A Summary of the Centers for Medicare and Medicaid Services Calendar Year 2020 Outpatient Prospective Payment System (OPPS) & ASC Payment System Proposed Rule

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Overview

On July 29, 2019, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2020 Hospital Outpatient Prospective Payment System (OPPS) and ASC Payment System proposed rule. CMS estimates that the OPPS fee schedule factor will increase by +2.7 percent; the ASC payment rate will also increase by +2.7%.

Page numbers in the summary refer to the public display version of the proposed rule which can be viewed here. Comments will be accepted through **September 27, 2019**. The final rule should be released in early November 2017.

CMS proposes to increase the CY 2020 OPPS conversion factor to $81.398 (p. 107). This is premised on a general overall increase of 2.7 percent (p. 103). The overall increase (before budget neutrality adjustments) is based on the proposed hospital inpatient market basket increase of 3.2 percent minus a productivity adjustment of 0.5 percent. Per usual, ***CMS proposes that if more recent data becomes available, it will use the updated data to alter the conversion factor in the OPPS final rule with comment period*** (p. 103).

In total, CMS estimates that CY 2020 OPPS payments will increase by approximately $5.0 billion over CY 2019 estimated payments to a total of approximately $80 billion (p. 371). In addition, CMS proposes to continue to reduce payments by 2.0 percent for hospitals that fail to meet the outpatient quality reporting requirements (p. 107).

APC Payment Policies

Recalibration of APC Relative Payment Weights (p. 38)

CMS uses the same annual process to update the APC relative weights and payments for CY 2020. CMS makes the payment rates (including the relative payment weights for each APC) available via the CMS Web site Addendum A and Addendum B updates. CY 2019 rates are based on data submitted from claims for services furnished after January 1, 2018 and before January 1, 2019. CMS proposes to continue its policy of using hospital cost-to-charge ratios to estimate costs for rate setting purposes (p. 40).

Proposed Comprehensive APCs (p. 58)

In CY 2015, CMS implemented several new Comprehensive APCs, which included the final transition of all Device-Dependent APCs to 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"). By CY 2019, CMS had finalized 65 Comprehensive APCs.

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 lists the C-APC excluded services on its website in Addendum J.

CMS made several other statements regarding its Comprehensive APC payment policy:

- *Complexity Adjustments*. CMS will allow 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 (p. 66):
    - Frequency of 25 or more claims reporting the code combination (frequency threshold); and
    - 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 (p. 67). The list of add-on codes eligible for the complexity adjustment can be found in Addendum J available on the CMS Web site.

- *Proposed CY 2020 Comprehensive APCs*. ***CMS proposes to continue the Comprehensive APC payment methodology implemented in CY 2015*** (p. 68). However, ***CMS proposes two (2) additional Comprehensive APCs for CY 2020***:
    - C-APC 5182 (*Level 2 Vascular Procedures*)
    - C-APC 5461 (*Level 1 Neurostimulator and Related Products*)

  CMS lists all Comprehensive APCs that would be effective in CY 2020 in Table 4.

  CMS also mentions that elsewhere in the rule it is considering developing an episode-of-care for skin substitutes and seeks comment on a future Comprehensive APC for procedures using skin substitute products furnished in the HOPD (p. 70).

- *Comprehensive APC Exclusion of Procedures Assigned to New Technology APCs*: CMS states that services that are assigned to New Technology APCs do not typically have sufficient claims history on which to set accurate payment (p. 72). CMS notes, 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 is typically 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." (p. 73). 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) (p. 74) (*See also*, section on New Technology APCs). CMS notes that it received comments regarding whether the policy applied to "comprehensive observation services" (p. 74).[1] For CY 2020, ***CMS proposes that payment for services assigned to a New Technology APC on a claim for Comprehensive Observation Services ("J2" indicator) will be packaged into the payment for the comprehensive service; however, CMS seeks comment on whether it would be clinically appropriate to exclude payment for any New Technology APCs from being packaged into the comprehensive "J2" service*** (p. 75).

[1] "We would not generally expect [a new technology service when providing comprehensive observation services] to be the case, because procedures assigned to New Technology APCs typically are new or low-volume surgical procedures, or are specialized tests to diagnosis a specific condition. In addition, it is highly unlikely a general observation procedure would be assigned to a New Technology APC because there are clinical APCs already established under the OPPS to classify general observation procedures" (p. 75).

Composite APCs (p. 75)

CMS has had a policy since 2008 for Composite APCs which provide a "single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service."

- Mental health services (Composite APC 8010): ***CMS proposes to continue its Composite APC policy for APC 8010***. Additional information is available beginning on p. 76.
- Multiple imaging services (Composite APCs 8004, 8005, 8006, 8007, and 8008): ***CMS proposes to continue its Composite APC policy for APCs 8004, 8005, 8006, 8007, and 8008***. Additional information is available beginning on p. 78 and in Table 5.

Packaged Items and Services (p. 85)

CMS has relied on packaging policies in the OPPS to "maximize hospitals' incentives to provide care in the most efficient manner." CMS examined HCPCS code definitions and outpatient billing patterns, and ***CMS proposes to generally maintain its packaging policies*** (p. 87).

Non-Opioid Pain Management Treatments (p. 87): In CY 2018, CMS sought comment on clinical scenarios of currently packaged items that should not be packaged under the OPPS, specifically citing drugs that function as supplies. CMS revisited its discussion from the CY 2019 rulemaking cycle regarding Exparel as the only identified current non-opioid pain management drug that is packaged as a "drug that functions as a supply" under the OPPS and ASC payment system (p. 88). In CY 2019, CMS finalized a policy to unpackage a pay separately (at ASP+6%) for Exparel in the ASC setting but refrained from doing so in OPPS setting due to a lack of evidence to support separate payment for non-opioid pain management in the hospital outpatient setting (p. 92). ***CMS proposes to continue its policy to pay separately (ASP +6%) for non-opioid pain management drugs that functions as surgical supplies in the ASC setting (but continue packaging in the OPPS setting)*** (p. 96).

CMS also notes that The SUPPORT Act, passed in 2018, 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" (p. 93). As part of this review, the statute states that the Secretary shall make changes beginning on or after January 1, 2020. CMS stated that its review included "services assigned to C-APCs, surgical APCs, and other pain management services" (p. 94).

- Peripheral Nerve Blocks and Neuromodulation: CMS states that the data "showed consistent or increasing utilization in receive years, with no products showing decreases in utilization" (p. 94).
- Drugs That Function as Surgical Supplies: CMS did not observe significant declines in the total number of units used in the hospital outpatient department, stating that it often saw the opposite effect (including for Exparel) (p. 94).

Based on its review, ***CMS states that it does not believe that there are no 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 this time*** (p. 95).[2] CMS notes that it received stakeholder comment to cinlude separate payment for:

- Continuous nerve blocks (including a disposable elastomeric pump that delivers non-opioid local anesthetic to a surgical sitte or nerve)
- Cooled thermal radiofrequency ablation

[2] CMS states that the Medicare Payment Advisory Commission (MedPAC) March 2019 Report to Congress supports CMS' conclusion (p. 97).

- Local anesthetics designed to reduce post-op pain for cataract surgery and other procedures.

Still, ***CMS requests public comments to support whether other products help deter or avoid opioid use and addiction with evidence that the packaging policies present a barrier to access to that care*** (p. 97).

OPPS Payments to Certain Cancer Hospitals (p. 121)

The 11 PPS-exempt cancer hospitals, while exempted from the Inpatient Prospective Payment System, are paid under the OPPS for covered outpatient services. The Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) required that designated cancer (as well as children's) hospitals receive OPPS payments based on their pre-Balanced Budget Act of 1997 (BBA) payment amounts so as to be "held harmless" from otherwise mandated cuts. This means that these cancer hospitals are paid for covered outpatient services at rates that they would have received prior to the implementation of the OPPS. The ACA required the Secretary to conduct a study to determine whether the 11 cancer hospitals did, in fact, have outpatient costs that exceeded other hospitals' costs. The ACA required that the Secretary take into consideration of drugs and biologicals. If the Secretary determined that the costs were indeed greater, then the Secretary should provide an appropriate adjustment to reflect those higher costs.

- The Secretary conducted the requisite study in 2011 and found that the 11 cancer hospitals did have greater outpatient costs than other OPPS hospitals. Based on this information, in CY 2012, CMS finalized a policy to provide additional payments to these cancer hospitals.
- The 21st Century Cures Act amended statute to mandate that the payment adjustment for services furnished on or after January 1, 2018, the target payment-to-cost ratio (PCR) adjustment should be reduced by 1 percentage point less than would otherwise apply and that the Secretary may consider making an additional percentage reduction to the target PCR that takes into account payment rates for applicable items and services furnished by an off-campus outpatient department of a provider and paid under a payment system under than the OPPS for hospitals that are not cancer hospitals. The statute also states that in making budget neutrality adjustments, the Secretary shall *not* take into account reduced expenditures for applicable items and services furnished by an off-campus outpatient department of a provider and paid under a payment system under than the OPPS (p. 124).
- ***CMS proposes to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR/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 is not proposing an additional reduction beyond the 1 percentage point*** (p. 124).
- For CY 2020, CMS estimates that other OPPS hospitals are approximately 90 percent of those of the 11 cancer hospitals (defined as the "percent of reasonable cost."). In applying the statutory 1 percentage point reduction, ***CMS proposes that the payment among associated with the cancer hospital payment adjustment is a proposed target PCR of 0.89 percent for each cancer hospital*** (p. 126).
- Table 6 shows the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2020.

Hospital Outpatient Outlier Payments (p. 127)

CMS provides outlier payments "to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss."

- CMS stated that CY 2019 outlier payments are provided when the cost of furnishing the service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount by at least $4,825 (p. 131). If the costs exceed both of those thresholds, the hospital receives an outlier payment at 50 percent of the amount that surpassed the thresholds.
- CMS attempts to maintain a target of no more than 1 percent of OPPS spending in outlier payments. CMS estimates that CY 2019 aggregate outlier payments will be approximately 1.03 percent of total OPPS payments. ***CMS proposes to continue its policy of estimating aggregate outlier payments at 1 percent of total payments under the OPPS*** (p. 128).
- In order to maintain outlier payments at 1 percent of OPPS spending, ***CMS is proposing to maintain the percentage threshold for outlier payments at 1.75 times the APC payment amount; CMS is proposing to increase the dollar amount threshold to $4,950*** (p. 129).

APC Group Policies

New CPT and Level II HCPCS Codes (p. 144)

Upon creation of new Level II HCPCS codes, CMS will assign the new codes to an interim status indicator and APC assignment through the quarterly update process and will finalize the policies in the OPPS/ASC final rule. Table 9 outlines the CMS timeframe for taking comments on new codes.

CMS is currently seeking comment on the APC assignments and status indicators for the following categories of codes:

- CMS states that for the April 2019 update there were no new CPT codes. However, CMS introduced 8 new Level II HCPCS codes which were effective April 1, 2019 (p. 146). These codes can be found in in Table 7.
- New HCPCS Codes Implemented in July 2019 in Table 8.
- New HCPCS Codes that will be effective on October 1, 2019. ***CMS proposes to continue its policy of assigning thse new codes an interim payment status of "NI" in Addendum B*** (p. 157).
- New and Revised HCPCS Codes Effective January 1, 2020: The codes are available for review in Addendum B with an "NP" comment indicator to indicate that the code is new for the next calendar year *or* it is an existing code that underwent a substantial revision to its code descriptor in the next calendar year (compared to the current calendar year) (p. 158; p. 160)

Variation Within APCs (p. 162)

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") (p. 164).

- When reassignments are necessary, in some cases, CMS proposes 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.
- CMS lists the reassignments to avoid violation of this rule on its Web site in Addendum B with the "CH" comment indicator.

CMS often makes exceptions when the 2 Times Rule has been violated, typically in cases of low-volume items or services (although the statute prohibits the Secretary may not make an for orphan drugs). ***CMS identified 18***

violations of the 2 times rule for CY 2020, and CMS determined that all 18 violations qualified for an exception (p. 167). CMS lists the 16 APCs where it proposes exceptions to the 2 times rule for CY 2018 in Table 10.

New Technology APCs (p. 168)

For CY 2020, CMS is including the proposed payment rates for New Technology APCs 1491 through 1599 and 1901 through 1908 in Addendum A to this CY 2020 OPPS proposed rule. Addendum B, also on the CMS website, includes the proposed payment rates by HCPCS codes.

Establishing Payment Rates for Low-Volume New Technology Procedures (p. 171)
CMS is proposing to continue to apply the policy adopted in CY 2019 under which CMS will 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.

Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1575, 5114, and 5414) (p. 176)
Currently, there are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which CMS is proposing to continue to assign to standard APCs and one that CMS is proposing to continue to assign to a New Technology APC for CY 2020. These codes include CPT 0071T and 0072T (procedures for the treatment of uterine fibroids), 0398T (procedures for the treatment of essential tremor), and HCPCS C9734 (procedures for pain palliation for metastatic bone cancer).

As shown in Table 11, CMS is proposing to continue to assign the procedures described by CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with status indicator "J1" (Hospital Part B services paid through a comprehensive APC). In addition, CMS is proposing to continue to assign the services described by HCPCS C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) to APC 5115 (Level 5 Musculoskeletal Procedures), with status indicator "J1".

For the procedure described by CPT 0398T, ***CMS is proposing to estimate the cost for the procedure by applying the median cost and assigning the procedure to APC 1575 (New Technology - Level 38 ($10,001-$15,000)), with a proposed payment rate of $12,500.50 for CY 2020, which would reflect no change from CY 2019.***

Retinal Prosthesis Implant Procedure (p. 180)
CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. The number of reported claims for the Argus® II procedure continues to be very low, with a substantial fluctuation in cost from year to year. Based on review of geometric mean, arithmetic mean, and median, ***CMS is proposing to maintain the assignment of the procedure described by CPT 0100T in APC 1908 (New Technology - Level 52 ($145,001-$160,000)), with a proposed payment rate of $152,500.50 for CY 2020.*** CMS notes that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841).

Additionally, CMS previously found that payment for the Argus® II procedure was sometimes bundled into the payment for another procedure, and therefore, ***CMS is proposing to continue the policy implemented in CY 2019 based on this finding to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C-APC.*** The proposal would continue to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator "J1." ***While CMS is not proposing to exclude payment for a***

procedure assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator "J2," CMS is seeking public comments on this issue.

Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (p. 187)
Effective January 1, 2019, CMS established HCPCS C9751 (*Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)*). CMS has not received any claims data for this service. Therefore, ***CMS is proposing to continue to assign the procedure described by HCPCS C9751 to New Technology APC 1571 (New Technology - Level 34 ($8,001-$8,500)), with a proposed payment rate of $8,250.50 for CY 2020.***

Pathogen Test for Platelets (p. 188)
Currently, there are two rapid bacterial detection tests cleared by the FDA that are described by HCPCS P9100. Based on CY 2018 claims data, for CY 2020, ***CMS proposes reassigning the service described by HCPCS P9100 to New Technology APC 1494 (New Technology - Level 1D ($31-$40)), with a proposed payment rate of $35.50***, which would provide higher payment than its current New Technology APC 1493 (*New Technology - Level 1C ($21-$30)*), with a payment rate of $25.50.

Fractional Flow Reserve Derived From Computed Tomography (FFRCT) (p. 189)
Fractional Flow Reserve Derived From Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. Based on CY 2018 claims data, ***CMS proposes reassignment of the service described by CPT 0503T to New Technology APC 1509 (New Technology - Level 9 ($701 - $800)), with a proposed payment rate of $750.50 for CY 2020***, which would provide lower payment than its current New Technology APC 1516 (*New Technology - Level 16 ($1,401 - $1,500)*), with a payment rate of $1,450.50.

APC-Specific Policies (p. 190)

CMS is proposing to make changes to APC clinical families to achieve better clinical and resource homogeneity.

