2019 Outpatient Prospective Payment System (OPPS) & Ambulatory Surgical Center (ASC) Payment System

A SIDE-BY-SIDE COMPARISON OF KEY PROVISIONS FROM THE PROPOSED AND FINAL RULES FOR CY 2019

HHS | Hart Health Strategies Inc.

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.

Hart Health Strategies, Inc. has prepared the below "side-by-side" comparison of the proposed and final provisions with the goal of helping organizations better understand how CMS modified its proposals in response to stakeholder feedback. Page numbers and hyperlinks refer to the display version of the final rule, which we have separately hosted online so as to avoid future agency changes to the URL.

The final rule was published in the *Federal Register* on November 2, 2018. While there is a comment period associated with this rule with a deadline of December 3, 2018, most policies are effective as of January 1, 2019. For the areas where there is an opportunity to provide comment, we have designated them in this document the Final Rule column as ***bold/italicized/underlined***.

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OPPS Provisions

Topic	Proposed Rule	Final Rule
General	CMS proposed to increase the CY 2019 OPPS conversion factor to **$79.546**. 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 proposed 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. 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. In addition, CMS proposed to continue to reduce payments by 2.0 percent for hospitals that fail to meet the outpatient quality reporting requirements.	Based on updated data, CMS finalized a CY 2019 OPPS conversion factor to **$79.490** (p. 147). This is premised on a CMS finalized overall increase factor of 1.35 percent for CY 2019 (p. 30; p. 147). The overall increase (before budget neutrality adjustments) is based on the proposed hospital inpatient market basket increase of **2.9 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). CMS states that it now estimates that total OPPS payments for CY 2019 will increase by approximately $360 million over CY 2018 (excluding changes in enrollment, utilization, and case-mix) (p. 29).

Recalibration of APC Relative Payment Weights

General	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 included the final rule payment rates in Addendum A and Addendum B on the CMS website.
	CMS proposed to continue its policy of using hospital cost-to-charge ratios (CCRs) to estimate costs for rate setting purposes.	***CMS finalized this policy (including policy to remove claims from providers that use "square feet" cost allocation method to calculate CT and MRI CCRs)*** (p. 55).
	CMS also proposed to continue its policy of establishing OPPS relative payment rates based on geometric mean costs as it has done since CY 2013.	***CMS finalized this proposal*** (p. 57). In addition, CMS agreed with a commenter that revenue code 0815 (*Allogenic Stem Cell Acquisition Services)* was inadvertently excluded from the packaged revenue code list used for OPPS ratesetting (p. 56). ***Therefore, CMS finalized adding revenue code 0815 to the packaged revenue code list for creating 2019 relative payments in the OPPS*** (p. 57).

Topic	Proposed Rule	Final Rule
Single Procedure APC Criteria-Based Costs: Brachytherapy Sources	Statute 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 proposed basing the payment rates for brachytherapy sources on the geometric mean unit costs for each source.	***CMS finalized its continuation of payment methodology for brachytherapy sources*** (p. 71). To demonstrate the stability of payments for brachytherapy sources, CMS lists the OPPS payment rates for CY 2015 – CY 2018 in Table 5.
	CMS proposed to continue its other payment policies for brachytherapy sources much of which was finalized in CY 2010. • CMS proposed 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 proposed 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 proposed 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.	***CMS finalized these policies*** (p. 71).
	CMS proposed 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.	***CMS finalized this proposal*** (p. 72).
	CMS continues to request input for new codes to describe brachytherapy sources.	***CMS reiterated that it continues to request input and that recommendations for new codes to describe new brachytherapy sources should be sent to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244*** (p. 72).

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").	
	Complexity Adjustments. CMS proposed 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.	***CMS finalized its proposal without modification.*** The finalized code combinations are available on the CMS website in Addendum J. CMS received requests for additional code combinations to be added to the policy, but CMS stated that these code combinations would not meet the cost and frequency criteria for the complexity adjustment (p. 88). (The requested codes that were not added to the list can be found in Table 6.)
	Proposed CY 2019 Comprehensive APCs. CMS proposed 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 finalized the addition of the new Comprehensive APCs*** (p. 94). CMS lists all CY 2019 Comprehensive APCs in Table 7. Data related to the Comprehensive APCs is available on the CMS website in Addendum J. • CMS received comments that it should discontinue Comprehensive APC packaging for several brachytherapy insertion procedures and single session stereotactic radiosurgery (SRS); CMS declined to accept these recommendations (p. 93). ***CMS stated that it will continue its policy of paying separately for "planning and preparation services" adjunctive to SRS treatment (for either Cobalt-60-based or LINAC based technology)*** (p. 93). • CMS received comments that requested a new Comprehensive APC for autologous stem cell transplants. The HOP Panel also requested that CMS study whether it should create a Comprehensive APC for autologous stem cell transplantation. CMS said it will take the comments into consideration for future rulemaking (p. 93).
	Comprehensive APC Exclusion of Procedures Assigned to New Technology APCs. CMS proposed exclusion of payment for any procedure from being packaged into a Comprehensive APC when that procedure is assigned to a New Technology APC (APCs 1491-1599).	***CMS finalized this proposal without modification*** (p. 99).
	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 proposed to continue to assign CPT 55875 a status indicator of J1 (i.e. Comprehensive APC status as primary service).	***CMS finalized this proposal*** (p. 100).

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Composite APCs	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. CMS previously developed and finalized the following Composite APCs: • Mental health services (Composite APC 8010): CMS proposed continuing its Composite APC policy for APC 8010. • 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.	***CMS finalized its Composite APC proposals*** (p. 103). ***CMS finalized its proposal*** (p. 103). ***CMS finalized its proposals and lists the HCPCS codes subject to the multiple imaging Composite APC policy in Table 8.*** CMS noted that in the proposed rule it inadvertently left out new CPT codes effective January 1, 2019 as part of the Composite APC payment policy for Multiple Imaging Services (although the codes were included in the appropriate proposed rule addendum). However, ***because the codes were not included in the proposed rule language, CMS is seeking comments as a final rule with comment period on these codes and their interim APC assignments and payment rates***. CMS refers stakeholders to codes with comment indicator "NI" in Addendum M.

Packaged Items and Services	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 proposed to generally maintain its packaging policies. However, CMS discusses packaging policies related to non-opioid pain management treatments. 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 noted 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	
	OPPS Setting. CMS proposed no changes under the OPPS packaged "drugs that function as a surgical supply" at this time.	CMS received comments that it should also pay separately for non-opioid pain management (i.e., Exparel) in the hospital outpatient department. However, CMS continues to believe that there is lacking evidence to support separate payment for non-opioid pain management in the hospital outpatient setting (p. 119). CMS stated that it will "continue to analyze the evidence and monitor utilization of non-opioid alternatives in the OPD and ASC settings for potential future rulemaking" (p. 121).
	ASC Setting. 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 proposed 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 in CY 2019.	***CMS finalized separate payment for Exparel in the ASC setting at ASP +6%*** (p. 127; p. 135); *see also*, implementation in ASC section of the rule). CMS stated that the manufacturer of Exparel submitted studies that showed that the proposed policy could decrease the dose, duration, and/or number of opioid prescriptions (p. 126). (CMS did not that MedPAC opposed the policy as it runs contrary to CMS packaging policies (p. 124)).
	Other products.	***CMS states that it did not find compelling evidence that products suggested other than Exparel (e.g. IV acetaminophen, IV ibuprofen, and epidural steroid injections) warrant separate payment under the ASC payment system at this time, but that if new non-opioid pain management drugs become available in 2019 that the policy would also apply to those new drugs*** (p. 127). Generally, CMS also received input that CMS should consider a similar policy for spinal cord stimulators, nerve blocks ("including a disposable elastomeric pump that delivers non-opioid local anesthetic to a surgical site or nerve"), cooled thermal radiofrequency ablation for non-surgical, chronic nerve pain, and physician therapy services, therapeutic massage, topically applied THC oil, acupuncture, dry needling procedures, and A4306 (*Disposable drug delivery system, flow rate of less than 50 ml per hour*). CMS stated that it will consider the comments for future rulemaking

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		(p. 131). CMS did note, however, that it does not intend to make payments for noncovered items and services (some of which were submitted for consideration) (p. 132).

