changing the assignment of HCPCS code C9751 to APC 1562 (New Technology - Level 25 ($3501-$4000)).*** (p. 229) |
| | *Fractional Flow Reserve Derived From Computed Tomography (FFRCT)*: CMS proposed 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. | ***CMS will continue to assign CPT code 0503T to New Technology APC 1511*** (New Technology— Level 11 ($901–$1000)) for CY 2021. (p. 232) |
| | *Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies*: CMS proposed to continue to assign these CPT codes to the same new technology APCs as they were in CY 2020. | ***CMS finalized this policy without modification.*** (p. 237) |
| | *Pathogen Test for Platelets/Rapid Bacterial Testing*: CMS proposed to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732, whose geometric mean cost is approximately $33. | ***CMS finalized this policy without modification.*** (p. 239) |
| | *V-Wave Interatrial Shunt Procedure (HCPCS code C9758; APC 1589)*: CMS proposed to continue to assign the service to New Technology APC 1589 for CY 2021. | ***CMS finalized this proposal with modifications.*** Similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure. Therefore, the difference in the payment for HCPCS codes C9758 and C9760 is based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed. Therefore, ***CMS will reassign HCPCS code C9758 to New Technology APC 1590***, which reflects the cost of having surgery every time and receiving the interatrial shunt one-half of the time when the procedure is performed. (p. 241) |
| | *Supervised Visits for Esketamine Self-Administration (HCPCS codes G2082 and G2083 APCs 1508 and 1511)*: CMS proposed to continue to assign HCPCS code G2082 to New Technology APC 1508 and to assign HCPCS code G2083 to New Technology APC 1511. | ***CMS finalized this policy without modification.*** (p. 248) |
| | **OPPS APC-Specific Policies**.<br>*CAR T-cell Therapy*: CMS made no specific proposed for the CAR-T cell preparation codes and proposed to continue to assign a status indicator of "B" (*Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)*). CMS proposed to continue to assign CPT 0504T with a status indicator of "S" (*Procedure or Service, Not Discounted when Multiple*) and to APC 5694 (*Level IV Drug Administration*). | ***CMS finalized the continuation of these policies*** (p. 257; p. 259). CMS refers stakeholders to Table 18 CAR T-cell HCPCS codes and Table 19 for assignments. |

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| | *Neurostimulator & Related Procedures*: CMS proposed adding a fifth level to the APC structure (between Level 2 and Level 3). | ***CMS finalized its proposal*** (p. 320). |
| | *IDx-DR: Artificial Intelligence System to Detect Diabetic Retinopathy*: CMS reviewed the FDA announcement regarding the technology and stated its belief that the service is a diagnostic test payable under the OPPS. CMS proposed to assigning the IDx-DR code (when it is received January 1, 2021) to APC 5732 (*Level 2 Minor Procedures*) with a status indicator of "Q1" to designate it as conditionally packaged. | ***CMS finalized its proposal with modification*** (p. 295). CMS instead finalizes that CPT 92229 (*Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral*) will be assigned to APC 5733 (*Level 3 Minor Procedures*) with a status indicator of "S" (*Procedure or Service, Not Discounted when Multiple*). |
| | *Intraocular Procedures*: CMS proposed that APC assignment will be based on the CY 2019 OPPS final rule median cost of $20,229.78. | ***CMS finalized its proposal*** (p. 304). |
| | *Musculoskeletal Procedures*: CMS revisited that there have been concerns about the granularity of the current APCs and request for additional levels CMS stated that it continues to believe that the six (6) level structure for the Musculoskeletal APC series is appropriate. | ***CMS finalized the musculoskeletal APCs (and updated geometric means) in Table 28.*** |
| | CMS also notes that in CY 2020 rulemaking, the Agency discussed APC assignment for CPT 22869 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar, single level*). CMS stated that it continues to believe that CPT 22869 is appropriately assigned to APC 5115 (*Level 5 Musculoskeletal Procedures*). | ***CMS finalized maintaining its current assignment for CPT 22869*** (p. 314). |
| | CMS also notes that it given the changes elsewhere in the rule regarding the elimination of the "Inpatient Only" list, that some of the procedures coming off the list will be assigned to Musculoskeletal Procedure APCs, which could trigger changes in the geometric means. | |
| | *Noncontact Real-Time Fluorescence Wound Imaging/MolecuLight*: CPT recently finalized two new CPT codes in this clinical area:<br>• **CPT 0598T** (Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (e.g., lower extremity)). Assigned to APC 5722 (Level 2 Diagnostic Tests and Related Services). CMS proposed continuing this for CY 2021. | ***CMS finalized continuation of its APC and status indicator assignments for these codes*** (p. 323). *See also*, Table 31. |

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| | • **CPT 0599T** (Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (e.g., upper extremity) (List separately in addition to code for primary procedure)). Because this is an add-on code, CMS assigned a status indicator of "N" to denote that payment is included with the primary procedure. CMS proposed continuing this for CY 2021. | |
| | In addition, CMS received a new technology application for MolecuLight i:X procedure, described by the aforementioned CPT codes. CMS sought comment on the appropriate OPPS payment from hospital-based providers who have used MolecuLight, including the cost of the service in the outpatient setting and the performance of the procedure. | Commenters noted the payment is insufficient to cover the cost of the procedure, which would dissuade hospitals from offering the service. Commenters also noted that the procedure requires the use of certain other technology and takes significant time as second and subsequent ulcers typically involve different anatomical sites. Commenters asked CMS to revise the APC assignment and status indicator, which CMS declined to do. (p. 322) |
| | Pathogen Test for Platelets/Rapid Bacterial Testing: CMS proposed to reassign the HCPCS code for pathogen test for platelets or rapid bacterial testing to APC 5732 (Level 2 Minor Procedures) from (New Technology – Level 1D ($31-$40)). | ***CMS finalized its proposal*** (p. 329). |
| | Urology & Related Services: CMS proposed increasing the number of levels for Urology & Related Procedures to eight (8) and makes several corresponding CPT reassignments. | ***CMS finalized its proposal to reorganize the Urology & Related Procedures APCs*** (p. 363).<br><br>*Hemodialysis Arteriovenous Fistula (AVF) Procedures (APC 5194)*: In January 2019, CMS introduced two new codes:<br>• C9754 (Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed))<br>• C9755 (Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed) |

At the time, these procedures were assigned to APC 5193 (*Level 3 Endovascular Procedures*) with a payment rate of $9,669.04; in 2020, this was revised to APC 5194 (*Level 4 Endovascular Procedures*) with a payment rate of $15,939.97 (p. 270).

These codes were subsequently deleted and replaced in July 2020 with:

- **G2170** (Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., 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 (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed)

***CMS finalized assignment of G2170 and G2171 to APC 5194 (Level 4 Endovascular Procedures)*** (p. 274).

*Implantable Interstitial Glucose Sensor System:* CMS proposed assigning

- CPT 0447T (*Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision*) to APC 5051 (*Level 1 Skin Procedures*) with a payment rate of $182.38 (p. 294).
- CPT 0446T (Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training) to APC 5053 (Level 3 Skin Procedures) with a payment rate of $530.98 (p. 296).
- CPT 0448T (Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sense, including system activation) to APC 5053 (Level 3 Skin Procedures) with a payment rate of $530.98 (p. 296)

A stakeholder pushed back on the assignments given the introduction of the Eversense Implantable Continuous Glucose System (CGS), which it

believed should be assigned to a New Technology APC. CMS disagreed and based on feedback from medical advisors and its cost analysis believed that inclusion in these codes was appropriate. Therefore, ***CMS finalized assignments for CPT 0447T as proposed; however, CMS did reassign CPT 0446T and 0448T to a higher APC Level, APC 5054 (Level 4 Skin Procedures)*** (p. 297).

*Intervertebral Disc Allogeneic Cellular and/or Tissue-based Product Percutaneous Injection*: For CY 2021, CMS proposed (initially using their predecessor placeholder codes) the following assignments:

- **CPT 0627T** (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) to APC 5443 (Level 3 Nerve Injections) with a status indictor of "T" and a payment rate of $836.26.
- **CPT 0628T** (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure) a status indicator of "N" (packaged) since it is an add-on code.
- **CPT 0629T** (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level) to APC 5443 (Level 3 Nerve Injections) with a status indictor of "T" and a payment rate of $836.26.
- **CPT 0630T** (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure) a status indicator of "N" (packaged) since it is an add-on code.