- *Intraocular Procedures* (p. 190): CMS discusses its review of Intraocular APCs (APC 5491 -APC 5494) on p. 191. CMS cites that CPT 0308T (*Insertion of ocular telescope including removal of crystalline lens or intraocular lens prosthesis*) has historically been assigned to APC 5495. However, in the CY 2019 OPPS final rule, because of having so few claims for CPT 0308T, CMS finalized the deletion of APC 5495 (*Level 5 Intraocular Procedures*) and reassigned CPT 0308T to APC 5494 (*Level 4 Intraocular Procedures*). Since that time, CMS received several claims more claims for 0308T, which showed a geometric mean cost much great than is supported by APC 5494. Based on the new information available, ***CMS proposes to reestablish APC 5494 (Level 5 Intraocular Procedures) and reassign CPT 0308T to the reestablished APC 5495*** (p. 192). CMS states that it believes the proposal is appropriate and would address a large discrepancy in payment that had occurred between reimbursement under the OPPS compared with the ASC setting. CMS says it will continue to monitor the volume of claims for future ratesetting.

- *Musculoskeletal Procedures* (p. 193): CMS is not proposing changes to the structure of the Musculoskeletal APCs for CY 2019 (p. 194). However, CMS again visits that there have been concerns about the granularity of the current APCs and request for additional levels. CMS also notes that this is the first year for which it has claims data for CPT 27447 (*Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing [total knee arthroplasty]*) in the

OPPS setting after being removed from the Inpatient Only list (p. 194). CMS received claims for approximately 60,000 procedures with a geometric mean cost of $12,472.05. Based on this information, ***CMS proposes to continue to assign CPT 27447 to APC 5115 (Level 5 Musculoskeletal Procedures)*** (p. 194). CMS notes that elsewhere in the rule it proposes to remove CPT 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft*) from the Inpatient Only list. ***CMS proposes to assign CPT 27130 to APC 5115 (Level 5 Musculoskeletal Procedures)*** (p. 195). See Table 13 for CY 2020 Musculoskeletal APCs and proposed geometric mean costs.

OPPS Payment for Devices (p. 195)

Pass-Through Payments for Devices

The period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. The pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category. Prior to CY 2017, device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through status payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period, CMS changed its policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. CMS also has an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates.

There currently is one device category eligible for pass-through payment: HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), which was established effective January 1, 2019. The pass-through payment status of the device category for HCPCS code C2624 will expire on December 31, 2022. Therefore, HCPCS code C2624 will continue to receive device pass-through payments in CY 2020.

New Device Pass-Through Applications (p. 197)

CMS received seven complete applications by the March 1, 2019 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this CY 2020 OPPS/ASC proposed rule. None of the applications were approved for device pass-through payment during the quarterly review process.

- ***Surefire® Spark™ Infusion System***: flexible, ultra-thin microcatheter with a self-expanding, nonocclusive one-way microvalve at the distal end featuring Pressure Enabled Drug Delivery™ technology to overcome intratumoral pressure in solid tumors and improve distribution and penetration of therapy during Transcatheter Arterial Chemoembolization (TACE) procedures. CMS identified several existing pass-through payment categories that may be applicable to the technology. It also raises concerns that large-scale studies with long-term follow-up are limited, that the majority of studies presented had a sample size of less than 25 and the highest sample size presented was less than 100 patients, and that patient follow-up occurred mostly within a 3 to 6 month timeframe with few studies occurring beyond this range. CMS asserts that additional data on mortality endpoints would be helpful to fully assess substantial clinical improvement. CMS believes the technology meets the cost significance requirements, and invites public comments on whether the technology meets the device pass-through payment criteria. (p. 202)

- ***TracPatch***: wearable device which utilizes an accelerometer, temperature sensor and step counter to allow the surgeon and patient to monitor recovery and help ensure critical milestones are being met. While CMS has determined that the technology is not a material or supply furnished incident to a service, it has concerns with the technology's eligibility because the devicve is not surgically implanted or inserted into the patient or applied in a wound or on other skin lesions. CMS did not identify an existing pass-through payment category that describes the technology, but expresses concerns that there is insufficient information to determine whether the use of the technology is a substantial clinical improvement over the current methods to monitor recovery from total knee arthroplasty. CMS asserts the technology appears to meet the cost significance requirements. CMS invites public comments on whether the technology is exempt from FDA clearance (as stated by the applicant) and whether it meets the device pass-through payment criteria. (p. 208)

- ***Vagus Nerve Stimulation (VNS) Therapy® System for Treatment Resistant Depression (TRD)***: a programmable electronic pulse generator and a bipolar electrical lead that is connected to the programmable electronic pulse generator to provide indirect modulation of brain activity through the stimulation of the vagus nerve. The technology was introduced to the market in September 2005, which means the device pass-through payment application would have needed to be submitted to CMS by September 2008. However, the pass-through application for the device was not received by CMS until March 2019. CMS also notes that it appears that the neurostimulator device used to treat treatment resistant depression (TRD) is the same device that has been used since 1997 to treat epilepsy. CMS has determined that the technology is not a material or supply furnished incident to a service, but questions whether the category descriptor suggested by the applicant is already represented by HCPCS C1767 (*Generator, neurostimulator (implantable), non-rechargeable*). CMS is concerned that the clinical utility of the technology has not been well demonstrated by the applicant, but asserts that the technology appears to meet the cost significance requirements. CMS invites public comments on whether the technology meets the device pass-through payment criteria. (p. 213)

- ***Optimizer® System***: implantable device that delivers Cardiac Contractility Modulation (CCM) therapy for the treatment of patients with moderate to severe chronic heart failure. CMS did not identify an existing pass-through payment category that describes the technology. CMS notes several concerns with the studies presented by the applicant – questioning the strength of the conclusions related to the use of CCM therapy improving patient outcomes, whether the included study population was representative of the Medicare beneficiary population, and noting the lack of evidence from large trials for the technology. CMS believes that the technology meets the cost significance requirements, and invites public comments on whether the technology meets the device pass-through payment criteria. (p. 237)

- ***Aqua Beam® System***: device intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) using a high velocity, nonheated sterile saline water jet (in a procedure called Aquablation). CMS did not identify an existing pass-through payment category that describes the technology, but expresses concerns that there is a lack of sufficient evidence that the technology provides a substantial clinical improvement over other similar products, particularly in the outpatient setting where large prostates are less likely to be treated. CMS believes that the technology meets the cost significance requirements, and invites public comments on whether the technology meets the device pass-through payment criteria. (p. 245)

- ***Eluvia™ Drug-Eluting Vascular Stent System***: sustained-release drug-eluting stent indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or the proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm. CMS did not identify an existing pass-through payment category that describes the technology, but expresses concerns that there is a lack of sufficient evidence that the technology provides a substiantial clinical improvement over other similar products. CMS does not believe the technology meets the second or third cost significance requirements, and invites public comments on whether the technology meets the device pass-through payment criteria. (p. 253)

- ***AUGMENT® Bone Graft***: a device/drug indicated for use as an alternative to autograft in arthrodesis of the ankle and/or hindfoot where the need for supplementa l graft material is required, composed of recombinant human platelet-derived growth factor-BB (rhPDGF-BB) solution (0.3 mg/mL) and Beta-tricalcium phosphate (β-TCP) granules (1000 – 2000 µm). CMS did not identify an existing pass-through payment category that describes the technology. CMS notes that the findings of a randomized, nonblinded, placebo controlled, noninferiority trial of the technology versus autologous bone graft were not tested for significance and were also not necessarily focused on relevance to the procedure. Should the findings be significant and related to the device, CMS notes they may suggest that the adverse outcomes due to the technology may outweigh its potential benefits. CMS also expresses concerns about whether the technology meets the second cost significance requirement. CMS invites public comments on whether the technology meets the device pass-through payment criteria. (p. 270)

RFI on OPPS Device Pass-Through Substantial Clinical Improvement Criterion (p. 277)

As CMS did in the FY 2020 Inpatient Prospective Payment System (IPPS) proposed rule in reference to IPPS New Technology Add On Payments, CMS discussed feedback from applicants on payments for new technology, here for device pass through payments, and have indicated that it would be helpful for CMS to provide greater guidance on what constitutes "substantial clinical improvement." ***CMS also referenced the specific questions on which it requested input in the FY 2020 IPPS proposed rule and continues to seek input in the context of the OPPS***.

Proposed Alternative Pathway to Device Pass-Through Substantial Clinical Improvement Criterion for "Transformative New Devices (p. 279)

Stakeholders over the years have requested that new technologies that receive marketing authorization and are part of an FDA expedited program be deemed as representing a substantial clinical improvement for purposes of OPPS device pass-through status (p. 280). CMS agrees that it would be appropriate to develop an alternative pathway for transformative medical devices.

In situations where a new medical device is part of the Breakthrough Devices Program and has received FDA marketing authorization (that is, the device has received PMA; 510(k) clearance; or the granting of a De Novo classification request), ***CMS proposes an alternative outpatient pass-through pathway*** (p. 281). Specifically, ***CMS proposes that, for applications received for pass through payments beginning on or after January 1, 2020, if a medical device is part of the FDA's Breakthrough Devices Program and received FDA marketing authorization, it would not be evaluated in terms of the current substantial clinical improvement criterion (although would need to meet the other criterion for pass-through status)*** (p. 282). Devices that are approved for OPPS device transitional pass through payment can be approved through the quarterly process already in effect. CMS notes that this proposal is designed to align with its proposal for New Technology Add-on Payments under the IPPS.

Device-Intensive Procedures (p. 283)

Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that given APC. In the CY 2017 OPPS/ASC final rule, CMS changed its methodology to assign device-intensive status at an individual HCPCS code level rather than at the APC level (p. 284). Procedures that meet the criteria listed below are identified as device-intensive procedures and are subject to all the relevant policies, including policies on device edits and no cost/full credit and partial credit devices discussed below.

Device-intensive procedures require the implantation of a device and additionally had been subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as "exceeding 40 percent of the procedure's mean cost."

For CY 2019, CMS modified the criteria "to better capture costs for procedures with significant device costs" (p. 286). First, CMS finalied that it would allow procedures that involve surgically inserted or implanted, single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. Second, CMS modified its criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive. Therefore, beginning in CY 2019 and for subsequent years, CMS' defines device-intensive as those that meet the following criteria (p. 287):

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost.

In addition, to further align the device-intensive policy with the criteria used for device pass-through status, CMS also finalized for CY 2019 and subsequent years that, for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that (p. 288):

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:
    - Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or
    - A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In accordance with the policy of lowering the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, CMS finalized a policy to apply a 31-percent default device offset to new HCPCS codes describing procedures

requiring the implantation of a medical device that do not yet have associated claims data, until claims data are available to establish the HCPCS code-level device offset for the procedures (p. 289). CMS also continued its policy of, in certain rare instances, temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a manufacturer (p. 289).

In addition, CMS clarified that the associated claims data used for purposes of determining whether to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, in limited instances where a new HCPCS code does not have a predecessor code but describes a procedure that was previously described by an existing code, CMS finalized that it would use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (p. 290). CMS will apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage (p. 290).

If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage will be used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage will be used to determine whether the new HCPCS code qualifies for device- intensive status (p. 291).

For CY 2020, CMS does not propose any changes to its device-intensive policy. The full list of proposed CY 2019 OPPS device-intensive procedures provided in Addendum P.

Device Edit Policy (p. 292)

CMS is not proposing any changes to current policy (p. 293).

Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices (p. 293)

For CY 2017 and subsequent years, CMS finalized its policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code "FD" when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. CMS updated the policies to align with the new device intensive policies for CY 2019. ***CMS proposes to continue to apply its no cost/full credit and partial credit device policies without modification*** (p. 295).

Low Volume Device Intensive Procedures (p. 295)

For CY 2020, ***CMS proposes to continue with its current policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost*** (p. 297).

For CY 2020, CMS has identified that this policy would apply to CPT 0308T (*Insertion of ocular telescope including removal of crystalline lens or intraocular lens prosthesis*) (which CMS proposes to assign to APC 5495 (*Level 5 Intraocular Procedures*); based on its low volume device policy, ***CMS proposes a payment rate of $19,740 (the mean cost)***; the geometric mean cost is approximately $28,237 (p. 298).

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals (p. 298)

CMS currently makes transitional pass through payments for certain drugs and biologicals. As in the case of devices, pass-through eligibility is for at least 2 but not longer than 3 years.

- In addition, the BBRA requires that the Secretary make additional payments to hospitals for orphan drugs (as defined under law) as well as drugs and biological and brachytherapy sources used in cancer therapy and radiopharmaceutical drugs and biologicals for which payment was made as of the date the OPPS was implemented.
- Transitional pass-through payments are also provided for new drugs and biologicals where the cost is "not insignificant" relative to the OPPS payment for the procedure or services associated with the drug or biological.
- Beginning with pass-through drugs and biologicals newly approved in CY 2017, CMS allows for a quarterly expiration of pass through status to afford a pass through period as close to the 3 year maximum as possible.

CY 2020 pass-through drugs and biologicals (and their designated APCs) can be found in Addenda A with a status indicator of "G."

Proposed Drugs and Biologicals with Expiring Pass-Through Status (*p. 301*)

CMS proposes that the pass-through payment status of six (6) drugs and biologicals would expire on December 31, 2019, as listed in Table 14. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status, CMS' standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be $130 for CY 2020). ***CMS proposes that if the estimated per day cost for the drug or biological is less than or equal to the applicable packaging threshold, it would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, CMS proposes to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2020)*** (p. 302)***.***

The proposed packaging or separately payable status of each of the drugs and biologicals with expiring pass-through status can be be found in Addendum B.

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2020 (p. 303)

CMS proposes to continue pass-through payment status in CY 2020 for 61 drugs and biologicals. These drugs and biologicals are listed in Table 15. In addition, there are four products that have already had 3 years of pass-through payment status but for which pass-through payment status is required to be extended for an additional 2 years per the Consolidated Appropriations Act of 2018, which means the last 9 months of pass-through status for these drugs will occur during CY 2020 (p. 303). That brings the total number of drugs and biologicals with proposed pass-through payment status in CY 2019 to 65.

For CY 2020, ***CMS proposes to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2020*** (p. 304)***. CMS proposes that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2020 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0***.

In the case of policy-packaged products, CMS proposes that their pass-through payment amount would be equal to ASP+6 percent for CY 2020 minus a payment offset for any predecessor drug products contributing to the pass-through payment (p. 304).

CMS proposes to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2020 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary (p. 304).

For CY 2020, CMS proposes to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP+6 methodology. ***If ASP data are not available for a radiopharmaceutical, CMS proposes to provide pass-through payment at WAC+3 percent***, the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. ***If WAC information also is not available, CMS proposes to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP*** (p. 304).

Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Sec. 1301 of the Consolidated Appropriations Act of 2020 (p. 310)

Section 1301(a)(1) of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141) provides that for drugs or biologicals whose period of pass-through payment status ended on December 31, 2017 and for which payment was packaged into a covered hospital outpatient service furnished beginning January 1, 2018, such pass-through payment status shall be extended for a 2-year period beginning on October 1, 2018 through September 30, 2020. There are four products[3] whose period of drugs and biologicals pass-through payment status ended on December 31, 2017. These products are listed in Table 16.

CMS proposes to extend pass-through payment for these drugs and biologicals through September 30, 2020 (p. 311). CMS proposes to continue to update pass-through payment rates for these drugs and biologicals on a quarterly basis on the CMS website during CY 2020 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment.

Included as drugs and biologicals with pass-through payment status under this provision are HCPCS Q4195 (*Puraply, per square centimeter*) and Q4196 (*Puraply am, per square centimeter*) both included as successor codes to HCPCS code Q4172 (*PuraPly, and PuraPly Antimicrobial, any type, per square centimeter*). PuraPly is a skin substitute product that was approved for pass-through payment status on January 1, 2015, through the drug and biological pass-through payment process. Beginning on April 1, 2015, skin substitute products were evaluated for pass-through payment status through the device pass-through payment process. However, CMS stated in the CY 2015 OPPS/ASC final rule that skin substitutes that are approved for pass-through payment status as biologicals effective on or before January 1, 2015 would continue to be paid as pass-through biologicals for the duration of their pass-through payment period. Because PuraPly was approved for pass-through payment status through the drug and biological pass-through payment pathway, CMS finalized a policy consider PuraPly to be a drug or biological and to be eligible for extended pass-through payment (p. 312).

[3] CMS notes that in CY 2019, HCPCS Q4172 (*PuraPly, and PuraPly Antimicrobial, any type, per square centimeter*) was discontinued and replaced with two new codes: HCPCS Q4195 (*Puraply, per square centimeter*) and Q4196 (*Puraply am, per square centimeter*). Given that the new codes are direct successors to HCPCS Q4172, they are included in this list (p. 310).

Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups (p. 313)

CMS deducts from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This is called the payment offset. The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals. For CY 2020, ***CMS proposes to continue to apply its policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes***. The proposed APCs to which a payment offset may be applicable for these products are identified in Table 17.

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status (p. 315)

CMS pays for drugs, biologicals, and radiopharmaceuticals either as a packaged item within an APC or separately (in which the item has its own APC). ***CMS sets a cost threshold for packaging based on cost and is proposing a packaging threshold for CY 2020 of $130*** (p. 316).

Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals under the Cost Threshold ("Threshold-Packaged Drugs") (p. 316)

As noted above, ***CMS proposes 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*** (p. 318)***.*** CMS policy has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule.

For the calculation of per day costs of HCPCS codes, CMS proposes to use ASP data from the fourth quarter of CY 2018, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2019 (p. 317).

Payment rates for HCPCS codes for separately payable drugs and biologicals will be based on ASP data from the third quarter of CY 2019 (p. 318). These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2019. These payment rates are then updated in the January 2020 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2020 (p. 319). ***For items that do not currently have an ASP-based payment rate, CMS proposes to recalculate their mean unit cost from all of the CY 2018 claims data and updated cost report information available for the CY 2020 final rule with comment period to determine their final per day cost*** (p. 319).

The packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule. Under such circumstances, ***CMS proposes to continue to follow established policies*** (p. 319).

Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages (p. 322)

CMS proposes to continue its policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages (p. 322). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2020 is displayed in Table 18.

Proposed Payment for Items without Pass-Through Status That Are Not Packaged (p. 324)

- CMS proposes to continue to apply the same payment policy to all separately payable drugs and biologicals and the statutorily defined "specific covered outpatient drugs" or SCODs. (p. 328)
- CMS proposes to continue its payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent. (p. 328)
- CMS proposes to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (although seeks additional comments on alternative policies) (p. 327)
- In the case of a drug or biological during an initial sales period in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer, the Secretary may make payments that are based on WAC. In the CY 2019 PFS proposed rule, CMS proposed that, effective January 1, 2019, WAC-based payments for Part B drugs would utilize a 3-percent add-on in place of the 6-percent add-on that had been previously used. For the CY 2020 OPPS, CMS proposes to continue to utilize a 3-percent add-on instead of a 6-percent add-on for WAC-based drugs (p. 328). CMS also applies this provision to non-SCOD separately payable drugs. CMS proposes that its policy 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 (p. 329). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 percent) would continue to apply. (p. 329)
- In the CY 2018 OPPS/ASC final rule, CMS finalized its proposed payment policy for biosimilar biological products, with the following technical correction: all biosimilar biological products will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product.
- In addition, in CY 2018, CMS adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid ASP (of the biosimilar) minus 22.5 percent of the reference product. In CY 2019, CMS changed the payment methodology for biosimilars acquired under the 340B Program. Specifically, in CY 2019, CMS finalized paying nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP; however, CMS seeks input on the appropriate remedy if there is an adverse decision on the appeal in the related litigation (See below) (p. 334).
- For CY 2020, CMS proposes to continue the payment policy for therapeutic radiopharmaceuticals as used since CY 2010. (p. 334)
- For CY 2020, CMS proposes to continue to pay for blood clotting factors at ASP+6 percent and to continue its policy for payment of the furnishing fee using an updated amount based on the Consumer Price Index for medical care. (p. 336)
- For CY 2022, CMS proposes to continue to use the same payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. The proposed CY 2019 payment status of products with HCPCS codes but without OPPS hospital claims data is listed in Addendum B (p. 337).

CY 2020 OPPS Payment Methodology for 340B Purchased Drugs (p. 337)

In this section, CMS provides a history of its attempt to address concerns about the Medicare Part B drug payment methodology for 340B hospitals. CMS explains that its finalized policy, which adjusted the payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP)+6 percent to ASP minus 22.5 percent, are the subject of ongoing litigation.[4] The United States District Court for the District of Columbia concluded that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent. CMS respectfully disagreed with the district court's understanding of the scope of its adjustment authority and asked the district court to enter final judgment so as to permit an immediate appeal, which was granted. While CMS intends to pursue its appeal rights, it is taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal.

To that end, and given the significant economic impact on facilities and beneficiaries, ***CMS solicits initial public comment on how to formulate a solution that accounts for all of the complexities that the district court recognized (p. 343).*** CMS intends to use this public input to further inform the steps that are required under the Administrative Procedure Act to provide adequate notice and an opportunity for meaningful comment on proposed policies, which would entail devising the specific remedy itself, presenting the specific budget neutrality implications of that remedy in the proposed rule, and potentially calculating all the different payment rates under the OPPS for 340B-acquired drugs, as well as all other items and services under the OPPS. CMS anticipates proposing the specific remedy for CYs 2018 and 2019, as well as changes to the CY 2020 rates, in the next available rulemaking vehicle, which is the CY 2021 OPPS/ASC proposed rule.

For CY 2020, CMS proposes to continue to pay ASP-22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the PFS.

CMS also seeks public comment on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP+3 percent could be an appropriate remedial payment amount for these drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019. This amount would result in payment rates that are well above the actual costs hospitals incur in purchasing 340B drugs, and it is being proposed solely because of the court decision. However, to the extent the courts are limiting the size of the payment reduction the agency can permissibly apply, the agency believes it could be appropriate to apply a payment reduction that is at the upper end of that limit, to the extent it has been or could be clearly defined, given the substantial discounts that hospitals receive through the 340B program. ***CMS welcomes public comments on payment rates other than ASP+3 percent that commenters believe would be appropriate for purposes of addressing CY 2020 payment as an alternative to its proposal above, as well as for potential future rulemaking related to CY 2018 and 2019 underpayments.***

CMS also seeks public comment on how to structure the remedy for CYs 2018 and 2019. For example, whether such a remedy should be retrospective in nature (e.g., made on a claim-by-claim basis), whether such a remedy could be prospective in nature (e.g., an upward adjustment to 340B claims in the future to account for any underpayments in the past), and whether there is some other mechanism that could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting the budget neutrality mandate. CMS seeks public comment on a potential remedy for alleged underpayments in 2018 and 2019 that would involve making additional payments to the parties who have demonstrated harm from the alleged underpayments (*See*, p. 347), along with other suggested approaches.

[4] *American Hospital Association et al. v. Azar et al.*

In considering these potential future proposals, CMS would rely on its statutory authority for determining the OPPS payment rates for drugs and biologicals as well as to review certain components of the OPPS not less often than annually and to revise the groups, relative payment weights, and other adjustments. ***CMS solicits public comments on the best, most appropriate way to maintain budget neutrality, either under a retrospective claim-by-claim approach, with a prospective approach, or any other proposed remedy. CMS also solicits comment on whether, depending on the amount of those additional expenditures, it should consider spreading out the relevant budget neutrality adjustment across multiple years. CMS would be interested to receive public comment on the advantages and disadvantages of such an approach.***

In addition, ***CMS is interested in public comments on the best, most appropriate treatment of Medicare beneficiary cost-sharing responsibilities under any proposed remedy.***

Proposed High/Low Cost Threshold for Packaged Skin Substitutes (***p. 349***)

CY 2020 Packaged Skin Substitue Proposal

CMS has continued the high cost/low cost categories policy since it implemented its unconditional packaging policy in CY 2014 (p. 349) ***and proposes to continue it for CY 2020*** (p. 350). Under this policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes.

CMS proposes to continue to determine the high cost/low cost status for each skin substitute product based on either:

- ***The product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold (the proposed CY 2020 MUC threshold is $49 per cm^2)*** (p. 351); ***or***
- ***The product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold (the proposed CY 2020 PDC threshold is $789)***(p. 351)***.***

CMS proposes to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group; CMS proposes to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group (p. 351; p. 361). ***Any skin substitute product that was assigned to the high cost group in CY 2019 would be assigned to the high cost group for CY 2020, regardless of whether it exceeds or falls below the CY 2020 MUC or PDC threshold*** (p. 351; p. 361).

For CY 2020, CMS proposes to continue to assign skin substitutes with pass-through payment status to the high cost category (p. 352). Skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC will be assigned 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 proposes to use WAC+3 percent to assign a product to either the high cost or low cost category. If neither ASP nor WAC is available, CMS would use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. CMS proposes to use WAC+3 percent instead of WAC+6 percent to conform to its proposed policy to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2020 MUC threshold.

Table 19 displays the proposed CY 2019 high cost or low cost category assignment for each skin substitute product.

Potential Changes to Skin Substitute Payment Policy for CY 2020 or Future Years

CMS states that it has continued to receive requests for possible refinements to the existing payment methodology for skin substitutes that would be consistent with the policy goal of providing payment stability for these products. ***CMS recounted the four potential methodologies that it sought comment on during CY 2019 rulemaking*** (p.354), discussing two in more detail[5]:

- **Establish a lump-sum "episode-based" payment for a wound care episode[6]**. CMS stated that this option has been discussed the most (p. 355). Support cited for episode-based payments was based on:
    - Allowance for "health care professionals to choose the best skin substitute to treat a patients wound and would give providers flexibility with the treatments they administer" (p. 355)
    - Reduction of incentives for providers to use excessive applications of skin substitute products or to use higher cost products to generate more payment (p. 355)
    - Assistance with innovations with skin substitutes by encouraging the development of products that require fewer applications (p. 355)
    - Promotion of more predictable wound care payment for hospitals (p. 355)
    - Provision of an incentive to manage the cost of care (p. 355)
    - Belief that "workable quality metrics" could be developed to monitor the quality of care and limit excessive application (p. 355)

  CMS also noted, however, that there was also opposition to episode-based payments for skin substitutes based on:
    - The complexity and variability of wound care (p. 356)
    - Differences in patients and wounds (p. 356)
    - Difficulty in risk-stratification and specialty-adjustment that would be needed (p. 356)
    - Confusion about how episodes would be defined for patients with multiple wounds (either concurrent or successive) (p. 356)

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[5] The other two options discussed in the CY 2019 OPPS proposed rule included: (1) **Allow for the payment of current add-on codes or create additional procedure codes to pay for skin graft services between 26 sq cm and 99 sq cm and substantially over 100 sq cm**. Under this option, payment for skin substitutes would be made more granularly based on the size of the skin substitute product being applied. This option also would reduce the risk that hospitals may not use enough of a skin substitute to save money when performing a procedure. However, such granularity in the use of skin substitutes could conflict with the goals of a prospective payment system, which is based on a system of averages. Specifically, it is expected that some skin graft procedures will be less than 25 sq cm or around 100 sq cm and will receive higher payments compared to the cost of the services. Conversely, services between 26 sq cm and 99 sq cm or those that are substantially larger than 100 sq cm will receive lower payments compared to the cost of the services, but the payments will average over many skin graft procedures to an appropriate payment rate for the provider. (p. 284 of the CY 2019 OPPS Proposed Rule); and (2) **Keep the high cost/low cost skin substitute categories, but change the threshold used to assign skin substitutes in the high-cost or low-cost group.** Consider using other benchmarks that would establish more stable thresholds for the high cost and low cost groups. Ideas include, but are not limited to, fixing the MUC or PDC threshold at amount from a prior year, or setting global payment targets for high cost and low cost skin substitutes and establishing a threshold that meets the payment targets. Establishing different thresholds for the high cost and low cost groups could allow for the use of a mix of lower cost and higher cost skin substitute products that acknowledges that a large share of skin substitutes products used by Medicare providers are higher cost products but still providing substantial cost savings for skin graft procedures. Different thresholds may also reduce the number of skin substitute products that switch between the high cost and low cost groups in a given year to give more payment stability for skin substitute products. (p. 284 of the CY 2019 OPPS Proposed Rule).

[6] Per the CY 2019 OPPS proposed rule, under this option, a hospital would receive a lump sum payment for all wound care services involving procedures using skin substitutes. The payment would be made for a wound care "episode" (such as 12 weeks) for one wound. The lump sum payment could be the same for all skin substitutes or could vary based on the estimated number of applications for a given skin substitute during the wound care episode. Under this option, payment to the provider could be made at the start of treatment, or at a different time, and could be made once or split into multiple payments. Quality metrics, such as using the recommended number of treatments for a given skin substitute during a treatment episode, and establishing a plan of care for patients who do not experience 30-percent wound healing after 4 weeks, could be established to ensure the beneficiary receives appropriate care while limiting excessive additional applications of skin substitute products (*See*, p. 283 of the CY 2019 OPPS proposed rule).

- Concern about operational and administrative burden on providers (including managing an influx of new APCs that would be needed to administer an episode-based payment system) (p. 356)
- Concern about use on higher cost skin substitutes, which would in turn impact innovation the skin substitute arena (p. 356)

Because of the complexity and concerns around such a system, while CMS does not make a proposal, ***CMS does seek additional comment regarding substitute payment polices for future years*** (p. 357). CMS specifically seeks input on the following potential policies under consideration:

- Establishment of a payment period for skin substitute application services (defined as CPT 15271 – 15278; and HCPCS C5271 – C5278) between 4 weeks and 12 weeks (p. 357)
- Under this scenario, CMS would assign the codes to Comprehensive APCs (with the option for a complexity adjustment)

- **Eliminate the high cost/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products**[7]. CMS stated that this option also generated a significant number of comments (p. 357). Under this option, the only available procedure codes available would be CPT 15271 – 15278 with one APC for graft skin substitute application procedures (p. 358). Stakeholders who provided support for this option cited:
  - Removal of incentives for manufacturers to develop and for providers to use high cost skin substitute products (p. 358)
  - Lowering of copayments for beneficiaries (p. 358)
  - Removal of incentive to "apply skin substitute products in excessive amounts" (p. 358)
  - Lack of evidence showing one skin substitute as superior to another (p. 359)

  However, there were commenters who expressed concern about the option based on:
  - Lack of incentives to furnish quality care leading to reduction in use of higher cost products (p. 359)
  - Lack of maintenance of homogeneity in APC assignments for services using skin substitutes (p. 359)
  - Limitation on innovation given the category would favor less expensive products and potential elimination of most expensive products (p. 359)
  - Incentive to avoid treatment of wounds that are difficult to treat and costly (p. 359)

  CMS acknowledged the concerns but stated that it is "persuaded that a single payment category could potentially provide a more equitable payment for many products used with graft skin substitute procedures, while recognizing that procedures performed with expensive skin substitute products would likely receive substantially lower payment" and that this "more equitable payment rate . . . could substantially reduce the amount Medicare pays for these procedures" (p. 359).

[7] Per the CY 2019 OPPS proposed rule, under this option, CMS' expectation is that it would reduce the financial incentives to use expensive skin substitutes and would provide incentives to use less costly skin substitute products that have been shown to have similar efficacy treating wounds as more expensive skin substitute products. A single payment category would likely have a payment rate that is between the current rates paid for high cost and low cost skin substitute procedures. Initially, a single payment category may lead to substantially higher payment for skin graft procedures performed with cheaper skin substitutes as compared to their costs. However, over time, payment for skin graft procedures using skin substitutes might reflect the lower cost of the procedures. (p. 283 of the CY 2019 OPPS Proposed Rule).

CMS is seeking input on:

- ***The possibility of using a single payment category for skin substitute products under the OPPS***
- ***Delaying implementation of a single category of payment for 1 or 2 years after it is adopted***
- ***Gradually lowering the MUC and PDC thresholds over 2 or more years to add more products into the high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category***

Based on input received, CMS states that it would consider modifying its payment policy in the CY 2020 OPPS final rule (p. 360; p. 361).

Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices (p. 364)

Statute limits pass-through payment spending at 2.0 percent of total OPPS payments. ***CMS estimates that pass-through spending in CY 2020 would equal approximately $268.8 million (approximately $10.6 million for device categories and approximately $258.2 million for drugs and biologicals) which represents 0.34 percent of total projected OPPS payments for CY 2020 (approximately $80 billion)*** (p. 371)**.** Therefore, the 2% program spending limit is not exceeded.

OPPS Payment for Hospital Outpatient Visits (p. 372)

CMS proposes to continue its current payment policy for clinic, emergency department hospital outpatient visits, and critical care services without change. CMS seeks comments on whether CMS should consider changes to these codes in future rulemaking, including data analysis that would justify changes (p. 372). Elsewhere in the rule, CMS discusses the changes it has made in past rulemaking and going forward related to clinic visits furnished in *off-campus provider based departments*.