OPPS Payments to Certain Cancer Hospitals

General	The 11 PPS-exempt cancer hospitals, while exempted from the Inpatient Prospective Payment System, are paid under the OPPS for covered outpatient services. The Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) required that designated cancer (as well as children's) hospitals receive OPPS payments based on their pre-Balanced Budget Act of 1997 (BBA) payment amounts so as to be "held harmless" from otherwise mandated cuts. This means that these cancer hospitals are paid for covered outpatient services at rates that they would have received prior to the implementation of the OPPS. CMS proposes to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR/target PCR for the other OPPS hospitals using the most recent submitted or settled cost report data that are available reduced by 1 percentage point but is not proposing an additional reduction beyond the 1 percentage point.	
	CMS proposed that the payment among associated with the cancer hospital payment adjustment is a proposed target PCR of 0.88 percent for each cancer hospital.	***CMS finalized its proposal*** (p. 176).

Hospital Outpatient Outlier Payments

General	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 proposed to continue its policy of estimating aggregate outlier payments at 1 percent of total payments under the OPPS.	***CMS finalized its proposal*** (p. 184).
	CMS proposed maintaining the percentage threshold for outlier payments at 1.75 times the APC payment amount; CMS proposed increasing the dollar amount threshold to $4,600.	***CMS finalized the 1.75 times the APC payment amount threshold for outlier payments, but finalized the fixed dollar amount threshold at $4,825*** (p. 184).

APC Group Policies

Topic	Proposed Rule	Final Rule
New CPT and Level II HCPCS Codes	Upon creation of new Level II HCPCS codes, CMS assigns 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. CMS sought comment on the APC assignments and status indicators.	CMS outlined the timeframe for assignment of new or revised HCPCS codes in Table 11. CMS includes the new Level II HCPCS codes effective April 1, 2018 in Table 12. CMS includes the new CPT MAAA and PLA Analyses codes effective April 1, 2018 in Table 13. CMS includes the new HCPCS codes effective July 1, 2018 in Table 14. CMS includes new CPT PLA codes effective July 1, 2018 in Table 15.
Variations within APCs	According to statute, the services within an APC cannot be considered "comparable" if the highest cost service in the APC is more than 2 times greater than the lowest costs for an item or service within the same APC ("2 Times Rule"). 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 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.	CMS determined that one (1) of the APCs it had proposed for an exception (APC 5735 (*Level 5 Minor Procedures*) was remedied and no longer in need of exception (p. 221); fifteen (15) listed in the proposed rule continued be in need of exception (list beginning on p. 221); and two additional APCs violated the 2 times rule and were eligible for an exception: APC 5193 (*Level 3 Endovascular Procedures)* and APC 5524 (*Level 4 Imaging without Contrast*) (p. 222). ***CMS finalized its policies with these stated changes*** (p. 222) and lists the APCs with exceptions to the 2 times rule for 2019 in Table 16.

New Technology APCs

General	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 finalized this policy without modification***. (p. 232)
	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.	***CMS finalized this policy without modification***. (p. 232)
	Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414). 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). 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. 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. 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.	***CMS finalized this policy without modification***. (p. 240) See Table 17.
	Retinal Prosthesis Implant Procedures. 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	CMS is reassigning the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology - Level 52 ($145,001-$160,000)) with a payment rate of $152,500.50 for CY 2019. (p. 247)

Topic	Proposed Rule	Final Rule
	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 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.	***CMS is finalizing its proposal to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C-APC for CY 2019***. (p. 248)

APC-Specific Policies

General	CMS proposed changes to APC clinical families to "achieve better clinical and resource homogeneity."	
	Endovascular Procedures. CMS proposed to maintain the existing four-level structure for the Comprehensive APC family.	***CMS finalized the four-level structure for endovascular procedures*** (p. 285).
	Imaging Procedures and Services. For CY 2019, CMS proposed to retain the current APC structure (4 without contrast; 3 with contrast) but to make minor reassignments to the HCPCS codes.	***CMS finalized its proposal*** (p. 330).
	Musculoskeletal Procedures. CMS seeks comment on the creation of a new APC level between current Level 5 and Level 6.	***CMS finalized maintenance of the current six level structure for musculoskeletal APCs rather than adding an additional level*** (p. 315).
	Intraocular Procedures. CMS proposes to reassign CPT 0308T to APC 5493 (Level 3 Intraocular Procedures) and proposes to delete APC 5495.	***CMS finalized its proposals with modification (assigning CPT 0308T to APC 5494 instead of APC 5493)*** (p. 307).
	Benign Prostatic Hyperplasia Treatments. CMS made several proposals related to TUMT, TUNA, and Rezum therapy procedures.	***CMS finalized APC assignments for TUMT, TUNA, and Rezum therapy procedures in Table 19.***
		Cardiac Resynchronization Therapy (APCs 5221, 5222, 5231, 5731, and 5741). CMS notes that in the OPPS proposed rule addendum, it had proposed assignment of eight new cardiac resynchronization therapy CPT codes to various APCs. ***CMS finalized its proposal with modification*** as found in Table 21 (p. 265)**.**

OPPS Payment for Devices

New Device Pass-Through Applications

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.
- 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.
- 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.
- 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.
- 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.
- 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.

- AquaBeam: CMS is not approving device pass-through payment status for CY 2019. (p. 347)
- BioBag® (Larval Debridement Therapy in a Contained Dressing): CMS is not approving device pass-through payment status for CY 2019. (p. 354)
- BlastX™ Antimicrobial Wound Gel: CMS is not approving pass-through payment status for CY 2019. (p. 356)
- EpiCord®: CMS is not approving EpiCord® for transition pass-through payment status in CY 2019 because the product does not meet the substantial clinical improvement criterion. (p. 367)
- remedē® System Transvenous Neurostimulator: CMS is approving the remedē® System Transvenous Neurostimulator for pass-through payment status for CY 2019. (p. 379)
- Restrata® Wound Matrix: CMS is not approving pass-through payment status for CY 2019. (p. 381)
- SpaceOAR® System: CMS is not approving pass-through payment status for CY 2019. (p. 399)

Device-Intensive Procedures	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. 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. 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. 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:	***CMS finalized its proposals 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 and to modify its criteria to lower the device offset percentage threshold from 40 percent to 30 percent***. (p. 415) The full listing of the final CY 2019 device-intensive procedures is included in Addendum P.