***CMS finalized its proposal with the modification to move 0627T and 0629T up to APC 5115 (Level 5 Musculoskeletal Procedure), which results in a payment rate of $12,314.76.***

*Additional Services:* CMS also addresses assignments for the following services:

- Imaging With and Without Contrast
- Cardiac CT (p. 276)

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| | | • Cardiac Magnetic Resonance Imaging (p. 284)<br>• Irreversible Electroporation Ablation of Tumors (NanoKnife System (p. 304)<br>• Medical Physics Dose Evaluation (p. 307)<br>• Nuclear Medicine Services: Single-Photon Emission Computed Tomography (SPECT) Studies (p. 324)<br>• Payment for Radioisotopes Derived From Non-Highly Enriched Uranium (non-HEU) Sources (p. 329)<br>• Percutaneous Transcatheter Ultrasound Nerve Ablation (p. 331)<br>• Remote Physiological Monitoring<br>• Initial Remote Monitoring of Physiological Monitoring (p. 337)<br>• Virtual Check-In Visits, E-visits, Telephone E/M and Medication Management Services (p. 339)<br>• Electrocorticograms from an Implanted Brain Neurostimulator (p. 351)<br>• Therapeutic Apheresis (p. 351)<br>• Tympanostomy Using an Automated Tube Delivery System (p. 353)<br>• Unlisted Dental Procedure (p. 355)<br>• Venous Mechanical Thrombectomy (p. 368) |
| | **Proposed Pass-Through Payments for Devices.**<br>*Alternative Pathway Device Pass-through Applications:* CMS 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 are eligible to apply under the alternative pathway:<br>(1) CUSTOMFLEX® ARTIFICIALIRIS is a foldable iris prosthesis that is custom-made for each individual patient and inserted at the time of cataract surgery or during a subsequent stand-alone procedure. CMS invites public comment on whether the CUSTOMFLEX® ARTIFICIALIRIS should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and have Breakthrough Device designation.<br>(2) EXALT™ Model D Single-Use Duodenoscope is 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. This application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, | **Pass-Through Payments for Devices.**<br>***CMS finalized approval for device pass-through payment status for CUSTOMFLEX® ARTIFICIALIRIS*** under the alternative pathway. (p. 379)<br>***CMS finalized approval for device pass-through payment status for EXALT™ Model D Single-Use Duodenoscope*** under the alternative pathway. (p. 387) |

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| | 2020. CMS invites public comment on whether the EXALTTM 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 have Breakthrough Device designation. | |
| | (3) BAROSTIM NEO™ System is indicated for the treatment of symptoms of patients with advanced heart failure. The therapy triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes of the progression of heart failure. BAROSTIM has FDA Breakthrough Device designation. CMS invites public comment on whether the BAROSTIM NEOTM System meets the device pass-through payment criteria, including the cost criterion. | ***CMS finalized approval for device pass-through payment status beginning CY 2021 for BAROSTIM NEO™*** under the alternative pathway. (p. 395) |
| | *Traditional Device Pass-through Applications:* | |
| | (1) Hemospray® Endoscopic Hemostat by Cook Medical. Hemospray® is indicated by FDA for hemostasis of nonvariceal gastrointestinal bleeding. CMS expressed concern with some of the presented studies as not being representative of the Medicare population. CMS further expressed concern about adverse events. CMS invites public comment on all criteria. | ***CMS approved the Hemospray® for device pass-through payment status*** beginning in CY 2021. (p. 405) |
| | (2) The SpineJack® Expansion Kit by Stryker, Inc. The SpineJack® system is an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures. CMS expressed concern about gaps in the clinical data, particularly any data comparing the SpineJack® system to other existing technology, such as the PEEK coiled implant, particularly since the PEEK coiled system was considered the predicate device for the SpineJack 510(k). Additionally, CMS noted a lack of data comparing the SpineJack system to conservative medical therapy. CMS invites public comment on all criteria. | ***CMS approved device pass-through payment status for the SpineJack® Expansion Kit*** beginning in CY 2021. (p. 425 |
| | *Technical Clarification to the Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Certain Transformative New Devices*: CMS proposed 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 | ***CMS finalized this policy without modification.*** (p. 458) |

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| | authorization for the indication covered by the Breakthrough Device designation." | |
| | *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)*: CMS is soliciting comments on whether it 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 CMS should implement that adjustment and for how long. Specifically, CMS is requesting public comment on utilizing its equitable adjustment authority 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. | CMS thanked the commenters for their submissions and will consider their input when determining whether a change is warranted in response to the PHE as the agency develops the 2022 OPPS/ASC proposed rule. (p. 460) |
| | **Proposed Device-Intensive Procedures**.<br>*Device-Intensive Procedure Policy for CY 2019 and Subsequent Years*: CMS is not proposing any changes to its device-intensive policy. | **Device-Intensive Procedures**. |
| | *Payment Policy for Low-Volume Device-Intensive Procedures*: For CY 2021, CMS proposed to continue its current policy of establishing the payment rate for any device-intensive procedure 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. | ***CMS finalized this policy without modification.*** (p. 483) |
| | CMS proposed to assign 0308T a payment weight based on the most recently available data and proposed to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Additionally, in the absence of CY 2019 claims data, CMS proposed to use the most recently available data to establish the device offset percentage for 0308T at 82.21 percent. | ***CMS finalized this policy without modification.*** (p. 301) ***Additionally, CMS finalized the offset percentage at 82.21%.*** (p. 483) |

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| OPPS Payment Changes for Drugs, Biologicals, and Radiopharma-ceuticals (p. 486) | **Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals**.<br><br>CY 2021, CMS proposed to continue the following payment policies:<br><br>• Paying 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. CMS proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS.<br>• For policy-packaged drugs, CMS proposed that the pass-through payment amount would equal ASP+6 percent for CY 2021 minus a payment offset for any predecessor drug products contributing to the pass-through payment.<br><br>Update pass-through payment rates on a quarterly basis on its website during CY 2021 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments are necessary. | **OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals**.<br><br>***CMS finalized these policies without modification*** (p. 486). |
| | *Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2021*: CMS proposed to end pass-through payment status in CY 2021 for 26 drugs and biologicals. | ***CMS finalized ending pass-through status for 29 drugs and biologics between 03/31/20 and 12/31/20, as listed in Table 36.***<br><br>***CMS finalized ending pass-through status for 25 drugs and biologics in CY 2021, as listed in Table 37.*** |
| | *Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing in CY 2021*: CMS proposed to continue pass-through payment status in CY 2021 for 46 drugs and biologicals. | ***CMS finalized the continuation of pass-through status for the 46 products from the proposed rule and another 22 since publication of the proposed rule. Thus, for CY 2021, there are 68 drugs and biologics with pass-through status, as listed in Table 38.*** |
| | For CY 2021, CMS proposed to provide payment for pass-through diagnostic and therapeutic radiopharmaceuticals based on the standard ASP+6 percent methodology. If ASP data are not available, CMS proposed to provide pass-through payment at WAC+3 percent. If WAC information is not available, CMS proposed to provide payment at 95% of the most recent AWP. | ***CMS finalized this policy without modification.*** (p. 498) |
| | *Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups*: For CY 2021, CMS proposed to continue to apply the same policy packaged offset policy to payment for pass- | ***CMS finalized this policy without modification.*** (p. 505) |

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| | through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. | |
| | **Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status.**<br>*Proposed Packaging of Payment for HCPCS Codes that Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold ("Threshold-Packaged Drugs")*: For CY 2021, CMS proposed 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. | **OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status.**<br>***CMS finalized this policy without modification.*** (p. 507) |
| | *Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages*: CMS proposed to continue its policy of making 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. | ***CMS finalized this policy without modification.*** (p. 518)<br><br>The packaging status of each drug and biological HCPCS code to which this methodology applies in CY 2021 is displayed in Table 40. |
| | *Payment for Drugs and Biologicals Without Pass-Through Status that are not Packaged*:<br>• For CY 2021, CMS proposed to continue to pay for separately payable drugs and biologicals at ASP+6 percent (the statutory default), with the exception of 340B-acquired drugs.<br>• For CY 2021, CMS proposed to continue to utilize a 3-percent add-on instead of a 6-percent add-on for WAC-based drugs. CMS also proposed to apply this provision to non-SCOD separately payable drugs. Thus, if finalized, CMS' 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). | ***CMS finalized this policy without modification.*** (p. 521)<br><br>***CMS finalized this policy without modification.*** (p. 521) |
| | Biosimilar Products:<br>• For CY 2021, CMS proposed to continue its policy to make all biosimilar products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.<br>• CMS proposed to continue its current policy for paying for non-pass-through biosimilars acquired under the 340B program, except that it proposed to pay for these biosimilars at the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP, instead of the reference product's ASP. | ***CMS finalized this policy without modification.*** (p. 528)<br><br>***CMS finalized its alternative proposal to pay non-pass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP, as explained below.*** (p. 528) |
| | *Payment Policy for Therapeutic Radiopharmaceuticals*: For CY 2021, CMS proposed to continue paying pay all non-pass-through, separately | ***CMS finalized this policy without modification.*** (p. 534) |

