

A Summary of the Centers for Medicare and Medicaid Services Calendar Year 2019 Outpatient Prospective Payment System (OPPS) & ASC Payment System Proposed Rule

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Overview

On July 25, 2018, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) and ASC Payment System proposed rule. CMS estimates that the OPPS fee schedule factor will increase by 1.25 percent.

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 24, 2018**. The final rule is expected for release in early November 2018.

CMS proposes to increase the CY 2018 OPPS conversion factor to \$79.546 (p. 107). This is premised on a general overall increase of 1.25 percent (p. 104). The overall increase (before budget neutrality adjustments) is based on the proposed hospital inpatient market basket increase of 2.8 percent minus a productivity adjustment of 0.8 percent, as well as a 0.75 percent reduction required by the Patient Protection and Affordable Care Act (ACA). 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 2019 OPPS payments will increase by approximately \$5.0 billion over CY 2018 estimated payments to a total of approximately \$75 billion (p. 359). 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).

OPPS Provisions (p. 41)

Recalibration of APC Relative Payment Weights (p. 41)

CMS uses the same annual process to update the APC relative weights and payments for CY 2019. 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, 2017 and before January 1, 2018. CMS proposes to continue its policy of using hospital cost-to-charge ratios to estimate costs for rate setting purposes (p. 43). CMS also proposes to continue its policy of establishing OPPS relative payment rates based on geometric mean costs as it has done since CY 2013 (p. 48).

Single Procedure APC Criteria-Based Costs: Brachytherapy Sources (p. 55)

[Social Security Act §1833\(t\)\(2\)\(H\)](#)¹ requires that CMS classify devices of brachytherapy consisting of seeds separately from other services or groups of services. CMS continues to base OPPS prospective payment methodology (i.e. use of claims data to set the relevant payment) to brachytherapy sources (while maintaining a separate payment category for brachytherapy sources as required under statute). Therefore, in order to maintain an underlying payment policy consistent with the rest of the OPPS, **CMS proposes to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source** as CMS proposes for other items and services under the OPPS elsewhere in the rule (p. 56).

Otherwise, **CMS proposes to continue its other payment policies for brachytherapy sources** much of which was finalized in CY 2010.

¹ “[W]ith respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.”

- ***CMS proposes to pay for the stranded and nonstranded ‘not otherwise specified’ (NOS) codes (C2698 and C2699) at a rate “equal to the lowest stranded or nonstranded prospective payment rate for such sources on a per source basis” (i.e. not per mCi).***
- ***CMS proposes to continue its payment for new brachytherapy sources for which CMS has no claims data by assigning new HCPCS codes for new brachytherapy sources to their own APCs with prospective payment rates set based on “consideration of external data and other relevant information regarding the expected costs of the sources to the hospitals.***
- ***CMS proposes to continue to assign status indicator “U” to C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and to use external data/invoice prices and other relevant information to establish the payment rate (p. 57).***

However, for CY 2019, ***CMS proposes to assign status indicator “E2” (Items and services for which pricing information and claims data are not available to C2644 (Brachytherapy cesium-131 chloride) because the code was not reported on CY 2017 claims and therefore there is no data on which to base a payment rate (p. 57).***

CMS continues to request input for new codes to describe brachytherapy sources (p. 58).² CMS will continue to add new brachytherapy source codes to its system on a quarterly basis.

Proposed CY 2019 payment rates are listed on [the CMS Web site in Addendum B](#) with the status indicator “U.”

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 2017, CMS had finalized an 62 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. 65):
 - Frequency of 25 or more claims reporting the code combination; and
 - Violation of the 2 times rule in the originating Comprehensive APC

² CMS directs this input to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244 (p. 58).

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 ([p. 66](#)). ***CMS proposes to apply the frequency and cost criteria to the primary service and to add-on codes where if any add-on code reported with the primary service code does not qualify for the complexity adjustments, payment for the add-on service would continue to be packaged into the payment for the primary service and not assigned to the next higher cost C-APC*** ([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 2019 Comprehensive APCs. CMS proposes to continue the Comprehensive APC payment methodology implemented in CY 2015*** ([p. 68](#)). However, ***CMS proposes three (3) additional Comprehensive APCs for CY 2019:***
 - C-APC 5163 (*Level 3 ENT Procedures*)
 - C-APC 5183 (*Level 3 Vascular Procedures*)
 - C-APC 5184 (*Level 4 Vascular Procedures*)

CMS lists all Comprehensive APCs that would be effective in CY 2019 in [Table 3](#).

- ***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. 72](#)). Therefore, ***CMS proposes to 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)*** ([p. 73](#)) (See also, [section on New Technology APCs](#)).
- ***Comprehensive APC 5375 (Level 5 Urology and Related Services):*** In the *Composite* APC section of the rule, CMS reminded stakeholders that in CY 2018, CMS finalized its proposal to delete *Composite* APC 8001 (LDR Prostate Brachytherapy Composite) and to reassign CPT 55875 (*Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy*) to Comprehensive APC 5375 (*Level 5 Urology and Related Services*). ***CMS proposes to continue assign CPT 55875 a status indicator of J1*** ([p. 74](#)).

Composite APCs ([p. 73](#))

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.” ***CMS proposes to generally continue its Composite APC payment policies*** ([p. 74](#)).

CMS previously developed and finalized the following Composite APCs ([p. 74](#)):

- Mental health services (Composite APC 8010): ***CMS proposes to continue its Composite APC policy for APC 8010***. Additional information is available beginning on [p. 75](#).
- 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. 77](#) and in [Table 4](#).

Packaged Items and Services (p. 83)

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. However, CMS discusses packaging policies related to non-opioid pain management treatments.***

Non-Opioid Pain Management Treatments (p. 86): 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. Since CY 2018 rulemaking, CMS also notes that the President’s Commission on Combatting Drug Addiction and the Opioid Crisis recommended that CMS examine its payment policies for drugs that function as a supply, specifically non-opioid pain management treatments (p. 87).

- **OPPS Setting:** In response, CMS reviewed its packaging policy for drugs that function as a supply. CMS states, “[w]e did not observe significant declines in the total number of units used in hospital outpatient department for a majority of [specific drugs that function as a supply] included in our analysis.” (p. 89). CMS said if its policy discouraged use of a packaged drug, it would expect to see a significant decline in utilization of these drugs over time (p. 89).³ Therefore, ***CMS proposes no changes under the OPPS packaged “drugs that function as a surgical supply” at this time (p. 90).***
- **ASC Setting:** In the review of data in the ASC setting, however, CMS observed a decrease in the utilization of a non-opioid pain management treatment after the drug’s pass-through status expired.⁴ CMS believes that it is possible that this phenomenon could occur in the ASC setting (while being simultaneously absent under the OPPS) because ASCs “provide specialized care and a more limited range of services” and are only paid at 55 percent of the OPPS rate (p. 92). Therefore, CMS posits, ASCs could be less likely to furnish typically more expensive non-opioid postsurgical pain management treatments (p. 92). CMS also notes, however, that ASCs do not report packaged items and services, and there could be undercounting in its analysis of the ASC setting (p. 93). Because of this analysis, ***CMS believes it could be appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the observed decreased utilization and to encourage use of them rather than prescription opioids. CMS proposes to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting CY 2019 (p. 93).*** (See also, [implementation of this proposal in ASC section](#)).
- **Additional requests/input (p. 94):**
 - Peer-reviewed evidence that demonstrates that non-opioid alternatives in the outpatient setting actually lead to a decrease in prescription opioid use
 - Evidence that demonstrates whether and how much non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure

³ CMS provided a detailed example of Exparel (C9290), the only current non-opioid pain management drug that is packaged as a “drug that functions as a supply” under the OPPS or ASC payment system. Exparel had pass-through status from CY 2012-2014 (and thus separately payable) and then was packaged as a surgical supply starting in CY 2015. From CY 2013 – CY 2017 there was a 229 percent utilization increase (including increases during the years after pass-through status expired) (p. 90) of Exparel in the hospital outpatient setting. In addition to generally retained its packaging policy for “drugs that function as a supply,” CMS also states that, based on its analysis, it believes that it is appropriate, explicitly for Exparel, to continue packaging it with other post-surgical pain management drugs when furnished in the hospital outpatient department (p. 91). However, ***CMS seeks input on whether separate payment would further incentivize appropriate use of Exparel and peer-reviewed evidence that increased use would lead to a decrease in opioid use and addiction among Medicare beneficiaries (p. 91; p. 94).***

⁴ Again examining Exparel, but in the ASC setting, CMS sought to study utilization rate changes post-pass-through status. Overall from CY 2013 – CY 2017, use of Exparel in the ASC setting decreased by 25 percent. More specifically, after pass-through status for Exparel expired, the total number of units of Exparel decreased by 70 percent (p. 92) (cf. increase between CY 2013 and 2014 (when it had pass-through status) of 238 percent (p. 92)).

- Whether the proposed ASC packaging policy would decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (esp. for beneficiaries at high-risk of opioid addiction)
- Whether there are other non-opioid pain management alternatives that would have similar effects and warrant a separate payment
- Whether single post-surgical analgesic injections or other non-opioid drugs or devices that are used during an outpatient visit or procedure are associated with decreased opioid prescriptions and reduced cases of associated opioid addiction following an outpatient visit or procedure⁵
- Evidence CMS could use to determine whether these products help to deter or avoid prescription opioid use and addiction
- Evidence that the current packaged payment for non-opioid alternatives presents a barrier to access to care and warrants a separate payment under the OPPS and/or ASC payment system
- Ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorders and improve access to treatment under the Medicare program
- Identification of barriers that may inhibit access to non-opioid alternatives for pain treatment and management or access to opioid use disorder treatment
- Suggestions to improve existing requirements in order to more effectively address the opioid epidemic
- Evidence related to products that have shown clinical improvement over other alternatives (e.g., a device shown to provide substantial clinical benefit over the standard of care for pain management)⁶ and whether a policy of providing separate payment for these products would incentivize use of alternative non-opioid alternatives (esp. for innovative and low-volume items and services).
- Whether CMS should provide separate payment for non-opioid pain management treatments or procedures using other mechanisms (e.g. an equitable payment adjustment as allowed under statute⁷) such as an add-on payment
- Whether a reorganization of the APC structure for procedures involving these products (or more granular APC groupings) would better achieve our goal of incentivizing increased use of non-opioid alternatives⁸
- How alternative payment structures would continue to balance the goals of incentivizing provider efficiencies with encouraging the use of non-opioid alternatives to pain management
- Identification of any cost implications for patients and the Medicare program caused by potential change in policy

OPPS Payments to Certain Cancer Hospitals (p. 125)

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"

⁵ CMS notes that evidence could include "an indication on the product's FDA label or studies published in peer-reviewed literature that such product aids in the management of acute or chronic pain and is an evidence-based non-opioid alternative for acute and/or chronic pain management" (p. 96).

⁶ CMS cites spinal cord stimulators to treat chronic pain as an example (p. 96).

⁷ [Social Security Act §1833\(t\)\(2\)\(E\)](#) states "the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals."

⁸ "For example, we would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items and services if such APCs would better recognize the resources involved in furnishing items and services and decrease or eliminate the need for prescription opioids" (p. 98).

