

A Summary of the Centers for
Medicare and Medicaid Services
Calendar Year 2018
Outpatient Prospective Payment
System (OPPS) &
ASC Payment System
Proposed Rule

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Overview	4
OPPS Provisions	4
Recalibration of APC Relative Payment Weights	4
<i>Single Procedure APC Criteria-Based Costs: Brachytherapy Sources</i>	4
<i>Comprehensive APCs</i>	5
<i>Composite APCs</i>	7
<i>Packaged Items and Services</i>	8
OPPS Payments to Certain Cancer Hospitals	9
Hospital Outpatient Outlier Payments	10
APC Group Policies	11
New CPT and Level II HCPCS Codes	11
Proposed Care Management Coding Changes Effective January 1, 2018	11
Variation Within APCs	11
New Technology APCs	11
APC-Specific Policies	12
OPPS Payment for Devices	13
<i>Pass-Through Payments for Devices</i>	13
OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals	14
<i>Proposed Drugs and Biologicals with Expiring Pass-Through Status</i>	14
<i>Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2018</i>	15
<i>Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups</i>	15
<i>OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status</i>	15
<i>Packaging of Payment for Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals under the Cost Threshold (“Threshold-Packaged Drugs”)</i>	16
<i>Proposed High/Low Cost Threshold for Packaged Skin Substitutes</i>	16
<i>Packaging Determination for Codes That Describe the Same Drug or Biological But Different Dosages</i>	17
<i>Proposed Payment for Items without Pass-Through Status That Are Not Packaged</i>	17
<i>Alternative Payment Methodology for Drugs Purchased under the 340B Drug Discount Program</i>	18
<i>Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices</i>	18
OPPS Payment for Hospital Outpatient Visits	18
Inpatient Only Procedures	19
Collecting Data on Services Furnished in Off-Campus Provider Based Departments	21
Expansion of Clinical Service Lines for Excepted Off-Campus PBDs	21
Treatment of Cancer Hospitals (21 st Century Cures Act Section 16002)	21
Medicare Site-of-Service Price Transparency	22
Appropriate Use Criteria for Advanced Diagnostic Imaging Services	22
Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals	22
Payment Changes for Film X-Ray Services and Proposed Payment Changes for X-Rays Taken Using Computed Radiography Technology	22
Laboratory Date of Service Policy	23

ASC Payment System Provisions	25
Definition of ASC Covered Surgical Procedures	25
Treatment of New and Revised Codes.....	25
<i>Treatment of New and Revised Level II HCPCS Codes Implemented in April 2017 and July 2017</i>	25
<i>Process for New and Revised Level II HCPCS Codes That Will Be Effective October 2017 and January 2018</i>	26
<i>Process for Recognizing New and Revised Category I and Category III CPT Codes Effective January 2018</i>	26
Update to Lists of ASC Covered Surgical Procedures and Covered Ancillary Services.....	27
<i>Covered Surgical Procedures Designated as Office-Based</i>	27
<i>Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive</i>	29
<i>Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices</i>	29
<i>Proposed Additions to the List of ASC Covered Surgical Procedures</i>	30
<i>Comment Solicitation on Adding Additional Procedures to the ASC Covered Procedures List</i>	30
<i>Covered Ancillary Services</i>	31
ASC Payment for Covered Surgical Procedures and Covered Ancillary Services	31
<i>Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2018</i>	31
<i>Proposed Payment for Covered Ancillary Services for CY 2018</i>	31
Proposed ASC Conversion Factor and Proposed ASC Payment Rates	32
<i>Proposed Calculation of the ASC Payment Rates</i>	32
Comment Solicitation on ASC Payment Reform	33
Hospital Outpatient Quality Reporting Program Updates	34
Accounting for Social Risk Factors in the Hospital OQR Program.....	34
Measures Proposed for Removal from the Hospital OQR Program	34
Hospital OQR Program Measures and Topics for Future Consideration	38
Public Display of Quality Measures	38
Administrative Requirements	38
Form, Manner & Timing of Data Submitted	39
<i>Hospital OQR Program Annual Payment Determinations</i>	39
<i>Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2020 Payment Determination</i>	39
Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2018 Payment Determination	39
ASC Quality Reporting (ASCQR) Reporting Program	40
Accounting for Social Risk Factors in the ASCQR Program	40
Proposed Measure Removal.....	40
Proposed New ASCQR Program Quality Measures for the CY 2021 and CY 2022 Payment Determinations.....	40
ASCQR Program Measures and Topics for Future Consideration.....	44
Form, Manner, and Timing of Data Submitted	45
Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements	45
Administrative Requirements.....	45
Requests for Information	46
Request for Information on CMS Flexibilities and Efficiencies	46
Eliminating Inappropriate Medicare Payment Differentials for Similar Services in the Inpatient and Outpatient Settings	46
Physician Owned Hospitals.....	46
Regulatory Impact Analysis	47

Overview

On July 13, 2017, 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 1.75 percent.

Page numbers in the summary refer to the public display version of the proposed rule which can be viewed [here](#). Comments will be accepted through **September 11, 2017**. The final rule should be released in early November 2017.

CMS proposes to increase the CY 2018 OPPS conversion factor to \$76.483 (p. 136). CMS proposes an overall increase CY 2018 OPPS payments by 1.75 percent (p. 37). This is based on the proposed hospital inpatient market basket increase of 2.9 percent minus a productivity adjustment of 0.4 percent, as well as a 0.75 percent reduction required by the Patient Protection and Affordable Care Act (ACA). Per usual, CMS proposes that if more recent data becomes available, it will use the updated data to alter the conversion factor in the OPPS final rule with comment period (p. 132).

In total, CMS estimates that CY 2018 OPPS payments will increase by approximately \$5.7 billion over CY 2017 estimated payments to a total of approximately \$70 billion. In addition, CMS proposes to continue to reduce payments by 2.0 percent for hospitals that fail to meet the outpatient quality reporting requirements (p. 37). When controlling for changes in enrollment, utilization and case-mix, CMS states that the overall impact of the policies in the rule would result in a 1.9 percent or \$897 million overall increase in OPPS payments to providers (p. 53).

OPPS Provisions (p. 58)

Recalibration of APC Relative Payment Weights (p. 58)

CMS uses the same annual process to update the APC relative weights and payments for CY 2018. 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 2018 rates are based on data submitted from claims for services furnished after January 1, 2016 and before January 1, 2017. CMS proposes to continue its policy of using hospital cost-to-charge ratios to estimate costs for rate setting purposes (p.61). CMS also proposes to continue its policy of establishing OPPS relative payment rates based on geometric mean costs as it has done since CY 2013 (p. 69; p. 127).

Single Procedure APC Criteria-Based Costs: Brachytherapy Sources (p. 74)

[Social Security Act §1833\(t\)\(2\)\(H\)](#)¹ requires that CMS classify devices of brachytherapy consisting of seeds separately from other services or groups of services. CMS continues to base OPPS prospective payment methodology (i.e. use of claims data to set the relevant payment) to brachytherapy sources (while maintaining a separate payment category for brachytherapy sources as required under statute). Therefore, in order to maintain an underlying payment policy consistent with the rest of the OPPS, **CMS proposes to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source** as CMS proposes for other items and services under the OPPS elsewhere in the rule (p. 75).

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

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

- **CMS proposes to pay for the stranded and nonstranded ‘not otherwise specified’ (NOS) codes (C2698 and C2699) at a rate “equal to the lowest stranded or nonstranded prospective payment rate for such sources on a per source basis” (i.e. not per mCi).**
- **CMS proposes to continue its payment for new brachytherapy sources for which CMS has no claims data by assigning new HCPCS codes for new brachytherapy sources to their own APCs with prospective payment rates set based on “consideration of external data and other relevant information regarding the expected costs of the sources to the hospitals.**

However, **for CY 2018, CMS proposes to assign status indicated “E2” (Items and services for which pricing information and claims data are not available to C2645 (Brachytherapy planar, p-103)** which was not reported on CY 2016 claims and therefore there is no data on which to base a payment rate ([p. 76](#)).

In addition, **for CY 2018, CMS proposes to assign a status indicator of “U” to HCPCS code 2644 (Brachytherapy cesium-131 chloride)** even though only one hospital submitted claim data for 2644 in CY 2016.

CMS continues to request input for new codes to describe brachytherapy sources ([p. 76](#)).² CMS will continue to add new brachytherapy source codes to its system on a quarterly basis.

Proposed CY 2018 payment rates are listed on [the CMS Web site in Addendum B](#) with the status indicator “U.”

Proposed Comprehensive APCs ([p. 77](#))

In CY 2015, CMS implemented several new Comprehensive APCs, which included the final transition of all Device-Dependent APCs to Comprehensive APCs. For Comprehensive APCs, there is a single payment for the stay regardless of how many days the beneficiary is a hospital outpatient. 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”). In CY 2017, CMS finalized an additional 25 Comprehensive APCs.³

Payment for Comprehensive APCs does not include payment non-OPPS charges or services that, because of statute, must be paid separately. These services include mammography and ambulance services; brachytherapy seeds; pass-through drugs and devices; and self-administered (non-Part B) drugs. CMS also excludes certain preventive services from the packaged payment.

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

- ***Complexity Adjustments***. CMS will allow for certain add-on codes (those that had previously been assigned to Device-dependent APCs) to qualify for a “complexity adjustment.” For those primary service and add-on code combinations that are determined to be sufficiently frequent and sufficiently costly, CMS believes that a payment adjustment is warranted. CMS applies the complexity adjustment when the code pairing represents “a complex, costly form or version of the primary service” according to the following criteria ([p. 84](#)):
 - Frequency of 25 or more claims reporting the code combination; and

² CMS directs this input to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244 ([p. 77](#)).