	○ 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 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 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.	
Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices	For CY 2017 and subsequent years, CMS finalized its policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code "FD" when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. CMS 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.	***CMS is finalizing its proposal to apply the no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under the finalized modified criteria discussed above, for CY 2019 and subsequent years***. (p. 422)
Low Volume Device Intensive Procedures	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.	***CMS will continue its current policy***. (p. 425)

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

Drugs and Biologicals with Expiring Pass-Through Status	CMS proposes that the pass-through payment status of 23 drugs and biologicals would expire on December 31, 2018, as listed in Table 19. 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).	***CMS is finalizing its proposal, without modification, to expire the pass-through payment status of the 23 drugs and biologicals listed in Table 37 (p. 433) on December 31, 2018***. (p. 433) The final packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B.
Drugs, Biologicals, and Radio-pharma-ceuticals with New or Continuing Pass-Through Status	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. 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. 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.	***CMS did not receive any public comments on these proposals and is finalizing them without modification***. (p. 437) The drugs and biologicals that continue to have pass-through payment status for CY 2019 or have been granted pass-through payment status as of January 2019 are shown in Table 38. (p. 438)

Drugs, Biologicals, and Radio-pharma-ceuticals with Pass-Through Status as a Result of Sec. 1301 of the Consolidated Appropriations Act of 2018	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.	***CMS is finalizing its proposal to continue pass-through payment status for these products***; see Table 39.
	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 is finalizing its proposal that pass-through payment for the covered drugs and biologicals will 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***. (p. 449)
	CMS proposes to consider PuraPly to be a drug or biological and to be eligible for extended pass-through payment.	***CMS is finalizing its proposals, with modification, to accommodate a coding change related to the PuraPly products***. After the proposed rule was published, CMS became aware that HCPCS code Q4172 (Puraply, and Puraply AM per square centimeter) will be deleted effective January 1, 2019, and will be replaced by three new HCPCS codes: Q4195 (Puraply, per square centimeter); Q4196 (Puraply am, per square centimeter); and Q4197 (Puraply xt, per square centimeter). Two of these products, PuraPly (HCPCS code Q4195) and PuraPly AM (HCPCS code Q4196), were products that received original pass-through payment status on January 1, 2015, and will continue to receive pass-through payment status in CY 2019. (p. 449)
Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups	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. 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.	***CMS received no comments and is finalizing this proposal without modification***. (p. 451)

OPPS Payment for Drugs, Biologicals, and Radio-pharma-ceuticals without Pass-Through Payment Status	CMS sets a cost threshold for packaging based on cost and is proposing a packaging threshold for CY 2019 of $125.	***CMS is finalizing a packaging threshold of $125 for CY 2019***. (p. 454)
Packaging for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radio-pharma-ceuticals under the Cost Threshold ("Threshold-Packaged Drugs")	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. 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.	***CMS is adopting a CY 2019 packaging threshold of $125***. (p. 456) ***CMS received no comments and is finalizing these two proposals without modification***. (p. 459)
High/Low Cost Threshold for Packaged Skin Substitutes	CMS has continued the high cost/low cost categories policy since CY 2014 and proposes to continue it for CY 2019. 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	CMS received many comments on the four potential methodologies. (p. 472) Additionally, CMS received comments that it should eliminate the high cost/low cost division and have only a single payment category in CY 2019. At this time, CMS does not believe that establishing one cost category for all skin substitute products is prudent. It would not be appropriate to establish such a major payment change in the final rule without having proposed it. (p. 472) One of the commenters requested that CMS establish new skin substitute payment policy for CY 2020. Another commenter requested that CMS maintain the current payment methodologies for up to 5 years until a new skin substitute payment system is implemented. (p. 473) For CY 2019, CMS will continue to use high cost/low cost categories. CMS is finalizing its proposal to assign to the high cost group any skin substitute

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.

CMS has identified four potential methodologies that it encourages the public to review and provide comments on:

- 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.
- 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.
- 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

product that exceeds the CY 2019 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2019 MUC or PDC thresholds and was not assigned to the high cost group in CY 2018. (p. 474)

CMS is finalizing its proposal to assign a 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, unless the product was assigned to the high cost group in CY 2018, in which case CMS would assign the product to the high cost group for CY 2019, regardless of whether it exceeds the CY 2019 MUC or PDC threshold. (p. 474)

Table 41 displays the final CY 2019 cost category assignment for each skin substitute product. (p. 474)

	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. • 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. 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.	
Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages	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.	***CMS did not receive any comments on this proposal and is finalizing it without modification***. (p. 479)
Payment for Items without Pass-Through Status That	For CY 2019, CMS proposes changes to the payment methodology for biosimilars acquired under the 340B Program. CMS proposes to pay non pass-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.	***CMS is finalizing its proposed policy to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's 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. 494)

Are Not Packaged	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.	***For CY 2019, CMS is finalizing its proposals without modification***. For CY 2019, CMS is continuing the 340B Program policies that were implemented in CY 2018 with the exception of the way the agency is calculating payment for 340B-acquired biosimilars as explained above. (p. 511)
Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radio-pharma-ceuticals, and Devices	CMS estimates that pass-through spending in CY 2019 would equal approximately $126.7 million (approximately $10 million for device categories and $116.7 million for drugs and biologicals) which represents 0.18 percent of total projected OPPS payments for CY 2019 (approximately $70 billion).	CMS estimates that pass-through spending in CY 2019 is approximately $100.8 million (approximately $10 million for device categories and approximately $90.8 million for drugs and biologicals), which represents 0.14 percent of total projected OPPS payments for CY 2019 (approximately $74 billion). (p. 519)

OPPS Payment for Hospital Outpatient Visits and Critical Care Services

General	CMS proposed 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.	CMS did not receive any comments related to this issue. Therefore, ***CMS will continue these policies without modification*** (p. 520). (*See below* for section where CMS makes separate policies related to outpatient visits in off-campus provider based departments (off-campus PBDs).

Inpatient Only Procedures

Topic	Proposed Rule	Final Rule
General	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). For CY 2019, CMS has identified two (2) procedures that it proposes for removal from the Inpatient Only list: • CPT 31241 (*Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery*) • CPT 01402 (*Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty*) CMS also seeks input on the potential removal of CPT 0266T (*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)*). For CY 2019, CMS also proposed 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 includes the full list of codes on the IPO list in Addendum E. ***CMS finalized removal of CPT 31241 from the IPO list*** (p. 574). ***CMS finalized removal of CPT 01402 from the IPO list*** (p. 578). CMS received several comments that procedures related to CPT 0266T are currently performed safely in the hospital outpatient department (p. 581). ***CMS agreed and is removing CPT 0266T from the IPO list for CY 2019*** (p. 582). ***CMS finalized the addition of C9606 to the IPO list*** (p. 580). Additional Requests: • Request to remove CPT 00670 (*Anesthesia for extensive spine and spinal cord procedures (eg, spinal instrumentation or vascular procedures*): ***CMS is removing CPT 00670 from the IPO list for CY 2019*** (p. 584). • Request to remove CPT 63265 (*Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical*): CMS will review and consider appropriateness of removal from the IPO list for future rulemaking (p. 584). • Request to remove CPT 63266 (*Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural;*

Topic	Proposed Rule	Final Rule
		thoracic): CMS will review and consider appropriateness of removal from the IPO list for future rulemaking (p. 584). • Request to remove CPT 63267 (*Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar*): CMS will review and consider appropriateness of removal from the IPO list for future rulemaking (p. 584). • Request to remove CPT 63268 (*Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral*): CMS will review and consider appropriateness of removal from the IPO list for future rulemaking (p. 584). • Request to remove ALL orthopaedic, arthroplasty, and joint replacement procedures: CMS does not have data to support removal of all these procedures, but encouraged stakeholders to submit evidence on specific procedures (p. 585).