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 OPSS. 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 OPSS 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, 2017, 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 OPSS 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 OPSS ([p. 127](#)).
- ***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 OPSS 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. 128](#)).
- For CY 2019, CMS estimates that other OPSS hospitals are approximately 89 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 0.88 percent for each cancer hospital*** ([p. 129](#)).
- [Table 6](#) shows the proposed estimated percentage increase in OPSS payments to each cancer hospital for CY 2019.

Hospital Outpatient Outlier Payments ([p. 130](#))

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 2017 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 \$4,150 ([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 OPSS spending in outlier payments. CMS estimates that CY 2018 aggregate outlier payments will be approximately 1.02 percent of total OPSS payments. ***CMS proposes to continue its policy of estimating aggregate outlier payments at 1 percent of total payments under the OPSS*** ([p. 132](#)).
- In order to maintain outlier payments at 1 percent of OPSS 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 \$4,600*** ([p. 133](#)).

APC Group Policies ([p. 148](#))

New CPT and Level II HCPCS Codes ([p. 148](#))

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 7](#) 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:

- New Level II HCPCS Codes Implemented in April 2018 in [Table 8](#); in addition CMS notes that there are several new lab CPT Multianalyte Assays with Algorithmic Assays (MAAA) codes and Proprietary Laboratory Analyses (PLA) codes (set as U codes) effective April 1, 2018 but too late to include in the April 2018 OPPS update. These were included in the July 2018 OPPS update and are available for review in [Table 9](#).
- New HCPCS Codes Implemented in July 2018 in [Table 10](#); There were also new PLA codes effective for July 1, 2018 but were provided too late to be included in the July 2018 OPPS Update. These will be included in the October 2018 update and can be viewed in [Table 11](#).
- New HCPCS Codes that will be effective on October 1, 2018 and January 1, 2019. ***CMS proposes to continue its policy of assigning these new codes an interim payment status of “NI” in [Addendum B](#) ([p. 159](#)).***
- New and Revised HCPCS Codes Effective January 1, 2019: 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. 161](#)).

Variation Within APCs ([p. 163](#))

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. 165](#)).

- 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. ***CMS identified 16 violations of the 2 times rule for CY 2019, and CMS determined that all 16 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 12](#).

New Technology APCs ([p. 169](#))

CMS proposes to establish a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims. CMS proposes to use up to 4 years of claims data to establish a payment rate for each applicable service both for purposes of assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC.

CMS also proposes to use the geometric mean, the median, or the arithmetic mean to calculate the cost of furnishing the applicable service, present the result of each statistical methodology in annual rulemaking, and

solicit public comment on which methodology should be used to establish the payment rate. The geometric mean may not be representative of the actual cost of a service when fewer than 100 claims are present because the payment amounts for the claims may not be distributed normally. Under this proposal, CMS would have the option to use the median payment amount or the arithmetic mean to assign a more representative payment for the service. Once CMS identifies the payment rate for a service, it would assign the service to the New Technology APC with the cost band that includes its payment rate.

Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414) (p. 177)

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 reassign to a different New Technology APC for CY 2019. These codes include CPT codes 0071T and 0072T (procedures for the treatment of uterine fibroids), 0398T (procedures for the treatment of essential tremor), and HCPCS code C9734 (procedures for pain palliation for metastatic bone cancer).

As shown in [Table 13](#), ***CMS proposes to continue to assign the procedures described by CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with a proposed payment rate of approximately \$2,410 for CY 2019.*** In addition, ***CMS proposes to continue to assign the services described by HCPCS code C9734 to APC 5115 (Level 5 Musculoskeletal Procedures), with a proposed payment rate of approximately \$10,936 for CY 2019.***

For procedures described by CPT code 0398T, CMS has only identified three paid claims CY 2016-2017. ***CMS proposes to reassign the procedures described by CPT code 0398T from APC 1576 (New Technology – Level 39 (\$15,001-\$20,000)) to APC 1575 (New Technology - Level 38 (\$10,001-\$15,000)), with a proposed payment rate of \$12,500.50.***

Retinal Prosthesis Implant Procedure (p. 182)

For CY 2019, the reported cost of the Argus® II procedure based on CY 2017 hospital outpatient claims data is approximately \$152,021, which is \$29,520 more than the payment rate for the procedure for CY 2018. The costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS, and the number of claims submitted has been very low and did not exceed 10 claims for CY 2017. Large decreases in the payment rate could potentially create an access to care issue for the procedure. CMS wants to mitigate the potential sharp increase in payment from CY 2018 to CY 2019 and ensure a more stable payment rate in future years. For CY 2019, ***CMS proposes to reassign the Argus® II procedure from APC 1904 (New Technology—Level 50 (\$115,001-\$130,000)) to APC 1906 (New Technology—Level 51 (\$130,001-\$145,000)), which would result in a proposed payment rate for the Argus® II procedure of \$137,500.50. This proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the device (HCPCS code C1841).***

CMS has also found that payment for the Argus® II procedure is sometimes bundled into the payment for another procedure. This occurs when the procedure is reported with other eye procedures assigned to a Comprehensive APC. ***CMS proposes to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a Comprehensive APC.*** This would allow for separate payment for the Argus® II procedure even when it is performed with another comprehensive service, which would provide more cost information regarding the procedure.

APC-Specific Policies (p. 187)

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

- Endovascular Procedures (p. 188): CMS received input from the HOP Panel that it should look into the APCs for endovascular procedures to determine whether more granularity is warranted. CMS notes that in CY 2018, it believed that the current Comprehensive APCs for the endovascular procedures family was appropriate (from both a cost and clinical homogeneity perspective). Per the HOP Panel request, CMS analyzed the data for the existing levels of endovascular procedures and continue to believe the APC structure is appropriate. Therefore, **CMS proposes to maintain the existing four-level structure for the Comprehensive APC family** (p. 189). The Comprehensive APCs (with proposed geometric mean cost) can be found in [Table 14](#).
- Imaging Procedures and Services (p. 190): Statute requires CMS to separately classify procedures that utilize contrast agents from those that do not (p. 191). CMS previously restructured APCs for imaging services resulting in 7 consolidated imaging APCs, including 4 imaging APCs *without* contrast and 3 imaging APCs *with* contrast. In CY 2018, CMS proposed, but did not finalize, the addition of a fifth level to the Imaging Without Contrast APCs. **For CY 2019, CMS proposes to retain the current APC structure (4 without contrast; 3 with contrast) but to make minor reassignments to the HCPCS codes** (p. 192). CMS lists the CY 2019 Imaging APCs with CY 2018 and CY 2019 payment comparisons in [Table 17](#). The specific APC assignments for service groupings are included in [Addendum B](#).
- Musculoskeletal Procedures (p. 193): CMS is not proposing changes to the structure of the Musculoskeletal APCs for CY 2019 (p. 193). However, CMS notes that there have been concerns about the granularity of the current APCs and request for additional levels. **CMS seeks comment on the potential creation of a new APC level between current Level 5 and Level 6** (p. 195). See [Table 18](#) for CY 2019 Musculoskeletal APCs and proposed geometric mean costs.
- Intraocular Procedures (p. 195): CMS discusses its review of Comprehensive APC 5495 (*Level 5 Intraocular Procedures*) on p. 195. 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. CMS notes that in the CY 2019 ratesetting data, it received only two claims for CPT 0308T. Based on the information available, **CMS proposes to reassign CPT 0308T to APC 5493 (Level 3 Intraocular Procedures)** (p. 195) **and proposes to delete APC 5495**. CMS states that it believes the geometric mean makes it more comparable for APC 5493. CMS says it will continue to monitor the volume of claims for future ratesetting.

OPPS Payment for Devices (p. 196)

Pass-Through Payments for Devices

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 payments have been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule, 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. 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.

New Device Pass-Through Applications (p. 197)

CMS received seven applications by the March 1, 2018 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2019 OPPS/ASC proposed rule. None of the seven applications were approved for device pass-through payment during the quarterly review process.

- **AquaBeam System:** intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). CMS questions whether the technology meets the substantial clinical improvement criterion. CMS invites public comment on whether the technology meets all of the criteria. ([p. 201](#))
- **BioBag® (Larval Debridement Therapy in a Contained Dressing):** a biosurgical wound treatment (“maggot therapy”) consisting of disinfected, living larvae (*Lucilia sericata*) in a polyester net bag to aid with removing dead tissue from wounds. CMS invites comments on whether this technology meets the criteria for pass-through payment. ([p. 207](#))
- **BlastX™ Antimicrobial Wound Gel:** for the management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, postsurgical wounds, first and second degree burns, and grafted and donor sites. This technology does not meet the basic criterion for being an eligible device for pass-through payment, so CMS does not comment on the other criteria. CMS invites comment. ([p. 212](#))
- **EpiCord®:** a minimally manipulated, dehydrated, devitalized cellular umbilical cord allograft for homologous use that provides a protective environment for the healing process. CMS did not receive documentation that this product is regulated as a device by FDA. CMS questions whether the technology represents a substantial clinical improvement. CMS invites public comment. ([p. 214](#))
- **remedē® System Transvenous Neurostimulator:** an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients. CMS questions whether this technology meets the substantial clinical improvement criterion. CMS invites comment. ([p. 220](#))
- **Restrata® Wound Matrix:** a sterile, single-use product intended for use in local management of wounds. CMS questions whether the technology meets the substantial clinical improvement criterion. CMS invites comment.
- **SpaceOAR® System:** a polyethylene glycol hydrogel spacer that temporarily positions the anterior rectal wall away from the prostate to reduce the radiation delivered to the anterior rectum during prostate cancer radiotherapy treatment. CMS questions whether the technology meets the substantial clinical improvement criterion. CMS invites comment.

Device-Intensive Procedures (p. 238)

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. 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 are subject to the following criteria:

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

For CY 2019, ***CMS proposes two modifications to the above criteria. First, CMS proposes to 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 proposes to modify 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.*** Specifically, for CY 2019 and subsequent years, ***CMS proposes that device-intensive procedures would be subject to the following criteria:***

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

In addition, to further align the device-intensive policy with the criteria used for device pass-through status, ***CMS proposes to specify, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:***

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by 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).

CMS solicits public comment on these proposed revised criteria and on the full list of proposed CY 2019 OPPS device-intensive procedures provided in [Addendum P](#).

In accordance with the proposal above to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, ***CMS proposes 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. CMS proposes to continue its current policy of, in certain rare instances, temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a manufacturer.***

In addition, CMS is clarifying 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 proposes to 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. CMS proposes to 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.

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.

Device Edit Policy (p. 248)

CMS is not proposing any changes to current policy.

Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices (p. 249)

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. For CY 2019 and subsequent years, ***CMS proposes to apply its no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under the proposed modified criteria discussed above.***

Low Volume Device Intensive Procedures (p. 251)

For CY 2019, ***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.*** For CY 2019, there are no procedures to which this policy would apply.

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals (p. 254)

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.

Proposed Drugs and Biologicals with Expiring Pass-Through Status (p. 257)

CMS proposes that the pass-through payment status of 23 drugs and biologicals would expire on December 31, 2018, as listed in Table 19. 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 \$125 for CY 2019). ***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 2019).

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status (p. 259)

CMS proposes to continue pass-through payment status in CY 2019 for 45 drugs and biologicals. These drugs and biologicals are listed in Table 20. 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. That brings the total number of drugs and biologicals with proposed pass-through payment status in CY 2019 to 49.