Inpatient Only Procedures

CMS conducts an annual assessment to identify procedures that would be paid only as inpatient procedures and therefore are not payable under the OPPS. CMS also reviews whether there are procedures on the list that should be removed (and thus payable under the OPPS). The criteria utilized by CMS for the analysis include (p. 408):

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be performed in most outpatient departments.
- The procedure is related to codes that CMS has already removed from the inpatient list.
- A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

A list of all codes on the Inpatient Only list are available in Addendum E.

Procedures Identified for Removal from the Inpatient Only List

For CY 2020, CMS has identified one (1) procedure that it proposes for removal from the Inpatient Only list (p. 409 and Table 24):

- ***CPT 27130*** (***Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft***). Additional information:
    - CMS has been discussing potential removal of total hip arthroplasty from the Inpatient Only list for years (p. 409).
    - CMS believes this meets the criteria that (p. 412):
        - "*the simplest procedure described by the code may be performed in most outpatient departments*"; and
        - "*the procedure is related to codes that we have already removed from the IPO list.*"
    - ***CMS proposes to assign CPT 27130 to Comprehensive APC 5115 (Level 5 Musculoskeletal Procedures)***

In addition to the code proposed for removal (included in Table 23), **CMS also seeks input on the *potential* removal of 6 additional codes:**

CPT	Descriptor	CMS Commentary
22633	*Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar*	CMS states that they believe that it has already removed codes from the IPO list that are similar to this code (i.e. CPT 22551 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2*). However, CMS is concerned that the data for this code does not provide a large enough sampling of outpatient procedures and do not address the criteria for removal from IPO list. CMS is seeking comment on the safety of performing this procedure in the outpatient hospital setting (p. 414).
22634	*Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar; each additional interspace and segment*	CMS states that they believe that it has already removed codes from the IPO list that are similar to this code (i.e. CPT 22551 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2*). However, CMS is concerned that the data for this code does not provide a large enough sampling of outpatient procedures and do not address the criteria for removal from IPO list. CMS is seeking comment on the safety of performing this procedure in the outpatient hospital setting (p. 414).
63265	*Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical*	CMS has received stakeholder input that this procedure should be considered "minimally invasive" and that it meets the requirement that "most outpatient departments are equipped to provide the services to the Medicare population" and "the simplest procedure described by the code may be performed in most outpatient departments." CMS states that it does not have enough information as to whether the code meets the criteria for removal. CMS seeks comment to demonstrate that the codes meet the criteria (p. 414).
63266	*Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic*	CMS has received stakeholder input that this procedure should be considered "minimally invasive" and that it meets the requirement that "most outpatient departments are equipped to provide the services to the Medicare population" and "the simplest procedure described by the code may be performed in most outpatient departments." CMS states that it does not have enough information as to whether the code meets the criteria for removal. CMS seeks comment to demonstrate that the codes meet the criteria (p. 414).
63267	*Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar*	CMS has received stakeholder input that this procedure should be considered "minimally invasive" and that it meets the requirement that "most outpatient departments are equipped to provide the services to the Medicare population" and "the simplest procedure described by the code may be performed in most outpatient departments." CMS states that it does not have enough information as to whether the code meets the criteria for removal. CMS seeks comment to demonstrate that the codes meet the criteria (p. 414).
63268	*Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral*	CMS has received stakeholder input that this procedure should be considered "minimally invasive" and that it meets the requirement that "most outpatient departments are equipped to provide the services to the Medicare population" and "the simplest procedure described by the code may be performed in most outpatient departments." CMS states that it does not have enough information as to whether the code meets the criteria for removal. CMS seeks comment to demonstrate that the codes meet the criteria (p. 414).

Changes in Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs

CMS has previously received concerns from the hospital community that critical access hospitals (CAHs) and small rural hospitals have a difficult time meeting the direct supervision requirements for hospital outpatient therapeutic services (and in provider based departments of hospitals). From 2010 to 2013, CMS had instructed all Medicare Administrative Contractors (MACs) to not evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs and small rural hospitals having 100 or fewer beds (p. 416). Congress extended the non-enforcement provision through December 31, 2016 (p. 416).

CMS continued to receive input about the difficulties of meeting the supervision requirements in these settings. CMS noted that it had not received quality complaints from beneficiaries or providers. Therefore, CMS finalized the reinstatement of the non-enforcement policy for direct supervision of outpatient therapeutic services for CAHs and small rural hospitals with 100 or fewer beds for CY 2018 and CY 2019 (currently set to expire December 31, 2019). The non-enforcement instruction is currently posted on the CMS Website.

CMS notes that it has comments stating that supervision requirements should be applied uniformly to ensure patient safety. In addition, CMS acknowledges that the enforcement instructions have "created a two-tiered system of physician supervision requirements for hospital outpatient therapeutic services for providers in the Medicare program, with direct supervision required for most hospital outpatient therapeutic services in most hospital providers, but only general supervision required for most hospital outpatient therapeutic services in CAHs and small rural hospitals with fewer than 100 beds" (p. 418). However, CMS states that it has not received any information that this has led to quality-related issues in these settings, noted that nothing precludes the sites from providing direct supervision, and stated that CAHs and hospitals are still subject to Condition of Participation requirements (p. 418).

CMS states that it believes "Medicare providers will provide a similar quality of hospital outpatient therapeutic services, regardless of whether the minimum level of supervision required under the Medicare program is direct or general" and that "the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers that reduces their flexibility to provider medical care" (p. 419). CMS goes on to state, "[W]e believe it is time to end what is effectively a two-tiered system of supervision levels for hospital outpatient therapeutic services" (p. 419). Therefore, ***CMS proposes to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from "direct supervision" to "general supervision"[8] for all hospitals and CAHs*** (p. 420). In addition, ***CMS seeks input on whether specific types of services (e.g. chemotherapy administration or radiation therapy) should be excepted from this proposal*** (p. 420).

[8] "General Supervision" is definied as "furnished under the the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure" (p. 420).

Short Inpatient Hospital Stays ("2 Midnight Rule")

Background. CMS reviewed its policies related to the 2 Midnight Rule for determining when an inpatient admission is considered "reasonable and necessary" for Part A payment (p. 421). CMS established a policy with "a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation"; in addition, admissions for services on the Inpatient Only list would be generally considered appropriate (p. 421). Additional guidance on medical reviews of admissions can be found on p. 423.

Rare and Unusual Circumstances Exception. CMS previously finalized a policy for case-by case exceptions to the 2 Midnight rule "whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inaptient hospital care" (p. 422).

Proposed Change for CY 2020 and Subsequent Years. CMS noted that if a procedure is removed from the Inpatient Only list are then "subject to initial medical reviews of claims for short-stay inpatient admissions conducted by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs)" that may also then refer providers to Recovery Audit Contractors (RACs) (p. 424). ***CMS proposes a one year exemption from RAC review for procedures that have been removed from the Inpatient Only list beginning in CY 2020*** *(p. 424)*. CMS notes that BFCC-QIOs might still review claims to provide education, but cannot be denied for site-of-service or referred to a RAC (p. 425). ***CMS specifically seeks input on the one year time frame and whether a shorter or longer exemption period would be appropriate*** (p. 425).

Off Campus Provider-Based Departments

Method to Control for Unnecessary Increases in the Volume of Outpatient Services (p. 426)

In the CY 2019 Medicare Physician Fee Schedule, CMS reviewed that the Bipartisan Budget Act of 2015 included a provision that "applicable items and services"[9] furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered OPD service . . . for purposes of payment under the OPPS and will instead be paid 'under the applicable payment system'; under Medicare Part B." The statute defines "off-campus outpatient department of a provider" as "a department of a provider . . . that is not located on the campus of such provider, or within the distance from a remote location of a hospital[10] facility." CMS previously finalized that the "applicable payment system" for the provisions covered by the Bipartisan Budget Act of 2015 would be the Medicare Physician Fee Schedule (MPFS). That is, most nonexcepted items and services furnished by off-campus PBDs will be paid under the MPFS. (p. 367 of the CY 2019 MPFS Proposed Rule).

CMS continued to believe "that the higher payment that is made under the OPPS, as compared to the payment under the PFS, is likely to be incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting" (p. 368 of the CY 2019 MPFS Proposed Rule). To address this ongoing site-of-service differential for what CMS views as the same service, CMS finalized a proposal to apply an amount equal to "the site-specific MPFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD" (i.e. the MPFS payment rate) for clinic visits (i.e., HCPCS G0463) when provided at an off-campus PBD excepted from the BBA provisions (p. 427). Non-excepted off-campus PBDs already receive a reduced rate from the usual OPPS rate. CMS is using its authority[11] to reduce the OPPS rates for G0463 visits (to match MPFS rates) for even those off-campus PBDs excepted from the BBA provisions. Those that were "excepted" under the statute were off-campus PBDs billing covered OPD services furnished "prior to November 2, 2015."

When CMS finalized this policy, it also finalized a two year phase in of the new payments (p. 427). In CY 2019, the policy would have generated a 60 percent reduction, but CMS reduced that by half so as to only implement a 30 percent reduction. For CY 2020, CMS had stated that it would apply the total reduction for departments that bill the ~PO modifier (*Excepted service provided at off-campus, outpatient, provider-based outpatient departments*). In essence, this requires in CY 2020 that departments that bill G0463 with the PO modifier will be paid 40 percent of the OPPS payment.

CMS proposes to continue a non-budget neutral application of the policy (p. 428).

[9] The statutory definition of "applicable items and services" specifically excludes items and services furnished by a dedicated emergency department. Therefore, these items and services will continue to be paid under the OPPS.

[10] Current regulation defines "remote location of a hospital" as "a facility or an organization that is either created by, or acquired by a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider . . ."

[11] As its authority, CMS cites Social Security Act §1833(t)(2)(F) (p. 370): "(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services"

Ambulatory Surgery Center Payment System (p. 433)

Definition of ASC Covered Surgical Procedures (p. 436)

As a reminder, in the CY 2019 OPPS/ASC final rule, CMS revised its definition of surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American Medical Association (AMA) defines as ''surgery'' (CPT codes 10000 through 69999), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that CMS has determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS.

Treatment of New and Revised Codes (p. 438)

April 2019 HCPCS Codes for Which CMS is Soliciting Public Comments in This Proposed Rule (p. 439)

Table 25 lists the new Level II HCPCS codes that were implemented April 1, 2019, along with their proposed payment indicators for CY 2020 (see Addendum BB, DD1 and DD2 for more details). ***CMS invites public comments on these proposed payment indicators and payment rates for the new HCPCS codes that were recognized as ASC ancillary services in April 2019 through the quarterly update CRs, as listed in Table 25. CMS proposes to finalize their payment indicators in the CY 2020 OPPS/ASC final rule with comment period.***

July 2019 HCPCS Codes for Which CMS is Soliciting Public Comments in This Proposed Rule (p. 441)

Table 26 lists the new HCPCS codes that are effective July 1, 2019 (see Addendum AA, BB, DD1 and DD2 for more details). In addition, through the July 2019 quarterly update CR, CMS is also implementing an ASC payment for one new Category III CPT code as an ASC covered ancillary service, effective July 1, 2019, listed in Table 27. ***CMS invites 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 2019 through the quarterly update CRs, as listed in Tables 25, 26, and 27. CMS proposes to finalize the payment indicators in the CY 2020 OPPS/ASC final rule with comment period.***

October 2019 HCPCS Codes for Which CMS Will Be Soliciting Public Comments in the CY 2020 OPPS/ASC Final Rule with Comment Period (p. 443)

CMS proposes that the Level II HCPCS codes that will be effective October 1, 2019, would be flagged with comment indicator "NI" in Addendum BB to the CY 2020 OPPS/ASC final rule with comment period to indicate that CMS has assigned the codes an interim ASC payment status for CY 2020. CMS will invite public comments in the CY 2020 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2021 OPPS/ASC final rule with comment period.

January 2020 HCPCS Codes (p. 444)

Level II HCPCS Codes for Which CMS Will Be Soliciting Public Comments in the CY 2020 OPPS/ASC Final Rule with Comment Period. CMS will incorporate those new Level II HCPCS codes that are effective January 1 in the CY 2020 OPPS/ASC final rule with comment period, as these codes are not released until sometime around November. Consistent with established policy, ***CMS proposes to assign comment indicator "NI" in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2020 to indicate that the agency is assigning them an interim payment indicator, which is subject to public comment.*** CMS will invite public comments in the CY 2020 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2021 OPPS/ASC final rule with comment period.

CPT Codes for Which CMS Will Be Soliciting Public Comments in in This Proposed Rule. ***For new and revised CPT codes effective January 1, 2020 that were received in time to be included in this proposed rule, CMS proposes the appropriate payment indicator assignments, and solicits public comments on the payment assignments.*** CMS will accept comments and finalize the payment indicators in the CY 2020 OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPS/ASC proposed rule, CMS may either make interim final assignments in the final rule with comment period or possibly use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until the agency can propose APC and status indicator assignments in the following year's rulemaking cycle.

Table 28 summarizes CMS' process for updating codes through its ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC.

Update to Lists of ASC Covered Surgical Procedures and Covered Ancillary Services (p. 448)

Covered Surgical Procedures Designated as Office-Based (p. 448)

Permanent office-based designations. CMS' review of the CY 2018 volume and utilization data resulted in the identification of 9 covered surgical procedures that meet the criteria for designation as permanently office-based (see Table 29), therefore, ***CMS proposes to permanently designate these 9 codes as office-based for CY 2020***.

CMS does not propose to designate CPT codes 36902 and 36905 (dialysis vascular access procedures) as office-based procedures. These procedures will retain their payment indicator of "G2" – non office-based surgical procedure based on OPPS relative weights.

- **CPT code 36902**: While this service was performed more than 50 percent of the time in physicians' offices based on 2018 volume and utilization data, its office-based utilization significantly fell between 2017 and 2018. CMS will reevaluate its decision when more data are available.
- **CPT code 36905**: Utilization data this code was not performed more than 50 percent of the time in physicians' offices.

Temporary office-based designations. Given a lack of CY 2018 claims data, ***CMS proposes to maintain the temporary office-based designations for 11 CPT codes for CY 2020 (see Table 30).***

- ***CMS proposes to assign CPT code 38222 (Diagnostic bone marrow; biopsy(ies) and aspiration(s)) a non-office-based payment indicator -- "G2" – for CY 2020, given CY 2018 data shows this code was not performed predominantly in physicians' offices.***

- ***CMS proposes to designate 7 new CY 2020 CPT codes for ASC covered surgical procedures as temporarily office-based (see Table 31) based on its review of clinical characteristics, utilization, and volume of related procedure codes.***

Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive (p. 456)

As a reminder, in the CY 2019 OPPS/ASC final rule with comment period, CMS modified its criteria for device-intensive procedures to better capture costs for procedures with significant device costs. Specifically, CMS adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. CMS specified that a device-intensive procedure must involve a device

that meets certain criteria. In addition, CMS modified its criteria to lower the device offset percentage threshold from 40 percent to 30 percent.

Based on the modified device-intensive criteria, for CY 2020, ***CMS proposes 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 this proposed rule.*** The ASC covered surgical procedures CMS proposes to designate as device-intensive for CY 2020 are assigned payment indicator "J8" and included in Addendum AA to this proposed rule.

CMS notes that it inadvertently omitted language finalizing its CY 2019 proposal to apply its device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system only when the device-intensive procedure is furnished with a surgically-inserted or implanted device (including single-used medical devices). As a result, ***for CY 2020 and subsequent calendar years, CMS proposes to only apply its device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices).*** The payment rate under the ASC payment system for device-intensive procedures furnished without an implantable or inserted medical device would be calculated by applying the uniform ASC conversion factor to both the device portion and service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure and summing both portions (device and service) to establish the ASC payment rate.

Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices (p. 459)

CMS is not proposing any changes to its existing policies finalized in the CY 2019 OPPS/ASC final rule with comment period.

Proposed Additions to the List of ASC Covered Surgical Procedures (p. 462)

Given the revised definition for ASC covered surgical procedures finalized in the CY 2019 OPPS/ASC final rule with comment period, ***CMS proposes to update the list of ASC covered surgical procedures by adding a mosiacplasty procedure and three coronary intervention procedures (including their add-on procedures) to the list for CY 2020 (See, Table 32).***

In addition, ***CMS proposes to add total knee arthroplasty (TKA) to the ASC CPL (see Table 32).*** Based on its review of encounter data, CMS notes that TKA is performed in ASCs on Medicare Advantage enrollees and believes traditional FFS beneficiaries should have this option based on their physicians' determinations. CMS is also persuaded by information received by commenters in support of adding TKA to the ASC CPL. Also, CMS believes TKA would meet its regulatory requirements for covered surgical procedures in the ASC setting.