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| | payable therapeutic radiopharmaceuticals at ASP+6 percent. CMS proposed 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. CMS proposed to update the payment rates according to its usual process on a quarterly basis. | |
| | *Payment for Blood Clotting Factors*: For CY 2021, CMS proposed to continue paying for blood clotting factors at ASP+6 percent and to continue its policy for payment of the furnishing fee using an updated amount. CMS proposed to announce the updated furnishing fee calculated based on that figure through program instructions and posting on its website, after the Bureau of Labor Statistics releases the applicable CPI data. | ***CMS finalized this policy without modification.*** (p. 535) |
| | *Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes But Without OPPS Hospital Claims Data*: For CY 2021, CMS proposed to continue to use the same payment policy as in CY 2020 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. | ***CMS finalized this policy without modification.*** (p. 537) |
| | *CY 2021 OPPS Payment Methodology for 340B Purchased Drugs:*<br><br>• Determining an Add-on Payment for 340B Drugs – For CY 2021 and subsequent years, CMS proposed 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.<br><br>• *Alternative Proposal to Continue Policy to Pay ASP-22.5 Percent*: CMS proposed in the alternative that the agency could continue the current Medicare payment policy of ASP minus 22.5 percent for CY 2021. If adopted, this proposed policy would continue the current policy for CY 2021 and subsequent years. | The 340B discussion begins on p. 538 of the Final Rule.<br><br>***CMS did not finalize this proposal; rather, the agency finalized its alternative proposal to continue current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.*** (p. 561)<br><br>Based on feedback from stakeholders, CMS believes maintaining the current payment policy of paying ASP minus 22.5 percent for 340B drugs is appropriate in order to maintain consistent and reliable payment for these drugs both for the remainder of the PHE and after its conclusion to give hospitals some certainty as to payments for these drugs. Continuing current policy also gives CMS more time to conduct further analysis of hospital survey data for potential future use for 340B drug payment. Any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.<br><br>While CMS believe its methods to conduct the 340B Drug Acquisition Cost Survey, as well as the methodology used to calculate the proposed average or typical discount received by 340B entities on 340B drugs, are |

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| | | valid, the utilization of the survey data is complex, and CMS wishes to continue to evaluate how to balance and weigh the use of the survey data, the necessary adjustments to the data, and the weighting and incorporation of ceiling prices – all to determine how best to take the relevant factors into account for potentially using the survey to set Medicare OPPS drug payment policy.<br><br>CMS notes that its proposal to pay for 340B-acquired drugs at ASP minus 34.7 percent based on hospital survey data, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent could be within the Secretary's authority under section 1833(t)(14). Additionally, commenters did not provide any evidence that ASP minus 22.5 percent is no longer a conservative estimate of their drug acquisition costs. The data collected in the 2020 Hospital Acquisition Cost Survey for 340B-acquired SCODs found the average 340B program drug discount to be 34.7 percent. CMS has not seen evidence that the current OPPS 340B drug payment policy has limited patient access to 340B drugs. Further, Medicare payments for drugs are not intended to cross-subsidize other programs. |
| | • 340B Payment Policy for Drugs for which ASP is Unavailable - CMS proposed 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. In that case, CMS would propose a payment rate of WAC minus 34.7 percent plus 3 percent of the drug's WAC. For CY 2021, CMS proposed to pay for drugs paid at AWP under the 340B program at 63.90 percent of AWP. | ***CMS finalized continuing the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP will continue to be paid an adjusted amount of 69.46 percent of AWP.*** (p. 564) |
| | • 340B Payment Policy Exemptions - For CY 2021 and subsequent years, similar to previous years, CMS proposed that rural sole community hospitals, 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. | ***CMS finalized these exemptions without modification.*** CMS noted that it may revisit its policy to exempt rural SCHs, as well as other hospital types, from the 340B drug payment reduction in future rulemaking. (p. 564) |

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| | • CMS proposed to pay non-pass-through biosimilars acquired under the 340B Program at the biosimilar'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. | As noted above, CMS finalized its alternate proposal to continue paying for 340B-acquired drugs under the OPPS at a rate of ASP minus 22.5 percent, and thus no changes to its biosimilar policy are necessary for CY 2021. |
| | *Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes*: CMS proposed to continue the high cost/low cost categories policy for CY 2021. | ***CMS finalized this policy without modification.*** (p. 585) |
| | *Discussion of CY 2019 and CY 2020 Comment Solicitations for Episode-Based Payment for Graft Skin Substitute Procedures*: CMS will continue its review of the feasibility of using episode-based payment for graft skin substitute procedures, and will not propose any episode-based payment for these procedures. | Several commenters expressed either their support for or their concerns about establishing episode-based payment for graft skin substitute procedures. Commenters made many suggestions about how a payment episode should be constructed and which services should be included or excluded from a payment episode. CMS will continue to study issues related to changing the methodology for paying for skin substitute products and procedures for possible future rulemaking. (p. 590) |
| | *Discussion of CY 2019 and CY 2020 Comment Solicitations to Have a Single Payment Category for Graft Skin Substitute Procedures*: CMS needs more time to consider the trade-offs between potential benefits of a single category against the potential substantial drawbacks. CMS also needs to consider the merits of this policy option compared to episode-based payment for graft skin substitute procedures. Therefore, CMS did not propose a single payment category for graft skin substitute procedures for CY 2021. | Several commenters expressed either their support or their concerns about a single payment category for graft skin substitute procedures. Commenters provided their views on whether a single payment category encourages value and cost savings for graft skin substitute procedures, or if a single payment category would discourage providers from using higher-cost skin substitute products that may have better clinical results for patients. CMS will continue to study issues related to changing the methodology for paying for skin substitute products. (p. 594) |
| | **Proposals for Packaged Skin Substitutes for CY 2021.** The proposed CY 2021 MUC threshold was $47 per $cm^2$ (rounded to the nearest $1) and the proposed CY 2021 PDC threshold was $936 (rounded to the nearest $1). | ***The final CY 2021 MUC threshold is $48 per $cm^2$ (rounded to the nearest $1) and the final CY 2021 PDC threshold is $949 (rounded to the nearest $1).*** (p. 598) |
| | CMS proposed to assign any skin substitute that exceeds the MUC threshold or the PDC threshold to the high cost group and any skin substitute with a MUC or a PDC that does not exceed either threshold to the low cost group. CMS proposed 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. | ***CMS finalized these policies without modification.*** |
| | For CY 2021, skin substitutes with pass-through payment status will be assigned to the high cost category. CMS proposed to assign skin substitutes with pricing information but without claims data to calculate | ***CMS finalized these policies without modification.*** Table 42 provides the final CY 2021 cost category assignment for each skin substitute product. |

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| | 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, CMS proposed to use WAC+3 percent. If neither ASP nor WAC is available, CMS proposed to use 95 percent of AWP. CMS proposed to continue to use WAC+3 percent instead of WAC+6 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. | |
| | *Proposal to Allow Synthetic Skin Graft Sheet Products to Be Reported with Graft Skin Substitute Procedure Codes*: 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. Initially, the synthetic product was not described as a graft skin substitute product, but CMS now proposed that both biological and synthetic products could be considered to be skin substitutes for Medicare payment purposes. This view was supported by a paper titled "Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2." Therefore, for CY 2021, CMS proposed to include synthetic products in addition to biological products in its description of skin substitutes. CMS also proposed to retain the additional 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..." | ***CMS finalized this proposal with modification.*** CMS will include synthetic products, in addition to biological products, in its description of skin substitutes. CMS' new description defines 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. CMS will retain the additional description of skin substitute products from the CY 2014 OPPS final rule: "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). CMS' definition of skin substitutes does not include bandages or standard dressings. (p. 609)<br><br>Multiple commenters agreed with CMS that synthetic graft skin substitute products should receive payment under the OPPS, even if the commenters did not support CMS' methodology for the payment. Several commenters requested that CMS establish product-specific HCPCS codes for synthetic graft skin substitute products. Commenters also expressed concerns about using a C-code to report synthetic graft skin substitute codes in Medicare.<br><br>So far, CMS has identified one synthetic graft skin substitute product that is described by HCPCS code C1849. The manufacturer was able to produce pricing data for the product, which showed that the synthetic product would be assigned to the high cost group. Some commenters expressed concern about the assignment of HCPCS code C1849 to the high cost skin substitute group. CMS is not in favor of a default assignment of HCPCS code C1849 to the low cost skin substitute group. As more synthetic graft skin substitute products are identified as |