For CY 2019, 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 2019. CMS proposes that a \$0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2019 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 2019 minus a payment offset for any predecessor drug products contributing to the pass-through payment.

CMS proposes to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2019 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary.

For CY 2019, 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.

Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Sec. 1301 of the Consolidated Appropriations Act of 2018 (p. 265)

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 whose period of drugs and biologicals pass-through payment status ended on December 31, 2017. These products are listed in Table 21.

For January 1, 2019 through March 31, 2019, ***CMS proposes that pass-through payment for these four drugs and biologicals would be the greater of:*** (1) ASP+6 percent based on current ASP data; or (2) the payment rate for the drug or biological on December 31, 2017. CMS proposes to continue to update pass-through payment

rates for these four drugs and biologicals on a quarterly basis on the CMS website during CY 2019 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 drugs or biologicals are necessary.

Included as one of the four drugs and biologicals with pass-through payment status for CY 2019 is 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 are 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 proposes to consider PuraPly to be a drug or biological and to be eligible for extended pass-through payment.***

Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups (p. 268)

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 2019, ***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 22](#).

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status (p. 270)

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 2019 of \$125.***

Packaging for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals under the Cost Threshold (“Threshold-Packaged Drugs”) (p. 272)

As noted above, ***CMS proposes to package items with a per day cost less than or equal to \$125 and identify items with a per day cost greater than \$125 as separately payable unless they are policy-packaged.*** 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 2017, 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, 2018, along with updated hospital claims data from CY 2017.

Payment rates for HCPCS codes for separately payable drugs and biologicals will be based on ASP data from the third quarter of CY 2018. 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, 2018. These payment rates would then be updated in the January 2019 OPPS update, based on the most recent ASP data to be used for physician’s office and OPPS payment as of January 1, 2019. ***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 2017 claims data and updated cost report information available for the CY 2019 final rule with comment period to determine their final per day cost.

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.**

Proposed High/Low Cost Threshold for Packaged Skin Substitutes (p. 277)

CMS has continued the high cost/low cost categories policy since CY 2014 and proposes to continue it for CY 2019. 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 a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. CMS proposes to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, 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. Any skin substitute product that was assigned to the high cost group in CY 2018 would be assigned to the high cost group for CY 2019, regardless of whether it exceeds or falls below the CY 2019 MUC or PDC threshold.

For CY 2019, CMS proposes to continue to assign skin substitutes with pass-through payment status to the high cost category. 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 2019 MUC threshold. [Table 23](#) displays the proposed CY 2019 high cost or low cost category assignment for each skin substitute product.

CMS received many responses to its requests for comments in the CY 2018 OPPS/ASC proposed rule about possible refinements to the existing payment methodology for skin substitutes that would be consistent with the policy goal of providing payment stability for these products. **CMS has identified four potential methodologies, described below, that it encourages the public to review and provide comments on.** CMS will consider the feedback received in response to this proposed rule in developing proposals for CY 2020.

- Establish a lump-sum "episode-based" payment for a wound care episode. 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. ([p. 283](#))

- 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. This option 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](#))
- 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](#))
- 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](#))

For CY 2020, CMS may revise its policy to reflect one of the potential new methodologies discussed above or a new methodology included in public comments.

Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages ([p. 288](#))

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. The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2019 is displayed in [Table 24](#).

Proposed Payment for Items without Pass-Through Status That Are Not Packaged ([p. 291](#))

- 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. 291](#))

- 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. 293](#))
- 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. ([p. 293](#))
- 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 is currently being used. For the OPPS, CMS is also proposing to utilize a 3-percent add-on instead of a 6-percent add-on for WAC-based drugs. CMS also applies this provision to non-SCOD separately payable drugs. CMS is proposing that, if finalized, its proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological. 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. 294](#))
- 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. CMS proposes to continue this policy. ([p. 296](#))
- 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. ***For CY 2019, CMS proposes changes to the payment methodology for biosimilars acquired under the 340B Program.*** Specifically, for CY 2019 and subsequent years, ***CMS proposes to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP*** ([p. 296](#)).
- For CY 2019, CMS proposes to continue the payment policy for therapeutic radiopharmaceuticals as used since CY 2010. ([p. 299](#))
- For CY 2019 and subsequent years, CMS proposes to continue to provide an additional \$10 payment for radioisotopes produced by non-HEU sources. CMS intends to reassess this payment policy once conversion to non-HEU sources is closer to completion or has been completed. ([p. 300](#))
- For CY 2019, 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. 302](#))
- For CY 2019, 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 \(p. 303\)](#).
- In the CY 2018 OPPS/ASC final rule, CMS 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) plus 6 percent to ASP minus 22.5 percent. Critical access hospitals (CAHs), rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals were exempted from this policy change. CMS has received requests to clarify whether drugs that do not have ASP pricing but instead receive WAC or AWP pricing are subject to the 340B payment adjustment. CMS clarifies that the 340B payment adjustment does apply to drugs that are priced using either WAC or AWP. The number of separately payable drugs receiving WAC or AWP pricing that are affected by the 340B payment adjustment is small--consisting of less than 10 percent of all separately payable drugs in April 2018. In the CY 2018 OPPS/ASC proposed rule, CMS stated its intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were

not acquired under the 340B Program. CMS implemented modifier “JG”, effective January 1, 2018. Non-exempted hospitals paid are required to report modifier “JG” on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. Exempted hospitals are required to report informational modifier “TB” for 340B-acquired drugs, and continue to be paid ASP+6 percent. **For CY 2019, CMS proposes to continue the 340B Program policies that were implemented in CY 2018 with the exception of the way it is calculating payment for 340B-acquired biosimilars, as outlined above.** ([p. 303](#))

Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices ([p. 308](#))

Statute limits pass-through payment spending at 2.0 percent of total OPPS payments. **CMS estimates that pass-through spending in CY 2019 would equal approximately \$126.7 million (approximately \$10 million for device categories and approximately \$116.7 million for drugs and biologicals) which represents 0.18 percent of total projected OPPS payments for CY 2019 (approximately \$70 billion).** Therefore, the 2% program spending limit is not exceeded.

OPPS Payment for Hospital Outpatient Visits ([p. 315](#))

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 ([p. 316](#)). [Elsewhere in the rule](#), CMS does make changes related to clinic visits furnished in *off-campus provider based departments*.

Inpatient Only Procedures ([p. 347](#))

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. 348](#)):

- 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 2019, CMS has identified two (2) procedures that it proposes for removal from the Inpatient Only list ([p. 349](#) and [Table 29](#)):

- **CPT 31241 (Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery).** Additional information:
 - CMS believes this meets the criterion that “the procedure is related to codes that CMS has already removed from the inpatient list” (Note: CMS does not specifically state what procedure that is).
 - CMS proposes to assign CPT 31241 to Comprehensive APC 5153 (Level 3 Airway Endoscopy)
- **CPT 01402 (Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty).** Additional information:

- CMS believes this meets the criterion that “*the procedure is related to codes that CMS has already removed from the inpatient list*”: Specifically CMS states that this procedure is typically billed with CPT 27447 (*Arthroplasty, knee, condyle and plateau; medical and lateral components with or without patella resurfacing (total knee arthroplasty)*), a code that CMS already removed from the Inpatient Only list ([p. 350](#))
- CMS believes this meets the criterion: “*a determination is made that the procedure is being performed in numerous hospitals on an outpatient basis*” (Note: CMS cites no additional information or utilization data for this).

In addition to the two codes proposed for removal, CMS also seeks input on the **potential removal of CPT 0267T (*Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)*)** ([p. 351](#)). Additional information:

- CPT 0266T has been on the Inpatient Only list since the code was effective in CY 2011
- CMS believes there are several codes similar to CPT 0266T that are not on the Inpatient Only list, including:
 - CPT 0267T (*Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)*)
 - CPT 0268T (*Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)*)
- The device billed with the two “similar procedures” has Category B Investigational Device Exemption (IDE) from the FDA.
- CMS states that there is “limited information available to determine the typical site of service and the ability for the procedure to be safely performed in the outpatient setting.”

Procedures Identified for Addition to the Inpatient Only List

CMS also reviews the general criteria for procedures being on the Inpatient Only list:

- The nature of the procedure;
- The underlying physical condition of the patient; or
- The need for at least 24 hours of postoperative recovery time for monitoring before the patient can be safely discharged

For CY 2019, CMS also proposes to add a code to the Inpatient Only List: C9606 (*Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel*). CMS believes C9606 is performed during AMI and it is similar to CPT 92941 (*Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, artherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel*) which CMS added to the Inpatient Only List in CY 2018 ([p. 351](#)). The code is also listed for addition in [Table 29](#).

Off Campus Provider-Based Departments

Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments (p. 352)

CMS references the Medicare Payment Advisory Commission ([MedPAC June 2017 Report to Congress](#)) where MedPAC recognizes the growth in the number of facilities “located apart from hospitals that are devoted primarily to emergency department services.” (p. 353). MedPAC includes both “off-campus provider-based emergency departments” (which are eligible for Medicare payments) and “independent freestanding emergency departments” not affiliated with a hospital (not eligible for payments under Medicare) in this group. Simultaneously, CMS states that it has seen a “noticeable increase” in hospital ED visits since 2010. CMS posits that this could be due to:

- Higher payment rates for services performed in off-campus provider-based EDs (i.e., higher than physician office visit or urgent care clinic rates)
- The emergency department services exemption from The Bipartisan Budget Act of 2015 provisions related to “off campus provider-based departments” ([See below](#)).

CMS agrees with MedPAC’s observations and believes it needs to better track these services. Therefore, **CMS proposes to implement a new modifier⁹ to be used on “every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department” (p. 355).** The HCPCS modifier will be implemented through the subregulatory process and effective January 1, 2019 (p. 354).

Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services (p. 355)

CMS provides a detailed history of the hospital OPPS beginning on p. 355, including long-running concerns about the volume increases in services paid under the OPPS. CMS notes that the OPPS has been “the fastest growing sector of Medicare payments out of all payment systems under Medicare Parts A and B” (p. 359). CMS shares OPPS expenditure growth data since CY 2010 in [Table 30](#) and “volume and intensity” growth data in [Table 31](#). CMS also expresses concern that payment incentives are affecting site-of-service selection rather than patient acuity or medical necessity (p. 359).¹⁰

CMS notes that much of the growth can be attributed to hospital purchase of freestanding physician practices, converting the payments for those services from the MPFS to the OPPS (p. 362).¹¹ In previous recognition of this phenomenon, CMS had implemented the use of a HCPCS modifier to report physicians’ services and hospital outpatient services furnished in an off-campus¹² provider-based department (PBD) of hospital (p. 364). Congress also eventually weighed in on the issue. The Bipartisan Budget Act of 2015 included a provision that “applicable items and services”¹³ 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

⁹ Modifier ~ER (*Items and services furnished by a provider-based off-campus emergency department*) (p. 355).

¹⁰ CMS reiterated its CY 2018 final rule statements that it intends to create a website to provide comparisons between OPPS and ASC payment and copayment rates (p. 359).

¹¹ CMS cites MedPAC analysis: “From 2012 to 2015, hospital-based E&M visits per beneficiary grew by 22 percent, compared with a 1-percent decline in office-based visits.” (p. 362).