³ CMS notes that it followed an HOP Panel recommendation to analyze the effects of the overall Comprehensive APC payment policy. CMS took a broad approach to determine whether “aberrant trends in the data existed.” CMS stated that it found no such aberrancies and believe that the Comprehensive APC policy is “working as intended.” ([p. 101](#)).

- Violation of the 2 times rule in the originating Comprehensive APC

If the criteria are met, CMS makes a “complexity adjustment” for the code combination by reassigning the primary services with the add-on code to the next higher cost Comprehensive APC within the same clinical family of Comprehensive APCs ([p. 86](#)). The list of add-on codes eligible for the complexity adjustment can be found in [Addendum J available on the CMS Web site](#).

- ***Proposed CY 2018 Comprehensive APCs. CMS proposes to continue the Comprehensive APC payment methodology implemented in CY 2015. However, CMS does not propose any additional Comprehensive APCs for CY 2018.*** CMS lists all Comprehensive APCs that would be effective in CY 2018 in [Table 4](#).
- ***Brachytherapy Insertion Procedures.*** When CMS finalized 25 new Comprehensive APCs in CY 2017, CMS assigned several HCPCS codes used to describe surgical procedures for inserting brachytherapy catheters/needles and other related brachytherapy procedures (e.g. insertion of tandem and/or ovoids and the insertion of Heyman capsules) to the appropriate Comprehensive APCs ([p. 90](#)). CMS received comments that brachytherapy delivery charges were underrepresented because correctly coded claims should typically include an insertion *and* a treatment delivery code combination. Yet, stakeholders noted, several insertion codes for brachytherapy devices often did not also contain a brachytherapy treatment deliver code (CPT 77750-77799) ([p. 91](#)). After its data analysis, CMS concurred that several of the codes identified were frequently billed without an associated brachytherapy treatment code. To address this, ***CMS proposes (for CY 2018 and subsequent years) to establish a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed (p. 91).***⁴ CMS lists the brachytherapy insertion codes that will be required to be billed with a brachytherapy treatment code under the code edit in [Table 5](#).
- ***Comprehensive APC 5627 (Level 7 Radiation Therapy) Stereotactic Radiosurgery (SRS):*** CMS has observed instances where providers are submitting separate claims for “planning services, imaging tests, and other ‘planning and preparation’ services that are integrally associated” with the primary service in various stereotactic radiosurgery (SRS) treatments. Additionally, the American Taxpayer Relief Act (ATRA) requires that Cobalt-60 based SRS (or gamma knife)⁵ payments be reduced to equal payments for robotic linear accelerator-based (LINAC) SRS⁶. The relevant Comprehensive APC to which HCPCS 77371 and 77372 for these services are assigned is Comprehensive APC 5627 (*Level 7 Radiation Therapy*) ([p. 94](#)).

As CMS sought to meet the SRS-related requirements of the ATRA, CMS conducted a data analysis and found that Cobalt-60 based SRS treatments typically included treatment planning services on the same day, which therefore, appeared on the same claim. However, CMS found that for LINAC-based SRS treatments imaging studies, radiation treatment aids, and treatment planning were provided and billed on separate dates from the actual SRS treatment. In order to identify these services that are adjunctive to SRS treatment (codes 77371 and 77372), but reported on a different claim, CMS established the CP required for use of throughout CY 2016 and CY 2017.

⁴ CMS notes that under its Composite APC proposals, it proposes to delete Composite APC 8001 (*LDR Prostate Brachytherapy Composite*) and provide 55875 (*Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy*) a status indicator of J1 and assign it to Comprehensive APC 5375 (*Level 5 Urology and Related Services*).

⁵ Identified by HCPCS 77371 (Radiation treatment delivery, stereotactic radiosurgery, complete course of treatment cranial lesion(s) consisting of 1 session; multi-source Cobalt 60-based) ([p. 94](#))

⁶ Identified by HCPCS 77372 (Linear accelerator-based) ([p. 94](#)).

While CMS engaged in data collection, it believe it was appropriate to unbundle payment for the adjunctive services in CY 2016 and CY 2017 and therefore, CMS made the following codes separately payable (regardless of whether reported on the same claim as 77371 or 77372) and removed the costs from the geometric mean of Comprehensive APC 5627 ([p. 95](#)).

CY 2016 & CY 2017 Separately Payable Comprehensive APC 5627 Codes ⁷	
Service Description	HCPCS Codes
CT Localization	77011, 77014
MRI Imaging	70551, 70552, 70553
Clinical Treatment Planning	77280, 77285, 77290, 77295
Physics Consultation	77336

CMS proposes to continue to make separate payments for the 10 planning and preparation codes adjunctive to the delivery of STS treatment (when furnished to a beneficiary within one month of SRS treatment) ([p. 97](#)). CMS states that this will allow it to complete analysis of data collected with the CP modifier for the remainder of CY 2017.

CMS identified several issues with the reporting that has occurred so far with respect to the the CP modifier:

- The modifier was only used by a small number of providers;
- Several of the codes on which the modifier appeared where the 10 already listed as paid separately and do not require the use of the CP modifier;
- Providers erroneously used the modifier on the delivery of the LINAC-based SRS treatment itself.

Due to these issues and the previous discontinuation date of December 21, 2017, ***CMS proposes to delete the modifier and discontinue its required use in CY 2018*** ([p. 96](#)).

CMS states that it will consider whether repackaging all adjunctive services back into cranial single session SRS is appropriate ([p. 97](#)).

- ***Blue Light Cystoscopy Procedures:*** While CMS continues to state that it does not generally believe it is appropriate to allow exceptions to its drug packaging or Comprehensive APC policy, CMS has received stakeholder input that payment for blue light cystoscopy procedures involving Cysview® are creating barriers to access. CMS' clinical advisors (including a urologist) determined that blue light cystoscopy represents "an additional elective but distinguishable service as compared to white light cystoscopy that in some cases may allow greater detection of bladder tumors in beneficiaries relative to white light cystoscopy alone." ([p. 99](#)). In order to address this, ***CMS proposes complexity adjustments for certain code combinations involving blue light cystoscopy procedures*** ([p. 101](#)).

Composite APCs ([p. 102](#))

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 previously developed and finalized the following Composite APCs ([p. 103](#)):

⁷ CMS notes that as part of the data already collected, it identified additional services that are adjunctive outside of the 10 codes already removed but did not list them ([p. 96](#)).

- Mental health services (Composite APC 8010): ***CMS proposes to continue its Composite APC policy for APC 8010.*** Additional information is available beginning on [p. 104](#).
- Multiple imaging services (Composite APCs 8004, 8005, 8006, 8007, and 8008): ***CMS proposes to continue its Composite APC policy for APCs 8004, 8005, 8006, 8007, and 8008.*** Additional information is available beginning on [p. 106](#) and in [Table 6](#).
- Low dose rate (LDR) prostate brachytherapy (Composite APC 8001): ***CMS proposes to:***
 - ***Delete Composite APC 8001 (LDR Prostate Brachytherapy Composite)***
 - ***Provide 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) a status indicator of J1; and***
 - ***Re-assign 55875 to Comprehensive APC 5375 (Level 5 Urology and Related Services)***

Packaged Items and Services ([p. 113](#))

CMS has relied on packaging policies in the OPPS to “maximize hospitals’ incentives to provide care in the most efficient manner.” ***CMS is proposing several modifications to its packaging policies.***

- ***Drug Administration*** ([p. 115](#)). CMS previously finalized a proposal to unconditionally package procedures described by add-on codes with their primary procedure but because of stakeholder concern did not finalize the proposal as it would have applied to *drug administration* add-on codes ([p. 116](#)). In addition, CMS previously finalized a policy to conditionally package payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to \$100, primarily minor diagnostic tests and procedures, but excluding preventive services, certain psychiatric and counseling-related services, and certain low-cost *drug administration* services.
 - CMS reviewed its policy of excluding low-cost drug administration services from the ancillary services packaging policy. CMS believes that it is no longer necessary to exclude low-cost drug administration services from packaging under the ancillary services policy previously finalized ([p. 118](#)). CMS believes that this change in policy would also promote more equitable payment between the physician office and hospital outpatient department. Therefore, ***CMS proposes to conditionally package payment for HCPCS codes in APC 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration)⁸ (except for add-on codes and preventive services⁹) when these services are performed with another service*** ([p. 119](#)). ***CMS is not proposing to package any drug administration services in APC 5693 (Level 3 Drug Administration Services) or APC 5694 (Level 4 Drug Administration Services).*** CMS lists the proposed status indicators to implement the policy for codes in APCs 5691 and 5692 in [Table 7](#).
 - CMS is not proposing to package drug administration add-on codes for CY 2018. However, ***CMS solicits stakeholder input on a payment methodology for drug administration add-on codes that “supports the principles of a prospective payment system while ensuring patient access to prolonged infusion services.”*** ([p. 121](#)). CMS requests comment on:
 - Whether conditionally or unconditionally packaging drug administration add on codes would create access to care issues or have other unintended consequences
 - Directly, whether CMS should conditionally or unconditionally package drug administration add-on codes
 - How CMS should incorporate the varied clinical drug protocols that result in different infusion times into a drug administration service add-on code payment proposal

⁸ Based on 2016 data, APC 5691 has a geometric mean cost of approximately \$37 and APC 5692 has a geometric mean cost of approximately \$59 ([p. 117](#)).

⁹ CMS notes that the exclusion on preventive services means CMS will still pay separate for Medicare Part B vaccine administration services ([p. 119](#)).

- Other recommendations on an encounter-based payment approach for drug administration services that are described by add-on codes when furnished in the hospital outpatient setting.
- *Pathology Services* (p. 121). CMS currently conditional packages multiple pathology services. CMS states: “When multiple conditionally packaged services are billed on the same claim, the costs of the lowest paying services are bundled into the cost of the highest paying service and payment is made based on the highest single payable service.” (p. 122).