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| | | described by HCPCS code C1849, CMS will average the pricing data from the various products to determine an amount for the products described by HCPCS code C1849 to compare against the MUC threshold. This comparison will determine if HCPCS code C1849 should be assigned to the high cost or low cost skin substitute category.<br><br>CMS notes that the creation of HCPCS code C1849 and the scope of its descriptor was not an attempt to promote one of the several payment methodologies discussed in the CY 2019 and CY 2020 comment solicitations regarding alternative payment methodologies for graft skin substitute products over the other payment methodologies. |
| Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices (p. 619) | **Proposed Estimate of Pass-Through Spending**. CMS estimates that total pass-through spending 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). This represents 0.934 percent of total projected OPPS payments for CY 2021. | **Estimate of Pass-Through Spending**. CMS estimates that total pass-through spending during CY 2021 would be approximately $769.3 million (approximately $309.8 million for device categories and approximately $459.5 million for drugs and biologicals). This represents 0.92 percent of total projected OPPS payments for CY 2021. (p. 619) |
| OPPS Payment for Hospital Outpatient Visits and Critical Care Services (p. 627) | CMS proposed continuing its current clinic and emergency department (ED) hospital outpatient visits payment policies, as well as its payment policy for critical care services. CMS sought comment on any changes to these codes that it should consider for future rulemaking cycles, providing data and analysis to justify recommended changes. | ***CMS finalized continuation of its hospital ED and critical care payment policy*** (p. 627). CMS noted that it again received comments asking that CMS develop a set of national guidelines for coding hospital ED visits, citing the June 2019 MedPAC report which recommended this activity (p. 628). |
| Site Neutral Payment Policy: Method to Control Unnecessary Increases in Volume (p. 630) | CMS previously adopted a method to control what it believed to be unnecessary increases in the volume of covered outpatient department services by utilizing a Medicare Physician Fee Schedule (PFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS G0463) when furnished by excepted off-campus provider-based departments (PBDs). The "PFS-equivalent" rate for CY 2021 is 40 percent of the OPPS rate. | ***CMS finalized continuation of its policy to set an MPFS-equivalent payment rate for G0463 under the OPPS*** (p. 630; p. 637). CMS also noted that it is not only over volume and program spending that is of concern, but also beneficiary cost-sharing if these services are paid at a higher rate under the OPPS (p. 631). CMS dismissed arguments that paying for this service at the MPFS rate inappropriately assumes that the PFS payment rate is sufficient and directed stakeholders to the MPFS potentially misvalued code process if there is concern about valuation of services (p. 634). CMS states that this policy will save Medicare |

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| | In September 2019, the district court vacated the volume control policy and CMS worked to ensure affected 2019 claims were paid consistent with the order, but did not revise the policy for CY 2020, as the agency was considering the ruling and possible appeal. Then, on July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit ruled in favor of CMS, holding that the 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. | approximately $340 million and beneficiaries approximately $90 million (p. 637).<br><br>CMS again leaned on the July 17, 2020 court ruling in its favor and cited that the petition for rehearing was denied on October 16, 2020 (p. 634) CMS also stated that it will decide the appropriate course of action after the 90 day deadline for the appellees to decide whether to see U.S. Supreme Court review (p. 635). |
| Inpatient Only Services (p. 678) | **Proposal to Eliminate the Inpatient Only (IPO) List**. CMS directed commenters to submit evidence on how quality of care could be negatively affected by elimination of the IPO list. | ***CMS finalized its proposal to eliminate gradually eliminate the IPO list*** (p. 708). ***The full list of procedures finalized for removal from the IPO list for CY 2021 can be viewed in Table 48.*** CMS acknowledged the many comments received opposing the elimination of the IPO list on the basis of patient safety (p. 690). CMS responded that it believes that "physicians can and should 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" (p. 690). ***CMS noted that it plans to "provide information on appropriate site of service selection to support physicians' decision-making" in the future, stating "these considerations will be for informational or educational purposes only and will not supersede physicians' medical judgment about whether a procedure should be performed in the inpatient or outpatient hospital setting"*** (p. 695).<br><br>CMS also acknowledged comments received that hospitals and payers sometimes override physician decision-making about site-of-service for a procedure (p. 692). However, CMS only responded that it would be a "misinterpretation of CMS payment policy for providers to create policies or guidelines that establish the outpatient setting as the baseline or default site of service for a procedure based on its removal from the IPO list or the elimination of the IPO list" (p. 693). CMS also added that commercial insurance providers "establish their own rules regarding payment for services (p. 694). |

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| | | CMS stated that it received comments about the impact of these changes on the SNF 3-Day inpatient stay requirement (p. 700). CMS replied that it expects that a patient who is a candidate for these procedures in the outpatient setting would not be expected to require SNF care following surgery anyway (p. 700). |
| | CMS reminded stakeholders that it had previously finalized a policy to exempt procedures removed from the IPO list for review under the 2 Midnight rule for two calendar years following removal. CMS proposed to continue this 2 year exemption from site-of-service claim denials. However, CMS sought comment on whether the exemption continues to be appropriate and whether it should be for a longer or shorter period. | ***CMS finalized a proposal to extend the review exemption period indefinitely for a service newly removed from the IPO list, beginning in CY 2021*** (p. 694). *See also, Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years* section of the final rule. |
| | CMS proposed to eliminate the IPO list over a 3 year transitional period that will begin in CY 2021 (with the list being completely eliminated by January 1, 2024). CMS sought comment on whether 3 years is the appropriate time for transition. | ***CMS finalized the 3 year transition period*** (p. 708). |
| | CMS proposed removing 266 musculoskeletal services from the IPO list for CY 2021, and made corresponding proposed APC assignments. | ***CMS finalized APC assignments for the 266 musculoskeletal services it removed from the IPO list, which can be viewed in Table 48*** (p. 699). In addition, stakeholders identified a number of anesthesia codes specific to musculoskeletal procedures that had been on the IPO list. ***CMS also finalized these musculoskeletal anesthesia codes for removal from the IPO list*** (p. 701); *See*, Table 46. |
| | CMS sought comment on whether there are other services that should be candidates for removal from the IPO list in the near term. | Beyond the musculoskeletal services (and related anesthesia services), ***CMS finalized an additional 16 procedures for removal from the IPO list in CY 2021*** (based on recommendations of the Advisory Panel for Hospital Outpatient Payment (HOP)) (p. 701); *See,* Table 47. |
| | CMS sought comment on the order of removal for additional clinical families and/or specific services for CY 2022 and CY 2023 rulemaking. | CMS notes that it will consider for future rulemaking comments received that cardiothoracic procedures and spine-related procedures should be removed from the list last (p. 706). |
| | CMS sought comment on whether it should restructure or create any new APCs to facilitate removal of some procedures from the IPO list. | CMS cited the concerns about APC assignments as procedures are removed from the IPO list (p. 698). CMS believes that current data available and its APC assignment process are sufficient (p. 699; *See also* p. 707). |

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| Nonrecurring Policy Changes (p. 727) | **Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)**.<br><br>*Proposal to Allow General Supervision of Outpatient Hospital Therapeutic Services Currently Assigned to the 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 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. CMS proposed to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. | **Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs**<br><br>*General Supervision of Outpatient Hospital Therapeutic Services Currently Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision:* ***CMS finalized its proposal without modification (p. 732).*** |
| | *Proposal to Allow Direct Supervision of Pulmonary Rehabilitation Services, Cardiac Rehabilitation Services, and Intensive Cardiac Rehabilitation Services using Interactive Telecommunications Technology*: For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, CMS proposed 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. | *Direct Supervision of Pulmonary Rehabilitation Services, Cardiac Rehabilitation Services, and Intensive Cardiac Rehabilitation Services using Interactive Telecommunications Technology:* ***CMS finalized its proposal with modifications. Specifically, CMS finalized its proposed policy to permit direct supervision of these services using virtual presence, but only until the later of the end of the calendar year in which the PHE ends or December 31, 2021. (p. 739)***<br><br>CMS noted that when this policy expires, CMS will resume its current policy to require direct physician supervision of these rehabilitation services, and that the supervising practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure.<br><br>CMS clarified that to the extent its policy allows direct supervision through virtual presence using audio/video real-time communications technology during the PHE, the requirement could be met by the supervising practitioner being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure. (p. 739)<br><br>CMS noted that this change is intended to align the virtual supervision policy with that finalized in the Physician Fee Schedule 2021 Final Rule. |

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| | **Proposed Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years.**<br><br>*Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years*: CMS discussed the current policy for medical review of inpatient hospital admissions, particularly as it applies to CMS' 2-midnight policy. CMS noted that the decision to formally admit a patient to the hospital is subject to medical review, but also that CMS previously finalized a policy to create exceptions for procedures on the IPO list and for "rare and unusual" circumstances. CMS also 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; CMS stated that such 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 they be reviewed by RACs for "patient status". During the 2-year period, BFCC-QIOs have the opportunity to review 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 Part A.<br><br>CMS noted that with the proposed elimination of the IPO list, any service that was once on the IPO list would be subject to the 2-midnight benchmark and 2-midnight presumption. However, procedures 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 list. CMS proposed to retain the existing 2-year exemption from site-of-service denials, BFCC-QIO referrals to RACs, and RAC reviews for "patient status" for procedures removed from the IPO list, even in the event that it finalizes the proposal to eliminate the IPO list, for CY 2021 and subsequent years. CMS sought comment on whether the 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. CMS | **Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years.**<br><br>*Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years:* ***CMS finalized its proposal with modification. Instead of the 2-year exemption proposed, procedures removed from the IPO list on or after January 1, 2021 will be indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC-QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for "patient status" (that is, site-of-service), until the procedure is more commonly performed in the outpatient setting than the inpatient setting. In order for the exemption to end for a specific procedure, CMS will review claims data to determine, whether in a single calendar year, data indicate that the procedure was performed more than 50 percent of the time in the outpatient setting. CMS will revisit in rulemaking whether and when an exemption for a procedure should be ended. Thus, for each procedure removed from the IPO list on or after January 1, 2021, the exemption will continue until terminated in future rulemaking. CMS may consider additional metrics in the future that could assist in determining when the exemption period should end for a procedure. This will only apply to procedures removed from the IPO list beginning in CY 2021 (p. 762). CMS may still conduct medical review in cases in which there is evidence of systemic fraud or abuse occurring. (p. 765)***<br><br>CMS noted that BFCC-QIOs will continue to conduct initial medical reviews for both the medical necessity of the services, and the medical necessity of the site-of-service. BFCC-QIOs will continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable and medically necessary. Additionally, providers are still expected to bill in compliance with the 2-Midnight rule even if the procedure is exempt from medical review activities. (p. 758)<br><br>CMS' change in policy was in response to stakeholder comments, which are detailed starting on p. 751. Stakeholders noted the large magnitude of change that providers would need to accommodate, and that a large number of these procedures will still need to be conducted in the inpatient settings. A few additional highlights are provided below: |