¹² CMS defines “campus” to be “the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS Regional Office, to be part of the provider’s campus” (p. 364).

¹³ 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.

‘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 hospital¹⁴ 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](#)).

While this policy is in place, CMS continues 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](#)).¹⁵ To address this ongoing site-of-service differential for what CMS views as the same service, ***CMS proposes 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. 370](#)). As described above, non-excepted off-campus PBDs already receive a reduced rate from the usual OPPS rate. CMS is using its authority¹⁶ 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.”

CMS proposes a non-budget neutral application of the policy given that CMS states the statutory provision from which they derive the authority for this policy does not require budget neutrality ([p. 371](#)). For more information, see [p. 372](#).

In addition, CMS solicits comment on how to maintain access to services and innovations while controlling for the volume of hospital outpatient services. Specifically, ***CMS requests input on the following*** ([p. 374](#)):

- How CMS can define “unnecessary” and “increase” for services (other than the clinic visit already identified) that can be performed in multiple settings of care and whether the method to control for unnecessary increases in the volume of outpatient services should include consideration of factors such as enrollment, severity of illness, and patient demographics
- Other methods to control for unnecessary increases in the volume of outpatient services (e.g., prior authorization)
- Reasons it could be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings
- Whether and how CMS could use its authority to implement utilization management cost-containment strategies
- How CMS should account for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas and whether rural providers should have exceptions from this policy (e.g., for providers who are at risk of hospital closure or that are sole community hospitals)
- What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered OPD services might have
- What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made

¹⁴ 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 . . .”

¹⁵ In comparing Level 3 E/M visits, for a new patient under the OPPS, Medicare pays a total of \$184.44 (whereas billed only under the MPFS Medicare pays \$109.46); for an established patient under the OPPS, Medicare pays a total of \$158.24 (whereas billed only under the MPFS Medicare pays \$73.93) ([p. 369](#)).

¹⁶ 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”

Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital ([p. 375](#))

In prior rulemaking, CMS did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs but indicated that it would consider adopting such a policy in future rulemaking. CMS agrees with comments that the difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments--excepted off-campus PBDs versus nonexcepted off-campus PBDs--creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining CMS' goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. Therefore, for CY 2019, ***CMS proposes changes to the Medicare Part B drug payment methodology for drugs and biologicals furnished and billed by nonexcepted off-campus departments of a hospital that were acquired under the 340B Program.*** Specifically, for CY 2019 and subsequent years, ***CMS proposes to pay (under the PFS) the adjusted payment amount of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program when they are furnished by nonexcepted off-campus PBDs of a hospital.*** Furthermore, ***CMS proposes to except rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment.***

CMS has previously noted that several recent studies and reports on Medicare Part B payments for 340B-acquired drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost. Because hospitals can, in some cases, acquire drugs and biologicals under the 340B Program for use in nonexcepted off-campus PBDs, CMS believes that not adjusting payment exclusively for these departments would present a significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted or nonexcepted PBD) they are furnished. This incongruity would distort the relative accuracy of the resource-based payment amounts under the site-specific PFS rates and could result in significant perverse incentives for hospitals to acquire drugs and biologicals under the 340B Program and avoid Medicare payment adjustments that account for the discount by providing these drugs to patients predominantly in nonexcepted off-campus PBDs. In light of the significant drug payment differences between excepted and nonexcepted off-campus PBDs, in combination with the potential eligibility for discounts, which result in reduced costs under the 340B Program for both kinds of departments, CMS' current payment policy could undermine the validity of the use of the OPPS payment structure in nonexcepted off campus PBDs. In order to avoid such perverse incentives and the resulting distortions, ***CMS proposes, pursuant to its authority at section 1833(t)(21)(C) of the Act to identify the PFS as the "applicable payment system" for 340B-acquired drugs and biologicals and, accordingly, to pay under the PFS instead of under section 1847A/1842(o) of the Act an amount equal to ASP minus 22.5 percent for drugs and biologicals acquired under the 340B Program that are furnished by nonexcepted off- campus PBDs.*** CMS believes this proposed change in policy would eliminate the significant incongruity between the payment amounts for these drugs, depending upon whether they are furnished by excepted off-campus PBDs or nonexcepted off-campus PBDs, which CMS believes is an unnecessary difference in payment where the 340B Program does not differentiate between PBDs paid under the OPPS and PBDs paid under the PFS using the PFS relativity adjuster.

Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider (p. 388)

As mentioned above, the Bipartisan Budget Act of 2015 included a provision that “applicable items and services”¹⁷ 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 hospital¹⁸ 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.

The statute also excepts from that definition “an off-campus PBD that was billing . . . with respect to covered OPD services furnished prior to” November 2, 2015,” effectively limiting the expansion of off-campus PBDs that would be paid under the OPPS (although those items and services would still be covered under the Medicare Physician Fee Schedule). CMS previously proposed that if an excepted off-campus PBD furnished services from a clinical family of services that it did not furnish prior to November 2, 2015, these new or expanded clinical families would not be covered OPD services and would be subject to the statute. However, CMS did not propose to limit the volume of items and services *within* a clinical family. CMS did not finalize this provision. This meant that an excepted off-campus PBD receives OPPS payments for *all* billed items and services regardless of whether it furnished those services prior to the date of enactment (p. 389). CMS stated, however, that it would continue to monitor this issue (p. 391).

As part of previous rulemaking, CMS requested input on the limitation on expansion of services of hospital outpatient departments as it relates to excepted off-campus PBDs (p. 391). CMS continued its data collection process (requirement to use claims data with modifier PO¹⁹ (for excepted services) and PN²⁰ (for nonexcepted services) in the meantime to will help monitor policies related to service line expansions.

CMS expressed continued concern that if excepted off-campus PBDs can furnish new “types of services” not previously provided at the excepted off-campus PBD prior to enactment of the statute, hospitals could purchase additional physician practices and bill for those services under the OPPS. CMS believes this would run contrary to the statute (p. 393). Not only does this run contrary to the statute according to CMS interpretation, CMS believes there is a “potential shift of services from nonexcepted PBDs to excepted PBDs” (p. 394).

To address these ongoing concerns, ***CMS proposes if an excepted off-campus PBD furnishes services from any clinical family of services from which it did not furnish services during the baseline period (November 1, 2014 – November 1, 2015²¹) that the services would not be “excepted services” and, therefore, would be paid under***

¹⁷ 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.

¹⁸ 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 . . .”

¹⁹ ~PO (*Excepted service provided at off-campus, outpatient, provider-based outpatient departments*) (p. 395); Use of the PO modifier was voluntary in 2015 and became mandatory in 2016 (p. 361).

²⁰ ~PN (*Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital*)

²¹ I.e., items are services furnished and billed by an excepted off-campus PBD *only* from the clinical families of services “for which the excepted off-campus PBD furnished (and subsequently billed under the OPPS) for at least one item or service from November 1, 2014 through November 1, 2015” (p. 397).

the MPFS rather than the OPFS ([p. 396](#)). CMS seeks comment on whether it should establish a shorter baseline period (e.g., three (3) or six (6) months) ([p. 399](#)).

- Excepted off-campus PBDs will be required to determine the clinical families from which they furnished services during the baseline period ([p. 398](#)).
- Items and services furnished by an excepted off-campus PBD that are not identified in the clinical families must be reported with modifier ~PN (nonexcepted services).
- CMS requests comment on the proposed clinical families, available for review in [Table 32](#).
- CMS requests comment on whether any specific group of hospitals should be excluded from the proposal (e.g. rural hospitals, sole community hospitals (SCHs) ([p. 399](#)).
- CMS seeks input on adoption and implementation of other methodologies (e.g. MedPAC approach to establish a baseline service *volume*) ([p. 400](#)).

Ambulatory Surgery Center Payment System ([p. 403](#))

Definition of ASC Covered Surgical Procedures ([p. 407](#))

CMS proposes to revise its definition of “surgery” for CY 2019 to account for “surgery-like” procedures that are assigned codes outside the CPT surgical range (10000-69999). For CY 2019, CMS proposes that these newly-eligible “surgery-like” procedures are procedures that are described by Category I CPT codes that are not in the surgical range but, like procedures described by Level II HCPCS codes or by Category III CPT codes under its current policy, directly crosswalk or are clinically similar to procedures in the Category I CPT surgical range. These Category I CPT codes would be limited to those that CMS has determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

CMS invites comments on its proposal to revise the definition of “surgery” for the ASC prospective payment system. CMS also solicits comments on whether it should expand its definition of “surgery” to include procedures that fall outside the CPT surgical range, but fall within the definition of “surgery” developed by the AMA Specialty Society Relative Value Scale Update Society for use in the agency’s PFS professional liability insurance relative values, that CMS determines do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

Treatment of New and Revised Codes ([p. 412](#))

[Table 33](#) 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 OPPS.

Treatment of New and Revised Level II HCPCS Codes Implemented in April and July 2018 ([p. 414](#))

[Table 34](#) lists the new Level II HCPCS codes that were implemented April 1, 2018, along with their proposed payment indicators for CY 2019. ***CMS seeks public comments on these proposed payment indicators and the proposed payment rates for the new HCPCS codes that were recognized as ASC covered surgical procedures and ancillary services in April 2018 through the quarterly update CRs, as listed in [Table 34](#). CMS proposes to finalize their payment indicators and their payment rates in the CY 2019 OPPS/ASC final rule with comment period.***

[Table 35](#) lists the new HCPCS codes that are effective July 1, 2018. Through the July 2018 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, 2018 (see [Table 36](#)). ***CMS seeks public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were or are expected to be newly recognized as ASC covered surgical procedures or covered ancillary services in July 2018 through the quarterly update CRs, as listed in [Tables 34](#), [35](#) and [36](#). CMS proposes to finalize their payment indicators and their payment rates in the CY 2019 OPPS/ASC final rule with comment period.***

New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 ([p. 418](#))

Consistent with established policy, ***CMS proposes that the Level II HCPCS codes that will be effective October 1, 2018, and January 1, 2019, would be flagged with comment indicator “NI” in Addendum B to the CY 2019 OPPS/ASC final rule with comment period to indicate that CMS has assigned the codes an interim OPPS payment status for CY 2019.*** CMS will invite public comments in the CY 2019 OPPS/ASC final rule with comment period on the interim status indicator and APC assignments, and payment rates for these codes that will be finalized in the CY 2020 OPPS/ASC final rule with comment period.

New and Revised Category I and III CPT Codes That Will Be Effective January 1, 2019 (p. 419)

For new and revised CPT codes effective January 1, 2019, that were received in time to be included in this proposed rule, CMS proposes APC and status indicator assignments. CMS will accept comments and finalize the APC and status indicator assignments in the OPPS/ASC final rule with comment period. For those new/revised CPT codes that were received too late for inclusion, 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 CMS can propose APC and status indicator assignments in the following year's rulemaking cycle.