Off-Campus Provider Based Departments (PBDs)

Topic	Proposed Rule	Final Rule
Collecting Data on Services Furnished in Off-Campus Provider Based Departments	CMS will implement a new modifier ("ER") to be used on "every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department."	CMS stated that it included the ~ER modifier as an "announcement" rather than as a proposal, "and therefore was not subject to public comment." CMS stated that it will consider the feedback received "in potential future policy development." (p. 589). Note: In general OPPS ratesetting, because services billed with the ~PN Modifier are paid out of the MPFS, CMS has removed claims that appear with ~PN from claims data used for ratesetting in the OPPS (p. 57).

Method to Control for Unnecessary Increases in Volume of Outpatient Services	CMS proposed to apply an amount equal to "the site-specific MPFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD" for clinical visits (i.e. HCPCS G0463) even when provided at an off-campus PBD excepted from the BBA provisions.	***CMS finalized its proposal with modification*** (p. 611; p. 624). CMS states that it received substantial support for its proposal and encouragement to work with Congress to find other mechanisms to support site-neutrality (pp. 608-610). CMS responded favorably to the MedPAC request that CMS phase in the policy, and therefore, ***CMS finalized implementation of this policy with a two-year phase-in*** (p. 613): ***In CY 2019, CMS apply "50 percent of the total reduction in payment that would apply if these departments were paid the site-specific PFS rate for the clinic visit service"*** (CMS states that this results in being paid about 70% of the OPPS rate in CY 2019) (p. 625); ***In CY 2020, CMS will pay the site-specific PFS rate for the service*** (p. 625). CMS also believes that the two-year phase-in will help lessen the immediate impact on rural hospitals, although CMS stated that it could consider potential exceptions to the policy in CY 2020 rulemaking (p. 624).
	CMS proposes a non-budget neutral application of the policy.	***CMS finalized this policy*** (p. 624). (CMS received pushback on its statutory authority to implement this policy. CMS' summary is available beginning on p. 613). CMS responds to critiques that it does not have the authority to apply the policy in a non-budget neutral manner on p. 621. CMS did not act on requests that, instead of applying the policy in a non-budget neutral manner, CMS should redistribute the savings to the MPFS (p. 611).
	CMS requests input on the following: • 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	CMS stated that it will take the following input into account for future rulemaking (p. 629). MedPAC suggested that CMS utilize MedPAC's "five criteria" that it developed for "identifying services for which it reasonable to have site-neutral payments between freestanding physician offices and HOPDs." (p. 628). CMS received comments that prior authorization, even when directed at controlling overutilization, can lead to administrative burden and patient access issues; or that if it is used it should only be used for providers that are statistical outliers (p. 628). CMS received input that a higher OPPS rate could be appropriate if the "higher payment can improve patient experience, efficiency, and quality of care" or to pay for comprehensive care management and coordination (p. 628).

	• Whether and how CMS could use its authority to implement utilization management cost-containment strategies	CMS stated that it received many comments in opposition to implementing utilization management; and that if CMS were to implemented it, it must be "based on clinical validity, support the continuity of patient care, be transparent and fair, provide timely access to care and administrative efficiency, and provide alternatives and exemptions to those clinicians with appropriate utilization rates"; others suggested appropriate use criteria and evidence-based clinical guidelines (p. 629).
	• 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)	CMS believes that the two-year phase-in will help lessen the immediate impact on rural hospitals, although CMS stated that it could consider potential exceptions to the policy in CY 2020 rulemaking (p. 624).

Topic	Proposed Rule	Final Rule
Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital	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. 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. CMS proposes to except rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment. 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 finalized these policies without modification***: for CY 2019, separately payable Part B drugs and biologicals (other than vaccines and drugs with pass-through payment status) acquired through the 340B Program will be paid at a rate of ASP minus 22.5 percent when billed by a hospital that is not excepted from the payment adjustment. For CY 2019, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are excepted. (p. 657)

Topic	Proposed Rule	Final Rule
Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider	CMS proposed 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, 2015) that the services would not be "excepted services" and, therefore, would be paid under the MPFS rather than the OPPS.	***CMS did not finalize this proposal because of operational challenges and administrative burden reasons*** (p. 674; p. 678). CMS stated that it will continue to monitor utilization and consider limiting expansion in future rulemaking (p. 679).

Definition of ASC Covered Surgical Procedures	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). 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.	***CMS finalized its proposal. (p. 692)*** Consistent with the majority of comments, CMS will now define a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American Medical Association (AMA) defines as "surgery" (CPT codes 10000 through 69999) (72 FR 42478), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that CMS determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS.
Treatment of New and Revised Level II HCPCS Codes Implemented in April and July 2018	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. 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.	Considering the comments received, ***CMS finalized the CY 2019 proposed payment indicators for new level II HCPCS codes for covered surgical procedures and ancillary services effective on April 1, 2018, as indicated in Table 53. (p. 698)*** See Table 53. Receiving no public comments, ***CMS finalized the proposed payment indicators and rates. (p. 700)*** See Table 54 and 55. *Note that several HCPCS C-codes have been replaces with HCPCS J-codes effective January 1, 2019.*
Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019	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 did not receive any public comments on its proposal. ***CMS invites public comments 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.*** These codes are flagged with comment indicator "NI" in Addendum B to the CY 2019 OPPS/ASC final rule w/comment period.

Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2019	For new and revised CPT codes effective January 1, 2019, that were received in time to be included in the 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. CMS requests comments on only those codes that are assigned to comment indicator "NP."	***CMS finalized the ASC payment indicators for the eight codes that it proposed to designate as temporarily office based effective January 1, 2019. (p. 704)*** Table 58 of this final rule with comment period contains the list of these eight codes and their final ASC payment indicators. In addition to the Level II HCPCS codes that will be effective October 1, 2018, and January 1, 2019, CMS flagged the new Category I and III CPT codes that will be effective January 1, 2019, that were omitted from the CY 2019 OPPS/ASC proposed rule, with comment indicator "NI" in ASC Addendum AA, BB, and EE to this CY 2019 OPPS/ASC final rule with comment period to indicate that CMS assigned the codes an interim ASC payment indicator for CY 2019. ***CMS invites public comments on the interim ASC payment indicator assignments and payment rates for these codes that it intends to finalize in the CY 2020 OPPS/ASC final rule with comment period. (p. 703)***

Update to Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

Covered Surgical Procedures Designated as Office-Based	The CPT codes that CMS proposes to permanently designate as office-based for CY 2019 are listed in Table 37. CMS proposes to maintain the temporary office-based designations for procedures described by CPT codes 38222, 65785, 67229, and 0402T for CY 2019. CMS proposes to assign payment indicator "P2", "P3", or "G2" to CPT codes 10030, 36473, 36901, 64461, and 64463, and HCPCS code G0429 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 2018 OPPS/ASC Final Rule with comment period. CMS proposes to designate 8 new CY 2019 CPT codes for ASC covered surgical procedures as temporary office-based, as displayed in Table 39. CMS proposes to make the office-based designation temporary rather than permanent, and CMS will reevaluate the procedures when data become available.	***With modification, CMS finalized its proposal to permanently designate as office-based the CPT codes listed in Table 56. (p. 711)*** Given commenter concerns, which the agency agreed with, CMS did not designate CPT codes 36902 and 36905 as office-based for CY 2019 and will reevaluate these procedures in CY 2020 rulemaking. ***CMS finalized its proposal, with modification, to designate the procedures in Table 57 as temporarily office-based for CY 2019. (p. 712)*** Note that CMS assigned CPT codes 10030, 64461, and 64463 payment indicators of "G2" (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in Table 38 of the CY 2019 OPPS/ASC proposed rule. CMS inadvertently indicated in the preamble of the proposed rule that those were office-based procedures; however, CMS did not designate CPT codes 10030, 64461, and 64463 as office-based procedures for CY 2019 and finalized payment indicators of "G2" for such procedures. As no comment were received, ***CMS finalized its proposal, without modification, to designate the procedures in Table 58 as temporarily office-based. (p. 716)***

ASC Covered Surgical Procedures To Be Designated as Device-Intensive	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. CMS proposes to modify its criteria to lower the device offset percentage threshold from 40 percent to 30 percent.
	