CMS has received concern on CMS’ policy regarding conditional packaging of multiple pathology services and a request to create a pathology composite to more appropriately pay for “claims with only multiple pathology services and no other separately payable service such as a surgical procedure or a clinic visit.”¹⁰ CMS considered a pathology Composite APC when multiple pathology services are performed and billed without a separately payable service on the same claim. [Table 8](#) shows the distribution of “pathology only” OPSS claims (using CPT 88300 to 88361). CMS determined that the majority of “pathology only” OPSS claims are reported with only one pathology code. However, CMS still modeled four hypothetical pathology Composite APCs (p. 123 and [Table 9](#)). ***CMS does not propose the creation of a Composite APC for pathology services***¹¹ in part because of the move toward larger bundles (i.e. Comprehensive APCs) (p. 125).

- *Comment Solicitation on Packaging of Items and Services Under the OPSS* (p. 125). CMS notes that a packaging payment policy involves “a balance between ensuring some separate payment for individual services or items while establishing incentives for efficiency through larger units of payment.” (p. 126). CMS continues to receive concern about the impact of packaging on patient access to care, however.
 - ***CMS seeks feedback on common clinical scenarios involving currently packaged HCPCS codes for which stakeholders believe packaged payment is not appropriate within the framework of existing packaging categories (e.g. drugs that function as supplies in a surgical procedure or diagnostic test or procedure)*** (p. 126).
 - ***For items and services outside of existing packaging categories, CMS seeks feedback on separately payable HCPCS codes for which payment would be most appropriately packaged under the OPSS*** (p. 127).

OPSS Payments to Certain Cancer Hospitals (p. 152)

The 11 PPS-exempt cancer hospitals, while exempted from the Inpatient Prospective Payment System, are paid under the OPSS 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 OPSS 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 OPSS. The ACA required the Secretary to conduct a study to determine whether the 11 cancer hospitals did, in fact, have outpatient costs that exceeded other hospitals’ costs. The ACA required that the Secretary take into consideration of drugs and

¹⁰ The HOP Panel also recommended that CMS develop a composite APC “for pathology services when multiple pathology services are provided on a claim with no other payable services.” The HOP Panel also recommended that CMS consider stakeholder comments made at the August 22, 2017 panel meeting regarding hospital pathology labs to determine whether an “accommodation can be made” and in particular concerns about limiting payment to the single highest paying code regardless of the number of services provided or specimens tested (p. 122).

¹¹ CMS notes that it also declined stakeholder requests for additional Composite APCs for X-ray services, respiratory services, cardiology, services, or allergy testing services (p. 125).

biologicals. If the Secretary determined that the costs were indeed greater, then the Secretary should provide an appropriate adjustment to reflect those higher costs.

- The Secretary conducted the requisite study in 2011 and found that the 11 cancer hospitals did have greater outpatient costs than other OPPS hospitals. Based on this information, in CY 2012, CMS finalized a policy to provide additional payments to these cancer hospitals.
- The 21st Century Cures Act amended statute to mandate that the payment adjustment for services furnished on or after January 1, 2017, the target payment-to-cost ratio (PCR) adjustment should be reduced by 1 percentage point less than would otherwise apply and that the Secretary may consider making an additional percentage reduction to the target PCR that takes into account payment rates for applicable items and services furnished by an off-campus outpatient department of a provider and paid under a payment system under than the OPPS for hospitals that are not cancer hospitals. The statute also states that in making budget neutrality adjustments, the Secretary shall *not* take into account reduced expenditures for applicable items and services furnished by an off-campus outpatient department of a provider and paid under a payment system under than the OPPS ([p. 155](#)).
- ***CMS proposes to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR/target PCR for the other OPPS hospitals using the most recent submitted or settled cost report data that are available reduced by 1 percentage point but is not proposing an additional reduction beyond the 1 percentage point*** ([p. 156](#)).
- For CY 2018, CMS estimates that other OPPS hospitals are approximately 90 percent of those of the 11 cancer hospitals (defined as the “percent of reasonable cost.”). In applying the statutory 1 percentage point reduction, ***CMS proposes that the payment among associated with the cancer hospital payment adjustment is a proposed target PCR of 0.89 percent for each cancer hospital*** ([p. 157](#)).
- [Table 11](#) shows the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2018.

Hospital Outpatient Outlier Payments ([p. 158](#))

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

- CMS stated that CY 2017 outlier payments are provided when the cost of furnishing the service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount by at least \$3,825. If the costs exceed both of those thresholds, the hospital receives an outlier payment at 50 percent of the amount that passed the thresholds.
- CMS attempts to maintain a target of no more than 1 percent of OPPS spending in outlier payments. CMS estimates that CY 2017 aggregate outlier payments will be approximately 1.0 percent of total OPPS payments. ***CMS proposes to continue its policy of estimating aggregate outlier payments at 1 percent of total payments under the OPPS*** ([p. 160](#)).
- In order to maintain outlier payments at 1 percent of OPPS spending, ***CMS is proposing to maintain the percentage threshold for outlier payments at 1.75 times the APC payment amount; CMS is proposing to increase the dollar amount threshold to \$4,325*** ([p. 160](#)).

APC Group Policies ([p. 176](#))

New CPT and Level II HCPCS Codes ([p. 176](#))

Upon creation of new CPT codes (Category I and III) as well as Level II HCPCS codes, CMS will assign the new codes to an interim status indicator and APC assignment through the quarterly update process and will finalize the policies in the OPPS/ASC final rule. [Table 12](#) outlines the CMS timeframe for taking comments on new codes.

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

- New Level II HCPCS Codes Implemented in April 2017 in [Table 13](#)
- New Category III CPT and Level II HCPCS Codes Implemented in July 2017 in [Table 14](#)
- New Category I and III CPT Codes that will be effective on October 1, 2017 and January 1, 2018. **CMS proposes to continue its policy of assigning these new codes an interim payment status of “NI” in [Addendum B](#) (p. 183)**
- New and Revised CY 2018 Category I and III CPT Codes Effective January 1, 2018: The codes are available for review in [Addendum B](#) with an “NP” comment indicator to indicate that the code is new for the next calendar year *or* it is an existing code that underwent a substantial revision to its code descriptor in the next calendar year (compared to the current calendar year) ([p. 185](#)).

Proposed Care Management Coding Changes Effective January 1, 2018 ([p. 186](#))

CMS proposes to adopt CPT replacement codes for CY 2018 for several of the care management services previously finalized. CMS also seeks comment on how it might further reduce reporting burden on providers. [Table 15](#) summarizes the proposed care management coding changes.

Variation Within APCs ([p. 187](#))

According to statute, the services within an APC cannot be considered “comparable” if the highest cost service in the APC is more than 2 times greater than the lowest costs for an item or service within the same APC (“2 Times Rule”) ([p. 189](#)).

- When reassignments are necessary, in some cases, CMS proposes to change the status indicators for some procedure codes, rename existing APCs, or create new clinical APCs to reflect the new APCs due to the reassignments.
- CMS lists the reassignments to avoid violation of this rule on its Web site in [Addendum B](#) with the “CH” comment indicator.

CMS often makes exceptions when the 2 Times Rule has been violated, typically in cases of low-volume items or services. CMS identified 12 violations of the 2 times rule for CY 2018 ([p. 191](#)). CMS lists the 12 APCs where it proposes exceptions to the 2 times rule for CY 2018 in [Table 16](#).

New Technology APCs ([p. 193](#))

There are currently 51 levels of New Technology APCs. For CY 2018, **CMS is proposing to narrow the increments for New Technology APCs 1901 – 1906 from \$19,999 cost bands to \$14,999 cost bands. CMS also proposes to add two New Technology APCs** to allow for appropriate payment of retinal prosthesis implantation procedures. [Table 17](#) includes the complete list of the proposed modified and additional New Technology APC groups for CY 2018.

CMS discusses the following technologies:

- **Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS)** (APCs 1537, 5114, and 5414).
Currently, there are four CPT/HCPCS codes that describe MRgFUS procedures:
 - CPT 0071T and CPT 0072T for the treatment of uterine fibroids

- CPT 0398T for the treatment of essential tremor, and
- C9734 for pain palliation for metastatic bone cancer.

CMS will continue to assign three of these to standard APCs and will continue to assign one (CPT 0398T, for treatment of essential tremor) to a New Technology APC.