For the 2019 ASC Update, the new and revised CY 2019 Category I and III CPT codes will be effective on January 1, 2019, and can be found in [ASC Addendum AA](#) and [Addendum BB](#) to this proposed rule (which are available via the Internet on the CMS website). **CMS requests comments on only those codes that are assigned to comment indicator "NP."**

Update to Lists of ASC Covered Surgical Procedures and Covered Ancillary Services (p. 421)

Covered Surgical Procedures Designated as Office-Based (p. 421)

CMS reviewed the CY 2017 volume and utilization data, which resulted in the identification of 4 covered surgical procedures that CMS believes meet the criteria for designation as office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and CMS believes that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. **The CPT codes that CMS proposes to permanently designate as office-based for CY 2019 are listed in [Table 37](#).**

CMS also reviewed CY 2017 volume and utilization data and other information for 10 procedures designated as temporary office-based in the CY 2018 OPPS/ASC final rule with comment period. Of these 10 procedures, there were very few claims in CMS' data and no claims data for 4 procedures described by CPT codes 38222, 65785, 67229, and 0402T. Consequently, **CMS proposes to maintain the temporary office-based designations for these 4 codes for CY 2019.** The volume and utilization data for the remaining six procedures that have a temporary office-based designation for CY 2018, described by CPT codes 10030, 36473, 36901, 64461, and 64463, and HCPCS code G0429, are sufficient to indicate that these procedures are performed predominantly in physicians' offices and, therefore, should be assigned an office-based payment indicator in CY 2018. Consequently, **CMS proposes to assign payment indicator "P2", "P3", or "G2" to these covered surgical procedure codes in CY 2019.**

[Table 38](#) lists the proposed CY 2019 payment indicators for ASC covered surgical procedures designated as temporary office-based in the CY 218 OPPS/ASC Final Rule with comment period.

For CY 2019, **CMS proposes to designate 8 new CY 2019 CPT codes for ASC covered surgical procedures as temporary office-based, as displayed in [Table 39](#).** After reviewing the clinical characteristics, utilization, and volume of related procedure codes, CMS determined that the procedures described by the new CPT codes would be predominantly performed in physicians' offices. However, because CMS had no utilization data for the procedures specifically described by these new CPT codes, **CMS proposes to make the office-based designation temporary rather than permanent, and CMS will reevaluate the procedures when data become available.**

ASC Covered Surgical Procedures To Be Designated as Device-Intensive (p. 429)

For CY 2019, **CMS proposes to modify its criteria for device-intensive procedures to better capture costs for procedures with significant device costs. CMS proposes to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures.** In addition, **CMS proposes to modify its criteria to lower the device offset percentage threshold from 40 percent to 30 percent.**

Specifically, for CY 2019 and subsequent years, ***CMS proposes that device-intensive procedures would be subject to the following criteria:***

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

Corresponding to this change in the cost criterion, ***CMS proposes that the default device offset for new codes that describe procedures that involve the implantation of medical devices would be 31 percent beginning in CY 2019.*** For new codes describing procedures that are payable when furnished in an ASC involving the implantation of a medical device, ***CMS proposes that the default device offset would be applied in the same manner as discussed [in the OPPS section](#).***

In addition, to further align the device-intensive policy with the criteria used for device pass-through status, ***CMS proposes to specify that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:***

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by 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 conjunction with CMS' proposed modifications to the device-intensive criteria, ***CMS proposes to amend § 416.171(b)(2) of the regulations to reflect the proposed new device criteria.***

Based on CMS' proposed modifications to its device-intensive criteria, ***CMS proposes to update the ASC list of covered surgical procedures that are eligible for payment according to its proposed device-intensive procedure payment methodology, reflecting the proposed individual HCPCS code device-offset percentages based on CY 2017 OPPS claims and cost report data available for this proposed rule.*** The ASC covered surgical procedures that CMS proposes to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2019, are assigned payment indicator "J8" and are included in [Addendum AA](#) to this proposed rule.

In addition, for CY 2019, ***CMS proposes to only apply its proposed 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. 433)

All ASC covered device-intensive procedures are subject to the no cost/full credit and partial credit device adjustment policy.

For partial credit, CMS proposes to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device.

The ASC would append the HCPCS “FC” modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either:

- (1) submitting the claim for the device replacement procedure to their Medicare contractor after the procedure’s performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or
- (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the “FC” modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device.

Beneficiary coinsurance would be based on the reduced payment amount.

Proposed Additions to the List of ASC Covered Surgical Procedures (p. 436)

CMS conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, and that meet its proposed definition of surgery to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, ***CMS proposes to update the list of ASC covered surgical procedures by adding 12 cardiac catheterization procedures to the list for CY 2019, as shown in Table 40. CMS is interested in hearing any specific safety concerns from stakeholders regarding these 12 cardiac catheterization procedures and are requesting comments on whether these procedures may be safely performed in an ASC in light of the regulatory criteria governing which procedures may be added to the ASC covered procedures list.***

CMS proposes to review all procedures that were added to the ASC CPL within the 3 calendar years prior to the year in which CMS is engaging in rulemaking to assess the safety, effectiveness, and beneficiary experience of these newly-added procedures when performed in the ASC setting. CMS’ review will begin with procedures added to the ASC CPL in CYs 2015, 2016, and 2017, and assess whether newly-added procedures continue to meet the agencies criteria, including whether they continue not to be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC and continue not to be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. This review would include taking into account recent clinical developments and available safety findings related to the recently-added procedures.

CMS proposes to review all 38 procedures that were added to the ASC CPL for CYs 2015, 2016, and 2017. The 38 procedures that were added to the ASC CPL during this time are displayed in Table 41 below, along with

their HCPCS code long descriptors, the CY 2018 payment indicators, and the calendar year that each procedure was added to the ASC CPL. CMS also seeks comment about these recently-added procedures from members of the public, including Medicare beneficiaries, ASC facilities, and physicians performing these procedures in the ASC setting. In addition, CMS seeks comment from the public on whether these procedures continue to meet the criteria to remain on the ASC CPL. CMS also intends to evaluate each of these 38 procedures using all available data, including clinical characteristics, utilization reflected in ASC claims and pricing data, prevailing medical practice, and any public comments CMS receives to determine whether they continue to meet the criteria to be a covered surgical procedure.

In addition, CMS solicits comment regarding how its systematic review should be structured in the future, including the length of time procedures should be considered recently-added, how frequently reviews should be performed in light of the time required to accumulate meaningful data and whether any future reviews should examine procedures added during a period of time greater or less than the previous 3 completed calendar years.

Covered Ancillary Services ([p. 448](#))

CMS proposes to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2019 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2019. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2018, but is proposed for packaged status under the CY 2019 OPPS, to maintain consistency with the OPPS, CMS would also propose to package the ancillary service under the ASC payment system for CY 2019. **CMS proposes to continue this reconciliation of packaged status for subsequent calendar years.** Comment indicator “CH” indicates covered ancillary services for which CMS proposes a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2019.

ASC Payment for Covered Surgical Procedures and Covered Ancillary Services ([p. 449](#))

ASC Payment for Covered Surgical Procedures ([p. 449](#))

CMS proposes to update ASC payment rates for CY 2019 and subsequent years using the established rate calculation methodologies and using its definition of device-intensive procedures. Because the proposed OPPS relative payment weights are based on geometric mean costs, the ASC system would use geometric means to determine proposed relative payment weights under the ASC standard methodology. **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 its established policies and, for device-intensive procedures, using its modified definition of device-intensive procedures. Therefore, 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 2019 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2019 MPFS nonfacility PE RVU-based amount or the proposed CY 2018 ASC payment amount calculated according to the ASC standard ratesetting methodology.

For CY 2019, 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 ASC Payment for Covered Ancillary Services ([p. 453](#))

For CY 2019 and subsequent years, ***CMS proposes to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2019 OPPS and ASC payment rates and subsequent year payment rates. CMS also proposes to continue to set the CY 2019 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 2019 and subsequent year payment rates.***

Proposed CY 2019 ASC Packaging Policy for Non-Opioid Pain Management Treatments ([p. 457](#))

In response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, CMS recently evaluated the impact of its packaging policy for drugs that function as a supply when used in a surgical procedure on the utilization of these drugs in both the HOPD and the ASC setting. CMS has not found evidence to support the notion that the OPPS packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management *in the hospital outpatient department*, thus, CMS does not believe that changes are necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply when used in a surgical procedure in this setting at this time. However, with respect to Exparel, [as noted in the OPPS portion of this summary](#), ***CMS seeks comments on whether separate payment would nonetheless further incentivize appropriate use of this drug in the hospital outpatient setting and peer-reviewed evidence that such increased utilization would lead to a decrease in opioid use and addiction among Medicare beneficiaries.***

Also, CMS' evaluation of packaging policies under the OPPS and the ASC payment system showed decreased utilization for certain drugs that function as a supply in the ASC setting when compared to the hospital outpatient department setting. This, coupled with the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, may warrant a change in how CMS pays for non-opioid pain management drugs that function as surgical supplies. In particular, CMS believes it may be appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids. Therefore, ***CMS proposes to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019.*** Because this policy is a departure from its usual policies, ***CMS is also interested in peer-reviewed evidence that demonstrates that use of non-opioid alternatives, such as Exparel, in the outpatient setting actually do lead to a decrease in prescription opioid use and addiction and are seeking comments containing the types of evidence that demonstrate whether and how such non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure.***

As noted in the OPPS section, CMS proposes to pay separately at average sales price (ASP) plus 6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in the ASC setting. Because the ASC payment rate also includes packaged payment for non-opioid pain management drugs, CMS intends to remove the packaged costs attributable to non-opioid pain management drugs--at this time, only Exparel qualifies--from the applicable OPPS rates prior to establishing the ASC rates in order to prevent potential overpayment of these procedures when separate payment is provided in the ASC setting. ***To the extent that other non-opioid drugs that function as surgical supplies come onto the U.S. market, CMS proposes that this policy would apply to them as well in CY 2019.***

See the [OPPS section](#) for additional proposals and comment solicitations related to non-opioid pain management treatments.

Proposed ASC Payment Rates and Conversion Factor ([p. 476](#))

Proposed Calculation of the ASC Payment Rates ([p. 482](#))

ASC Relative Payment Weights for CY 2019 and Future Years ([p. 482](#))

Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2017, CMS proposes to compare the total payment using the CY 2018 ASC relative payment weights with the total payment using the CY 2019 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2018 and CY 2019. CMS proposes to use the ratio of CY 2018 to CY 2019 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2019. ***The proposed CY 2019 ASC weight scalar is 0.8854*** 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.

Updating the ASC Conversion Factor ([p. 484](#))

CMS is exploring ways to align payments with the costs of care and to incentivize use of the most efficient and clinically appropriate sites of care including hospital outpatient departments, ASCs, and physician offices, to the extent feasible, in future rulemaking. In the near term, however, there is concern by some stakeholders that the differential between payment updates for HOPDs and ASCs is resulting in inefficient and unnecessary shifts of care to the hospital outpatient setting and away from ASCs. CMS is concerned about the potential unintended consequences of using the CPI-U to update payments for ASCs, such as consolidation of ASCs or fewer physician-owned ASCs, which may contribute to higher prices; stagnation in number of ASC facilities and number of multispecialty ASC facilities; and payments being misaligned with the cost of treatment for complex patients.

According to CMS, if a migration of services from the hospital setting to ASCs occurred, it may potentially yield savings to the Medicare program and beneficiaries if the savings from the migration of services net of any increases in total volume of services does not exceed the cost of a higher rate update factor. And, to the extent that it is clinically appropriate for a beneficiary to receive services in a lower cost setting, CMS believes it would be appropriate to continue to develop payment incentives and remove payment disincentives to facilitate this choice.