Nevertheless, CMS highlights the fact that TKA procedures were still predominantly performed in the inpatient hospital setting in CY 2018 (82 percent of the time) based on professional claims data and the majority of beneficiaries may not be suitable candidates to receive TKA in an ASC setting. To provide safeguards for Medicare beneficiaries who should not receive the TKA procedure in an ASC setting, ***CMS seeks public comment on methods to ensure beneficiaries receive surgical procedures in the ASC setting only as clinically appropriate.*** Options CMS identifies include:

- A claims-based modifier to indicate the physician believes that the beneficiary would not be expected to require active medical monitoring and care at midnight following a particular procedure furnished in the ASC setting,
- requiring that an ASC has a defined plan of care for each beneficiary following a surgical procedure, and

- establishing certain requirements for ASCs that choose to perform certain surgical procedures on Medicare patients, such as requiring an ASC to have a certain amount of experience in performing a procedure before being eligible for payment for performing the procedure under Medicare.

CMS solicits comment on these options, and other options, for ensuring that beneficiaries receive surgical procedures, including TKA, that do not pose a significant safety risk when performed in an ASC.

CMS also solicits comment on how it should think about the role of the ASC-CPL compared to State regulations and market forces in providing payment for certain surgical procedures in an ASC and whether any modifications should be made to the ASC-CPL. Comments on this topic could help formulate the basis for future policy development regarding how CMS determines what procedures are payable for Medicare fee-for-service beneficiaries in the ASC setting and maintain the balance between safety and access. ***Finally, CMS seeks comment on how its proposed additions to the list of ASC covered surgical procedures might affect rural hospitals to the extent rural hospitals rely on providing such procedures.***

Comment Solicitation on Coronary Intervention Procedures. As noted above, CMS proposes to add three coronary intervention procedures (along with the codes describing their respective add-on procedures). CMS also reviewed several other coronary intervention procedures but did not believe the procedures (see Table 33) met the agency's criteria for inclusion on the ASC CPL at this time. However, ***CMS solicits comment on whether stakeholders believe they can be safely performed in an ASC setting and to provide any materials supporting their position.*** Comments should include information and data that address the agency's regulatory requirements. CMS will consider comments received in future rulemaking.

Covered Ancillary Services (p. 472)

CMS proposes to continue its policy of updating the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2020 OPPS. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2019, but is proposed for packaged status under the CY 2020 OPPS, CMS would also propose to package the ancillary service under the ASC payment system for CY 2020. All ASC covered ancillary services and their proposed payment indicators for CY 2020 are included in Addendum BB to this proposed rule.

Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services (p. 473)

Proposed ASC Payment for Covered Surgical Procedures (p. 473)

CMS proposes to update ASC payment rates for CY 2020 and subsequent years using the established rate calculation methodologies and using the definition of device-intensive procedures. CMS proposes to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2."

CMS proposes to calculate payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") and device-intensive procedures (payment indicator "J8") according to established policies and, for device-intensive procedures, using the modified definition of device-intensive procedures. As such, CMS proposes to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2020 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Note that payment for office-based procedures would be at the lesser of the proposed CY 2020 MPFS nonfacility PE RVU-based amount or the proposed CY 2020 ASC payment amount calculated according to the ASC standard ratesetting methodology.

For CY 2020, CMS proposes to 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 these procedures and would continue to be paid separately under the ASC payment system.

Proposed Limit on ASC Payment Rates for Low Volume Device-Intensive Procedures (p. 476)

For low-volume device-intensive procedures, the proposed relative payment weights are based on median costs, rather than geometric mean costs (which is generally used under the standard methodology). CMS explains that this policy helps provide more appropriate payment for low-volume device intensive procedures, although these procedures can still have data anomalies as a result of the limited data available in CMS' ratesetting process.

To address concerns where large differences in cost calculations occur, CMS proposes to limit the ASC payment rate for low-volume device intensive procedure to a payment rate equal to the OPPS payment rate for that procedure. Where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, CMS proposes to establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure. CMS proposes to add regulatory language to require that low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device-intensive procedures would exceed the payment rate for the same procedure set under the OPPS, the payment rate for the procedure under the ASC payment system would be equal to the payment rate for the same procedure under the OPPS.

Proposed ASC Payment for Covered Ancillary Services (p. 479)

CMS proposes to update the ASC payment rates and to make changes to ASC payment indicators to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2020 OPPS and ASC payment rates and subsequent year payment rates. CMS also proposes 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 2020 and subsequent year payment rates.

In addition, and despite public commenter requests, ***CMS does not propose to add CPT code 91040 (Esophageal balloon distension study, diagnostic, with provocation when performed) as a covered ancillary service. Based on available data and other information related to CPT code 91040, CMS does not believe this diagnostic test is integral to the covered surgical procedures of CPT codes 43235 (Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 43239 (Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple).***

Proposed CY 2020 ASC Packaging Policy for Non-Opioid Pain Management Treatments (p. 484)

As required by the SUPPORT Act, CMS will continue to review and revise ASC payments for non-opioid alternatives for pain management, as appropriate.

Proposed Calculation of the ASC Payment Rates and Conversion Factor (p. 490)

For CY 2020, the proposed CY 2020 ASC wage indexes fully reflect the OMB labor market area delineations.

Proposed Calculation of the ASC Payment Rates (p. 494)

Updating the ASC Relative Payment Weights for CY 2020 and Future Years (p. 494)

Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2018, CMS proposes to compare the total payment using the CY 2019 ASC relative payment weights with the total payment using the

CY 2020 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2019 and CY 2020. CMS proposes to use the ratio of CY 2019 to CY 2020 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2020. ***The proposed CY 2020 ASC weight scalar is 0.8452*** and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.[12]

Updating the ASC Conversion Factor (p. 496)

For CY 2020, CMS proposes to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the MFP-adjusted hospital market basket update factor of 2.7 percent, which results in a ***proposed CY 2020 ASC conversion factor of $47.827 for ASCs meeting the quality reporting requirements***.

For ASCs not meeting the quality reporting requirements, CMS proposes to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.7 percent discussed above, which results in a ***proposed CY 2020 ASC conversion factor of $46.895***.

[12] Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison. The ASC payment weights for those services without predetermined national payment amounts would be scaled to eliminate any difference in the total payment between the current year and the update year.

Quality Reporting Programs

Hospital Outpatient Quality Reporting (OQR) Program (p. 502)

The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program.

Hospital OQR Program Quality Measures (p. 504)

CY 2022 Payment Determination

Table 34 summarizes the proposed Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years (including previously adopted measures and excluding the one measure proposed for removal in this rule, as discussed below).

OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases. CMS proposes to remove this measure under its previously finalized measure removal criteria Factor 8: the costs associated with a measure outweigh the benefit of its continued use in the program. This measure would be removed beginning with October 2020 encounters used in the CY 2022 payment determination and for subsequent years. This measure assesses the "percentage of patients (all-payer) with painful bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule." The Hospital OQR Program implemented the EBRT measure using "radiation delivery" Current Procedural Terminology (CPT) codes, which are appropriate for hospital-level measurement. However, CMS has identified issues with reporting this measure, finding that more questions are received about how to report the EBRT measure than about any other measure in the program. In addition, the measure steward has received feedback on data collection of the measure in the outpatient setting, and has indicated new and significant concerns regarding the "radiation delivery" CPT coding used to report the EBRT measure in the Hospital OQR Program, including complicated measure exclusions, sampling concerns, and administrative burden, which are discussed in more detail in this section.

This EBRT measure was also adopted into the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (79 FR 50278 through 50279), which initially used "radiation planning" CPT codes billable at the physician level, but beginning in March 2016, the PCHQR program updated the measure to enable the use of ''radiation delivery'' CPT codes. In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19502 through 19503), CMS proposed to remove the measure from the PCHQR Program because the burden associated with the measure outweighs the value of its inclusion in the program. CMS notes that while the version of the measure using "radiation planning" CPT codes is less burdensome, HOPDs do not have access to physician billing data, and so it is not operationally feasible to use "radiation planning" CPT codes (as opposed to the current "radiation delivery" CPT codes) for the EBRT measure in the Hospital OQR Program.

Measures and Topics for Future Consideration (p. 512)

Request for Comment on the Potential Future Adoption of Four Patient Safety Measures

CMS seeks comment on the potential future adoption of four patient safety measures[13] for the Hospital OQR Program that were previously adopted for the ASCQR Program:

- ***ASC-1: Patient Burn: assesses the percentage of admissions experiencing a burn prior to discharge;***
- ***ASC-2: Patient Fall: assesses the percentage of admissions experiencing a fall;***
- ***ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant: assesses the percentage of admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant***

[13] Specifications available here.

- ***ASC-4: All-Cause Hospital Transfer/Admission: assesses the rate of admissions requiring a hospital transfer or hospital admission upon discharge***

Additional information about these measures is available here and here.

CMS notes that data collection for these measures was suspended in the ASCQR Program due to concerns with their data submission method using quality data codes (QDCs), as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123; 59134 through 59135). However, later in this proposed rule, CMS requests comment on updating the submission method for these measures under the ASCQR Program in the future. CMS requests comment on potentially adding these measures, with the updated submission method using a CMS online data submission tool, to the Hospital OQR Program in future rulemaking. Also note that these measures are currently specified for the ASC setting; CMS is considering having them specified for the hospital outpatient setting and would seek collaboration with the measure steward if it does so.

CMS cites multiple reasons for adopting these ASCQR measures in the Hospital OQR Program including: to address a Meaningful Measure Initiative quality priority, Making Care Safer by Reducing Harm Caused in the Delivery of Care; to further transparency; to better align the two programs; and to provide patients with more meaningful data to compare sites of service.

Although NQF endorsement for these ASC measures was removed for each of the measures, CMS clarifies that endorsement was allowed to lapse by the measure steward, not because they failed the endorsement maintenance process (83 FR 59119).

Future Outcome Measures

CMS is moving towards greater use of outcome measures and away from clinical process measures across its Medicare quality reporting programs. ***As such, CMS requests comment on any outcome measures that would be useful to ad, as well as feedback on any process measures that should be eliminated from the Hospital OQR Program to further its goal of developing a comprehensive set of quality measures for informed decision-making and quality improvement in HOPDs.***

Form, Manner, and Timing of Data Submitted for the Hospital OQR Program (p. 521)

Data submission deadlines for CY 2022 payment determination and subsequent years are illustrated in Table 35. Other previously finalized data submission requirements are summarized in this section, as well.

Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2020 Payment Determination (p. 527)

CMS proposes 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 2020 annual payment update factor. For the CY 2020 OPPS, the proposed reporting ratio is 0.980.***
- ***To apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2020 OPPS, it proposes to apply the reporting ratio, when applicable, to all HCPCS codes to which CMS has proposed status indicator assignments of "J1", "J2", "P", "Q1", "Q2", "Q3", "R", "S", "T", "V", and "U" (other than new technology APCs to which CMS has proposed status indicator assignment of "S" and "T").***
- ***To exclude services paid under New Technology APCs.***

- ***To continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements.***
- ***To continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program.***
- ***To continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.***

ASC Quality Reporting (ASCQR) Reporting Program (p. 531)

Proposed New Quality Measure for the ASCQR Program Measure Set (p. 534)

CMS proposes to adopt ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) into the ASCQR Program for the CY 2024 payment determination and subsequent years. The measure outcome is all-cause, unplanned hospital visits within 7 days of any general surgery procedure performed at an ASCs. "Hospital visits" include emergency department visits, observation stays, and unplanned inpatient admissions. The target group of procedures includes those that: (1) are routinely performed at ASCs; (2) involve some increased risk of post-surgery hospital visits; and (3) are within the scope of general surgery training. These include the following types of procedures: abdominal (e.g., hernia repair), alimentary tract (e.g., hemorrhoid procedures), breast (e.g., mastectomies), skin/soft tissue (e.g., skin grafting), wound (e.g., incision and drainage of skin and subcutaneous tissue), and varicose vein stripping. The measure does not include gastrointestinal endoscopy, endocrine, or vascular procedures, other than varicose vein procedures, because for these procedures, reasons for hospital visits are typically related to patients' underlying comorbidities. CMS also clarifies that the scope of general surgery overlaps with that of other specialties (e.g., vascular surgery and plastic surgery). Since the type of surgeon performing a particular procedure may vary across ASCs in ways that affect quality, the measure is neutral to surgeons' specialty training.

The proposed ASC-19 measure was developed in conjunction with two other measures adopted for the ASCQR Program beginning with the CY 2022 payment determination as finalized in the CY 2018 OPPS/ASC final rule with comment period: ASC-17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures (82 FR 59455) and ASC-18: Hospital Visits After Urology Ambulatory Surgical Center Procedures (82 FR 59463). All three measures assess the same patient outcome for care provided in the ASC setting and use the same risk-adjustment methodology. These three measures differ in surgical procedures considered, specific risk variables included, and reporting of the outcome, unplanned hospital visits. The proposed ASC-19 measure reports the outcome as a risk-standardized ratio because the diverse mix of procedures included in the proposed ASC-19 measure can have varying levels of risk of unplanned hospital visits; while the ASC-17 and ASC-18 measures report a risk-standardized rate that reflects clinically specific cohorts with fairly comparable mixes of procedures.

A more comprehensive overview of the measure, data sources, cohort, risk adjustment, and calculation begins on p. 539. Note that CMS removed 15 individual skin/soft tissue and wound procedure codes from the measure that are outside the scope of general surgery practice during development of the measure. For the current list of codes that define the proposed ASC-19 measure and a description of updates since development, CMS refers readers to the zip file labeled "Version 1.0 Hospital Visits General Surgery ASC Procedures Measure Technical Report" located at here.

CMS also discusses the MAP's conditional support of the measure, but clarifies that the measure has subsequently been field tested and endorsed by the NQF's Consensus Standards Approval Committee.

Finally, CMS also proposes that if the proposed ASC-19 measure is adopted, it would publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards. CMS will conduct a dry run with confidential reporting and feedback before the official data collection period or any public reporting.

Summary of ASCQR Program Quality Measure Set Proposed for the CY 2024 Payment Determination and for Subsequent Years (p. 551)

Table 36 summarizes the proposed ASCQR Program measure set for the CY 2024 payment determination and subsequent years (including previously adopted measures).

ASCQR Program Measures and Topics for Future Consideration (p. 552)

CMS is considering, for future implementation, updates to the submission method for the following measures:

- ASC-1: Patient Burn
- ASC-2: Patient Fall
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4: All-Cause Hospital Transfer/Admission

Additional information about these measures is available here and here.

ASC-1, ASC-2, ASC-3, and ASC-4 were adopted into the ASCQR Program in the CY 2012 OPPS/ASC final rule with comment period beginning with the CY 2014 payment determination (76 FR 74496 through 74500). These measures were calculated via quality data codes (QDCs)— ASCs were formerly required to submit the appropriate QDCs on individual Medicare FFS claims billed by the facility. However, ASCs that identified an erroneous or missing QDC were unable to correct or add a QDC if the claim has already been submitted to Medicare and been processed. Due to this data collection issue, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123; 59134 through 59135), CMS retained these measures in the ASCQR Program, but suspended their data submission until further action with the goal of updating their data submission method.

In this proposed rule, CMS requests comment about, in the future, potentially updating the data submission method to a CMS online data submission tool (CMS currently uses the QualityNet website as its CMS online data submission tool). CMS also seeks input on the potential burden associated with this update. CMS believes this proposal would address concerns about the current inability of ASCs to correct data submission errors because ASCs would simply report their data via the online tool. CMS clarifies that if data for these measures were submitted via QualityNet, ASCs would still submit claims for reimbursement to CMS, but would not be required to include QDCs.

Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements (p. 564)

In this section, CMS discusses its previously finalized policies regarding reduction to the ASC payment rates for ASCs that fail to meet the ASCQR program requirements. Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program.

Requirement to Make Hospital Standard Charges Public

Background

CMS reviewed its past implementation of statutory requirements for hospitals to post their standard charges for items and services provided by the hospital (p. 569). Previous policy required hospitals to either:

- Make public a list of their "standard charges"; or
- Make public their policies for allowing the public to view a list of those charges in response to an inquiry.