- **Pathogen Test for Platelets.** The CMS HCPCS Workgroup has established Q9987 (*Pathogen(s) test for platelets*) effective July 1, 2017. **Q9987 will be used to report any test used to identify bacterial or other pathogen contamination in blood platelets.** Effective July 1, 2017, **Q9987 is assigned to New Technology APC 1493 (New Technology - Level 1C (\$21-\$30)), with a payment rate of \$25.50.**

APC-Specific Policies (p. 204)

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

- ***Blood-Derived Hematopoietic Cell Harvesting* (p. 204).** CPT 38205 (*Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection, allogeneic*) represents the donor acquisition cost for an allogeneic hematopoietic stem cell transplant (HSCT), which CMS previously assigned to status indicator “B” to indicate that the code is not recognized by the OPPS when submitted on an outpatient hospital Part B bill. CMS previously finalized a Comprehensive APC for HSCT and donor acquisition costs are included when the transplant occurs in the hospital setting. In order to ensure that acquisition costs are properly captured, **CMS proposes to change the status indicator for CPT 38205 from “B” (Non-Allowed item or service for OPPS) to “S” (Significant procedure not subject to multiple procedure discounting).** **CMS proposes to assign CPT 38205¹² to APC 5242 (Level 2 Blood Exchange and Related Services) (p. 205).**
- ***Radiology and Imaging Procedures* (p. 206)**
 - **Imaging APCs.** CMS previously restructured APCs for imaging services resulting in 7 consolidated imaging APCs, including 4 imaging APCs *without* contrast and 3 imaging APCs *with* contrast. CMS reviewed its data and believes that splitting the current Level 4 Imaging *Without* Contrast into two APCs would more appropriately group imaging services with higher resources costs. Therefore, **CMS proposes to add a fifth level to the Imaging Without Contrast APCs (p. 207).** CMS lists the CY 2017 Imaging APCs in [Table 19](#) and the proposed CY 2018 Imaging APCs in [Table 20](#). The specific APC assignments for service groupings are included in [Addendum B](#).¹³
 - **Non-Ophthalmic Fluorescent Vascular Angiography (p. 208).** **CMS proposes to reassign C9733 (Non-ophthalmic fluorescent vascular angiography) from APC 5523 (Level 3 Imaging Without Contrast) to APC 5524 (Level 4 Imaging Without Contrast) (p. 209).** CMS will maintain the status indicator of Q2 (T-packaged) to indicate it is conditionally packaged when performed with other procedures; but paid separately when performed as a stand-alone service. CMS believes that the reassignment will improve the clinical homogeneity of APC 5524 and better align resource costs (p. 210).
- ***Intraocular Procedure APCs* (p. 211).** CMS discusses its review of Comprehensive APC 5491 (*Level 1 Intraocular Procedures*) beginning on p. 211. CMS seeks input on whether CMS should create a new Comprehensive APC that includes complex cataract surgeries identified by CPT 66982 (*Cataract surgery complex*) separate from CPT 66984 (*Cataract surgery with IOL 1 stage procedure*) (p. 212).

¹² CMS notes that CPT 38205 2016 data yields a geometric mean cost of ~\$580 based on 2 single claims (out of 8) (p. 205).

¹³ CMS again notes that the Imaging APCs affected by this proposal do not include all imaging procedures as some are in a separate APC set (e.g. nuclear medicine and vascular procedure APCs) (p. 208).

OPPS Payment for Devices ([p. 213](#))

Pass-Through Payments for Devices

Beginning Eligibility Date for Pass-Through and Quarterly Expiration of Device Pass-Through Payments

Devices eligible for a transitional pass-through payment are eligible for at least 2, but not more than 3 years. The pass-through eligibility period begins on the first date on which pass-through payment is made. CMS allows for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible.

The following devices with pass-through status that will retain their payment status until December 31, 2017:

- C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) (effective April 1, 2015)
- C2613 (Lung biopsy plug with delivery system) (effective July 1, 2015)
- C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system) (effective January 1, 2016).

CY 2018 Device Pass-Through Applications

CMS received five applications by the March 1, 2017 quarterly deadline:

Architect® Px ([p. 219](#)): skin substitute for wound care. CMS does not believe that the two references provided by the applicant meet the substantial clinical improvement criterion.

- *Dermavest and Plurivest Human Placental Connective Tissue Matrix (HPCTM)* ([p. 224](#)): skin substitute for wound care. CMS expresses doubt as to whether the newness criterion is met. CMS also notes it is “not yet convinced” that the technology provides a substantial clinical improvement over existing wound care treatment.
- *FloGraft®/Flograft Neogenesis®* ([p. 231](#)): injection for wound care. CMS states that “it is unclear” whether the newness criterion is met due to a lack of clarity when the FDA CBER filing occurred. CMS also notes there is “insufficient data” to determine whether the technology offers a substantial clinical improvement over existing wound care.
- *Kerecis™ Omega3 Wound (Skin Substitute)* ([p. 236](#)): skin substitute for wound care. The applicant is proposing a pass-through payment device category for this technology with the category descriptor of “Piscine skin substitute.” CMS invites public comment on this issue. CMS notes there is “no clinical data” provided by the applicant to indicate substantial clinical improvement over existing technology.
- *X-WRAP®* ([p. 243](#)): skin substitute for wound care. CMS notes it is unclear whether the newness criterion is met due to lack of clarity around the FDA CBER filing date. There is insufficient data to determine whether the technology offers a substantial clinical improvement.

Device-Intensive Procedures ([p. 247](#))

CMS assigns device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent regardless of the APC assignment. In addition, for new HCPCS codes (requiring the implantation of a device) that do not yet have associated claims data, CMS establishes a default device offset amount of 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedure. In rare circumstances of a very expensive implantable device, CMS might establish a temporary higher offset percentage if additional information is presented (e.g. pricing data from the device manufacturer).

The full listing of proposed CY 2018 device-intensive procedures is included in [Addendum P](#).

Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices (p. 252)

In CY 2007, CMS established a payment policy to account for situations where a hospital receives a device at no or reduced cost or provides a device without cost. CMS is continuing use of the three criteria implemented in 2007 for use at the APC level now at the HCPCS level:

- 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 procedure must be device-intensive; that is, the device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

CMS proposes no changes to its payment policy for No Cost/Full Credit and Partial Credit devices.

Low Volume Device Intensive Procedures (p. 255)

The payment rate for any device-intensive procedure that is assigned to a clinical APC with few than 100 total claims for all procedures in the APC is calculated using the median cost instead of the geometric cost.

CMS proposes to continue that policy, which, for CY 2018, would continue to apply only to a procedure described by CPT 0308T in Comprehensive APC 5495 (Level 5 Intraocular Procedures). CMS believes that this approach will help to mitigate significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for low-volume device-intensive procedures.

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals (p. 258)

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

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

Proposed Drugs and Biologicals with Expiring Pass-Through Status (p. 261)

CMS is proposing that 19 drugs and biologicals' pass-through status would expire on December 31, 2017. The list of these drugs and biologicals is available in [Table 21](#).

With the exception of products that are always packaged when they do not have pass-through payment status and products that function as supplies when used in a surgical procedure, the standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be \$120 for CY 2018).

CMS proposes that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug 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 2018. The proposed packaged or separately payable status of each of the 19 drugs or biologicals is listed in [Addendum B](#).

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2018 ([p. 264](#))

- ***CMS proposes to continue pass-through payment status in CY 2018 for 38 drugs and biologicals. The list is available in [Table 22](#).***
- ***CMS proposes to continue to pay for pass-through drugs and biologicals at the Average Sales Price plus 6 (ASP+6) percent level.***
- ***CMS proposes that “a \$0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2018 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 ASP+6% is \$0.”([p. 265](#))***
- ***CMS proposes to continue to update pass-through payment rates on a quarterly basis during CY 2018 if later quarter ASP submissions indicate that adjustments are necessary ([p. 255](#)).***
- ***CMS also proposes to continue its policy to pay for pass-through diagnostic and therapeutic radiopharmaceuticals based on the ASP methodology; if the ASP is not available, CMS proposes to provide a payment at the Wholesale Acquisition Cost plus 6 (WAC+6) percent rate. If WAC information is not available, CMS will pay for the pass-through radiopharmaceutical at 95 percent of its most recent Average Wholesale Price (AWP) ([p. 266](#)).***

Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups ([p. 269](#))

CMS proposes to continue its policies and methodologies for reducing the amount of the pass-through payment by the amount of the APC payment attributable to the cost of the drug, biological, or radiopharmaceutical predecessor product. This policy applies equally to pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. CMS proposes to continue to annually post a file with the APC offset amounts on the [CMS OPPS Web site](#).

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status ([p. 272](#))

CMS pays for drugs, biologicals, and radiopharmaceuticals either as a packaged item within an APC or separately (in which the item has its own APC). ***CMS sets a cost threshold for packaging based on cost and proposes a packaging threshold for CY 2018 of \$120 ([p. 273](#)).***

Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals under the Cost Threshold (“Threshold-Packaged Drugs”) (p. 273)

CMS proposes to package items with a per day cost less than or equal to \$120, and identify items with a per day cost greater than \$120 as separately payable. For calculation of per day costs of HCPCS codes, CMS proposes to use ASP data from the fourth quarter of CY 2016, which is the basis for calculating payment rates for drugs and biologicals in the physician’s office setting using the ASP methodology, effective April 1, 2017, along with updated hospital claims data from CY 2016. CMS will also use these data for budget neutrality estimates and impact analyses for the CY 2018 OPPI/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals will be based on ASP data from the second quarter of CY 2017. These data will be the basis for calculating payment rates for drugs and biologicals in the physician’s office setting using the ASP methodology, effective October 1, 2017. These payment rates would then be updated in the January 2018 OPPI update, based on the most recent ASP data to be used for physician’s office and OPPI payment as of January 1, 2018. For items that do not currently have an ASP-based payment rate, CMS plans to recalculate their mean unit cost from all of the CY 2016 claims data and updated cost report information available for the CY 2018 final rule with comment period to determine their final per day cost.

Consequently, 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 the established policies initially adopted for the CY 2005 OPPI.***

Proposed High/Low Cost Threshold for Packaged Skin Substitutes (p. 279)

The proposed CY 2018 MUC threshold is \$47 per square centimeter; the proposed CY 2018 PDC threshold is \$755 (p. 281). ***CMS proposes to continue its high cost/low cost categories policy with a modification.*** CMS notes that skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year. In addition, these stakeholders also were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

In order to allow more time to evaluate concerns and suggestions about the threshold volatility, ***CMS proposes for CY 2018 to retain all skin substitutes that were assigned into the CY 2017 high cost category, even if those skin substitutes do not otherwise exceed the MUC or PDC threshold for CY 2018. CMS proposes to assign to the high cost group skin substitute products that exceed the CY 2018 MUC or PDC threshold and assign to the low cost group skin substitute products that did not exceed either the CY 2017 or CY 2018 MUC or PDC thresholds and were not assigned to the high cost group in CY 2017.***

In addition:

- ***CMS proposes to continue to use payment methodologies including ASP+6 percent, WAC+6 percent, or 95 percent of AWP for skin substitute products that have pricing information but do not have claims data to determine if their costs exceed the CY 2018 MUC threshold.***
- ***CMS plans to continue to assign new skin substitute products without pricing information to the low cost group.***

CMS analysis found that seven skin substitute products that would have otherwise been assigned to the low cost group for CY 2018 will instead be assigned to the high cost group under this proposed policy. (The seven are identified with an "*" in [Table 24](#).)