Until CMS has information on the ASC cost structure, the agency would like to balance its desire to promote migration of services away from the HOPD to ASCs where clinically appropriate with its desire to minimize increases in beneficiary out-of-pocket costs. Therefore, ***CMS proposes to apply a hospital market basket update to ASCs for an interim period of 5 years but seeks comments on ASC costs to assess whether the hospital market basket is an appropriate proxy for ASC costs. CMS would assess whether there is a migration of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences (for example, an unnecessary increase in the overall volume of services or beneficiaries' out-of-pocket costs). CMS welcomes comment on whether implementing the hospital market basket update for a different number of years might be more appropriate.***

CMS is also interested in commenter feedback on additional ways the agency can evaluate the impacts of this payment change over the 5-year period. For example, how CMS should delineate between changes in the volume of a particular service due to the higher update, versus changes in the volume of a service due to changes in enrollment, patient acuity, or utilization, and what would be an appropriate interval to measure such migration of services.

During this 5-year period, CMS intends to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information.

CMS also seeks comments on an alternative proposal to maintain CPI-U while collecting evidence to justify a different payment update, or adopting the new proposed payment update based on the hospital market basket permanently. CMS request comments on what type of evidence should be used to justify a different payment update and how CMS should go about collecting that information in the least burdensome way possible.

CMS also seeks comment on the application of an additional adjustment of 0.75, mandated by the ACA for hospitals, which would lower the ASC rate update to 1.25 from the proposed 2.0.

CMS intends to reassess whether application of the hospital market basket update to ASC rates has provided more patient choice to obtain services at a lower cost beginning with the CY 2024 rulemaking period, or sooner if appropriate.

For CY 2019, CMS proposes to adjust the CY 2018 ASC conversion factor (\$45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the MFP-adjusted hospital market basket update factor of 2.0 percent discussed above, which results in a ***proposed CY 2019 ASC conversion factor of \$46.500 for ASCs meeting the quality reporting requirements.***

For ASCs not meeting the quality reporting requirements, CMS proposed to adjust the CY 2018 ASC conversion factor (\$45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.0 percent discussed above, which results in a ***proposed CY 2019 ASC conversion factor of \$45.589.***

Quality Reporting Program Provisions

Hospital Outpatient Quality Reporting (OQR) Program ([p. 500](#))

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. CMS discusses how, similar to other recent rules it released impacting other payment systems, it developed the proposals for the OQR Program within the framework of its [Meaningful Measures Initiative](#). CMS' goal is to improve the usefulness and usability of program data by streamlining how facilities are reporting and accessing data.

Hospital OQR Program Quality Measures ([p. 503](#))

Accounting for Social Risk Factors in the Hospital OQR Program ([p. 503](#))

Similar to other recent rules, CMS summarized recent work that has been done in this area and summarizes feedback it received on the issue during last year's rulemaking. As a next step, CMS is considering options to reduce health disparities among patient groups within and across health care settings by increasing the transparency of disparities as shown by quality measures. It also is considering how this work applies to other CMS quality programs in the future. CMS refers readers to the [FY 2018 IPPS/LTCH PPS final rule](#) (82 FR 38403 through 38409) for more details, where it discusses the potential stratification of certain Hospital IQR Program outcome measures. CMS continues to consider options to address equity and disparities in its value-based purchasing programs. It plans to continue working with ASPE, the public, and other key stakeholders on this issue to identify policy solutions that achieve health equity while minimizing unintended consequences.

Removal of Quality Measures from the Hospital OQR Program Measure Set (p. 506)

Consideration Factors for Removing Measures (p. 507)

CMS previously finalized a set of factors for determining whether to remove measures from the Hospital OQR Program (77 FR 68472 through 68473). These factors are:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped out” measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences such as patient harm.

A similar measure removal policy was finalized for the ASC Quality Reporting (ASCQR) Program.

CMS clarifies that it will make determinations about removing a measure on a case-by-case basis and that a measure will not be removed solely on the basis of meeting any specific factor.

Proposed Update to Measure Removal Factor 7 (p. 509)

CMS proposes to change measure removal Factor 7 in the Hospital OQR Program to “collection or public reporting of a measure leads to negative unintended consequences other than patient harm” so that it aligns with measure removal Factor 7 in the ASCQR Program. CMS clarifies that measures causing patient harm would be removed from the program immediately, outside of rulemaking, in accordance with previously finalized policy regarding measures with patient safety concerns.

Proposed New Measure Removal Factor 8 (p. 509)

CMS proposes to adopt an additional removal factor for the Hospital OQR Program: Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program. As noted earlier, measures would be removed on a case-by-case basis.

Later in this rule, CMS proposes this same additional removal factor for the [ASCQR Program](#) and has the proposed it for a range of other programs, including the Hospital Value-Based Purchasing Program, the Hospital Inpatient Quality Reporting Program, the Hospice Quality Reporting Program, the Inpatient Rehabilitation Facility Quality Reporting Program, and the Skilled Nursing Facility Quality Reporting Program.

Clarification of Removal Factor 1: “Topped-Out” Measures (p. 514)

CMS previously finalized two criteria for determining when a measure is “topped out” under the Hospital OQR Program:

1. When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and
2. When the measure’s truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942).

Here, CMS clarifies its process for calculating the TCOV, particularly for two of the measures ([OP-11](#) and [OP-14](#)) proposed for removal from the Hospital OQR Program, which assess the rate of rare, undesired events for which a lower rate is preferred (as opposed to most measures for which a higher rate is the preferred outcome). Because these measures are different, CMS utilizes the mean of non-adverse events in its calculation of the TCOV, which allows it to assess rare-event measures by still generally using its previously finalized topped-out criteria.

Proposed Removal of Quality Measures from the Hospital OQR Program Measure Set ([p. 515](#))

CMS proposes to remove a total of 10 measures from the Hospital OQR Program measure set across the CY 2020 and CY 2021 payment determinations.

Beginning with the CY 2020 payment determination:

- 1) **OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)** ([p. 571](#)). **CMS proposes to remove this NHSN measure under removal Factor 8, the costs associated with this measure outweigh the benefit of its continued use in the program.** CMS describes the costs imposed on providers and the agency to collect this measure. It also notes that the vast majority of Hospital OQR Program eligible hospitals already report this measure in the Hospital IQR Program for workers providing any services to inpatient care. CMS also expects that a portion of MIPS-eligible clinicians nationwide will report on the Preventive Care and Screening: Influenza Immunization measure through the Quality Payment Program (QPP). This measure is also being proposed for removal from the ASCQR Program.

Beginning with the CY 2021 payment determination:

- 2) **OP-5: Median Time to ECG (NQF #0289)** ([p. 522](#)). **This measure is being proposed for removal due to Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program.** OP-5 is a chart-abstracted measure, which can be potentially more challenging for facilities to report than claims-based or structural measures. Variation in performance between hospitals is also minimal and CMS believes the benefit is limited.
- 3) **OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)** ([p. 524](#)) **This measure is being proposed for removal due to Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program.** This is a chart-abstracted measure, which can be potentially more challenging for facilities to report than claims-based or structural measures, and there is another similar claims-based outcomes measure, OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF# 2539), that does not require chart abstraction and is also included in the Merit-Based Incentive Payment System (MIPS) for 2019.
- 4) **OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use** (NQF #0659) ([p. 527](#)) **This measure is being proposed for removal due to Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program.** This is a chart-abstracted measure, which can be potentially more challenging for facilities to report than claims-based or structural measures, and there is another similar claims-based outcomes measure, OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF# 2539)), that does not require chart abstraction and is also included in MIPS for 2019.
- 5) **OP 31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery** (NQF #1536) ([p. 531](#)) **This measure is being proposed for removal due to Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program.**
- 6) **OP-9: Mammography Follow-up Rates** (no NQF number) ([p. 534](#)). **CMS proposes to remove this measure under measure removal Factor 3, the measure does not align with current clinical guidelines or practice.** CMS intends to investigate respecification of this measure and consider it for adoption to

the program through future rulemaking. Specifically, it will consider ways to capture a broader, more comprehensive spectrum of mammography services including adding diagnostic digital breast tomosynthesis (DBT).

- 7) **OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material** (NQF #0513) ([p. 538](#)) ***CMS proposes to remove this measure under removal Factor 1, measure performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. In an earlier section, CMS clarifies how it determines topped out status for measures that assess the rate of rare, undesired events for which a lower rate is preferred, such as OP-11.***
- 8) **OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT** (no NQF number) ([p. 539](#)) ***CMS proposes to remove this measure under removal Factor 1, measure performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. In an earlier section, CMS clarifies how it determines topped out status for measures that assess the rate of rare, undesired events for which a lower rate is preferred, such as OP-14.***
- 9) **OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data** (NQF endorsement removed) ([p. 541](#)) ***CMS proposes to remove this web-based process measure under removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.*** CMS believes that provider performance in the measure is not an indicator for patient outcomes and continued collection provides little benefit.
- 10) **OP-17: Tracking Clinical Results between Visits** (NQF endorsement removed) ([p. 542](#)) ***CMS proposes to remove this web-based process measure— which assesses the extent to which a provider uses a certified/qualified EHR system to track pending laboratory tests, diagnostic studies, or patient referral— under removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.*** CMS notes that this measure tabulates only the ability for transmittal of data, but does not directly assess quality or patient outcomes.

A table on [p. 543](#) summarizes the proposed Hospital OQR Program measure sets for the CY 2020 and 2021 payment determinations and subsequent years (including previously adopted measures and excluding measures proposed for removal in this proposed rule).

Hospital OQR Program Measures and Topics for Future Consideration ([p. 546](#))

CMS notes that it is moving towards greater use of outcome measures and away from use of clinical process measures across our Medicare quality reporting and value-based purchasing programs. ***It invites public comments on possible measure topics for future consideration in the Hospital OQR Program; specifically, comment on any outcome measures that would be useful to add, as well as any process measures that should be eliminated from the Hospital OQR Program.***

Public Display of Quality Measures ([p. 547](#))

CMS refers readers to the CY 2014 and CY 2017 OPPTS/ASC final rules with comment period (78 FR 75092 and 81 FR 79791 respectively) for its previously finalized policies regarding public display of quality measures. In this rule, CMS is not proposing any changes to these policies.

Administrative Requirements ([p. 547](#))

Beginning with the CY 2018 reporting period/CY 2020 payment determination, CMS proposes to remove submission of the Notice of Participation (NOP) form as a requirement for the Hospital OQR Program since this form is unnecessarily burdensome for hospitals to complete and submit. Instead, hospitals would need to do the following to be a participant in the Hospital OQR Program: (1) register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) submit data.

Form, Manner & Timing of Data Submitted ([p. 549](#))

Data Submission Deadlines

The finalized clinical data submission deadlines for the CY 2020 payment determination and subsequent years are illustrated in a table on [p. 550](#).

Hospital Outpatient Quality Reporting Specifications Manual ([p. 550](#))

CMS proposes to update the frequency with which it releases [Hospital Outpatient Quality Reporting Specifications Manuals](#). Instead of every 6 months, CMS would release Specifications Manuals one to two times per year, beginning with CY 2019, depending on the need for an updated release. CMS believes that unnecessarily releasing two manuals a year has the potential to cause confusion for participants.