	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.
	
	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.
	
	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).
		Finalized as proposed with support from commenters. (p. 730)

CMS proposes to amend § 416.171(b)(2) of the regulations to reflect the proposed new device 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. 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).	

Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices	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.	***As no comments were received, CMS finalized the policy as proposed. (p. 734)***
Additions to the List of ASC Covered Surgical Procedures	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 finalized its proposal to add 12 cardiac catheterization procedures to the list of ASC covered surgical procedures. In addition, based on public comments, CMS added CPT codes 93566, 93567, 93568, 93571, and 93572, which are performed during cardiac catheterization procedures, to the list of ASC covered surgical procedures. In total, CMS added 17 procedures to the ASC CPL, which are listed in Table 60. (p. 745)***
Review of Recently Added Procedures 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 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. 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. 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.	Following its review and considering comments received, ***CMS retained the 36 procedures displayed in Table 61 on the ASC CPL for CY 2019, with the exception of CPT codes 0171T and 0172T, which were deleted from the ASC CPL effective January 1, 2017 and, therefore, will not be included on the ASC CPL for CY 2019. (p. 752)*** Given public comments, CMS does not believe it is necessary to finalize any proposal regarding ongoing reviews of recently added procedures at this time. CMS will take all commenters' suggestions into account as it considers future refinements to the review of the ASC CPL. (p. 752)

Covered Ancillary Services	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.	***Finalized without modification, as no comments were received. (p. 760)***

ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

ASC Payment for Covered Surgical Procedures	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. 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. 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.	***CMS finalized its proposed policies, without modification, to calculate the CY 2019 payment rates for ASC covered surgical procedures according to its established methodologies using the modified definition of device-intensive procedures***. For those covered office-based surgical procedures where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the PFS nonfacility PE RVU-based amount, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2019. (p. 767) Responses to code specific payment policies are also discussed beginning on p. 764.

ASC Payment for Covered Ancillary Services	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.	Commenters requested CMS develop policies for a variety of code/procedure specific changes, beginning on p. 772.
CY 2019 ASC Packaging Policy for Non-Opioid Pain Management Treatments	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. 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.	***CMS finalized its policy and to make conforming changes to 42 CFR 416.164(a)(4) as proposed. CMS is also adding a new paragraph (6) to 42 CFR 416.164(b) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as covered ancillary services that are integral to a covered surgical procedure. (p. 796)*** With regard to Exparel, CMS continues to believe the separate payment is appropriate for Exparel in the ASC setting based on the studies it received from commenters. To the extent that other non-opioid pain management drugs that function as a surgical supply become available in the U.S. market in CY 2019, this policy would also apply to those drugs. (p. 788)

ASC Payment Rates and Conversion Factor

ASC Relative Payment Weights for CY 2019 and Future Years	The proposed CY 2019 ASC weight scalar is 0.8854.	The CY 2019 ASC weight scalar is 0.8792. (p. 827)

Updating the ASC Conversion Factor	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. 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. 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.	***CMS finalized its proposal and will modify its regulation under 42 CFR 416.171(a)(2), which address the annual update to the ASC conversion factor. (p. 827)*** CMS received a plethora of comments on ways it can evaluate the impact of this payment change, which CMS will consider for future rulemaking. To determine the CY 2019 ASC update for this final rule with comment period, CMS incorporated a more recent estimate of the hospital market basket update and the MFP adjustment. The MFP-adjusted hospital market basket update for CY 2019 is 2.1 percent (that is, the hospital market basket increase of 2.9 percent minus the MFP adjustment of 0.8 percentage point). Therefore, CMS finalized the application of a 2.1 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2019 ASC payment amounts. For ASCs that fail to meet the ASCQR Program requirements, CMS finalized to utilize the hospital market basket update of 2.9 percent reduced by 2.0 percentage points and then subtracted the 0.8 percentage point MFP adjustment. The result is a 0.1 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs not meeting the quality reporting requirements. For CY 2019, CMS adjusted the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0004 in addition to the MFP-adjusted hospital market basket update factor of 2.1 percent, which results in a CY 2019 ASC conversion factor of $46.551 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, CMS adjusted the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0004 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.1 percent discussed above, which results in a CY 2019 ASC conversion factor of $45.639. (p. 828)

Hospital OQR Program Quality Measures

Accounting for Social Risk Factors in the Hospital OQR Program	CMS did not specifically request comment on social risk factors in the CY 2019 proposed rule, but updates the public on various efforts, including the National Quality Forum's (NQF) 2-year trial to determine if risk adjustment for social risk factors is appropriate for certain measures and the Office of the Assistant Secretary for Planning and Evaluation's (ASPE) study of the influence of social risk factors in CMS value-based purchasing programs.	CMS thanks commenters for sharing feedback on this issue. CMS takes this feedback seriously and will continue to review social risk factors on an on-going and continuous basis. ***CMS welcomes feedback as it continues to work on these issues.*** 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. 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 Inpatient Quality (IQR) Reporting Program outcome measures. CMS also continues to consider options to address equity and disparities in its value-based purchasing programs.
Removal of Quality Measures from the Hospital OQR Measure Set	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. **Update to Measure Removal Factor 7.** CMS proposes to change measure removal Factor 7 in the Hospital OQR Program to "collection or public reporting of a measure	**Update to Measure Removal Factor 7**. ***CMS finalized this policy as proposed*** (p. 841).

	leads to negative unintended consequences other than patient harm" so that it aligns with measure removal Factor 7 in the ASCQR Program. **New Measure Removal Factor 8.** 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." CMS would remove measures based on this factor assessing costs versus benefits on a case-by-case basis. **Clarification of Removal Factor 1: "Topped-Out" Measures.** In the CY 2015 OPPS/ASC final rule (79 FR 66769), CMS finalized the following 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). In this rule, CMS clarifies its process for calculating the truncated coefficient of variation (TCOV), particularly for two of the measures (OP-11 and OP-14) proposed for removal from the Hospital OQR Program which are unique in that they assess the rate of rare, undesired events for which a lower rate is preferred.	**New Measure Removal Factor 8.** ***CMS finalized this policy as proposed*** (p. 849). As suggested by commenters, CMS will consider stakeholder input when evaluating both the costs of quality reporting as well as the benefits of collecting and reporting quality data. The revised and finalized measure removal factors list for the Hospital OQR Program is listed on p. 849. **Clarification of Removal Factor 1: "Topped-Out" Measures.** CMS reiterates these clarifications.
Removal of Quality Measures from the Hospital OQR Program Measure Set	As part of its Meaningful Measures Initiative, 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). 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.	For all of the measures listed below that were finalized for removal, CMS clarifies that it is not removing them more immediately than proposed since data collection has already begun on them and by the effective date of this final rule, hospitals will have already reported almost three quarters of data for these measures. OP-27: Influenza Vaccination Coverage Among Healthcare Personnel ***CMS finalized this measure for removal as proposed*** (p. 863). In response to concerns about the public health impact of removing this measure, CMS noted that the effects of removing this measure are mitigated as the issue is addressed by other initiatives such as State laws and employer programs that require influenza vaccination of healthcare workers. Further, CMS has retained the measure in the Hospital IQR Program (83 FR 41579), thus requiring reporting in the short-term, acute care hospital setting. Additionally, HOPDs may independently choose to voluntarily report data to NHSN on vaccination rates using the NHSN Healthcare Personnel Safety Component.