For CY 2019 and subsequent years, ***CMS seeks public comment on how it should calculate data for products in determining the MUC and PDC thresholds that are included in the high cost group solely based on assignment to the high cost group in CY 2017. CMS seeks public comments on the methodologies that are used to calculate pricing thresholds as well as the payment groupings that recognize a low cost group and a high cost group. CMS is especially interested in suggestions that are based on analysis of Medicare claims data from hospital outpatient departments that might better promote improved payment stability for skin substitute products under the OPPIs.*** This proposal is intended to apply for CY 2018 to allow time for the public to submit other ideas that could be evaluated for the CY 2019 rulemaking.

[Table 24](#) lists skin substitutes and their proposed 2018 classifications.

Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages ([p. 286](#))

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. [Table 25](#) lists the proposed HCPCS codes to which the CY 2018 drug specific packaging methodology would apply.

Proposed Payment for Items without Pass-Through Status That Are Not Packaged ([p. 289](#))

- ***CMS proposes to continue to apply the same payment policy to all separately payable drugs and biologicals and the statutorily defined "specific covered outpatient drugs" or SCODs.***
- ***CMS is proposing to continue its payment policy to pay for separately payable drugs and biologicals at ASP +6% ([p. 292](#))***
- ***CMS proposes to pay for separately payable, nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent.*** (See below for detail.) CMS continues to list separately payable drugs and biologics in [Addenda A and B](#).
- ***CMS proposes to continue the same payment policy for biosimilar biological products as finalized for CY 2016 ([p. 293](#)).*** CMS notes that it seeks comments on the Part B biosimilar payment policy in the 2018 MPFS proposed rule.
- ***CMS proposes to continue the same payment policy for therapeutic pharmaceuticals as used since 2010 ([p. 294](#)).***
- ***CMS proposes to continue to pay for blood clotting factors at ASP+6% ([p. 297](#)).***

Alternative Payment Methodology for Drugs Purchased under the 340B Drug Discount Program (p.298)

Given the growth in the number of providers participating in the 340B program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, CMS believes it is timely to reexamine the appropriateness of continuing to pay the current OPSS methodology of ASP+6 percent to hospitals that have acquired those drugs under the 340B program at significantly discounted rates. This is especially important because of the inextricable link of the Medicare payment rate to the beneficiary cost-sharing amount. In addition, CMS is concerned about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of the Medicare payment rate for these drugs. CMS is concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs.

CMS proposes 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. Because a significant portion of hospitals paid under the OPSS participate in the 340B program, CMS believes it is appropriate to presume that a separately payable drug reported on an OPSS claim was purchased under the 340B program, unless the hospital identifies that the drug was not purchased under the 340B program. CMS plans to provide further details about this modifier in the final rule and/or through subregulatory guidance. Additionally, for CY 2018, ***CMS proposes to apply an average discount of 22.5 percent of the average sales price for nonpass-through separately payable drugs purchased under the 340B program.***

CMS also seeks comments in the following areas:

- ***Whether it should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPSS, or under Part B generally, in CY 2018, rather than simply increasing the conversion factor.***
- ***Whether the payment change should be phased in over two or three years.***
- ***Whether, as a longer term option, Medicare should require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim***
- ***Whether certain groups of hospital should get exceptions, whether certain types of drugs should be excluded from reduced payment, and whether hospital-owned or affiliated ASCs have access to 340B discounts.***

Estimate of OPSS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices (p. 312)

Statute limits pass-through payment spending at 2.0 percent of total OPSS payments. ***CMS estimates that pass-through spending in CY 2018 would equal approximately \$26.2 million (\$10M for devices and \$16.2M for drugs and biologicals) or 0.24 percent of total projected CY 2018 OPSS spending and would therefore not cross the 2.0 percent program spending limit.***

OPSS Payment for Hospital Outpatient Visits (p. 320)

CMS proposes to continue its current payment policy for clinic, emergency department hospital outpatient visits, and critical care services without change. CMS seeks comments on whether CMS should consider changes to these codes in future rulemaking.

Inpatient Only Procedures (p. 343)

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

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

For CY 2018, CMS has identified two (2) procedures that it proposes for removal from the Inpatient Only list (p. 344 and Table 29):

- CPT 27447 (*Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)*): CMS previously requested input on removal of CPT 27447 from the Inpatient Only list¹⁴ and received comments both in support and against its removal. CMS determined that it is appropriate to remove the total knee arthroplasty (TKA) procedure from the Inpatient Only list, but noted that it expects providers “to carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA procedure.” (p. 346).
 - **CMS also proposes that CPT 27447 would be assigned to Comprehensive APC 5115 (Level 5 Musculoskeletal Procedures) (p. 347).**
 - CMS also noted that, if the proposal is finalized, **CMS would prohibit Recovery Audit Contractor (RAC) review for patient status for TKA procedures performed in the inpatient setting for 2 years (p. 347).**
 - **CMS also solicits comments on whether TKA meets the criteria to be added to the list of ASC Covered Surgical Procedures (p. 349).**
 - **CMS seeks input on potential removal from the Inpatient Only List of CPT 27125 (Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)) or Total Hip Arthroplasty (THA) and CPT 27130 Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft) and whether the codes should be on the list of ASC Covered Services (p. 352).** In particular, CMS seeks input on the following question (p. 353):
 - Are most outpatient departments equipped to provide PHA and/or THA to some Medicare beneficiaries?
 - Can the simplest procedure described by CPT codes 27125 and 27130 be performed in most outpatient departments?
 - Are the procedures described by CPT codes 27125 and 27130 sufficiently related to or similar to other procedures that CMS has already removed from the IPO list?
 - How often is the procedure described by CPT codes 27125 and 27130 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?
 - Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of either

¹⁴ CMS did not address the implications of the removal of TKA from the Inpatient Only list on additional programs like the Comprehensive Care for Joint Replace (CJR) model or the Bundled Payment for Care Improvements (BPCI) model, but referred stakeholders to the question raised in the 2017 request for comments (p. 354).

a PHA or THA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?

- CPT 55866 (*Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed*): If finalized, **CMS proposes to assign CPT 55866 to Comprehensive APC 5362 (Level 2 Laparoscopy & Related Services)** ([p. 348](#)).

Collecting Data on Services Furnished in Off-Campus Provider Based Departments (p. 355)

The Bipartisan Budget Act of 2015 included a provision that “applicable items and services”¹⁵ furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered OPD service . . . for purposes of payment under the OPSS and will instead be paid ‘under the applicable payment system; under Medicare Part B.” The statute defines “off-campus outpatient department of a provider” as “a department of a provider . . . that is not located on the campus of such provider, or within the distance from a remote location of a hospital¹⁶ facility.” CMS previously finalized that the “applicable payment system” for the provisions covered by the Bipartisan Budget Act of 2015 would be the Medicare Physician Fee Schedule (MPFS). That is, most nonexcepted items and services furnished by off-campus PBDs will be paid under the MPFS.

Expansion of Clinical Service Lines for Excepted Off-Campus PBDs

The statute also excepts from that definition “an off-campus PBD that was billing . . . with respect to covered OPD services furnished prior to” November 2, 2015,” effectively limiting the expansion of off-campus PBDs that would be paid under the OPSS (although those items and services would still be covered under the Medicare Physician Fee Schedule.

- CMS had proposed that if an excepted off-campus PBD furnished services from a clinical family of services that it did not furnish prior to November 2, 2015, these new or expanded clinical families would not be covered OPD services and would be subject to the statute. However, CMS did not propose to limit the volume of items and services *within* a clinical family (p. 357). CMS did not finalize this provision. This means that in CY 2017 an excepted off-campus PBD receives OPSS payments for *all* billed items and services regardless of whether it furnished those services prior to the date of enactment (p. 358).
- CMS had discussed (but did not propose) specifying a timeframe in which service lines had to be billed under the OPSS for covered OPD services furnished prior to November 2, 2015 (p. 358).

As part of previous rulemaking, CMS requested input on the limitation on expansion of services of hospital outpatient departments as it relates to excepted off-campus PBDs. CMS also notes that it is currently in the data collection process (requirement to use claims data with modifier PO¹⁷ (for excepted services) and PN (for nonexcepted services) that will help monitor policies related to service line expansions (p. 361). CMS summarized the comments received, but **CMS is *not* proposing to limit clinical service line expansion or volume increases at excepted off-campus PBDs** (p. 364). CMS will monitor claims data and continues to invite public comments.

Treatment of Cancer Hospitals (21st Century Cures Act Section 16002)

The 21st Century Cures Act amended statute to clarify that the term “off-campus outpatient department of a provider” excludes certain cancer hospitals (p. 365). The statute applies the provision to cancer hospitals as defined under the Social Security Act §1886(d)(1)(B)(v) (certain comprehensive cancer centers or clinical cancer research centers recognized by the National Institutes of Health (NIH)). The statute requires that it receives an attestation by providers to qualify under this provision by December 13, 2016 (at least 60 days after the enactment of the 21st Century Cures Act) (p. 366). CMS provided guidance to all Medicare Administrative Contractors (MACs) on this provision.

¹⁵ The statutory definition of “applicable items and services” specifically excludes items and services furnished by a dedicated emergency department. Therefore, these items and services will continue to be paid under the OPSS.