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| | solicited public comment regarding what the appropriate period of time for the exemption should be and why. | • CMS noted its belief that the use of the 2-midnight benchmark gives appropriate consideration to the judgment of physicians and furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Part A. (p. 757)<br>• CMS noted its belief that the documentation requirements are not overly burdensome because they are consistent with Medicare's longstanding documentation requirements, which predate the adoption of the 2-Midnight rule. (p. 760)<br>• CMS plans to provide considerations for the selection of site-of-service for a procedure to support physicians' decision-making, for informational or educational purposes only. (p. 761)<br>• CMS noted that a 2-year exception to the 2-Midnight rule was appropriate in prior years since procedures removed from the IPO were targeted and selected in small numbers. (p. 763)<br>• CMS agreed that an indefinite exemption period will allow providers time to gather information on procedures newly removed from the IPO list to help inform education and guidance for the broader provider community, develop patient selection criteria to identify which patients are, and are not, appropriate candidates for outpatient procedures, and to develop related policy protocols. (p. 764)<br>• CMS may revisit procedures that were removed from the IPO list prior to January 1, 2021, and extend or shorten their exemption if necessary. (p. 763) |
| | **Comment Solicitation on OPPS Payment for Specimen Collection for COVID-19 Tests**. CMS proposed to continue to assign HCPCS code C9803 to APC 5731 with a status indicator of "Q1", with the presumption that this code will be deleted when COVID-19 PHE ends. CMS sought comment on the proposed APC and status indicator assignment for HCPCS code C9803 for CY 2021, as well as whether CMS should keep HCPCS code C9803 active beyond the COVID-19 PHE, maintain the current APC and status indicator assignments, and extend or make permanent the OPPS payment associated with specimen collection for COVID-19 tests after the COVID-19 PHE ends. | **Comment Solicitation on OPPS Payment for Specimen Collection for COVID-19 Tests**. CMS did not address this policy in the preamble of the final rule. However, C9803 is included under Addendum B with a Comment Indicator of NC (*New code for the next calendar year or existing code with substantial revisions to its code descriptor in the next calendar year as compared to current calendar year for which CMS requested comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code*) and Status Indicator of Q1 (*STV-Packaged Codes*), with a payment rate of $24.67. |

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| CY 2021 OPPS Payment Status and Comment Indicators (p. 765) | **Proposed CY 2021 OPPS Payment Status Indicator Definitions**. CMS did not propose changes to the existing status indicators and definitions (listed in Addendum D1 to the CY 2020 OPPS/ASC Final Rule), but sought comment on them. | ***Finalized as proposed***, as no comments were received. (p. 766) |
| | **Proposed CY 2021 Comment Indicator Definitions**. CMS proposed to continue using the existing four comment indicators and their definitions for CY 2021, without modification, as noted below:<br>• "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.<br>• "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 CMS requested comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.<br>• "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.<br>• "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. | ***Finalized as proposed***, as no comments were received. (p. 768) |
| Hospital Outpatient Department (OPD) Prior Authorization Process (p. 1108) | **Proposed Addition of Two (2) New Service Categories**. CMS proposed to require prior authorization for two new service categories:<br>• Cervical Fusion with Disc Removal<br>• Implanted Spinal Neurostimulators<br><br>CMS proposed that prior authorization would be effective for these services for dates of service on or after July 1, 2021. | **Proposed Addition of Two (2) New Service Categories**. ***CMS finalized its proposal without modification to add these two new service categories (p. 1132).*** Table 74 includes the overall list of services subject to prior authorization with the effective dates of each.<br><br>CMS discussed comments and responses starting on p. 1118. Highlights from this discussion are included below.<br>• In response to concerns about provider burden, CMS noted that it believes that the HOPD prior authorization process will not have similar problems as seen with other payers, as CMS has established |

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| | | timeframes for contractors to render decisions as well as an expedited review process. Additionally, CMS noted that its prior authorization policy "does not create any new documentation or administrative requirements." (p. 1120)<br>• CMS noted that "because the prior authorization process is not a final determination and a provider has the ability to resubmit a prior authorization request multiple times, it is not necessary to provide appeal rights. Appeal rights still exist once a claim is actually denied." (p. 1120)<br>• In response to questions on why ASCs and physicians are exempt from the prior authorization process, CMS noted that the authority CMS is using to require prior authorization is specific to OPPS, and therefore CMS cannot extend the process to other settings. (p. 1122)<br>• CMS addressed comments suggesting an inadequate timeframe for training and education starting on p. 1123.<br>• In response to comments regarding MACs' clinical review capabilities, CMS detailed its requirements that, for all FFS medical review programs, MACs utilize registered nurses when reviewing medical documentation, as well as Medical Directors provide oversight and additional clinician engagement if necessary. CMS also notes that it is committed to incorporating automation into its prior authorization processes, and that it continues to monitor other federal and industry initiatives to improve the efficiency of its prior authorization process. (p. 1125)<br>• CMS responds to comments regarding its rationale for selecting the two services for prior authorization starting on p. 1127.<br><br>**Economic Impact.** CMS estimates that its finalized policies will result in approximately $47.9 million in economic costs over 10 years, but overall Medicare savings of $31.8 million on an annual basis. (p. 1252) |
| Requirements for the Hospital Outpatient Quality Reporting (OQR) Program (p. 915) | **Hospital OQR Program Quality Measures.** CMS does not propose any changes to the previously finalized measure set for the CY 2023 payment determination and subsequent years. | **Hospital OQR Program Quality Measures.** No change from proposed rule. Table 62 summarizes the previously finalized Hospital OQR Program measure set for the CY 2023 payment determination and subsequent years. |
| | **Form, Manner, and Timing of Data Submitted for the Hospital OQR Program**. To align with statute, CMS proposed that all deadlines falling | **Form, Manner, and Timing of Data Submitted for the Hospital OQR Program**. ***CMS finalized its proposal as proposed. (p. 926)*** |

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| | on a nonwork day (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) be moved forward beginning with the effective date of this rule. | |
| | In this rule, CMS proposed to expand its 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. | ***CMS finalized its proposal as proposed. (p. 931)*** |
| | **Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2020 Payment Determination.** CMS proposed to continue its 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 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 82.016. | **Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2020 Payment Determination.** ***For the CY 2021 OPPS/ASC final rule, the final reporting ratio is 0.9805, which when multiplied by the final full conversion factor of 82.797 equals a final conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of 81.183.*** *(p. 941)* |
| Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years (p. 963) | **Background**. 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. The Overall Star Ratings include data from these programs (with certain exceptions), but 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, CMS proposed to continue to use data publicly reported on a CMS website from the programs described above as a basis to calculate the Overall Star Ratings. CMS proposed to codify this, along with the Overall Hospital Quality Star Rating and methodology, at §412.190 as such:<br>• 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; and | **Background.** ***CMS finalized its policies as proposed. (p. 973)*** |

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| | • 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. | |
| | **Critical Access Hospitals in the Overall Star Rating**. For the Overall Star Rating beginning in CY 2021 and subsequent years, CMS proposed to continue to include voluntary measure data from CAHs for the purpose of calculating Overall Star Rating. 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. CMS proposed to codify this at §412.190. | **Critical Access Hospitals in the Overall Star Rating**. ***CMS finalized its policies as proposed. (p. 979)*** |
| | **Veterans Health Administration Hospitals in Overall Star Rating**. CMS proposed to include quality measure data from Veterans Health Administration (VHA) hospitals for purposes of calculating Overall Star Rating beginning with CY 2023. | **Veterans Health Administration Hospitals in Overall Star Rating. *CMS finalized its policies as proposed. (p. 982)*** Details of the inclusion of VHA hospitals within the Overall Star Rating, including impact analyses, will be addressed through future rulemaking. |
| | **Current and Proposed Overall Star Rating Methodology**.<br>The current Overall Star Rating methodology can be outlined within six steps, summarized below and described in more detail in the rule. 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 (i.e., 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. | **Current and Proposed Overall Star Rating Methodology.** |