Beginning with the CY 2021 payment determination:	
2) OP-5: Median Time to ECG (NQF #0289). 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: Median Time to ECG ***CMS finalized this measure for removal as proposed*** (p. 867).
3) OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) 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-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients ***CMS did not finalize its proposal to remove this measure*** (p. 876). After consideration of public comments and reevaluating its data, CMS now believes that OP-29 is a more critical measure for the Hospital OQR Program than initially perceived. Upon reviewing the measure set as a whole, CMS now believes that OP-29 assesses a distinct clinical area not addressed by OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF# 2539). Further, CMS believes that OP-29 is significantly less burdensome than OP-30 due to the significant burden of obtaining patient histories required for that measure.
4) OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use. 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-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use ***Due, in part, to the duplication of this measure through MIPS and the additional burden to hospitals of obtaining patient records, CMS finalized its proposal to remove this measure from the Hospital OQR Program*** (p. 886). CMS believes that removing OP-30 while retaining OP-29 best enables it to assess an important clinical area while ensuring that the costs of measure do not outweigh the benefits. CMS understands that the measure steward is planning to update OP-30; but, because these updates will not eliminate the need to collect patient histories, CMS does not believe such updates will lessen burden.
5) OP 31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. 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 31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery After consideration of public comments and reevaluating its data, ***CMS did not finalize its proposal to remove this measure*** (p. 893)
6) OP-9: Mammography Follow-up Rates. CMS proposes to remove this measure under measure removal Factor 3, the measure does not align with current clinical guidelines or practice.	OP-9: Mammography Follow-up Rates ***CMS finalized this measure for removal as proposed*** (p. 896).
7) OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material. 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.	OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material ***CMS finalized this measure for removal as proposed*** (p. 901). In response to concerns about removing measures solely based on topped out status, CMS said it would consider re-proposing this measure and OP-14 in the future if data and research indicate that performance in this area has declined.

8) OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT. 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.	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT ***CMS finalized this measure for removal as proposed*** (p. 901). See discussion above.
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. 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.	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 ***CMS finalized this measure for removal as proposed*** (p. 904)
10) OP-17: Tracking Clinical Results between Visits. 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.	OP-17: Tracking Clinical Results between Visits ***CMS finalized this measure for removal as proposed*** (p. 906)
	The **final Hospital OQR Program Measure Set for the CY 2020 Payment Determination** can be found on p. 906. The **final Hospital OQR Program Measure Set for the CY 2021 Payment Determination** can be found on p. 908.

Hospital OQR Program Measures and Topics for Future Consideration

General	CMS notes it is moving towards greater use of outcome measures and away from use of clinical process measures across its 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.	CMS acknowledges the stakeholder recommendations for possible future measure topics that are listed below. CMS will consider suggested topic areas for future rulemaking and intends to work with stakeholders as it continues to develop the Hospital OQR Program measure set: 1. Antibiotic-use related measures to assess inappropriate prescribing; 2. A focus on clinical and population based outcome measures; 3. Cancer care measures including two measures related to referral to radiation therapy for both post-breast conserving surgery (NQF 0219) and post-mastectomy (MASTRT); 4. Psychiatric care and behavioral health measures; 5. Measures identified as meaningful to providers as well patients and their families;

		6. Rural health measures; 7. Measures assessing access to care; 8. Measures assessing substance abuse; 9. Management of chronic conditions; 10. Measures that promote advance care planning and shared-decision making; 11. Surgical site infections (SSIs) and medication safety measures such as the Ambulatory Breast Procedure SSI Outcome Measure (NQF #3025) measure; 12. Measures using the same unit of analysis that allow comparison between hospitals and ASCs; and Adult immunization measures

Administrative Requirements

Removal of Notice of Participation Form Requirement	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.	***CMS finalized this policy as proposed*** (p. 914).

Form, Manner & Timing of Data Submitted

Hospital Outpatient Quality Reporting Specifications Manual	CMS proposes to update the frequency with which it releases Hospital Outpatient Quality Reporting Specifications Manuals. Instead of every six months, CMS would release Specifications Manuals one to two times per year, beginning with CY 2019, depending on the need for an updated release.	***After consideration of public comments, CMS finalized a modification of its proposal, beginning with CY 2019 and for subsequent years, such that it will instead release a manual once every 12 months and release addenda as necessary*** (p. 918).
Claims-Based Measure Data Requirements for the CY 2020 Payment Determination and Subsequent Years	CMS proposes to extend the reporting period for OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018).	***CMS finalized this policy change as proposed*** (p. 927).

Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2019 Payment Determination

General	CMS proposes to continue: • Its established policy of applying the reduction of the Outpatient Department (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.	***CMS finalized these policies as proposed and confirms that for the CY 2019 OPPS, the final reporting ratio is 0.980*** (p. 937).

ASC Quality Reporting (ASCQR) Reporting Program

ASCQR Program Quality Measures

Topic	Proposed Rule	Final Rule
Accounting for Social Risk Factors in the Hospital OQR Program	See discussion related to the Hospital OQR Program.	See discussion related to the Hospital OQR Program.
Removal Factors for ASCQR	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	

Topic	Proposed Rule	Final Rule
Program Measures	made ("topped out" measures[1]). • 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. 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. 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 finalized its proposal to remove measure removal Factor 2 from the ASCQR Program beginning with the effective date of this CY 2019 OPPS/ASC final rule*** (p. 946). ***CMS also finalized its proposal to add a new removal factor to the ASCQR Program, "performance or improvement on a measure does not result in better patient outcomes"*** (p. 947) ***and to adopt measure removal "Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program,"*** (p. 954) ***beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period, as proposed.*** The revised and finalized measure removal factors list for the ASCQR Program is listed on p. 954.
Clarification of Removal Factor 1: "Topped-Out" Measures	In the CY 2015 OPPS/ASC final rule (79 FR 66769), CMS finalized the following 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).	CMS reiterates these clarifications.

[1] 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).

Topic	Proposed Rule	Final Rule
	In this rule, CMS clarifies its process for calculating the truncated coefficient of variation (TCOV) for four of the measures (ASC-1, ASC-2, ASC-3, and ASC-4) proposed for removal from the ASCQR Program. These are unique in that they assess the rate of rare, undesired events for which a lower rate is preferred.	

Removal of Quality Measures from the ASCQR Program Measure Set

Topic	Proposed Rule	Final Rule
General	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) ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). 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. Beginning with the CY 2021 payment determination: 2) ASC-1: Patient Burn (NQF #0263) 3) ASC-2: Patient Fall (NQF #0266) 4) ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267) 5) ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265)	***CMS finalized the removal of two measures out of the eight measure removals proposed, as described below:*** Beginning with the CY 2020 payment determination: ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel ***CMS finalized this measure for removal as proposed*** (p. 968) ASC-1: Patient Burn (also see p. 976) ASC-2: Patient Fall (also see p. 978) ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (also see p. 979) ASC-4: All-Cause Hospital Transfer/Admission (also see p. 981) ***CMS did not finalize its proposal to remove ASC-1, ASC-2, ASC-3, and ASC-4*** (p. 972). After considering stakeholder input, CMS has come to believe that these topped out measure measures may be more valuable to stakeholders than it initially perceived. Despite being topped out, CMS feels these measures provide beneficiaries and ASCs with vital information and that it would be prudent to keep them in the program at this time in order to continue to detect and prevent these events. CMS also acknowledges that having measures that apply to all ASCs (vs. those that focus on specialty-specific procedures) provides beneficiaries with the most comprehensive patient safety data to use when making decisions about a site of care.