¹⁶ Current regulation defines “remote location of a hospital” as “a facility or an organization that is either created by, or acquired by a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider . . .”

¹⁷ Use of the PO modifier was voluntary in 2015 and became mandatory in 2016 (p. 361).

Medicare Site-of-Service Price Transparency ([p. 367](#))

The 21st Century Cures Act requires that, beginning in 2018, the Secretary shall make public via a searchable Web site estimated payment amounts for items and services paid for under both the OPPS and ASC payment system. ***CMS provides notice of its plan to establish a searchable Web site that will be made available in early CY 2018, the details of which will be provided through the subregulatory process.***

Appropriate Use Criteria for Advanced Diagnostic Imaging Services ([p. 367](#))

Information on the latest proposals for requirements for the AUC program can be found in Hart Health Strategies' summary of the CY 2018 MPFS proposed rule. Public comments should be submitted through that rule.

Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals ([p. 369](#))

CMS has previously received concerns from the hospital community that critical access hospitals (CAHs) and small rural hospitals have a difficult time meeting the direct supervision requirements for hospital outpatient therapeutic services (and in provider based departments of hospitals). From 2010 to 2013, CMS had instructed all Medicare Administrative Contractors (MACs) to not evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs and small rural hospitals having 100 or fewer beds ([p. 369](#)). Congress [extended the non-enforcement provision](#) through December 31, 2016 ([p. 370](#)).

CMS continues to receive input about the difficulties of meeting the supervision requirements in these settings. CMS noted that it had not received quality complaints from beneficiaries or providers. Therefore, ***CMS proposes to reinstate the non-enforcement policy for direct supervision of outpatient therapeutic services for CAHs and small rural hospitals with 100 or fewer beds for CY 2018 and CY 2019.*** CMS noted that these hospitals are still subject to conditions of participation and other rules regarding supervision ([p. 371](#)).

Payment Changes for Film X-Ray Services and Proposed Payment Changes for X-Rays Taken Using Computed Radiography Technology ([p. 371](#))

The Consolidated Appropriations Act of 2016 reduces payment amounts under the PFS for the technical component (including the technical component of a global service) of imaging services that are X-rays taken using film by 20 percent effective for services furnished beginning January 1, 2017. CMS previously finalized Modifier FX to be reported on claims for imaging services that are X-rays taken using film beginning on January 1, 2017.

The statute also provides for a 7 percent cut in payments for imaging services under the PFS that are X-rays using computed radiography technology¹⁸ (including the X-ray component of a packaged service) in CYs 2018, 2019, 2020, 2021, or 2022. The statute also provides for a 10 percent reduction for such imaging services taken using computed radiography technology in CY 2023 or a subsequent year. ***CMS proposes to establish a new modifier¹⁹ to be used on claims beginning January 1, 2018 for the technical component of X-rays (including the X-ray component of a packaged service) taken using computed radiography technology*** ([p. 373](#)). CMS notes that when payment is made for an X-ray service taken using computed radiography imaging, it is packaged into

¹⁸ Computed radiography technology is defined as "cassette-based imaging that utilizes an imaging plate to create the image involved." ([p. 109](#)).

¹⁹ CMS uses a placeholder modifier of "XX" and states that the new modifier and long descriptor will be published in the CY 2018 OPPS/ASC final rule with comment period ([p. 373](#)).

the payment for other items and services under the OPSS and so there is no payment amount that can be attributed to the X-ray. Therefore, ***CMS states that under the OPSS, “the amount of the payment reduction for a packaged X-ray service would be \$0 (7 percent of \$0, and 10 percent of \$0).*** The imaging services to which the policy applies can be found in [Addendum B](#).

Laboratory Date of Service Policy (p. 374)

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

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

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

- For “archived specimens”, which are specimens stored for more than 30 calendar days before testing, the DOS is the date the specimen was obtained from storage.
- Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected, except as follows:
 - When “the 14-day rule” applies ([p. 376](#)): The DOS is the date the test was performed (rather than the specimen collection date) if the following conditions are met:
 - The test is ordered by the patient’s physician at least 14 days following the date of the patient’s discharge from the hospital;
 - The specimen was collected while the patient was undergoing a hospital surgical procedure;
 - It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
 - The results of the test do not guide treatment provided during the hospital stay; and
 - The test was reasonable and medically necessary for the treatment of illness
 - For chemotherapy sensitivity tests, the DOS is the date the test was performed, if similar criteria are met, except that the first criterion above is replaced by the following criterion: The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge ([p. 377](#)).

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

Additionally under current OPSS regulations, CDLTs that are listed on the CLFS are packaged with the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim, except for under a few conditions (See [p. 379](#)), including if the CDLT is a molecular pathology test or if the CDLT is an advanced diagnostic laboratory test (ADLT).²⁰

Stakeholders have raised concerns (see [p. 382](#)) related to operational issues the current DOS policy creates for hospitals and laboratories with respect to molecular pathology tests and ADLTs. In light of such concerns, ***CMS is considering potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for certain laboratory tests excluded from the OPSS packaging policy. One approach would create a new exception to the DOS policy for molecular pathology tests and ADLTs. CMS is seeking public comment on whether these tests, by their nature, are appropriately separable from the hospital stay that preceded the test and therefore should have a DOS that is the date of performance rather than the date of collection.***

For example, CMS is considering specifying that in the case of a molecular pathology test or an ADLT, the DOS must be the date the test was performed only if:

- The physician orders the test following the date of a hospital outpatient’s discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined [42 CFR 410.2](#));
- It would be medically inappropriate to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

CMS is requesting specific comments on this potential modification to the current laboratory DOS policy, which would allow laboratories to bill Medicare directly for molecular pathology tests and ADLTs that meet the above criteria. (p. 384)

CMS is also considering potentially revising the DOS rule to create an exception only for ADLTs, but not for molecular pathology tests (p. 385). CMS is requesting comment on this alternative. CMS is also requesting public comment on how the current laboratory DOS policy may affect billing for other separately payable laboratory test codes that are not packaged under the OPSS, such as a laboratory test that is the only service provided to a beneficiary on a claim or molecular pathology tests.

Finally, CMS is inviting public comments on alternative approaches to addressing stakeholders’ concerns regarding the DOS policy, such as potentially modifying the “under arrangements” provisions (p. 386). Specifically, CMS is requesting comments on whether an exception should be added for molecular pathology tests and ADLTs that are excluded from the OPSS packaging policy and how such an exception should be framed. CMS is especially interested in comments regarding how the current DOS policy and “under arrangements” provisions may affect access to care for Medicare beneficiaries. CMS notes that it would consider finalizing the modifications described in this section.

²⁰ Under [section 1834A\(d\)\(5\)\(A\) of the Act](#), an ADLT is a “CDLT that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and . . . is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient- specific result.” CMS has established a regulatory definition for this type of ADLT in [42 CFR 414.502](#). Payment for ADLTs under the CLFS is also subject to special rules.

ASC Payment System Provisions (p. 391)

Definition of ASC Covered Surgical Procedures (p. 394)

CMS notes that some stakeholders have suggested that certain procedures that are outside the CPT surgical range but that are similar to surgical procedures currently covered in an ASC setting should be ASC covered surgical procedures (e.g., certain cardiac catheterization services, cardiac device programming services, and electrophysiology services). While using the CPT code range to define surgery represents a logical, appropriate, and straightforward approach to defining a surgical procedure, CMS also believes it may be appropriate to use the CPT surgical range as a *guide* rather than a *requirement* as to whether a procedure is surgical, which would give the agency more flexibility to include “surgery-like” procedures on the ASC Covered Procedures List (CPL).

CMS solicits public comments regarding services that are described by Category I CPT codes outside of the surgical range (10000 through 69999), or Level II HCPCS codes or Category III CPT codes that do not directly crosswalk and are not clinically similar to procedures in the CPT surgical range, but that nonetheless may be appropriate to include as covered surgical procedures payable when furnished in the ASC setting. In particular, CMS is interested in commenters’ views regarding additional criteria CMS might use to consider when a procedure that is surgery-like could be included on the ASC CPL. CMS requests that commenters take into consideration whether each individual procedure can be safely and appropriately performed in an ASC as required by the regulations at 42 CFR 416.166 (including that standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure), and whether the procedure requires the resources, staff, and equipment typical of an ASC. CMS is also are interested in commenters’ views on whether and how, if CMS were to include such services as ASC covered surgical procedures, it would need to revise its definition of ASC covered surgical procedures.

Treatment of New and Revised Codes (p. 397)

Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in April 2017 and July 2017 for Which We Are Soliciting Public Comments in This Proposed Rule (p. 400)

CMS invites public comment on proposed payment indicators and the proposed payment rates for new Level II HCPCS codes and a new Category III CPT code newly recognized as ASC covered surgical procedures or covered ancillary services in April 2017 and July 2017 through the quarterly update CRs, as listed in Tables 31, 32, and 33 below. CMS proposes to finalize their payment indicators and their payment rates in the CY 2018 OPPS/ASC final rule with comment period.