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| | Generally, CMS proposed 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 a quarter within the prior year; for e.g., the Overall Star Ratings published in January 2020 used data publicly reported from the October 2019 refresh; | ***CMS finalized this policy as proposed. (p. 999)*** |
| | • Suppression policy for subsection (d) hospitals; | ***CMS finalized its policies as proposed (see below).*** |
| | • 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; | ***CMS finalized its measure inclusion criteria proposals (p. 1005); its measure exclusion proposals (p. 1009); and its measure score standardization proposals (p. 1012).***<br><br>CMS detailed comments and responses on its measure inclusion and exclusion proposals starting on p. 1001. Highlights are provided below.<br>• In response to a comment for CMS to evaluate measures for validity and reliability if data from CY 2020 are excluded and measurement periods are extended due to COVID-19, CMS noted that it is currently analyzing how its exemptions and the COVID-19 pandemic impact the measures within various CMS quality programs. CMS may consider suppression of the Overall Star Rating if it determines that underlying measure data were substantially affected. (p. 1005) |
| | • 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 | ***CMS finalized its policies as proposed (p. 1069; p. 1074).*** |
| | • 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. | ***CMS finalized its policies as proposed (p. 1096).*** |

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| | CMS proposed to make the following updates to the Overall Star Rating methodology:<br>• Regroup measures as a result of the Meaningful Measure Initiative by combining the three process measure groups into one group, Timely and Effective Care, within Step 2: Assignment of Measures to Groups.<br>  ○ Beginning in CY 2021 and subsequent years, CMS proposed 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. This change accounts for recent measure removals from CMS quality programs and would ensure a sufficient number of measures in each group.<br>  ○ CMS also proposed to retain the current structure of the Mortality, Safety of Care, and Readmission, and the Patient Experience measure groups. The outcomes categories—mortality, safety of care, readmission and patient experience—would continue to account for 22 percent of the total rating while the timely and effective care group would account for 12 percent. | ***CMS finalized its policies as proposed (p. 1018 and p. 1023).*** |
| | • 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 the LVM.<br>  • CMS would use averages to determine the weight assigned to quality measures. The weight of each measure would be determined by the number of measures a hospital reported in each group divided by 100, resulting in each measure in each group being weighted equally.<br>  • Whereas the 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, a simple average of measure scores would result in hospitals having varying measure weights depending on differences in the number of measures reported. | ***CMS finalized its policies as proposed (p. 1044 and p. 1046)***<br><br>See Table 68 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.<br><br>CMS notes that, given this final policy, CMS does not believe that measure score Winsorization should be retained. (p. 1014)<br><br>***CMS did not finalize its proposals related to stratification of the Readmission measure group score (p. 1064).*** |

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| | • Stratify the Readmission measure group scores using the proportion of dual-eligible patients at each hospital within Step 3: Calculation of Measure Group Scores. | CMS detailed comments and responses to this proposal starting on p. 1058. Highlights are provided below.<br>• In response to comments, CMS acknowledges that stratifying the readmission measure group based on the proportion of dual-eligible patients may be confusion and misleading to patients. In addition, CMS notes that analyses reveal the stratification may not result in the intended effect, with significantly more hospitals losing a star rating than gaining a star rating. CMS also refers to the ASPE report on *Social Risk Factors and Performance In Medicare's Value-Based Purchasing Programs,* which recommended removal of stratification of hospitals by the proportion of dual-eligible patients from the Hospital Readmission Reduction Program, and which indicated the need to hold providers accountable for outcomes regardless of social risk. CMS identifies these as factors for not finalizing its proposal. However, CMS will continue to evaluate approaches for increasing comparability of hospital star ratings. (p. 1060)<br>• CMS discusses how its proposal would not necessarily increase comparability of hospital star ratings on p. 1063. |
| | • 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. | ***CMS finalized its policies as proposed (p. 1079).*** |
| | • 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. 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. | ***CMS finalized its policies as proposed (p. 1092).***<br><br>CMS discussed comments and responses starting on p. 1087. A few highlights from this discussion are included below:<br>• CMS notes that it plans to make public the summary score cutoffs for each peer group along with each publication of the Overall Star Ratings. (p. 1090)<br>• CMS noted that the impact of variation in the COVID-19 hospitalizations, and healthcare broadly, is under active surveillance by CMS, and any updates to the individual measures as a result of COVID-19 will subsequently be incorporated within the Overall Star Rating. (p. 1091) |

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| | | • CMS will continue its practice of publicly posting, for each publication of the Overall Star Raring, the Overall Star Rating input file and SAS pack on QualityNet and Overall Star Rating results on data.cms.gov, which will include all specifications and results, including peer grouping. (p. 1091) |
| | **Preview Period**. For the Overall Star Rating beginning with the CY 2021 and subsequent years, CMS proposed to continue its current process regarding the preview period. | ***CMS finalized its policies as proposed (p. 1099).*** |
| | **Overall Star Rating Suppressions.**<br>*Subsection (d) Hospitals*: CMS proposed 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, CMS would 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:<br>• There is an Overall Star Rating calculation error by CMS;<br>• There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation (e.g., 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 calculations that affects a substantial number of hospitals reporting those measures); or<br>• A Public Health Emergency substantially affects the underlying measure data.<br>Consistent with past practices, CMS also proposed that it would not suppress an individual hospital's Overall Star Rating because the hospital or one of its agents (e.g., authorized vendors, representatives, or contractors) submitted inaccurate data to CMS, including inaccurate underlying measure data and claims records. | **Overall Star Rating Suppressions.**<br>*Subsection (d) Hospitals: CMS finalized its policies as proposed* (p. 1103).<br><br>CMS discussed comments and responses starting on p. 1101. Notably, in response to concerns about the impact of COVID-19, CMS notes that it is currently analyzing how its exemptions granted and the COVID-19 pandemic impact the measures within various CMS quality programs. Data excluded from CMS quality programs (that feed into the Overall Star Rating) will be subsequently excluded from the Overall Star Rating. CMS may also consider suppression of the Overall Star Rating if it determines that underlying measure data were substantially affected due to the PHE. (p. 1103) |
| | *CAHs*: For the Overall Star Rating beginning in CY 2021 and subsequent years, CMS proposed to continue to allow CAHs to withhold their Overall Star Rating. Specifically, 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. CMS also proposed that CAHs may request to have their Overall Star Rating withheld from public release on | *CAHs:* ***CMS finalized its policies as proposed*** (p. 1108). |

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| | 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 used to calculate the Overall Star Ratings. | |

## Proposed Payment Policies for Ambulatory Surgery Centers

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| Updates to the Ambulatory Surgical Center (ASC) Payment System (p. 771) | **Proposed ASC Treatment of New and Revised Codes**.<br>*April 2020 HCPCS Codes for Which CMS Is Soliciting Public Comments in This Proposed Rule*: In Table 32, CMS listed the new Level II HCPCS codes that were implemented April 1, 2020, along with their proposed payment indicators for CY 2020. CMS invited public comments on these proposed payment indicators and payment rates for the new HCPCS codes that were recognized as ASC ancillary services in April 2020 through the quarterly update CRs, and proposed to finalize their payment indicators in the CY 2021 OPPS/ASC final rule with comment period. | **ASC Treatment of New and Revised Codes**.<br>*April 2020 HCPCS Codes for Which CMS Solicited Public Comments in the Proposed Rule*: ***Finalized as proposed***, as no comments were received. See Table 49 for details. (p. 778) |
| | *July 2020 HCPCS Codes for Which CMS Is Soliciting Public Comments in This Proposed Rule*: In Table 33, CMS listed the new HCPCS codes that were effective July 1, 2020. In addition, through the July 2020 quarterly update CR, CMS implemented an ASC payment for two new Category III CPT codes as ASC covered ancillary services, effective July 1, 2020, listed in Table 34. CMS invited public comments on these proposed payment indicators for the new Category III CPT code and Level II HCPCS codes newly recognized as ASC covered surgical procedures or covered ancillary services in July 2020 through the quarterly update CRs, and proposed to finalize the payment indicators in the CY 2021 OPPS/ASC final rule with comment period. | *July 2020 HCPCS Codes for Which CMS Solicited Public Comments in the Proposed Rule*: ***Finalized as proposed***, as no comments were received. See Tables 50 and 51 for details. (p. 779) |
| | *October 2020 HCPCS Codes for Which CMS Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule with Comment Period*: Consistent with its established policy, CMS proposed that the Level II HCPCS codes that became 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 CMS had assigned the codes an interim ASC payment status for CY 2020. | *October 2020 HCPCS Codes for Which CMS Is Soliciting Public Comments in this CY 2021 OPPS/ASC Final Rule with Comment Period*: CMS did not receive any comments on its proposal. (p. 784) |
| | *January 2021 HCPCS Codes*:<br>• Level II HCPCS Codes for Which CMS Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule with Comment Period: CMS proposed to assign comment | *January 2021 HCPCS Codes*:<br>• Level II HCPCS Codes for Which CMS Is Soliciting Public Comments in this CY 2021 OPPS/ASC Final Rule with Comment Period: **COMMENT: *CMS solicits comments on the new Level II HCPCS*** |