CMS states that hospitals were supposed to update the information at least annually and that they encouraged hospitals to "engage in consumer-friendly communication of their charges to enable consumers to compare charges for similar services across hospitals and to help consumers understand what their potential financial liability might be for items and services they obtain at the hospital." (p. 569). CMS subsequently updated its policies "to require hospitals make available a list of their current standard charges via the Internet in a machine-readable format" (p. 569).[14]

Citing continued cost increases partially due to lack of transparency in health care pricing, CMS makes a series of proposals regarding hospital charges public posting. CMS supporting information and overview of State-initiated efforts can be found beginning on p. 570. In addition, CMS outlined the stakeholder engagement it has conducted beginning on p. 576 leading up to its decision to make additional proposals.

Proposals

CMS is generally proposaing an expansion of hospital charge data public display requirements as well as provisions related to monitoring and enforcement (p. 578). CMS states that the main goal of this series of proposals is to "address barriers related to lack of hospital data by standardizing the release of two types of hospital standard charge information – gross charges and payer specific negotiated charges" (p. 580). CMS also states that it is continue to look at other areas in which HHS has authority "to further advance our goal of getting patients the information they need to make informed health care decisions" (p. 581).

Definitions

Definition of "Hospital" (p. 581). CMS did not anchor to existing definitions of "hospital" out of concern that it would inappropriately limit the institutions who would be covered by the provisions (p. 581). In order to achieve the goals stated for the new proposals, ***CMS proposes to define a "hospital" as "an institution in any State[15] in which State or applicable local law provides for licensing of hospitals, (1) is licensed as a hospital pursuant to such law or (2) is approved, by the agency of such State or locality responsible for licensing hospitals as meeting the standards established for such licensing"*** (p. 581). CMS states that this is intended to capture hospitals that are both Medicare-enrolled as well as institutions that might not be considered hospitals for purposes of Medicare participation[16] (p. 582).

Special Requirements for Certain Hospitals (p. 584). For the requirements CMS puts forward for hospitals, ***CMS proposes that the requirements would not apply to federally-owned or operated hospitals (including Indian Health Service (IHS) facilities, VA facilities, and Department of Defense Military Treatment Facilities (MTFs) by deeming these facilities to have met the requirements "when their charges for hospital provided services are***

[14] CMS FAQs available via this link.

[15] CMS proposes that a "State" includes each State, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands (p. 582).

[16] CMS cites that it is its intent that this definition captures critical access hospitals (CAHs), inpatient psychiatric facilities (IPFs), sole community hospitals, and inpatient rehabilitation facilites (IRFs); and that it does not include ambulatory surgery centers (ASCs) or "other non-hospital sites-of-care" (also mentioning laboratory or imaging services) (p. 583); however, CMS states that it *encourages* non-hospital sites-of-care to list their standard charges in alignment with these proposals (p. 584).

publicized* to their patients in advance" (including the Federal Register)** (p. 584; p. 585). Among CMS' stated rationales for the exception is that "with the exception of some emergency services, these facilities do not provide services to the general public and the established payment rates for services are not subject to negotiation" (p. 584). In addition, ***CMS seeks input on whether it should make similar accomodations for hospitals in rural areas, CAHs, or non-federally-owned or operated hospitals that treat special populations (e.g., children's hospitals or State psychiatric hospitals) (p. 586).

Definition of "Items and Services" Provided by Hospitals (p. 586). For purposes of these provisions, ***CMS proposes to define "items and services" provided by a hospital as "all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or outpatient department visit for which the hospital has a standard charge"***[17] (p. 587).

- In order to standardize the terminology, ***CMS also proposes to define "chargemaster" as "the list of all individual items and services maintained by a hospital for which the hospital has established a standard charge"*** (p. 587).
- ***CMS proposes to define "service package" as "an aggregation of individual items and services into a single service with a single charge"*** (p. 589).
- CMS states that this definition is intended to include "the services furnished by physicians and non-physician practitioners who are employed at the hospital" (p. 589). CMS states that it considered (but decided against) including services provided by physicians and non-physician practitioners who are not employed by the hospitals (but provide services at that hospital location); however, CMS states that it believes that this information would be "exceptionally valuable to give consumers a more complete picture of the total amount they be be charged in connection with an inpatient admission or an outpatient department visit at a hospital location" citing the ongoing concers with "surprise billing" (p. 590). However, because these clinicians practice independently, CMS did not believe they were services "provided by the hospital" (p. 591).

Definitions for Types of "Standard Charges" (p. 591). CMS received input that while hospitals might be posting gross charges, those gross charges are likely to only apply to a small subset of patients, particularly self-pay patients or patients with insurance plans for which the hospital is not in the network. Therefore, ***CMS proposes to define "standard charges" as "gross charges" and "payer-specific negotiated charges"*** (p. 594).

- Gross Charges (p. 595). ***CMS proposes to define a "gross charge" as "the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts"*** (p. 596). CMS notes that the chargemaster does not reflect charges that might have been negotiated for "service packages" (e.g. per diem rates or DRGs) and, therefore, "gross charges" do not include standard charges for "service packages" (p. 596). While CMS acknowledges the limited utility of "gross charges," CMS stated that it is still requiring publication because it believes "gross charges are useful to the general public, necessary to promote price transparency, and necessary to drive down premium and out-of-pocket costs for consumers of health care" (p. 596).

[17] According to CMS, examples include supplies, procedures, room and board, use of the facility and other items (e.g. facility fees), services of employed physicians and non-physician practitioners (i.e. professional charges), and "any other items or services for which a hospital has established a charge" (p. 587).

- Payer-Specific Negotiated Charge[18] (p. 598). ***CMS proposes to define a "payer-specific negotiated charge" as "the charge that the hospital has negotiated with a third party payer[19] for an item or service"*** (p. 598).
    - CMS stated that it specifically directed the definition at "negotiated rates" rather than "all payer rates" because charges that are not negotiated (e.g. Medicare and Medicaid fee-for-service) are often already publicly available (p. 600).
    - CMS also stated that "the impact resulting from the release of negotiated rates is largely unknown" and lists some of the concerns submitted by stakeholders (p. 600).

- Alternative: "Standard Charges" Related to Groups of Invididuals with Third Party Payer Coverage (p. 602). CMS notes that it can be difficult to obtain the rate that a third payer payer has negotiated on behalf of its insured lives (p. 603). CMS notes that its definition would not capture charges that are not "negotiated." ***CMS specifically considered (but did not propose) the following definitions and seeks input***:
    - *"Volume Driven Negotiated Charge":* CMS considered defining "Standard Charge" as "Modal Negotiated Charge," which would in turn be defined as "the most frequently charged rate across all rates the hospital has negotiated with third party payers for an item or service" (p. 603). CMS believes using this definition could provide useful information but limit the amount of data hospitals are required to make public.
    - *Minimum, Median & Maximum Negotiated Charge*: CMS considered defining this as "the lowest, median, and highest charges of the distribution of all negotiated charges across all third party payer plans and products." (p. 604). CMS again believes this could be useful information but limit what hospitals are required to make public. In addition, CMS stated that it could address concerns about the potential that the release of charge data could have on increasing health care costs in some markets (p. 604).
    - *All Allowed Charges*: This would be "the charges for all items and services for all third party payer plans and products, *including charges that are non-negotiated (such as FFS Medicare rates)* (p. 604). CMS declined proposing this option, however, because it believes consumers already have "adequate and centralized access" to non-negotiated charges, and for those that do have non-negotiated health care coverage, CMS states they are largely protected from out-of-pocket costs which would make them less sensitive to price shopping (p. 605).

- Alternative: "Standard Charges" for Groups of Individuals that are Self-Pay (p. 605). CMS states that for the most part self-pay patients do not need additional charge information beyond "gross charges" to determine out-of-pocket liabilities. However, CMS did receive comments that hospitals "often offer discounts off the gross charge or make other concessions to individuals who are self pay." Because of this, ***CMS specifically considered (but did not propose) the following definitions and seeks input:***
    - *Discounted Cash Price*: CMS would define this as "the price the hospital would charge individuals who pay cash (or cash equivalent) for an individual item or service or services package" (p. 605). Noting that the lastest data show that there were 24.7 million uninsured individuals in the United States in 2017, CMS stated that there is a large number of inviduals who could benefit

[18] CMS acknowledges this will result in the release of a large amount of data; CMS attempted to estimate the number of negoated rates a hospital might have based on information it had available and estmiates that "the number of products or lines of service per rating area ranges from approximately 1 to 200 in the individual market (averaging nearly 20 products or lines of service in each rating area) with in the small group market, the number ranges from 1 to 400 (averaging nearly 40 products or lines of service in each rating area" (p. 601).

[19] CMS also defines a "third party payer" as "an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service"; CMS states that this definition is specifically intended to exclude individuals who pay for health care services (e.g. self-pay patients) (p. 598), but that it is intended to include Medicare Advantage plans (p. 601).

from the information. CMS also said that insured individuals who are willing to bear the full cost of services not covered or out of network could also benefit from the information (p. 606).

- *Median Cash Price*: This option was considered so that the policies could take into account sliding scale cash discounts. CMS noted that for uninsured patients who could qualify for financial assistance, median cash price information could be useful to raise awareness of availably options including the ability to apply for financial assistance (p. 608).

Public Disclosure Requirements

CMS proposes requiring that "hospitals" make public their "standard charges" (1) in a "comprehensive machine-readable file that makes public all standard charge information for all hospital tems and services"; and (2) in a "consumer-friendly display of common 'shoppable' services derviced from the machine-readable file" (p. 608).

Standardized Data Elements (p. 610). Out of concern that there is lack of uniformity in reporting, ***CMS proposes that hospitals will be required to make public a list of each "item or service" the hospital provides with the corresponding information[20] (as applicable)*** (p. 611):

- Description of each item or service (including both individual items and services and service packages)
- The corresponding gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting
- The corresponding payer-specific negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each list of payer-specific charges must be clearly associated with the name of the third party payer
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG), National Drug Code (NDC), or other common payer identifier (additional information on p. 612)
- Revenue code, as applicable (additional information on p. 612)

Comprehensive Machine-Readable File (p. 614).

- ***CMS proposes requiring that hospitals post charge information "in a single digital file that is in a machine-readable format"*** (p. 614).
- ***CMS proposes to define "machine-readable format" as "a digital representation of data or information in a file that can be importated or read into a computer system for further processing,"[21]*** which could include .XML, JSON, and .CSV formats (p. 614).
- CMS had considered an alternate proposal to require a single standardized file format (specifically .XML) but decided against it because "we did not want to be overly prescriptive in our requirements for formatting" (p. 614). However, ***CMS seeks comment on whether it should designate a single file type*** (p. 615).
- ***CMS is also seeking comment on technologies or standards that could "facilitate public access to real-time updates in a format to make it easier for information to be available when and where consumers want to use it"*** (p. 615).[22]

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[20] CMS purposesfull omitted the follow elements: numeric designation for hospital department; general ledger number for accounting purposes; long text description; and other identifying elements (p. 613).

[21] "A PDF would not meet this definition because the data containted within the PDF file cannot be extracted without further processing or formatting" (p. 614).

[22] Additional information and comment request regarding whether this should be an open API can be found beginning on p. 615.

Location and Accessibility Requirements (p. 617). CMS is concerned about how hospitals have implemented the current requirements and how it is often difficult for the public to find posted charge information. In light of these concerns:

- ***CMS proposes hospitals will have the discretion to choose the Internet location where it posts its file so long as the file is displayed on a publicly available webpage, it is "displayed prominently," and it clearly identifies the hospital location with which the standard charges information is associated, and the standard charge data are "easily accessible," without barriers, and the data can be digitally searched*** (p. 617); in separate provisions related to the "Consumer Friendly Display of Shoppable Services," ***CMS proposes that hospitals make the required data available online "in such a way that the payer-specific negotiated charge and associated data elements can be located and accessed easily by consumers"*** (p. 636).
- "Displayed prominently" means "the value and purposes of the webpage and its content is clearly communicated, there is no reliance on breadcrumbs" (p. 618; p. 636).
- "Easily accessible" means "standard charge data are presented in a single machine-readble file that is searchable" and "that the standard charges file posted on a website can be accessed with the fewest number of clicks" (p. 618; p. 636).
- "Without barriers" means "the data can be accessed free of charge, users would not have to input information (such as their name, email address, or other PHI) or register to access or use the standard charge file" (p. 618; p. 637).
- ***CMS requests comment on an alternative that would require hospitals to submit a link to the standard charges file to CMS, which CMS would make public*** (p. 618).
- ***CMS also seeks comment on potential additional requirements (e.g. easily-searchable file name conventions) and whether it should specify the website location for posting*** (p. 618).

Frequency of Updates (p. 620). ***CMS proposes requiring hospitals to make public and update the file "at least once annually" containing the list of all standard charges for all items and services "at least once annually"*** (p. 620; p. 637 for the section on Consumer Friendly Shoppable Services). In addition, ***CMS proposes requiring hospitals to clearly indicate date of last update.***

Requirements for Separate Files for Different Hospital Locations (p. 621). CMS acknowledges thtat State licensing can affect whether sites are consolidated or functioniong separately (and with separate charges). To address this, ***CMS proposes that the policies would separately apply to each hospital location such that each hospital location would be required to make public a separate identifiable list of standard charges*** (p. 621).

"Consumer-Friendly" Display of "Shoppable Services" (p. 621). CMS has remained concerned about the usability of charge data that has been posted so far. In order to increase the utility of information provided, ***CMS proposes that "hospitals must make public their payer-specific negotiated charges for common services for which consumers may have the opportunity to shop"*** (p. 622).

- Definition of "Shoppable Services" (p. 623). ***CMS proposes to define a "shoppable service" as "a service package that can be scheduled by a health care consumer in advance"*** (p. 623). CMS notes that this definition requires the charges be displayed as a "grouping of related services," (e.g. associated ancillary services) which will make it more consumer-friendly and patient focused (p. 624). To achieve this, ***CMS proposes to define "ancillary service"[23] as "an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service"*** (p. 624).
- Proposed "Shoppable Services" (p. 625).

[23] CMS lists as examples laboratory, radiology, drugs, delivery room (including maternity labor room), operating room (including post-anesthesia and postoperative recovery rooms), therapy services (physical, speech occupational), hospital fees, room and board charges, and charges for employed professional services (p. 624).

- ***CMS proposes to require hospitals to make public a list of their payer-specific negotiated charges for a specific list of services as identified in Table 37*** (p. 625). CMS states that these 70 shoppable services "were selected based on an analysis of shoppable services that are currently made public under State price transparency requirements, a review of services that frequently appear in web-based price transparency tools, an analysis of high volume services and high cost procedures derived from External Data Gathering Environment (EDGE) serve data, and a review by CMS medical officers" (p. 629). ***CMS particularly seeks comment on "the specific services . . . identified as shoppable services and whether other services should be included because they are more common, more shoppable or both"*** (p. 632).
- In addition to the list in Table 37, ***CMS proposes that each hospital would select at a minimum 230 additional shoppable services (as identified by a primary HCPCS, CPT, or DRG or other widely used industry code as applicable) and make publicly available a list of its payer-specific negotiated charges in both the inpatient and outpatient setting*** (p. 629). CMS believes this policy would allow hospitals to tailor their list for their patient populations and area of expertise (e.g. a children's hospital) (p. 630).
- Acknowleding that not every hospital will provide all of the shoppable services listed in Table 37,[24] ***CMS proposes that hospitals make public the list of as many of the shoppable services in Table 37 as possible "plus as many additional shoppable procedures as is necessary to reach a total of at least 300 shoppable services"*** (p. 630). CMS noted that it had considered but did not propose an alternative where it would allow hospitals to select up to 70 from a larger list plus another 230 to reach 300 but did not put this forward becaue it believes most hospitals provide the 70 selected services (p. 630). ***CMS also seeks comment on whether it should require more or less than a total of 300 shoppable services (and whether a list of 100 shoppable services (or less) is a reasonable starting point)*** (p. 632).