Claims-Based Measure Data Requirements for the CY 2020 Payment Determination and Subsequent Years ([p. 554](#))

CMS proposes to extend the reporting period for [OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy](#) from 1 year to 3 years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018). Under this proposal, the annual reporting requirements for facilities would not change, because this is a claims-based measure. This proposal also would not disrupt payment determinations or public display because CMS would utilize data already collected to supplement current data.

Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2019 Payment Determination ([p. 563](#))

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 2019 annual payment update factor. For the CY 2019 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 2019 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. 568](#))

CMS discusses how, similar to other payment systems, it developed the proposals for the OQR Program within the framework of its [Meaningful Measures Initiative](#). CMS’ goal is to improve the usefulness and usability of program data by streamlining how facilities are reporting and accessing data.

ASCQR Program Quality Measures ([p. 570](#))

Accounting for Social Risk Factors in the ASCQR Program ([p. 516](#))

See [Hospital OQR discussion](#).

Removal Factors for ASCQR Program Measures (p. 574)

CMS previously finalized the following ASCQR Program measure removal factors:

- Factor 1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped out” measures²²).
- Factor 2. Availability of alternative measures with a stronger relationship to patient outcomes
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences such as patient harm.

CMS proposes to remove Factor 2, “availability of alternative measures with a stronger relationship to patient outcomes,” beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period since it is repetitive with Factor 6.

To ensure the ASCQR Program measure removal factors are fully aligned with the Hospital OQR Program, ***CMS proposes to add “performance or improvement on a measure does not result in better patient outcomes” as the new removal Factor 2 for the ASCQR Program*** (replacing the previously adopted factor proposed for removal above).

CMS also proposes to adopt an additional factor to consider when evaluating measures for removal from the ASCQR Program measure set: “Factor 8, The costs associated with a measure outweigh the benefit of its continued use in the program.”

CMS also clarifies policies related to Factor 1: “Topped-Out” Measures and how it would apply to ASC-1, ASC-2, ASC-3, and ASC-4, which are later proposed for removal and which are unique in that they assess the rate of rare, undesired events for which a lower performance rate is preferred. See [Hospital OQR discussion](#).

Proposed Removal of Quality Measures from the ASCQR Program Measure Set (p. 583)

CMS proposes to remove a total of 8 measures from the ASCQR Program measure set across the CY 2020 and CY 2021 payment determinations.

Beginning with the CY 2020 payment determination:

- 1) ***SC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) (p. 584).*** CMS proposes to remove this measure due to Factor 8, the costs associated with this measure outweigh the benefit of its continued use in the program. See [Hospital OQR discussion](#).

²² CMS previously finalized two criteria for determining when a measure is “topped out” under the Hospital OQR Program: (1) when there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure’s truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942).

Beginning with the CY 2021 payment determination:

- 2) **ASC-1: Patient Burn (NQF #0263) (p. 589)**. This claims-based outcome measure is being proposed for removal under Factor 1, measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.
- 3) **ASC-2: Patient Fall (NQF #0266) (p. 590)**. This claims-based measure is being proposed for removal under Factor 1, measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.
- 4) **ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267) (p. 591)**. This claims-based outcome measure is being proposed for removal under Factor 1, measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.
- 5) **ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265) (p. 592)**. This claims-based outcomes measure, which assesses the rate of ASC admissions requiring a hospital transfer or admission upon discharge from the ASC, is being proposed for removal under Factor 1, measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.
- 6) **ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (p. 593)**. This chart-abstracted process measure is being proposed for removal under Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.
- 7) **ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659) (p. 597)**. This chart-abstracted process measure is being proposed for removal due to Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.
- 8) **ASC-11: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (p. 601)**. This measure is being proposed for removal under Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

At the end of this section, CMS summarizes the proposed ASCQR Program measure sets for the [CY 2020](#), [2021](#), and [2022](#) payment determinations.

ASCQR Program Measures and Topics for Future Consideration (p. 606)

CMS requests public comment on the possible future validation of ASCQR Program measures. There is currently no validation of ASCQR measure data, and CMS believes ASCs may benefit from the opportunity to better understand their data and examine potential discrepancies; to produce a more reliable estimate of whether an ASC's submitted data have been abstracted correctly; and provide more statistically reliable estimates of the quality of care delivered in each selected ASC, as well as at the national level. CMS believes the Hospital OQR Program validation policy, which requires validation of its chart-abstracted measures, could be a good model for the ASCQR Program. ***CMS requests comment on whether the Hospital OQR Program's validation policies could be an appropriate model for the ASCQR Program; the possible ASC sample size, sampling methodology, number of cases to sample, validation score methodology, and reduced annual payment updates for facilities that do not pass validation requirements; and on possibly starting with only one measure, specifically ASC-13: Normothermia Outcome, before expanding to more measures.***

Form, Manner, and Timing of Data Submitted (p. 611)

CMS proposes to extend the reporting period for ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (p. 616) from 1 year to 3 years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018). Under this proposal, the annual reporting requirements for ASCs would not change because this is a claims-based measure.

However, with a 3-year reporting period, the most current year of data would be supplemented by the addition of 2 prior years.

Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements ([p. 621](#))

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.

Hospital Inpatient Quality Reporting (IQR) Program Policies ([p. 664](#))

Proposed Updates to the HCAHPS Survey Measure (NQF #0166) for the FY 2024 Payment Determination and Subsequent Years ([p. 665](#))

Since finalization of the Communication About Pain questions, CMS has received feedback that some stakeholders are concerned that, although the revised questions focus on communications with patients about their pain and treatment of that pain, rather than how well their pain was controlled, the questions still could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey. In addition, in its final report, the [President's Commission on Combating Drug Addiction and the Opioid Crisis](#) recommended removal of the HCAHPS Pain Management questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.

CMS continues to believe that pain management is a critical part of routine patient care on which hospitals should focus and an important concern for patients, their families, and their caregivers. It also clarifies that the HCAHPS Survey does not specify any particular type of pain control method. The revised questions focus entirely on communication about pain with patients and do not refer to, recommend, or imply that any particular type of treatment is appropriate (82 FR 38333). In addition, appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, proper prescription practices, and alternative treatments for pain management.

Although CMS is not aware of any scientific studies that support an association between scores on the prior or current iterations of the Communication About Pain questions and opioid prescribing practices, out of an abundance of caution and to avoid any potential unintended consequences, CMS proposes to update the HCAHPS Survey by removing the Communication About Pain questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. This would reduce the overall length of the HCAHPS Survey from 32 to 29 questions, and the final four quarters of reported Communication About Pain data (comprising data from the first, second, third, and fourth quarters 2021) would be publicly reported on Hospital Compare in October 2022 and then subsequently discontinued.

In proposing removal of the Communication About Pain questions, CMS is not proposing to change how performance scores are calculated for the remaining questions on the HCAHPS Survey. Also, since the Hospital IQR Program is a quality data reporting program, payments to hospitals will not be affected so long as hospitals timely submit data on required measures and meet all other program requirements. CMS would continue to use the remaining 29 questions of the HCAHPS Survey to assess patients' experience of care, and would continue to publicly report hospital scores on those questions.

Despite this proposal, CMS is interested in feedback on whether the Communication About Pain questions should be retained in both the HCAHPS Survey and the Hospital IQR Program, but with a further delay in public reporting. Delay in public reporting would allow further time to engage a broad range of stakeholders and assess their feedback regarding use of the Communication About Pain questions in the HCAHPS Survey and the Hospital IQR Program and to assess the impact of the new Communication About Pain questions.

In crafting this proposal, CMS also considered proposing earlier removal of the Communication About Pain questions from the HCAHPS Survey effective as early as January 2020 discharges, for the FY 2022 payment determination and subsequent years. However, CMS believes removing the questions effective with January 2020 discharges would not allow sufficient time to make necessary updates to the data collection tools, including the CMS data submission warehouse and associated reporting tools, as well as to update the HCAHPS Survey administration protocols and the survey tool itself. Also, the proposal to make these updates effective with January 2022 discharges, would allow time to assess the potential impact of using the Communication About Pain questions while monitoring unintended consequences. It would also allow time for empirical testing for any potential effect the removal of the Communication About Pain questions might have on responses to the remaining non-pain related survey items.

Because some hospitals have identified patient experience of care as a potential source of competitive advantage, CMS has heard from stakeholders that some hospitals may be disaggregating their raw HCAHPS Survey data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. Some hospitals also may be using the HCAHPS Survey to assess their emergency and outpatient departments. CMS clarifies that the HCAHPS Survey was never designed or intended to be used in these ways. In its HCAHPS Quality Assurance Guidelines, which sets forth current survey administration protocols, it strongly discourages the unofficial use of HCAHPS scores for comparisons within hospitals, such as for comparisons of particular wards, floors, and individual staff hospital members.

CMS is particularly interested in receiving feedback on any potential implications on patient care related to removing these questions. It is also interested in feedback from stakeholders on:

- The importance of receiving feedback from patients related to communication about pain management and the importance of publicly reporting this information for use both by patients in healthcare decision-making and by hospitals in focusing their quality improvement efforts;
- Additional analyses demonstrating a relationship between the use of pain questions in patient surveys and prescribing behavior, including unpublished data, if available;
- Input from clinicians and other providers concerning whether it would be valuable for CMS to issue guidance suggesting that hospitals do not administer any surveys with pain-related questions, including adding hospital-specific supplemental items to HCAHPS, as well as the potential implementation of a third party quality assurance program to assure that hospitals are not misusing survey data by creating pressure on individual clinicians to provide inappropriate clinical care;
- Information from clinicians and other providers concerning instances of hospital administrators using results from the HCAHPS Survey to compare individual clinician performance directly to other clinicians at the same facility or institution and examples where, as a result, clinicians have felt pressured to prescribe opioids inappropriately (in terms of either quantity or appropriateness for particular patients);
- Suggestions for other measures that would capture facets of pain management and related patient education, for instance, for collecting data about a hospital's pain management plan, and provide that information back to consumers; and
- How other measures could take into account provider-supplied information on appropriate pain management and whether patients are informed about the risks of opioid use and about non-opioid pain management alternatives.

Requests for Information (RFIs) ([p. 626](#))

RFI on Promoting Interoperability and Electronic Health Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers ([p. 627](#))

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). As of 2015, 96 percent of Medicare- and Medicaid participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care. While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the nation.

CMS is firmly committed to the use of certified HIT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In this rule, CMS is interested in hearing from stakeholders on how it could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (i.e., the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals such as: requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (e.g., required discharge instructions) via electronic means if requested.

CMS specifically invites stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related

to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and implementation of relevant policies in the 21st Century Cures Act?

- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (e.g., participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?
- Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. It is particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records, as well as innovative thoughts on addressing these barriers, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. CMS has received stakeholder input on the need to address HIT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and CMS would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

RFI for Information on Price Transparency (p. 638)

This CMS request for information (RFI) is a follow-up to similar provisions included in the [FY 2019 Inpatient Prospective Payment System \(IPPS\) proposed rule](#) and the [CY 2019 Physician Fee Schedule proposed rule](#). In those rules, 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. CMS also [proposed, as part of the IPPS proposed rule](#), to mandate that hospitals make their standard charges available via the internet in a machine-readable format, updated annually or more often as appropriate.