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| | indicator "NI" to the new Level II HCPCS codes that will be effective January 1, 2021 to indicate that the agency is assigning them an interim payment indicator, which is subject to public comment.<br><br>• CPT Codes for Which CMS Is Soliciting Public Comments in This Proposed Rule: For the CPT codes that were received from the AMA in time to be included in the CY 2021 proposed rule, CMS assigned comment indicator "NP" along with an appropriate payment indicator assignment, for which CMS solicited public comments. | ***codes (that are effective January 1, 2021 in this CY 2021 OPPS/ASC final rule with comment period) and on the payment indicator assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.*** (p. 785) (See OPPS Addenda)<br><br>• CPT Codes for Which CMS Solicited Public Comments in This Proposed Rule: Comments and responses to these codes are found in the "Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Procedures." **COMMENT:** CMS notes that it inadvertently omitted four new HCPCS codes (CPT 0627T, 0628T, 0629T, and 0630T). As such, ***CMS assigned these codes with comment indicator "NI" and an interim payment indicator that is subject to public comment and will be finalized in the CY 2022 OPPS/ASC final rule with comment period.*** (p. 788) (See OPPS Addenda) |
| | **Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services**.<br>*Covered Surgical Procedures Designated as Office-Based*: For CY 2021, CMS proposed to permanently designate as office-based the CPT codes in Table 36 and to continue to designate as temporarily office-based the CPT codes in Table 37. CMS also proposed to permanently assign one of the office-based payment indicators (i.e., "P2," "P3" or "R2") and non-office-based payment indicators (i.e., "G2") to the CPT codes in Table 38. In addition, CMS proposed to designate as temporarily office-based two new CY 2021 CPT codes in Table 39. | **Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services**.<br>*Changes for CY 2021 to Covered Surgical Procedures Designated as Office-Based:* ***CMS finalized its proposals with few modifications.*** (p. 797) Note that CMS finalized the designation of the procedures shown in Table 57 as temporarily office-based and the procedures shown in Table 58 as permanently office-based, both beginning CY 2021. |
| | *ASC Covered Surgical Procedures to Be Designated as Device-Intensive*: Based on CMS modified device-intensive criteria, for CY 2021, CMS proposed to update the ASC CPL to indicate procedures that are eligible for payment according to its 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 OPPS/ASC proposed rule. | *ASC Covered Surgical Procedures to Be Designated as Device-Intensive*: ***Finalized as proposed.*** Under this policy, CMS notes that (elsewhere in this rule) it finalized CPT code 0266T for transitional pass-through device payment status and assigned a device offset percentage of 96.04. (p. 806)<br><br>Commenters also requested CMS restore or reconsider device-intensive status for other CPT codes, which CMS declined to do. Additionally, commenters supported the Advisory Panel on Hospital Outpatient Payment (HOP) recommendation to lower the ASC device-intensive threshold from 30 to 25 percent. CMS declined to do this given it "*would have the effect of assigning a greater amount of device costs, and increasing estimated ASC expenditures for the prospective year*." |

| TOPIC | PROPOSED RULE | FINAL RULE |
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| | *Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices*: CMS proposed to apply its existing policy for partial credits. | *Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices*: ***Finalized as proposed.*** (p. 816) |
| | *Additions to the List of ASC Covered Surgical Procedures (ASC-CPL)*: As a reminder, in the CY 2020 OPPS/ASC final rule, CMS added total knee arthroplasty and several coronary intervention procedures to the ASC-CPL. Given lessons learned as part of the current COVID-19 PHE, CMS believed it would 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. Thus, CMS proposed to continue applying its current policies and criteria for updating the ASC-CPL. CMS also proposed two alternative options for modifying its 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 CMS would revise its regulatory criteria at 42 CFR 416.166 to evaluate potential additions to the ASC-CPL. | *Additions to the List of ASC Covered Surgical Procedures*: See p. 1295 for the revised language for § 416.166 – Covered Surgical Procedures. |
| | Standard ASC-CPL Review Process for CY 2021<br>CMS proposed to update the list of ASC covered surgical procedures by adding eleven procedures to the list for CY 2021 as shown in Table 40. CMS sought public comment on its proposal, including any medical evidence or literature to support the commenters' views on whether or not CMS should add any of these procedures to the ASC-CPL for CY 2021. | Standard ASC-CPL Review Process for CY 2021<br>***Finalized as proposed.*** (p. 826) That is, CMS added the eleven procedures to the ASC-CPL as proposed, which are listed in Table 59. |
| | CMS also proposed to revise the regulatory language and modify the standard to exclude procedures designated as requiring inpatient care. | ***Finalized as proposed.*** (p. 828) That is, CMS revised the definition of covered surgical procedures at § 416.166(a) to conform to the changes it made to the requirements for covered surgical procedures at §§ 416.166(b)(1) and (2), and (c), whereby CMS will determine whether the four specified criteria are met as the basis for adding surgical procedures to the ASC CPL. (p. 851) |
| | Alternative Proposals under Consideration for CY 2021<br>Nomination Process: | Alternative Proposals under Consideration for CY 2021<br>Nomination Process: In general, ***CMS finalized a simpler process than the nomination process it originally proposed. Under the new, simpler "notification process," which CMS added at new paragraph § 416.166(e), titled "Additions to the list of ASC covered surgical procedures beginning January 1, 2021," CMS provided that it will add surgical procedures to the ASC CPL as follows: (1) CMS identifies a surgical procedure that meets the requirements at paragraph (b)(2) of this section. (2) CMS is notified of a surgical procedure that could meet*** |

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| | | ***the requirements at paragraph (b)(2) of this section and CMS confirms that such surgical procedure meets those requirements.*** (p. 848) |
| | CMS proposed 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, as well as modify § 416.166(c)(6) to align the regulatory text with the proposed elimination of the IPO list. CMS also proposed that nominated procedures would need to meet the general exclusions at 42 CFR 416.166(c)(7) and (c)(8). | ***CMS finalized its proposal to eliminate the general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5).*** (p. 842) |
| | In addition, CMS sought public comment on the suggested parameters including language changes, recommendations for additional parameters, potential unintended implications of the parameters proposed, and whether CMS should finalize suggested parameters if this alternative proposal is finalized in the CY 2021 final rule. | ***CMS did not finalize the parameters discussed in the proposed rule given it decided against finalizing its original nomination process.*** (p. 549). ***However, recognizing that the aforementioned general exclusion criteria are important for physicians to consider, CMS will continue to display them under a new paragraph 416.166(d).*** (p. 842)<br><br>CMS also recognizes that physicians are better-positioned than CMS to determine whether a surgical procedure is not expected to pose a significant safety risk for a specific beneficiary and is one for which standard medical practice for the specific beneficiary dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. As such, ***CMS shifted the responsibility for these two considerations to physicians, as now reflected in § 416.166(d)(1) and (2).*** (p. 843) ***CMS also revised § 416.166(b) to specify that covered surgical procedures may not include those surgical procedures that are designated as requiring inpatient care under 42 CFR 419.22(n) as of December 31, 2020.*** (p. 843) |
| | Broad, Immediate Approach: CMS proposed and may finalize in the CY 2021 final rule to keep the existing general standards under 42 CFR 416.166(b) and eliminate five of the current general exclusion criteria at 42 CFR 416.166(c)(1) through (c)(5) (retaining 42 CFR 416.166(c)(6) through (c)(8)). CMS sought public comment on whether any of these procedures would typically require care after midnight, and, therefore, should not be added to the ASC-CPL. | Broad, Immediate Approach: As noted above, ***CMS finalized its proposal to eliminate the general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5).*** (p. 842) |
| | In addition, CMS requested comments on whether or not the ASC CfCs should be revised in the CY 2021 final rule to ensure that its health and safety standards are sufficient to reflect the additional range of complex | **CMS declined to modify the ASC CfCs at this time, noting it may revisit this in the future should the need arise.** (p. 850) However, at this time, |