"Consumer Friendly"

- **Data Elements** (p. 632). ***CMS proposes that the "consumer-friendly display of payer-specific negotiated charge information contain the following corresponding information"*** (beginning on p. 632):
  - A plain-language description of each shoppable service
  - The payer-specific negotiated charge that applies to each shoppable service[25]
  - Each payer-specific charge must be clearly associated with the name of the third party payer
  - A list of all the associated ancillary items and services that the hospital provides with the shoppable service, including the payer-specific negotiated charge for each ancillary item or service
  - The location at which each shoppable service is provided by the hospital ("for example, Smithville Campus or XYZ Clinic")
  - Whether the payer-specific negotiated charge for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting or the outpatient department setting or both
  - If the payer-specific negotiated charge for the shoppable service varies based upon location or whether the hospital provides the shoppable service in the inpatient setting versus the outpatient setting, the hospital would be required to identify each payer-specific negotiated charge

[24] Note: CMS makes an error in the rule and states "Table 36" here, which is actually the table in the rule designated for "Proposed ASCQR Program Measure Set for the CY 2024 Payment Determination and Subsequent Years."

[25] "If the hospital does not provide one or more of the CMS-selected shoppable services, the hospital may indicate "N/A" for the corresponding charge or otherwise make it clear that the service is not provided by the hospital" (p. 633).

- Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, (including, but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis-Related Group (DRG), or other commonly used service billing code)

- **Format of Display** (p. 634). ***CMS proposes that hospitals retain the flexibility on how to display payer-specific negotiated charge data online so long as the website is easily accessible to the public*** (p. 635). However, in addition on online information, ***CMS proposes that hospitals make the data elements listed above available in a consumer-friendly manner offline*** given that not all consumers have access ot the internet (p. 635); that is, ***CMS proposes that the hospital must provide a paper copy of the information to consumers "upon request within 72 hours of the request"*** (p. 636).

Monitoring and Enforcement

- ***CMS proposes that its monitoring methods may include, but are not limited to:***
  - ***CMS evaluation of complaints made by individuals or entities to CMS***
  - ***CMS review of individuals' or entities' analyses of noncompliance*** (p. 641).
- CMS noted that in the future it might consider self-initiating audies of hospitals' websites (p. 641).
- ***CMS proposes that hospitals identified as noncompliant "would be notified of their deficiencies and given an opportunity to take corrective action*** (p. 641).
- ***CMS proposes that for hospitals determined to be noncompliant that fail to respond to CMS requests to submit a corrective action plan (CAP) or comply with the requirements of a CAP, it may impose Civil Monetary Penalties (CMPs) on hospitals and publicize the penalties on the CMS website*** (p. 642).
- More information on the process is available beginning on p. 642 and proposals related to CMS imposition of CMPs can be found beginning on p. 644.
- ***CMS also proposes the addition of an appeals process***, the details of which can be found beginning on p. 649.

RFI for Information on Price Transparency

CMS reviewed the requests for information that it included in last year's MPFS proposed rule, IPPS proposed rule, and OPPS proposed rule. CMS discussed its continued efforts to post charge data for hospitals and physicians on the CMS website as well as its general desire to improve transparency and comments received from stakeholders (p. 653).

CMS reiterated ongoing concerns about challenges that continue to exist for patients due to insufficient price transparency and requests additional comment in the following areas:

- Improving availability and access to existing quality of health care information for third parties and health care entities to use when developing price transparency tooks and when communicating charges for health care. More detailed question can be found on p. 655.
- Improving incentives and assessing the ability of health care providers and suppliers to communicate and share charge information with patients. More detailed question can be found on p. 656.

Organ Procurement Organizations CfCs (p. 657)

Background (p. 657)

Organ procurement organizations (OPOs) are responsible for identifying eligible donors, recovering organs from deceased donors, and complying with all CMS outcome and process performance measures. OPOs must abide by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) that have been approved by the Secretary. OPOs are required to report specific information to the OPTN, including the data used to calculate the outcome measures for OPOs. CMS established Conditions for Coverage (CfCs) for OPOs to be able to receive payments from the Medicare and Medicaid programs. These regulations set forth the certification and recertification processes, outcome requirements, and process performance measures for OPOs and were effective on July 31, 2006 (71 FR 30982). According to these regulations, transplant hospitals and OPOs must report data to the OPTN and those data are transmitted on a monthly basis to the Scientific Registry of Transplant Recipients (SRTR) contractor. More specifically, the CfCs for OPOs regulations at 42 CFR 486.318(a) and (b) require that an OPO must meet two of three outcome measures, one of which is:

- The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re–recertification, as calculated by SRTR

The expected donation rate used in this outcome measure is calculated by the SRTR. The CfCs for OPOs at 42 CFR 486.302 defines "expected donation rate" as the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas (DSAs). This rate is adjusted for the following hospital characteristics:

- Level I or Level II trauma center;
- Metropolitan Statistical Area (MSA) size;
- Metropolitan Statistical (MS) case-mix index;
- total bed size;
- number of intensive care unit (ICU) beds;
- primary service;
- presence of a neurosurgery unit; and
- hospital control/ownership.

However, in 2009, the SRTR modified the definition of "expected donation rate" used for this outcome measure. The updated SRTR's definition states: "[t]he expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. This rate is adjusted for the distributions of age, sex, race, and cause of death among eligible deaths." The SRTR believed that this was a more precise method of calculation that would adjust for characteristics that allow for isolation of the effects that OPOs' practices were having on donation in that DSA.

Proposed Revision of the Definition of "Expected Donation Rate" (p. 660)

Due to an oversight, CMS did not make a corresponding change to the definition in the CfCs for OPOs at the time that the SRTR made its change. Thus, ***CMS proposes to change its requirements so that it is consistent with the SRTR's definition for the second outcome measure.***

- ***This change would take effect on the effective date of the final rule with comment period, which would occur during the 2022 recertification cycle***.
- ***Because the final regulation change would not be retroactive and, in order to give OPOs adequate time to comply with the change to the definition for "expected donation rate," CMS proposes to reduce the time period for the observed donation rate for the second outcome measure for the 2022 recertification cycle only.***

- ***It proposes to calculate the expected donation rate using 12 of the 24 months of data following the effective date of the final rule with comment period (using data from January 1, 2020 through December 31, 2020).***
- ***After the 2022 recertification cycle, and if there are no other changes to the OPO outcome measures, CMS would assess OPO performance based on 36 months of data.***

Request for Information Regarding Potential Changes to the Organ Procurement Organization and Transplant Center Regulations (p. 663)

Since the OPO and the transplant center regulations were finalized, CMS has received substantial feedback from the organ procurement and transplant communities recommending modifications to the current requirements. ***Thus, CMS seeks input regarding what revisions may be appropriate for the current CfCs for OPOs that are set forth at 42 CFR 486.301 through 486.360 and the current CoPs for transplant centers that are set forth at 42 CFR 482.68 through 482.104. Specific issues of interest to CMS are listed on p. 664.***

CMS also solicits comment on whether the following two potential OPO outcome measures would be valid measures and would be consistent with statutory requirements. CMS is especially interested in comments about the validity and reliability of these possible measures:

- A potential measure evaluating the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. The data on inpatient deaths, including additional related demographic data, would be derived from the CDC Detailed Mortality File and the National Center for Health Statistic's National Vital Statistics Report
- A potential measure evaluating the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. This measure also would reward efforts to maximize total organ procurement and efforts to improve placements of all procured organs

CMS is also interested in comments on appropriate parameters for these measures:

- How should it determine what percentage indicates that an OPO's performance is acceptable or successful?
- If commenters cannot recommend a specific percentage, how should CMS determine what the parameters for the outcome measures should be?

For additional information on these potential outcome measures, please see *Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States,* published in the American Journal for Transplantations.[26]

CMS will consider the comments it receives for future rulemaking.

[26] *Changing Metrics of Organ Procurement Organization Performance in order to Increase Organ Donation Rates in the United States*, Am J Transplant, 2017 Dec; 17(12): 3183-3192. doi: 10.1111/ajt. 14391. Epub 2017 Jul20.

Clinical Laboratory Fee Schedule: Revisions to Laboratory Date of Service Policy (p. 667)

Under current practice, a laboratory service may take place over a period of time, and the date of each of the following could differ:

- The date the physician orders the test;
- The date the specimen is collected;
- The date the laboratory accesses the specimen;
- The date the laboratory performs the test; and
- The date results are produced.

Under currently regulations, the date of service (DOS) reported on claims for clinical diagnostic laboratory services is generally the date the specimen is collected. However, in response to concerns raised by stakeholders, including for tests related to cancer care, CMS has made refinements to regulations regarding DOS for clinical laboratory tests over the years, as follows:

- For "archived specimens", which are specimens stored for more than 30 calendar days before testing, the DOS is the date the specimen was obtained from storage.
- Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected, except as follows:
    1. When "the 14-day rule" applies (p. 668)[27]: The DOS is the date the test was performed (rather than the specimen collection date) if the following conditions are met:
        - The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
        - The specimen was collected while the patient was undergoing a hospital surgical procedure;
        - It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
        - The results of the test do not guide treatment provided during the hospital stay; and
        - The test was reasonable and medically necessary for the treatment of illness
    2. For chemotherapy sensitivity tests performed on live tissue[28], the DOS is the date the test was performed, if similar criteria are met, except that the first criterion above is replaced by the following criterion: The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge (p. 669).
    3. CMS also references a third exception in addition to the two above, which it details later in this discussion.

These DOS requirements are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether – as with the 14-day rule and chemotherapy sensitivity test exceptions noted above – the laboratory performing the test bills Medicare directly and is paid under the Clinical Laboratory Fee Schedule (CLFS). This is because separate regulations generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which CMS calls the "under arrangements" provisions, require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

[27] As specified at § 414.510(b)(2)
[28] As specified at § 414.510(b)(3)

In the case of the three exceptions noted above (with the third exception explained in more detail below), the DOS is the date the test was performed. In this situation, the laboratory would bill Medicare directly for the test and would be paid under the CLFS directly by Medicare. In all other non-archived cases besides these three exceptions, the DOS would be the date the specimen was collected from the patient, and in those cases, the hospital would bill Medicare for the test and then would pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

Additionally under current OPPS regulations, certain CDLTs that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Specifically, CMS conditionally packages most CDLTs and only pay separately for a laboratory test when it is:

- The only service provided to the beneficiary on a claim
- Considered a preventive service
- A molecular pathology test[29]
- An advanced diagnostic laboratory test (ADLT) that meets specified statutory criteria at 1834A(d)(5)(A), as specified under paragraph (1) of the definition of ADLT in 42 CFR 414.502 [30]

CMS provides additional background information about ADLTs on p. 672 and refers readers to the CMS website for more information.

Additional Laboratory DOS Policy Exception for the Hospital Outpatient Setting at § 414.510(b)(5) (p. 674)

CMS provides information about the third exception that allows for the DOS to be considered the date the test is performed, and thereby subject to separate payment under the CLFS, which is specified at § 414.510(b)(5). In the CY 2018 OPPS/ASC final rule, CMS established an additional exception for the hospital outpatient setting such that the DOS for molecular pathology tests and certain ADLTs that are excluded from the OPPS packaging policy is the date the test was performed (instead of the date of specimen collection) if certain conditions are met. Under this new exception, in the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

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[29] In the CY 2016 OPPS/ASC final rule with comment period, CMS excluded all molecular pathology laboratory tests from packaging because CMS believed these relatively new tests may have a different pattern of clinical use which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

[30] Under section 1834A(d)(5)(A) of the Act, an ADLT is a "CDLT that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and . . .(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result." CMS has established a regulatory definition for this type of ADLT in 42 CFR 414.502 under paragraph (1) of the definition of ADLT. Payment for ADLTs under the CLFS is also subject to special rules. CMS excluded all ADLTs that meet this criterion from packaging in the CY 2017 OPPS/ASC final rule with comment period.

CMS details its rationale for adding this third exception starting on p. 674 and notes that a list of the specific laboratory tests currently subject to this laboratory DOS exception is available on the CMS website.

Following publication of the CY 2018 OPPS/ASC final rule with comment period, CMS issued Change Request (CR) 10419, Transmittal 400, the claims processing instruction implementing this DOS exception, with an effective date of January 1, 2018 and an implementation date of July 2, 2018. Due to implementation challenges raised by stakeholders, CMS announced that it would exercise enforcement discretion for a 6-month period, which was extended for two additional 6-month periods. The enforcement discretion is currently in effect until January 2, 2020. The latest enforcement discretion announcement as well as the CR is available on the CMS website.

CMS notes that stakeholders have continued to note challenges implementing the laboratory DOS exception, including related to transfer of information between hospitals and labs and lack of enrollment in Medicare by certain entities such as blood banks and blood centers (see p. 678). CMS also notes that protein-based Multianalyte Assays with Algorithmic Analysis (MAAAs) that are not considered molecular pathology tests and are not designated at ADLTs that fall under this exception are also conditionally packaged under the OPPS at this time. Several stakeholders have suggested that they believe that the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service, though they do not currently qualify for this third DOS exception solely because they are MAAAs. CMS notes that a protein-based MAAA that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be eligible for this third DOS exception, and CMS intends to consider policies regarding MAAAs for future rulemaking.

Potential Revisions to Laboratory DOS Policy and Request for Public Comments (p. 679)

CMS is considering three options for potential changes to the laboratory DOS exception at § 414.510(b)(5) discussed above, and CMS seeks comment on these changes as follows.

1. Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv);
2. Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs; and/or
3. Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception at 42 CFR 414.510(b)(5).

Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv) (p. 680)

Since finalizing the laboratory DOS exception at §414.510(b)(5), CMS has continued to review and analyze the factors used to determine whether a molecular pathology test or Criterion (A) ADLT is unrelated to the hospital treatment and used to determine posthospital care, and therefore should have a DOS that is the date of performance rather than the date of specimen collection. One such factor, in § 414.510(b)(5)(iv), is that the results of the test must not guide treatment provided during the hospital outpatient encounter—meaning, the encounter in which the specimen was collected. CMS is no longer convinced that the determination as to whether a molecular pathology test or ADLT is separable from a hospital service should be based on whether the test results guide treatment during the specific hospital outpatient encounter in which the specimen was collected. CMS believes that a molecular pathology test or an ADLT that is performed on a specimen collected during a hospital outpatient encounter, in which the results of the test are intended to guide treatment during a future hospital outpatient encounter, is a hospital service, and therefore should be billed by the hospital that collected the specimen under arrangements, just like if the test does not meet one of the other prongs of § 414.510(b)(5). In contrast, if the results of the test are not intended to guide treatment during a hospital outpatient encounter, and if all other requirements in § 414.510(b)(5) are met, the test is separable from a hospital service and therefore, should be considered a laboratory service and the performing laboratory should bill for the test.

Per CMS, a test's relationship to a hospital outpatient encounter depends on many factors, including the patient's current diagnosis (or lack of a current diagnosis), the procedure(s) being considered for the patient, the patient's current and previous medical history, and other factors and that the ordering physician would be aware of these beneficiary characteristics. As such, CMS believes that it should be the role of the ordering physician to determine whether the results of a molecular pathology test or ADLT are or are not intended to guide treatment during a hospital outpatient encounter.

Therefore, ***CMS is considering a revision to its current laboratory DOS policy at § 414.510(b)(5)(iv) to specify that the ordering physician would determine whether the results of the ADLT or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter, if the other four requirements under § 414.510(b)(5) are met.*** Under this approach, the test would be considered a hospital service unless the ordering physician determines that the test does not guide treatment during a hospital outpatient encounter:

- If the ordering physician determines that the test results are not intended to guide treatment during the hospital outpatient encounter from which the specimen was collected or during a future hospital outpatient encounter, the DOS service of the test would be the date of test performance. In this situation, the test would not be considered a hospital service and the performing laboratory would be required to bill for the test.
- Conversely, if the ordering physician determines that the results of the laboratory test are intended to guide treatment during a hospital outpatient encounter, the DOS would be the date of specimen collection. As a result, the hospital that collected the specimen would bill for the laboratory test under arrangements and the laboratory would seek payment from the hospital for the test.

CMS is requesting comments from hospitals, laboratories, physicians and non-physician practitioners, and other interested stakeholders regarding this potential revision to the laboratory DOS exception at § 414.510(b)(5). CMS is particularly interested in comments regarding its position that when the results of molecular pathology testing and Criterion (A) ADLTs are intended to guide treatment during a future hospital outpatient encounter, the test is a hospital service. CMS also is interested in receiving public comments regarding the administrative aspects of requiring the ordering physician to determine when the test results are not intended to guide the treatment during a hospital outpatient encounter, as well as the process for the ordering physician to document this decision and provide notification to the hospital that collected the specimen for billing purposes. CMS notes that it would consider finalizing this potential revision to the laboratory DOS policy as a result of its review of the comments received on this topic.