Topic	Proposed Rule	Final Rule
		Although CMS will retain these claims-based measures in the ASCQR Program program, after considering public comments and reevaluating concerns about data submission (e.g., concerns about under-reporting and the fact that only 50 percent of claims are required to have QDCs), ***CMS will also suspend data collection on these four measures beginning with the CY 2019 reporting period/CY 2021 payment determination until further action in rulemaking with the goal of updating the data submission method for the measures***. In other words, starting with the CY 2021 payment determination, facilities would not be required to submit data for these measures as part of ASCQR Program requirements although the measures would remain in the ASCQR Program measure set. As CMS develops future revisions for the data collected for these measures, it will take into consideration other data submission methods that may allow for the reporting of adverse events across payers and will consider commenters' feedback (p. 975).
	6) ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)	ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients ***After consideration of the comments received, CMS did not finalize its proposal to remove this measure*** (p. 996). CMS no longer believes that the costs associated with this measure outweigh the benefit of its continued use in the program since this measure assesses a unique and clinically important topic area not covered otherwise addressed by the ASCQR Program measure set. Note that CMS is similarly retaining the corresponding measure, OP-29, under the Hospital OQR Program.
	7) ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659)	ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use ***CMS finalized removal of this measure as proposed*** (p. 1005).
	8) ASC-11: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)	ASC-11: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery ***CMS did not finalize this measure for removal, as proposed*** (p. 1012). It is retaining a similar measure, OP-31, under the Hospital OQR Program.
		The **Finalized ASCQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years** can be found on p. 1013.
		The **Finalized ASCQR Program Measure Set for the CY 2021 Payment Determination and Subsequent Years** can be found on p. 1014.

Topic	Proposed Rule	Final Rule
		The **Finalized ASCQR Program Measure Set for the CY 2022 Payment Determination and Subsequent Years** can be found on p. 1015.
ASCQR Program Measures and Topics for Future Consideration		
General	CMS requests public comment on the possible future validation of ASCQR Program measures. 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, 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.	CMS summarizes input received on possible validation strategies, including concerns about facility burden. CMS will take this input into consideration as it determines future policy in this area.
Form, Manner, and Timing of Data Submitted		
Extension of the Reporting Period for ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	CMS proposes to extend the reporting period for ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018).	***CMS finalized this change as proposed*** (p. 1038).
Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements Administrative Requirements		
General	Any annual update will be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program.	***CMS finalized this policy without modification and will continue existing policies for CY 2019*** (p. 1044).
Hospital Inpatient Quality Reporting (IQR) Program Policies		
Updates to the HCAHPS Survey Measure (NQF #0166) for the FY 2021	In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), out of an abundance of caution, in the face of a nationwide epidemic of opioid overprescription, CMS finalized a refinement to the HCAHPS Survey measure as used in the Hospital IQR Program by removing the previously adopted pain management questions and incorporating new Communication About Pain questions beginning with patients discharged in January 2018, for the FY 2020 payment determination and	Commenters indicated the Communication About Pain questions in the HCAHPS Survey unduly influence providers' decision-making by encouraging providers to focus on improving patient satisfaction scores regarding pain management. The majority of commenters supported CMS' proposal to remove the questions from the HCAHPS Survey. A number of

Topic	Proposed Rule	Final Rule
Payment Determination and Subsequent Years	subsequent years. CMS also finalized public reporting on the Communication About Pain questions, such that hospital performance data on those questions would be publicly reported on the Hospital Compare website beginning October 2020, using CY 2019 data. CMS also stated that it would provide performance results based on CY 2018 data on the Communication About Pain questions to hospitals in confidential preview reports, upon the availability of four quarters of data, as early as July 2019. Since CMS finalized the updated questions, it 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. 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 proposal 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. CMS did not propose to change how performance scores are calculated for the remaining questions on the HCAHPS Survey. 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.	commenters who supported removal of the questions also recommended CMS remove the questions earlier than proposed. In addition, section 6104 of the Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Pub. L. 115-271), enacted on October 24, 2018, prohibits HCAHPS Surveys conducted on or after January 1, 2020 from including questions about communication by hospital staff with an individual about such individual's pain, unless such questions take into account, as applicable, whether an individual experiencing pain was informed about risks associated with the use of opioids and about non-opioid alternatives for the treatment of pain. Section 6104 of the SUPPORT for Patients and Communities Act also states that the Secretary shall not include any measures based on the pain communication questions on the HCAHPS Survey in 2018 or 2019 on the Hospital Compare website and in the Hospital Value-Based Purchasing (VBP) Program. ***Given these considerations, CMS finalized a modification to its proposal and will remove the Communication About Pain questions effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years*** (p. 1084). ***In light of this decision, CMS also finalized a modification to its public display proposal. CMS will not publicly report data from the Communication about Pain questions at all*** (p. 1062). However, CMS still plans to provide performance results based on these data to hospitals in confidential preview reports upon the availability of four quarters of CY 2018 data, as early as July 2019. Updated confidential reports will be provided on a quarterly basis with the availability of each new calendar quarter of data. The last confidential preview report containing the Communication About Pain questions data will reflect data from the fourth quarter of 2018 (October 1, 2018) through the third quarter of 2019 (September 30, 2019). CMS clarifies that data collected from these questions will not be scored for purposes of CMS payments to hospitals, because the Hospital IQR Program is a pay-for-reporting, not pay-for-performance quality program and these questions are not part of the Hospital VBP Program. CMS discusses inappropriate applications of HCAHPS scores, noting that:

- HCAHPS scores are designed and intended for use at the hospital level for the comparison of hospitals (designated by their CMS Certification Number) to each other;
- CMS does not review or endorse the use of HCAHPS scores for comparisons within hospitals, such as comparison of HCAHPS scores associated with a particular ward, floor, individual staff member, etc. to others. Such comparisons are unreliable unless adequate sample sizes are collected at each level;
- Since HCAHPS questions inquire about broad categories of hospital staff (such as doctors in general and nurses in general rather than specific individuals), HCAHPS is not appropriate for comparing or assessing individual hospital staff members.

In this section, CMS also discusses how many commenters did not support removal of the Communication About Pain questions based on concerns that removal of the questions may minimize the importance of appropriate communication about pain management in the hospital setting. Specifically, a number of commenters stated 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, and expressed concern that removing the Communication About Pain questions may result in potential negative consequences for both patients and providers. A few commenters expressed particular concern that removal of these questions could have a negative impact on the appropriate treatment of pain associated with complex chronic and end-of-life illnesses. Some of these commenters expressed concern that removing these questions might lead hospitals and providers to place less importance on communicating with patients about their pain and pain management.

CMS acknowledges these concerns, but remains concerned about the potential negative consequences resulting from retaining the questions, including confusion regarding the appropriate use of the questions. CMS believes these concerns, coupled with the severity and urgency of the nationwide opioid epidemic, warrant removing the questions to relieve any potential pressure clinicians may feel to prescribe opioids in order to achieve higher scores on the HCAHPS Survey. In regard to assertions that removal of the questions might lead hospitals and providers to place less importance on communication with their patients about their pain and pain management, CMS notes that engaging patients in treatment decisions about their pain management is required under the enhanced pain

Topic	Proposed Rule	Final Rule
		assessment and management requirements, applicable to all Joint Commission-accredited hospitals, effective January 1, 2018. Overall, CMS reiterates its belief 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. Beginning on p. 1079, CMS summarizes feedback regarding other measures that could capture facets of pain management and related patient education.