**TABLE 31—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES
EFFECTIVE ON APRIL 1, 2017**

CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2018 Payment Indicator
C9484	Injection, eteplirsen, 10 mg	K2
C9485	Injection, olaratumab, 10 mg	K2
C9486	Injection, granisetron extended release, 0.1 mg	K2
C9487*	Ustekinumab, for intravenous injection, 1 mg	K2
C9488	Injection, conivaptan hydrochloride, 1 mg	K2
J7328	Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg	K2

*HCPCS code C9487, which was effective April 1, 2017, was deleted June 30, 2017 and replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

TABLE 32—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2017

CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2018 Payment Indicator
C9489	Injection, nusinersen, 0.1 mg	K2
C9490	Injection, bezlotoxumab, 10 mg	K2
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J8
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed	J8
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	G2
Q9986	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K2
Q9989*	Ustekinumab, for Intravenous Injection, 1 mg	K2

*HCPCS code C9487, which was effective April 1, 2017, was deleted June 30, 2017 and replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

TABLE 33—NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURE EFFECTIVE ON JULY 1, 2017

CY 2017 HCPCS Code	CY 2017 Long Descriptor	Proposed CY 2018 Payment Indicator
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space	J8

Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2017 and January 1, 2018 for Which CMS Will Be Soliciting Public Comments in the CY 2018 OPPTS/ASC Final Rule with Comment Period ([p. 403](#))

For CY 2018, CMS proposes that Level II HCPCS codes that will be effective October 1, 2017, and January 1, 2018, would be flagged with comment indicator “NI” in Addendum B to the CY 2018 OPPTS/ASC final rule with comment period to indicate that CMS has assigned the codes an interim OPPTS payment status for CY 2018. CMS will invite public comments in the CY 2018 OPPTS/ASC final rule with comment period on the interim status indicator and APC assignments, and payment rates for these codes that will be finalized in the CY 2019 OPPTS/ASC final rule with comment period.

Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2018 for Which We Will Be Soliciting Public Comments in the CY 2018 OPPTS/ASC Final Rule With Comment Period ([p. 403](#))

For new and revised CPT codes effective January 1, 2018, 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 OPPTS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in the OPPTS/ASC proposed rule, CMS may either make interim final assignments in the final rule with comment period or possibly use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until it can propose APC and status indicator assignments in the following year’s rulemaking cycle. The new and revised CY 2018 Category I and III CPT codes are assigned to new comment indicator “NP” to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year, as compared to the current calendar year, and that comments will be accepted on the proposed payment indicator.

Update to Lists of ASC Covered Surgical Procedures and Covered Ancillary Services (p. 405)

Covered Surgical Procedures Designated as Office-Based (p. 405)

CMS previously finalized its policy to designate as “office-based” those procedures that are added to the ASC list of covered surgical procedures that it determines are performed predominantly (more than 50 percent of the time) in physicians’ offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes.

CMS’ review of the CY 2016 volume and utilization data resulted in the identification of two covered surgical procedures that meet the criteria for designation as office-based (see Table 34 below).

TABLE 34— ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2018

CY 2018 CPT Code	CY 2018 Long Descriptor	CY 2017 ASC Payment Indicator	Proposed CY 2018 ASC Payment Indicator*
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	G2	P2/P3
67227	Destruction of extensive or progressive retinopathy (eg, diabetic retinopathy), cryotherapy, diathermy	G2	P2/P3

* Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS proposed rule.

CMS also reviewed CY 2016 volume and utilization data and other information for 10 procedures designated as temporary office-based in the CY 2017 OPPS/ASC final rule with comment period. Of these 10 procedures, there were very few claims in CMS’ data and no claims data for 8 procedures. **CMS proposes to maintain the temporary office-based designations for these eight codes for CY 2018, which are listed in Table 35 below.**

Data are sufficient to show that HCPCS code G0429 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies) is performed predominantly in physicians’ offices and, therefore, should be assigned an office-based payment indicator in CY 2018. **CMS proposes to assign payment indicator “P2/P3” to HCPCS code G0429 in CY 2018.**

Given HCPCS code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound) will be deleted by the AMA effective December 31, 2017, it will no longer be designated as office-based.

CMS invites comment on these proposals.

TABLE 35— PROPOSED CY 2018 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED IN THE CY 2017 OPFS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2018 CPT Code	CY 2018 Long Descriptor	CY 2017 ASC Payment Indicator*	CY 2018 Proposed ASC Payment Indicator**
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2*	NA
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)	R2*	R2**
10030	Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma, seroma, lymphocele, cyst), soft tissue (e.g., extremity abdominal wall, neck), percutaneous	P2*	P2/P3**
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated	P2*	P2/P3**
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report	P2*	P2/P3**
64461	Paravertebral block (PVB) (paraspinal block), thoracic; single injection site (includes imaging guidance, when performed)	P3*	P2/P3**
64463	Continuous infusion by catheter (includes imaging guidance, when performed)	P3*	P2/P3**
65785	Implantation of intrastromal corneal ring segments	R2*	P2/P3**
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2*	P2/P3**
G0429	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	P3*	P2/P3**

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS proposed rule.

CMS proposes to designate one new CY 2018 CPT code for ASC covered surgical procedures as temporary office-based, as displayed in Table 36 below. CMS did not have enough data to propose making the office-based designation permanent and will reevaluate the procedure when data become available. **CMS invites public comment on the proposal.**

TABLE 36—PROPOSED CY 2018 PAYMENT INDICATORS FOR NEW CY 2018 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED

Proposed CY 2018 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code	CY 2018 Long Descriptor	Proposed CY 2018 ASC Payment Indicator**
382X3	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	P2/P3*

* If designation is temporary.

Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive ([p. 413](#))

CMS proposes to update the ASC list of covered surgical procedures that are eligible for payment according to the agency’s device-intensive procedure payment methodology, reflecting the proposed individual HCPCS code device offset percentages based on CY 2016 OPPS claims and cost report data available for the proposed rule. The ASC covered surgical procedures CMS proposes to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2018, are assigned payment indicator “J8” and are included in Addendum AA. **CMS invites public comments on the proposed list of ASC device-intensive procedures.**

Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices ([p. 416](#))

CMS proposes to update the list of ASC covered device-intensive procedures, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2018.

No Cost/Full Credit: Specifically, when a device-intensive procedure is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS “FB” modifier on the line in the claim with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC.

Partial Credit: CMS proposes to reduce the payment for implantation procedures that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC would append the HCPCS “FC” modifier to the HCPCS code for a device-intensive surgical procedure that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device.

To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either:

(1) submitting the claim for the device replacement procedure to their Medicare contractor after the procedure’s performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or

(2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the “FC” modifier appended to

the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device.

Beneficiary coinsurance would be based on the reduced payment amount. To ensure CMS’ policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost/full credit or partial credit, CMS applies the FB/FC policy to all device-intensive procedures.

CMS invites public comments on its proposals to adjust ASC payments for no cost/full credit and partial credit devices.

Proposed Additions to the List of ASC Covered Surgical Procedures (p. 419)

CMS proposes to update the list of ASC covered surgical procedures by adding three procedures to the list for CY 2018, which are listed in Table 37 below. According to CMS, these procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. ***CMS invites comment on its proposals.***

TABLE 37— PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2018

CY 2018 CPT Code	CY 2018 Long Descriptor	Proposed CY 2018 ASC Payment Indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical	J8
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure)	N1
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g	G2

Comment Solicitation on Adding Additional Procedures to the ASC Covered Procedures List (p. 420)

CMS proposes to remove the following two procedures described by CPT codes from the OPPS inpatient only list for CY 2018: CPT codes 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed). CMS understands that these procedures typically require more than 24 hours of active medical care following the procedure, therefore the agency believes they should continue to be excluded from the list of ASC covered surgical procedures. ***CMS solicits public comments on whether the TKA procedure should be added to the ASC list of covered surgical procedures. CMS also invites public comments on its proposed continued exclusion of CPT code 55866 from the list of ASC covered surgical procedures (considering the current criteria for adding surgical procedures to the ASC CPL, as described above).***

In addition, CMS solicits comment on whether CPT codes 27125 (Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)) and 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft) meet the criteria to be removed from the OPPS IPO list. CMS also solicits comment on whether these two procedures meet the criteria to be added to the ASC covered surgical procedure list.

Covered Ancillary Services ([p. 422](#))

CMS proposes to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2018 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 2018. Comment indicator “CH” is used in Addendum BB to indicate covered ancillary services for which CMS proposes a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2018. ***CMS invites public comments on this proposal.***

ASC Payment for Covered Surgical Procedures and Covered Ancillary Services ([p. 423](#))

Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2018 ([p. 426](#))

CMS proposes to update ASC payment rates for CY 2018 and subsequent years using the established rate calculation methodologies under § 416.171 and using CMS’ 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, as discussed above. Payment for office-based procedures would be at the lesser of the proposed CY 2018 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 invites public comments on these proposals.

Proposed Payment for Covered Ancillary Services for CY 2018 ([p. 430](#))

For CY 2018 and subsequent years, ***CMS proposes to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2018 OPPS and ASC payment rates and subsequent year payment rates. CMS also proposes to continue to set the CY 2018 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 2018 and subsequent year payment rates.***

Covered ancillary services and their proposed payment indicators for CY 2018 are listed in Addendum BB. For those covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates effective January 1, 2018.

Proposed ASC Conversion Factor and Proposed ASC Payment Rates ([p. 436](#))

Proposed Calculation of the ASC Payment Rates ([p. 441](#))

Updating the ASC Relative Payment Weights for CY 2018 and Future Years ([p. 441](#))

CMS proposes to scale the CY 2017 relative payment weights for ASCs consistent with previously established policy. The proposed CY 2017 ASC scalar is 0.8995 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Updating the ASC Conversion Factor ([p. 443](#))

Based on IHS Global Insight's (IGI's) 2017 first quarter forecast with historical data through the fourth quarter of 2016, for the 12-month period ending with the midpoint of CY 2018, the CPI-U update was projected to be 2.3 percent. Also, based on IGI's 2017 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2018 was projected to be 0.4 percent. Given these projections, for CY 2018, **CMS proposes to reduce the CPI-U update of 2.3 percent by the MFP adjustment of 0.4 percentage points, resulting in an MFP-adjusted CPI-U update factor of 1.9 percent for ASCs meeting the quality reporting requirements. For ASCs that do not meet quality reporting requirements, CMS proposes to reduce the CPI-U update of 2.3 percent by 2.0 percentage points and then apply the 0.4 percentage point MFP adjustment, resulting in a -0.1 percent MFP-adjusted CPI-U update factor for ASCs not meeting the quality reporting requirements.** If more recent data are subsequently available, CMS would use such data, if appropriate, to determine the CY 2018 ASC update for the final rule with comment period.