At this time, CMS is only soliciting comments on potential changes to the laboratory DOS exception at § 414.510(b)(5), and not the 14-day rule DOS exception and the chemotherapy sensitivity test DOS exception, despite acknowledging that the same considerations may apply. These exceptions would continue to include the requirement that the results of the test do not guide treatment provided during the hospital stay, meaning the hospital stay in which the specimen was collected. Any potential changes to the 14- day rule DOS exception and the chemotherapy sensitivity test DOS exception would be addressed in future rulemaking.

Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs (p. 683)

In the CY 2018 OPPS/ASC proposed rule, CMS considered revising the DOS rule to create an exception only for ADLTs that meet the criteria in section 1834A(d)(5)(A) of the Act (and not molecular pathology tests) because ADLTs are offered and furnished only by a single laboratory consistent with regulations, which may create special access issues for ADLTs that may not apply to the molecular pathology tests. In the final rule, however, CMS agreed with commenters that limiting the new laboratory DOS exception to include only ADLTs would be inconsistent with the OPPS packaging policy and that relatively few laboratories may perform certain molecular pathology testing; CMS therefore applied the exception to molecular pathology tests as well as ADLTs. However,

after further review of this issue, CMS no longer believes the same beneficiary access concerns that apply to ADLTs also apply to molecular pathology tests, as discussed on p. 685. CMS also discusses how limiting the laboratory DOS exception to ADLTs is not consistent with OPPS packaging, but also notes that access concerns were the primary reason for establishing the laboratory DOS exception at § 414.510(b)(5).In light of the billing and enrollment concerns raised by the blood banks and blood centers and administrative issues raised by other stakeholders, CMS believes the policy reasons for removing molecular pathology tests from the laboratory DOS exception at § 414.510(b)(5) outweigh the difference it creates with the OPPS packaging policy.

Therefore, CMS is considering a potential revision that would limit the laboratory DOS provisions of § 414.510(b)(5) to tests designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502. Molecular pathology tests would be removed from the provisions of § 414.510(b)(5). However, CMS notes that molecular pathology tests would still be subject to the 14-day rule and chemotherapy sensitivity test laboratory DOS exceptions.

CMS is requesting comments on potentially limiting the laboratory DOS exception policy at § 414.510(b)(5) to Criterion (A) ADLTs that have been granted ADLT status by CMS. CMS notes that it would consider finalizing this approach as a result of the public comments received.

Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception at 42 CFR 414.510(b)(5) (p. 686)

Following publication of the CY 2018 OPPS/ASC final rule with comment period, stakeholders informed CMS that blood banks and blood centers perform some of the molecular pathology test codes that are subject to the laboratory DOS exception policy at § 414.510(b)(5). CMS provides background information about blood banks and blood centers starting on p. 687, noting how they perform molecular pathology tests for different reasons (e.g. to identify compatibility of blood products rather than for diagnostic purposes) than billing laboratories. Examples of molecular pathology testing performed by blood banks and centers include red blood cell phenotyping, as described by HCPCS code 81403, red blood cell antigen testing as described by HCPCS code 0001U, and platelet antigen testing as described by HCPCS code 81105.

Under the current laboratory DOS exception at § 414.510(b)(5), blood banks or blood centers that perform tests meeting the criteria would have to bill Medicare separately. However, given the different purpose of molecular pathology testing performed by the blood banks and centers, that is, blood compatibility testing, CMS questions whether the molecular pathology testing performed by blood banks and centers is appropriately separable from the hospital stay, given that it typically informs the same patient's treatment during a future hospital stay. CMS instead states its belief that such testing is so connected to the treatment furnished to the patient in the hospital that it must be considered a hospital service.

CMS is considering a regulatory change that would exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5). Under this potential revision, the DOS for laboratory testing performed by blood banks and centers on specimens collected from a hospital outpatient during a hospital outpatient encounter would, depending on the underlying service, be the date of specimen collection. As a result, the hospital would bill for the laboratory test under arrangements and the blood bank or center performing the test would seek payment from the hospital. In addition, for purposes of excluding blood banks and centers from the provisions of § 414.510(b)(5), CMS would define a blood bank and center as an entity whose primary function is the collection, storage and dissemination of blood products, in order to distinguish these entities from nonblood bank and blood center laboratories that perform the same molecular pathology test codes but for diagnostic purposes rather than for blood compatibility testing.

CMS is requesting comments from hospitals, blood banks and centers, and other interested stakeholders regarding a potential revision to laboratory DOS policy that would exclude blood banks and centers from the laboratory DOS exception policy at § 414.510(b)(5). CMS also is requesting specific comments as to how a blood bank and blood center may be defined in the context of this provision, and particularly how to distinguish blood banks and centers from other laboratories. CMS notes that CMS would consider finalizing this approach as a result of comments received on this topic.

Proposed Prior Authorization for Certain Hospital Outpatient Services (p. 689)

CMS found higher than expected volume increases for five general categories of services: (1) blepharoplasty; (2) botulinum toxin injections; (3) panniculectomy; (4) rhinoplasty; and (5) vein ablation. CMS believes the increases in volume associated with these covered OPD services are unnecessary because the data show that the volume of utilization of these services far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries; these procedures are often considered cosmetic and, in those instances, would not be covered by Medicare; and CMS is unaware of other factors that might contribute to clinically valid increases in volume. CMS is authorized to develop a method for controlling unnecessary increases in the volume of covered OPD services. Therefore, in light of the above concern, ***CMS proposes to use its authority to require prior authorization for certain covered OPD services as a condition of Medicare payment***.

Proposal for a Prior Authorization Process for Certain OPD Services (p. 692)

CMS proposes to use its authority to establish a process through which providers would submit a prior authorization request for a provisional affirmation of coverage before a covered OPD service is furnished to the beneficiary and before the claim is submitted for processing. In order to allow time for providers to better understand this proposed prior authorization process, for CMS to ensure sufficient time is allowed for outreach and education to affected stakeholders, and for contractor operational updates to be in place, ***CMS proposes that this requirement would begin for dates of service on or after July 1, 2020.***

CMS proposes to establish a new subpart I under part 419 (containing §§ 419.80 through 419.89 (§§ 419.84 through 419.89 would be reserved)) to codify the following proposed policies for prior authorization for certain covered OPD services.

Definitions (*p. 694*)

CMS proposes to define key terms associated with the proposed prior authorization process for certain covered OPD services under its proposed new subpart, as noted below:

- "Prior authorization" means a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted.
- "Provisional affirmation" means a preliminary finding that a future claim for the service will meet Medicare's coverage, coding, and payment rules.
- "List of hospital outpatient department services requiring prior authorization" means the list of outpatient department services CMS publishes in accordance with proposed new subpart that require prior authorization as a condition of payment.

Prior Authorization as a Method for Controlling Unnecessary Increases in the Volume of Covered Outpatient Services (p. 695)

CMS proposes that, as a condition of Medicare payment, a provider must submit a prior authorization request for services on the list of hospital outpatient department services requiring prior authorization to CMS that meets CMS' proposed new requirements.

- In submitting a prior authorization request, the provider must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and that the request be submitted before the service is provided to the beneficiary and before the claim is submitted.
- ***CMS proposes that claims submitted for services that require prior authorization (including associated anesthesiology services, physician services, and/or facility services) that have not received a***

provisional affirmation of coverage from CMS or its contractors would be denied, unless the provider is exempt (see below).

- ***CMS proposes that even when a provisional affirmation has been received, a claim for services may be denied based on either technical requirements that can only be evaluated after the claim has been submitted for formal processing or information not available at the time the prior authorization request is received (see below).***
- ***CMS proposes that CMS or its contractor would initiate an expedited review of a prior authorization request when requested by a provider and where CMS or its contractor determines that a delay could seriously jeopardize the beneficiary's life, health or ability to regain maximum function, and a provisional affirmation or non-affirmation would be provided under an expedited timeframe of two (2) business days.***
- ***CMS proposes that the agency (or its contractor) will review a prior authorization request for compliance with applicable Medicare coverage, coding, and payment rules, and if the request is compliant (or not compliant), CMS or its contractor would issue a provisional affirmation (or non-affirmation decision) to the requesting provider within ten (10) business days.***
- ***CMS proposes that, if the provider receives a non-affirmation decision, it would allow the provider to resubmit a prior authorization request with any applicable additional relevant documentation.***

Consistent with other established policies, ***CMS proposes to update its regulations such that OPD prior authorization requests that are determined non-affirmed also would not be considered an initial determination and, therefore, would not be appealable.*** However, the provider will still have the opportunity to resubmit a prior authorization request provided the claim has not yet been submitted and denied. If a claim is submitted for the services that require prior authorization without a provisional affirmation, it will be denied. The claim denial is an initial determination and a redetermination request may be submitted in accordance with existing requirements.

Consistent with current policy, ***CMS also proposes that any claims associated with or related to a service that requires prior authorization (e.g., anesthesiology services, physician services, and/or facility services) for which a claim denial is issued will be denied as well since these services would be unnecessary if the service requiring prior authorization had not been provided***. These associated claims would be denied whether a non-affirmation was received) or the provider did not request a prior authorization request. CMS also notes that a contractor is not required to request medical documentation from the provider who billed the associated claims before making such a denial. ***CMS requests public comments on whether this requirement should be included in the new subpart for prior authorization of OPD services or be co-located with the regulatory provisions governing initial determinations.***

Proposed List of Outpatient Department Services That Would Require Prior Authorization (p. 698)

CMS proposes that the list of covered OPD services that would require prior authorization are those identified by the CPT codes in Table 38. Details regarding CMS' decision to require prior authorization for these services start on p. 700.

CMS proposes that CMS may elect to exempt a provider from the prior authorization process upon its demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS elects to withdraw the exemption.

- Specifically, ***CMS would exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment.*** By achieving this percentage, the provider would be demonstrating an understanding of the requirements for submitting accurate claims.
- ***CMS proposes that it might withdraw an exemption if evidence becomes available based on a review of claims that the provider has begun to submit claims that are not payable based on Medicare's***

billing, coding or payment requirements (i.e., the rate of nonpayable claims submitted becomes higher than 10 percent during a biannual assessment).

CMS proposes that it may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on CMS' webpage. This is unlikely to occur, however, CMS believes it is necessary to retain this flexibility in the event of certain circumstances, such as where the cost of the prior authorization program exceeds the savings it generates.

Comment Solicitation on Cost Reporting, Maintenance of Hospital Chargemasters & Related Medicare Payment Issues (p. 704)

The Department is examining the relationship of hospital chargemasters to the Medicare cost report and its use in setting Medicare payment for hospital services in connection with the Department's effort to increase innovation in its programs. For this cause, ***the Department is seeking public comments on innovative and streamlined methods for establishing hospital payment to the extent permitted by law***, including comments from hospitals and revenue cycle management experts, cost report experts, accounting firms, or others who understand hospital cash flows.

Medicare-certified institutional providers are required to submit an annual cost report to CMS, which contains a range of information including charges by cost center. ***CMS is seeking public comments on:***

- ***The continued value of the chargemaster charges in setting hospital payment and to other stakeholders, as well as the costs associated with maintaining the chargemaster for purposes of Medicare cost reporting and payment.***
- ***Whether it would be possible to modernize or streamline the Medicare cost reporting process, for example, by replacing it with other processes, or if it could be modified in content, methodology, or approach.***
- ***Whether and how the replacement or modification of the chargemaster might affect the submission of data used by CMS to calculate payments (e.g. recalibrating relative weights, outlier payments, CAH payments, new technology add-on payments, and pretransplant cost reimbursement), as well as alternative sources that could be used for the information necessary to calculate these payments.***
- ***The decision process, and why the chargemaster might be updated more frequently than on an annual basis, and how this more frequent updating could affect costs for patients.***

Collection of Information Requirements (p. 675)

This proposed rule has been designated as an "economically significant" rule and a major rule under the Congressional Review Act.

CMS estimates that the proposed total increase in Federal government expenditures under the OPPS for CY 2020, compared to CY 2020, due only to the proposed changes to OPPS in this proposed rule, would be approximately $940 million. Taking into account CMS' estimated changes in enrollment, utilization, and case-mix for CY 2020, CMS estimates that the OPPS expenditures, including beneficiary cost-sharing, for CY 2020 would be approximately $79.2 billion, approximately $6.2 billion higher than estimated OPPS expenditures in CY 2019. CMS notes that the spending estimates include the CY 2020 completion of the phase-in, finalized in CY 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based departments in CY 2020 at a rate that will be 40 percent of the OPPS rate for a clinic visit service.

Table 41 displays the distributional impact of the proposed CY 2020 changes in OPPS payment to various groups of hospitals and for CMHCs. Overall, CMS estimates that the total proposed change in payments between CY 2019 and CY 2020 would increase total estimated OPPS payments by 2.8 percent.

CMS also estimates the proposed total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2020 compared to CY 2019 to be approximately $200 million. Table 42 and Table 43 display the redistributive impact of the proposed CY 2020 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

CMS provides additional discussion on several policies, including the following two select policies of interest:

- **Hospital Price Transparency**
  - Information Collection Burden (p. 713) – $6,105,474 in annualized costs
  - Economic Impact (p. 761) – CMS states its difficulty in conducting a detailed quantitative analysis of this proposal, so instead produces a qualitative discussion that addresses effects on the private sector and effects on consumers
  - Alternatives Considered (p. 775) – CMS discusses several alternatives it considered, CMS considered proposals to require release of hospital standard charge data in an API format, or other types of "standard charges" that could be useful to consumers (e.g. a volume-driven negotiated charge, the minimum/median/maximum negotiated charge, all allowed charges). CMS seeks comment on a definition of "standard charge" that might be relevant to subgroups of individuals who are self-pay, specifically, types of standard charges representing the discounted cash price for a service package, or the median cash price. CMS also considered, but is not proposing, that hospitals would display a set of at least 100 shoppable services with their payer-specific negotiated rates (instead of at least 300 shoppable services as currently proposed).
- **Prior Authorization for Certain Outpatient Department Services**
  - Information Collection Burden (p. 718) – $3,851,504
  - Economic Impact (p. 776) – CMS estimates that the overall economic impact of this proposal is approximately $8.4 million in administrative costs in the first year, based on 6 months due to a July start date. The 10-year impact is approximately $152 million, which would be offset by some savings. CMS breaks down private sector versus Medicare costs in Table 47. CMS discusses estimated benefits that are difficult to project on p. 782.

Additionally, CMS includes discussion of the following specific policies in its economic analyses:

- **Separately Payable Drugs Acquired under the 340B Program (p. 727)** – CMS notes that the impact tables have modeled payments as if separately payable drugs acquired under the 340B program from hospitals not excepted from the policy are paid in CY 2020 under the OPPS at ASP – 22.5 percent. CMS notes ongoing litigation on this policy, and that a policy to pay for 340B-acquired drugs and biologicals under the CY 2020 OPPS at an amount of ASP + 3 percent would necessitate an accompanying budget neutrality adjustment to the OOPPS conversion factor, which would result in a reduction of approximately $1.4 billion in payments for non-drug items and services for CY 2020.
- **Completion of Phase-In to Control for Unnecessary Increases in the Volume of Outpatient Services (p. 730)** – CMS an estimate of the policy, including the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2020 President's budget, approximates the estimated decrease in total payment under the OPPS at $810 million, with Medicare OPPS payments decreasing by $650 million and beneficiary copayments decreasing by $160 million in CY 2020. This policy is not budget neutral.

CMS also discusses some potential alternatives to proposals that were considered, including:

- **Skin Substitutes (p. 747)** – CMS considered reinstating its methodology from CY 2017 and assigning skin substitutes to the high cost group based on whether an individual product's MUC or PDC exceeded the overall CY 2019 MUC or PDC threshold based on calculations done for either the proposed rule or the final rule.
- **Payment for Non-Opioid Pain Management Treatments (p. 747)** – CMS discusses an alternative policy that would use CMS' equitable adjustment authority to establish an incentive payment for certain non-opioid alternatives that would apply to drugs and devices under the OPPS.
- **Proposed Changes in Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs (p. 748)** – CMS considered reevaluation of the level of physician supervision for cardiac rehabilitation services to determine whether CMS should propose a change to the supervision level from direct supervision to general supervision, leaving direct supervision as the minimum required default level for most outpatient therapeutic services.

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