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program Policies

Topic	Proposed Rule	Final Rule
Retention of Two Safety Measures in the PCHQR	In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20503), CMS proposed to remove the following two National Healthcare Safety Network (NHSN) chart-abstracted measures from the PCHQR Program beginning with the FY 2021 program year under Factor 8, "the costs associated with the measure outweigh the benefit of its continued use in the program": • NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH-5/NQF #0138); and • NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH-4/NQF #0139). CMS also noted that it has become difficult to publicly report these measures due to the low volume of data produced and reported by the small number of facilities participating in the PCHQR Program and the corresponding lack of an appropriate methodology to publicly report these data. In the FY 2019 IPPS/LTCH PPS proposed rule, CMS invited public comment on this proposal, but stated that it would defer making a final decision on these measures in order to conduct additional data analyses to assess measure performance based on new information provided by the CDC, which was not available at the time CMS had proposed the removal of these measures.	***CMS did not finalize its proposal to remove the CAUTI Outcome Measure and CLABSI Outcome Measure from the PCHQR measures beginning with the FY 2021 program year*** (p. 1091). CMS agrees with the conclusions drawn from updated CDC data analyses, which, according to CMS, demonstrate that reporting PCH CAUTI and CLABSI performance measure data is just as important as reporting acute care hospital CAUTI and CLABSI performance measure data. CMS also believes that these measures have the potential to provide beneficiaries with valuable information on PCH performance in avoiding hospital-acquired infections and improving patient safety. However, CMS is continuing to defer public reporting of these measure data for reasons discussed in the next section. CMS hopes to introduce the refined CAUTI and CLABSI measures with adequate risk adjustment into the PCHQR Program in the near future. Any such change will be made via rulemaking, and CMS will solicit input from the Measures Application Partnership (MAP) to garner multi-stakeholder input on the updated versions prior to proposing to adopt these refined measures. CMS is aware that the CLABSI and CAUTI measures specifications were recently updated to use new standard infection ratio (SIR) calculations that can be applied to cancer hospitals, including PCHs. CMS intends to propose to adopt these updated versions of the CLABSI and CAUTI measures in future rulemaking but believe that, until that time, the importance of

Topic	Proposed Rule	Final Rule
		emphasizing patient safety in quality care delivery justifies retaining the current versions of the measures. CMS will work closely with the CDC to assess the updated risk-adjusted versions of CAUTI and CLABSI, and evaluate the data provided in the form of SIRs for each PCH, for the purposes of future program implementation and public reporting. The final **PCHQR Program measure set for the FY 2021 program year** is listed on p. 1092.
Continued Deferment of Public Display of the NHSN Measures	In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41622), CMS finalized a modification of its proposal to delay public reporting of data for the SSI, MRSA, CDI, and HCP measures until CY 2019. Based on stakeholder feedback, it finalized a policy to provide stakeholders with performance data as soon as practicable (i.e., if useable data is available sooner than CY 2019, CMS will publicly report it on the Hospital Compare website via the next available Hospital Compare release).	As discussed above, CMS finalized its proposal to remove the CAUTI and CLABSI measures. However, it will continue to defer public reporting for these two measures as indicated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38423). Based on CMS' intent to propose to adopt the revised versions of the measures in the PCQHR Program in future rulemaking, it is continuing to evaluate the performance data for the updated versions of the CAUTI and CLABSI measures to draw conclusions about their statistical significance, in accordance with current risk adjustment methods defined by CDC. For these reasons, ***CMS is finalizing that it will provide stakeholders with performance data for the CAUTI and CLABSI measures as soon as practicable*** (p. 1095).
Update on Public Display of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure	In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57187 through 57188), CMS stated it would publicly report the risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR) for the Admissions and ED Visits for the Patients Receiving Outpatient Chemotherapy measure for all participating PCHs with 25 or more eligible patients per measurement period to maintain a reliability of at least 0.4.	CMS notes in this rule that it recently completed the confidential national reporting (dry run) for this measure and is currently assessing the results to ensure data accuracy and completeness. CMS intends to propose a timeframe for public reporting of this measure in the FY 2020 IPPS/LTCH PPS proposed rule. On p. 1096, CMS provides a summary of all **PCHQR Measure Public Display Requirements for the FY 2021 Program Year.**

Requests for Information

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

Topic	Proposed Rule	Final Rule
General	CMS invites stakeholder feedback on the several questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information. The original RFI can be found here.	CMS received over 60 comments on this RFI and noted its appreciation for the input.

RFI for Information on Price Transparency

General	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 several questions to address these issues. The original RFI can be found here.	CMS received over 90 comments on this RFI and noted its appreciation for the input.

RFI on Leverage the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

General	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. CMS is soliciting public comments on several design considerations and on how to best initially test and then broaden the scope of a potential CAP-like model, as well as on several related issues. The original RFI can be found here.	CMS received over 80 comments on this RFI and noted its appreciation for the input.

Topic	Final Rule
Collection of Information Requirements	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 782,686 hours, and the reduction in cost is $28.2 million. **ICRs for the Hospital OQR Program** CMS provides estimates of burden reduction under the Hospital OQR Program associated with the following final policies: • Policy 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. • Policy to remove three measures submitted via a Web-based tool for the CY 2021 payment determination and subsequent years. CMS estimates that the removal of the three web-based measures will reduce burden by 530,075 hours and $19.4 million. **ICRs for the ASCQR Program** CMS provides estimates of burden reduction under the ASCQR Program associated with the following proposal: • Policy to remove one chart-abstracted measure for the CY 2021 payment determination and subsequent years. CMS estimates a total reduction in information collection burden of 62,008 hours and $2,268,244.
Economic Analyses	CMS estimates that the total increase in Federal government expenditures under the OPPS for CY 2019, compared to CY 2018, due only to the finalized changes to OPPS in this rule, will be approximately $440 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 will be approximately $74.1 billion, approximately $5.8 billion higher than estimated OPPS expenditures in CY 2018. Table 62 displays the distributional impact of the 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 final rates for CY 2019 will increase Medicare OPPS payments by an estimated 0.6 percent. CMS provides estimated effects of the finalized policy to control for unnecessary increases in the volume of outpatient services, with Medicare OPPS payments estimated to decrease by $300 million and beneficiary copayments estimated to decrease by $80 million in CY 2019. This is reduced from the proposed rule due to CMS' decision to finalize a two-year phase-in. CMS separately identifies the effects of this policy in Column 5 of Table 62. CMS provides estimated effects of the finalized policy to apply the 340B drug payment policy to nonexcepted off-campus departments of hospitals. Specifically, CMS estimates that the Medicare program and beneficiaries will save approximately $49.1 million under the Physician Fee Schedule, which CMS specifies represents an upper bound of potential savings. CMS also estimates the total increase (from final changes to the ASC provisions in this 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 $200 million. Table 63 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group, and Table 64 shows a comparison of estimated CY 2018 payments to estimated CY

2019 payments for procedures receiving the most Medicare payment in CY 2018. CMS notes that payments for separately payable covered ancillary items and services (as shown in Table 63) are estimated to increase by 79 percent for CY 2019, largely due to the introduction of utilization data for two codes, C9447 (Inj, phenylephrine ketorolac) and Q4172 (puraply or puraply am), a high cost skin substitute.

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

- The method to control for unnecessary increases in the volume of outpatient services (p. 1139)
- Assigning skin substitutes to high or low cost groups (p. 1140)
- The methodology for payment for non-opioid pain management treatments (p. 1140)
- Continuing to use CPI-U as the CY 2019 ASC rate update (p. 1151)

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