CMS reiterated ongoing concerns about challenges that continue to exist for patients due to insufficient price transparency, including:

- Patients being surprised by out-of-network bills for physicians (e.g. anesthesiologists and radiologists) who provide services at in-network hospitals;
- Patients being surprised by facility fees and physician fees for emergency room visits or for fees for other episodes of care involving a hospitalization but that are not services furnished by the hospital;
- Charge data do are not helpful to patients in determining what the patient is likely to pay for a particular service or facility encounter.

CMS is considering ways to improve the accessibility and usability of current charge information, including to help patients understand what their financial liability might be and to compare charges across providers and suppliers. Therefore, CMS is seeking public comment on the following:

- How to define standard charges for various providers in various settings
- What types of information can providers and suppliers provide that would be most beneficial in enabling patients to use charge and cost information
- Whether providers and suppliers can and should be required to inform patients what the patient's out-of-pocket costs will be prior to furnishing the service
- How Medicaid coverage affects patient understanding of out-of-pocket costs before receipt of care

Additional detail on CMS' contemplation of these issues is provided starting on [p. 640](#).

RFI on Leverage the Authority for the Competitive Acquisition Program (CAP for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model ([p. 642](#))

Following up on the President's American Patients First blueprint/RFI, CMS is requesting more information on a potential model design that would accelerate the move to a value-based health care system building upon the Competitive Acquisition Program (CAP) established under section 1847B of the Act. The CAP was established as an alternative to the average sales price (ASP) methodology. Instead of buying drugs for their offices, the CAP would allow physicians to voluntarily choose to participate in the CAP and place patient specific drug orders with an approved CAP vendor; the CAP vendor would acquire and distribute (or supply) the drugs to the physician's office and then bill Medicare and collect cost-sharing amounts from the beneficiary.

The initial CAP was suspended at the end of 2008, and CMS sought input from physicians and other interested parties about potential improvements to the program. Although CMS received some useful suggestions, several concerns could not be addressed under the existing statutory requirements. The CAP also was hindered by low physician enrollment and that some physicians perceived physician election, drug ordering and billing processes, and post pay documentation as burdensome. Also, an evaluation of the CAP found that it did not generate savings.

In June 2017, the Medicare Payment Advisory Commission ([MedPAC recommended](#)) the development of a voluntary alternative to the ASP payment system, calling it the Part B Drug Value Program (DVP). The DVP would be designed differently from the CAP to address several issues encountered with the CAP program and to allow hospitals to obtain drugs through the DVP. Additionally, in response to the Innovation Center "New Direction" RFI issued in September 2017, MedPAC encouraged the Innovation Center to consider its DVP proposal. Numerous other stakeholders also referenced or recommended similar approaches to MedPAC's DVP proposal in response to the New Direction RFI, involving the use of a private vendor to structure alternative payment arrangements for a small subset of therapies.

The CMS Innovation Center is exploring leveraging the authority for the CAP to test improvements to the CAP and to test whether allowing private-sector model vendors to enter into and administer value-based arrangements with manufacturers of separately payable Medicare Part B drugs and biologicals improves beneficiary access and quality of care while reducing Medicare expenditures. Such a CAP-like model would test an alternative to the current system, under which health care providers (physicians, hospital outpatient departments, and potentially other providers and suppliers) would acquire drugs through value-based agreements with manufacturers administered by CAP-like model vendors (“vendor-administered payment arrangements”), building on lessons learned from CMS’ experience with the CAP.

Such a potential model would include competitively selected private-sector vendors that would establish vendor-administered payment arrangements with the manufacturers of separately payable Part B drugs and biologicals included in the model. CMS has considered that model vendors’ vendor-administered payment arrangements under a potential model could be required to include value-based pricing strategies, such as outcomes-based agreements, indication-based pricing, payment over time, shared savings or performance-based payments based on the impact on total cost of care, and reduced beneficiary cost-sharing. This could more closely tie the Medicare payment and beneficiary cost-sharing for an included drug or biological to the value of such therapy. Such a model could start with a subset of therapies, with an increasing number of included drugs and biologicals over time.

CMS is considering how to structure a model vendor role, and whether a CAP-like model test should include an approach similar to the CAP (where model vendors would purchase and take title to the included drugs and biologicals) or an approach similar to MedPAC’s envisioned DVP (where providers and suppliers purchase and receive included drugs and biologicals through pricing arrangements and model vendors would not take title to the included drugs and biologicals). CMS is also considering whether testing either or both of these approaches may be appropriate for certain drugs and biologicals, such as testing one approach for high-cost drugs and biologicals, single source drugs and biologicals, or certain drug classes, and testing another approach for other types of drugs and biologicals.

CMS is also considering whether model vendors, if they did take title to included drugs and biologicals, would take possession of the included drugs and biologicals, or if existing distribution channels could be leveraged such that model vendors would take title to, but not possession of, the included drugs and biologicals and the products would be distributed directly to the providers and suppliers. In addition, CMS is considering whether providers and suppliers could have a formal custodial agreement with one or more model vendors, under which the model vendor would agree to ensure onsite availability of an included therapy without the provider or supplier taking ownership of the product, making payment, or otherwise being financially at risk for obtaining the product, subject to the provider’s or supplier’s obligation to ensure the physical safety and integrity of the included drug and biological until the therapy is administered to the beneficiary. In addition, CMS is considering how custodial agreements of this nature could address concerns with existing CAP requirements that CAP drugs could only be delivered upon receipt of a prescription, with limited exceptions. CMS is also considering whether providers and suppliers under such a custodial agreement with a model vendor could continue to collect beneficiary cost-sharing to address issues encountered under the CAP, such as eliminating the need for the provider or supplier to share beneficiary billing information with model vendors, reducing model vendors’ financial risk for uncollected beneficiary cost-sharing, and lessening beneficiaries’ burden associated with model vendors’ billing for cost-sharing. However, potential financial relationships between providers and suppliers and model vendors could increase program risks, and CMS seeks information on how CMS might structure a potential model to avoid these risks while testing improvements to the CAP.

CMS is also considering how a potential CAP-like model could include other payers including Medicare Advantage organizations, State Medicaid agencies, as well as Medicaid Managed Care Organizations (MCOs).

Specifically, CMS is considering ways to allow these other payers to have access to the same or similar value-based vendor-administered payment arrangements available under a potential CAP-like model, such as by paying for included drugs and biologicals for their enrollees through model vendors.

CMS is soliciting public comments on all of the above design considerations and on how to best initially test and then broaden the scope of a potential CAP-like model. Additionally, CMS is posing a series of categorized questions for public comment in the following areas:

- Questions related to “Included Providers and Suppliers” begin on [p. 657](#)
- Questions related to “Included Drugs and Biologicals” begin on [p. 657](#)
- Questions related to “Beneficiary Cost Sharing, Protections and Fiscal Considerations” begin on [p. 659](#)
- Questions related to “Model Vendors” begin on [p. 659](#)
- Questions related to “Regulatory Barriers and Transparency Issues” begin on [p. 662](#)
- Questions related to “Manufacturer Participation” begin on [p. 663](#)
- Questions related to “Model Scope” begin on [p. 663](#)

Collection of Information Requirements ([p. 675](#))

As required under the Paperwork Reduction Act (PRA), CMS is soliciting public comment in advance of the following information collection requirements. Overall, CMS estimates that the total reduction in the burden hours for its identified information collection requests is 1,496,031 hours, and the reduction in cost is \$54.3 million.

ICRs for the Hospital OQR Program ([p. 676](#))

CMS provides estimates of burden reduction under the Hospital OQR Program associated with the following proposals:

- Proposal to remove chart-abstracted measures for the CY 2021 payment determination and subsequent years. CMS estimates burden reduction of 151,800 hours and \$5.6 million. ([p. 680](#))
- Proposal to remove measures submitted via a Web-based tool for the CY 2021 payment determination and subsequent years. CMS estimates that the removal of five web-based measures would reduce burden by 1,164,843 hours and \$42.6 million. ([p. 681](#))

ICRs for the ASCQR Program ([p. 683](#))

CMS provides estimates of burden reduction under the ASCQR Program associated with the following proposal:

- Proposal to remove chart-abstracted measures for the CY 2021 payment determination and subsequent years. CMS estimates a total reduction in information collection burden of 140,585 hours and \$5,142,600. ([p. 686](#))

ICRs for the Proposed Update to the HCAHPS Survey Measure in the Hospital IQR Program ([p. 688](#))

CMS believes its proposal to remove the Communication About Pain questions from the HCAHPS Survey for the FY 2024 payment determination and subsequent years would not significantly reduce estimates of hospital burden. CMS anticipates a total cost reduction for survey respondents of \$1,036,428.

Economic Analyses ([p. 691](#))

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 2019, compared to CY 2018, due only to the proposed changes to OPPS in this proposed rule, would be approximately \$90 million. Taking into account CMS’ estimated changes in enrollment, utilization, and case-mix for CY 2019, CMS estimates that the OPPS expenditures, including beneficiary cost-sharing, for CY 2019 would be approximately \$74.6 billion, approximately \$4.9 billion higher than estimated OPPS expenditures in CY 2018.

[Table 42](#) displays the distributional impact of the proposed CY 2019 changes in OPPS payment to various groups of hospitals and for CMHCs, not including changes in volume and service mix. Overall, CMS estimates that the proposed rates for CY 2019 would decrease Medicare OPPS payments by an estimated 0.1 percent.²³

CMS provides estimated effects of the proposal to control for unnecessary increases in the volume of outpatient services, with Medicare OPPS payments estimated to decrease by \$610 million and beneficiary copayments estimated to decrease by \$150 million in CY 2019. ([p. 699](#)) CMS separately identifies the effects of this policy in Column 5 of [Table 42](#).

²³ These numbers reflect values presented in the Economic Analyses section. However, it is not clear how the 0.1 percent decrease aligns with the increase of \$90 million noted in the prior paragraph.

CMS provides estimated effects of the proposal to apply the 340B drug payment policy to nonexcepted off-campus departments of hospitals. Specifically, CMS estimates that the Medicare program and beneficiaries would save approximately \$48.5 million under the Physician Fee Schedule, which they specify represents an upper bound of potential savings. ([p. 700](#))

CMS also estimates the 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 under the ASC payment system for CY 2019 compared to CY 2018 to be approximately \$240 million. [Table 43](#) and [Table 44](#) display the redistributive impact of the proposed CY 2018 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

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

- **Skin Substitutes.** 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. ([p. 716](#))
- **Payment for Non-Opioid Pain Management Treatments.** CMS is soliciting comments on an whether to pay separately for other non-opioid treatments for pain under the OPPS and the ASC payment system, and on an alternative that would use CMS' equitable adjustment authority under section 1833(t)(2)(E) of the Act to establish an incentive payment for non-opioid alternatives that would apply to drugs and devices in the hospital and ASC settings that are not already currently separately paid, are supported by evidence that demonstrates such drugs and devices are effective at treating acute or chronic pain, and would result in decreased use of prescription opioid drugs and any associated opioid addiction. ([p. 717](#))
- **ASC Rate Updates.** CMS is considering whether to continue applying the CPI-U as the update factor, rather than changing the update factor as proposed. ([p. 727](#))

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