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| | services that would be added to the ASC-CPL, and, if so, the recommended revisions. CMS also requested comment on possible additions or revisions to the quality measures under ASCQR if additional procedures are added to the ASC-CPL.<br><br>CMS proposed to finalize only one of these alternative proposals, and welcomes public comment as to which policy should be adopted in the final rule. | CMS believes there are numbers considerations in place that effectively incentivize careful patient selection in ASCs.<br><br>Overall, ***CMS added 267 procedures to the ASC CPL, based upon the aforementioned changes to the regulatory criteria. CMS also added a new § 416.166(d) to reflect these considerations, as well as a new § 416.166(e) describing how CMS will add a surgical procedure to the ASC CPL, either on its own initiative or based on a notification from the public that a procedure not currently on the ASC CPL meets the criteria for addition to the ASC CPL.*** (p. 851) See Table 60. |
| | | **Covered Ancillary Services.**<br>This section was inadvertently omitted from the CY 2021 OPPS/ASC Proposed Rule. However, ***CMS finalized the continuation of its existing policies relating to covered ancillary services without change.*** (p. 865) |
| | Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services.<br>*Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2021*: CMS proposed to:<br>• update ASC payment rates for CY 2021 and subsequent years using the established rate calculation methodologies and using its definition of device-intensive procedures.<br>• continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2", and to calculate payment rates for office-based procedures (payment indicators "P2", "P3", and "R2") and device-intensive procedures (payment indicator "J8") according to its established policies and using its modified definition of device-intensive procedures.<br>• 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. | Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services.<br>*Update to ASC Covered Surgical Procedure Payment Rates for CY 2021*: ***Finalized as proposed.*** (p. 872) CMS also received comments requesting that the agency increase payment in the ASC setting for five CPT codes, and to eliminate the prohibition against ASC billing for services using unlisted CPT codes, both of which CMS declined. |

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| | • continue its 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. | |
| | *Proposed Payment for Covered Ancillary Services for CY 2021*: CMS proposed 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. CMS also proposed 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. | *Payment for Covered Ancillary Services for CY 2021*: Covered ancillary services and their final payment indicators for CY 2021 are listed in Addendum BB of this CY 2021 OPPS/ASC final rule with comment period. |
| | CMS proposed to add, as covered ancillary services:<br>• CPT 0598T (Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)),<br>• 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)),<br>• C9762 (Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging), and<br>• C7963 (Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging). | ***Finalized as proposed.*** See Tables 50 and 51. |
| | *CY 2021 ASC Packaging Policy for Non-Opioid Pain Management Treatments* – Evaluation and CY 2021 Proposal for Payment for Non-Opioid Alternatives: CMS proposed to continue its 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 | *CY 2021 ASC Packaging Policy for Non-Opioid Pain Management Treatments* – Evaluation and CY 2021 Proposal for Payment for Non-Opioid Alternatives: ***Finalized as proposed.*** (p. 890) |

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| | as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. | CMS also responded to comments regarding a number of other non-opioid alternatives.<br>• IV acetaminophen (J0131): Commenters urged CMS to pay for this drug separately, but CMS declined given its current packaging policies. (p. 887)<br>• "Pain block" codes (64415, 64416, 64417, 64445, 64446, 64447, 64448, and 64450): CMS notes that these services do not qualify as non-opioid pain management drugs that function as surgical supplies, and therefore, do not qualify for separate payment when furnished in the ASC setting. (p. 887)<br>• ERAS ® protocols or SCS: Commenters sought separate payment for these non-drug pain management treatments, but CMS did not find compelling evidence to change its policies at this time. (p. 889) |
| | **Proposed ASC Payment and Comment Indicators.**<br>*ASC Payment and Comment Indicators for CY 2021*: CMS proposed 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 to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available. | **ASC Payment and Comment Indicators.**<br>*ASC Payment and Comment Indicators for CY 2021*:<br>***Finalized as proposed.*** (p. 896) |
| | **Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor**.<br>*Calculation of the ASC Payment Rates*:<br>CMS noted that the proposed CY 2020 ASC weight scalar is 0.8494.<br><br>CMS proposed 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.<br><br>For ASCs not meeting the quality reporting requirements, CMS proposed 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. | **Calculation of the ASC Payment Rates and the ASC Conversion Factor**.<br>*Calculation of the ASC Payment Rates*:<br><br>No change.<br><br>For CY 2021, ***CMS adjusted the CY 2020 ASC conversion factor ($47.747) by a wage index budget neutrality factor of 1.0012 in addition to the MFP-adjusted hospital market basket update of 2.4 percent, which resulted in a final CY 2021 ASC conversion factor of $48.952 for ASCs meeting the quality reporting requirements.*** (p. 912)<br><br>***For ASCs not meeting the quality reporting requirements, CMS adjusted the CY 2020 ASC conversion factor ($47.747) by the wage index budget neutrality factor of 1.0012 in addition to the quality reporting/MFP-adjusted hospital market basket update of 0.4 percent, which resulted in a final CY 2021 ASC conversion factor of $47.996.*** (p. 912) |

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| Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program (p. 941) | **ASCQR Program Quality Measures**. CMS did not propose to remove any existing measures or to adopt any new measures for the CY 2023 payment determination. CMS invites public comment on new measures for its consideration that address care quality in the ASC settings, as well as on additional measures that could facilitate meaningful comparisons of care provided in ASCs and hospitals. | **ASCRQ Program Quality Measures.** No change from proposed rule. Table 64 summarizes the previously finalized ASCQR Program measure set for the CY 2024 payment determination and subsequent years.<br><br>CMS addresses comments submitted in response to its request for comment on new measures starting on p. 945. |
| | **Form, Manner, and Timing of Data Submitted for the ASCQR Program.** CMS proposed that all deadlines falling on a nonwork day (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) be moved forward beginning with the effective date of this rule. | **Form, Manner, and Timing of Data Submitted for the ASCQR Program.** ***CMS finalized its proposal as proposed. (p. 956)*** |
| | CMS also proposed to create a review and corrections period similar to that being proposed for the Hospital OQR Program. For the ASCQR Program, CMS proposed 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. | ***CMS finalized its proposal as proposed. (p. 959)*** |

## CLFS: Revisions to the Laboratory Date of Service (DOS) Policy (p. 1135)

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| | **Proposed Revision to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs**. CMS proposed to exclude five cancer-related protein-based MAAAs (i.e., CPT codes 81500, 81503, 81535, 81536, and 81539) from the OPPS packaging policy (see more in the section Clinical Diagnostic Laboratory Tests Packaging Policy), and create an exception to the laboratory DOS rule for them. | **Revision to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs**. ***CMS revised the current laboratory DOS exception at 42 CFR 414.510(b)(5) to include cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536, 81539, as well as the test described by CPT code 81490 (Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score).*** (p. 1158) |
| | CMS also proposed to add cancer-related protein-based MAAAs to its current laboratory DOS exception rule at § 414.510(b)(5). | ***CMS also finalized that it would exclude cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future, from the laboratory DOS policy.*** (p. 1158) |

## Physician-owned Hospitals (p. 1158)

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| **Background.** CMS provided background information on the physician self-referral law, which prohibits physicians from making referrals for certain designated health services to an entity with which he or she has a financial relationship, unless an exemption applies. Statue sets forth exceptions related to ownership or investment interests held by a physician (or immediate family member), and CMS notes an exception for ownership or investment interests in rural providers (the "rural provider exception") and for ownership or investment interests in a hospital located outside of Puerto Rico (the "whole hospital exception"). | CMS reviewed the background for its proposals. (Additional information and analysis on the policies can be found in the Information Collection Requirements discussion). |
| **Prohibition on Facility Expansion**. 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, but also required that the Secretary establish and implement an exception process that would allow expansion of facility capacity for hospitals that qualify as either an "applicable hospital" or a "high Medicaid facility." | |
| CMS proposed 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 for which CMS has not issued a decision. CMS also proposed removing the restriction that, for high Medicaid facilities only, 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. CMS proposed removing the restriction that permitted expanded facility capacity must occur only in facilities on the hospital's main campus. | ***CMS finalized its proposal without modification*** (p. 1165). *See also*, p. 1167. |
| **Community Input.** CMS also considered whether to eliminate the opportunity for community input in the review process with respect to high Medicaid facilities. CMS stated it was interested in comments regarding the importance of community input, which allows for confirmation of (or disagreement with) the data provided by a high | ***CMS is not revising its regulations regarding community input*** (p. 1166). |

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| | Medicaid facility seeking an exception to the prohibition on expansion of facility capacity. CMS stated its interest 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. CMS solicited 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. | |
| | **Deference to State Law for Purposes of Determining the Number of Beds for which a Hospital is Licensed.** CMS proposed revising the definition of "*baseline number of operating rooms, procedure rooms, and beds*" 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.<br><br>CMS sought comment on its proposal to include this language in regulation text 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*." | ***CMS finalized its proposal*** (p. 1175). |

## Notice of Teaching Hospital Closure & Residency Slot Applications (p. 1175)

The ACA included provisions that allowed the HHS Secretary to redistribute residency slots after an approved medical residency program closes (p. 1175). In line with its previously established process for the redistribution of available slots, CMS is providing notice of the closure of two programs:

- Westlake Community Hospital (Melrose Park, Illinois) (p. 1176)
- Astria Regional Medical Center (Yakima, Washington) (p. 1177)

CMS provides an overview of the application process for the available resident slots on p. 1178. Applications should be submitted to ACA5506application@cms.hhs.gov. Interested hospitals must ensure CMS receives the application no later than 90 days after the display of the CY 2021 OPPS Final Rule (p. 1011). CMS notes that it has not established a deadline by which they will notify the recipients of the redistributed slots (p. 1179).