For CY 2018, CMS proposes to adjust the CY 2017 ASC conversion factor (\$45.003) by the proposed wage index budget neutrality factor of 1.0004 in addition to the MFP-adjusted CPI-U update factor of 1.9 percent discussed above, which results in a proposed CY 2018 ASC conversion factor of \$45.876 for ASCs meeting the quality reporting requirements.

For ASCs not meeting the quality reporting requirements, CMS proposes to adjust the CY 2017 ASC conversion factor (\$45.003) by the proposed wage index budget neutrality factor of 1.0004 in addition to the quality reporting/MFP-adjusted CPI-U update factor of -0.1 percent discussed above, which results in a proposed CY 2018 ASC conversion factor of \$44.976.

CMS invites public comments on these proposals.

Comment Solicitation on ASC Payment Reform (p. 448)

CMS is broadly interested in feedback, including recommendations and ideas for ASC payment system reform.

The current ASC payment system was implemented in 2008 and major revisions have not been made since that time, yet average ASC payment rates have declined relative to OPPS payments rates (56 percent, as proposed). In the absence of ASC-specific cost data, it is difficult, if not impossible, to determine whether ASC facility payment rates are in line with ASC facility resource costs and the impact on beneficiary access to care.

The statute does not mandate the adoption of any particular update mechanism, except in the absence of any update, when it requires the payment amounts to be increased by the increase in the CPI-U. CMS adopted a policy, codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years. ***CMS solicits comment on the ASC payment system update factor and is interested in data from ASCs that would help determine whether the ASC payment system should continue to be updated by the CPI-U, or by an alternative update factor, such as the hospital market basket, the Medicare Economic Index, a blend of update factors or other mechanism.***

CMS seeks public comment on information related to ASC costs for items such as supplies, drugs, employee compensation, rent and other inputs as compared to those of hospitals or physician offices, including qualitative and quantitative data from ASCs. Information on the cost structure of ASCs will help to identify an appropriate alternative update factor.

In addition, ***CMS seeks public comment on whether the Secretary should collect cost data from ASCs to use in determining ASC payment rates.*** To the extent commenters recommend that ASC cost data should be used in the determination of ASC payment rates, ***CMS seeks comment on what specific method of cost collection commenters recommend (such as cost reports or a survey).*** Recognizing that the submission of costs may be an administrative burden to ASCs, ***CMS is interested in comments that detail how the agency could mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs.***

With respect to the ability to adopt payment policies that exist under the OPPS into the ASC payment system, as discussed in prior rulemaking, due to differences in the systems used to process claims for hospitals and ASCs, we were not able to implement certain OPPS payment policies in the ASC payment system. Toward that end, CMS is also interested in stakeholder comments on whether billing on an institutional claim form rather than a professional claim form would address some of the issues affecting ASC payment reform.

Hospital Outpatient Quality Reporting Program Updates ([p. 458](#))

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

Accounting for Social Risk Factors in the Hospital OQR Program ([p. 461](#))

CMS understands that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (i.e., socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. Here, CMS summarizes work being done in the area of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs. Nevertheless, CMS reiterates its concerns about holding providers to different standards for the outcomes of their patients with social risk factors because it does not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, ***CMS seeks public comment on whether it should account for social risk factors in the Hospital OQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors.*** Examples of methods include: confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence. ***In addition, CMS seeks public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure.*** Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. CMS would like feedback on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk.

CMS will take commenters' input into consideration as it continues to assess the appropriateness and feasibility of accounting for social risk factors in the Hospital OQR Program.

Measures Proposed for Removal from the Hospital OQR Program ([p. 466](#))

In this proposed rule, CMS does not propose any new measures for the Hospital OQR Program. However, it proposes to remove or delay a number of measures for both the CY 2020 and 2021 payment determinations to alleviate the maintenance costs and administrative burden to hospitals associated with retaining them:

- **Remove OP-21: Median Time to Pain Management for Long Bone Fracture Beginning with the CY 2020 Payment Determination.** This process of care measure assesses the median time from emergency department arrival to time of initial oral, nasal, or parenteral pain medication (opioid and non-opioid) administration for emergency department patients with a principal diagnosis of long bone fracture (LBF). CMS recognizes that this measure only assesses the time to initial, acute administration of pain medication in a specific acute clinical situation, and does not promote long-term pain medication prescriptions. In addition, the measure assesses the use of both opioid and non-opioid pain medications. Nevertheless, CMS is concerned that this measure may create undue pressure for hospital staff to prescribe more opioids. Although CMS is unaware of any scientific studies that support an association between this measure and opioid prescribing practices, out of an abundance of caution, it proposes to remove the measure to avoid misinterpretation of the intent of the measure.
- **Remove OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures Beginning with the CY 2020 Payment Determination.** This measure collects surgical procedure volume data on eight categories of procedures frequently performed in the outpatient hospital setting. CMS believes there is a lack of evidence to support this measure's link to improved clinical quality. The [measure](#) requires hospitals to report on the volumes of surgical procedures performed at the facility. This information, number of surgical procedures, does not offer insight into the facilities' overall performance or quality improvement in regards to surgical procedures and thus, does not result in better patient outcomes. CMS believes the burden of this measure, which is submitted via a web-based

tool, outweighs the value.

- **Remove OP-1: Median Time to Fibrinolysis Beginning with the CY 2021 Payment Determination.** This chart-abstracted measure assesses the median time from ED arrival to administration of fibrinolytic therapy in ED patients with ST-segment elevation on the ECG performed closest to ED arrival and prior to transfer. CMS proposes this measure for removal since the currently adopted OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (72 FR 66862 through 66865), which has been designed with a threshold that is based on a clinical standard, allows CMS to measure this topic area, and provides meaningful and clinically relevant data on the receipt of fibrinolytic therapy. CMS notes that national guidelines recommend that fibrinolytic therapy be given within 30 minutes of hospital arrival in patients with ST-segment elevation myocardial infarction. Since OP-1 measures only the median time from door to needle and does not note whether or not that value exceeds the clinical best practice of 30 minutes, CMS does not believe that reporting OP-1 improves quality of care or patient outcomes.
- **Remove OP-4: Aspirin at Arrival Beginning with the CY 2021 Payment Determination.** This chart-abstracted measure assesses the rate of patients with chest pain or possible heart attack who received aspirin within 24 hours of arrival or before transferring from the emergency department. CMS has determined that this measure is topped out and thus, the burden of reporting it is not justified by the value of retaining it.
- **Remove OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional Beginning with the CY 2021 Payment Determination.** This chart-abstracted measure assesses the time from ED arrival to provider contact for Emergency Department patients. During regular measure maintenance, specific concerns about OP-20 were raised by a Technical Expert Panel (TEP), including (1) limited evidence linking the measure to improved patient outcomes; (2) validity concerns related to wait times and the accuracy of door-to-door time stamps; and (3) potential for skewed measure performance due to disease severity and institution-specific confounders. CMS agrees with this concern, that the measure does not result in better patient outcomes, and that the burden of continuing to include this measure in the program outweighs the benefits.
- **Remove OP-25: Safe Surgery Checklist Use Beginning with the CY 2021 Payment Determination.** This structural measure of hospital process assesses whether a hospital employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period. CMS has determined this measure to be topped out and believes removal is appropriate since there is little room for improvement and doing so would alleviate administrative burden for hospitals. CMS believes that the safe surgical checklist is widely used and that hospitals will continue its use.
- **Delay OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning with the CY 2020 Payment Determination (2018 data collection).** These measures assess patients' experience with care following a procedure or surgery in a hospital outpatient department by rating patient experience as a means for empowering patients and improving the quality of their care. Since CMS's adoption of these measures, it has realized it lacks important operational and implementation data. CMS wants to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national OAS CAHPS survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care. CMS also notes commenters' earlier concerns over the burden associated with the survey. Nevertheless, CMS continues to believe that these measures address an area of care that is not adequately addressed in its current measure set and will enable objective and meaningful comparisons between hospital outpatient departments. CMS believes that the national implementation of the survey, which began in January 2016 and will conclude in December 2017, would provide valuable information moving forward.

The tables below list the Hospital OQR Program measure sets for the CY 2020 and CY 2021 payment determination and subsequent years, if the proposals in this rule are finalized.

Hospital OQR Program Measure Set Proposed for the CY 2020 Payment Determination	
NQF #	Measure Name
0287	OP-1: Median Time to Fibrinolysis [†]
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0286	OP-4: Aspirin at Arrival [†]
0289	OP-5: Median Time to ECG [†]
0514	OP-8: MRI Lumbar Spine for Low Back Pain
None	OP-9: Mammography Follow-up Rates
None	OP-10: Abdomen CT – Use of Contrast Material
0513	OP-11: Thorax CT – Use of Contrast Material
None	OP-12: Ability for Providers with HIT to Receive Lab Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT
0491	OP-17: Tracking Clinical Results between Visits [†]
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
0499	OP-22: Left Without Being Seen [†]
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None	OP-25: Safe Surgery Checklist Use
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use*
1536	OP-31: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery**
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
1822	OP-33: External Beam Radiotherapy for Bone Metastases
None	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff***
None	OP-37b: OAS CAHPS – Communication About Procedure***
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery***
None	OP-37d: OAS CAHPS – Overall Rating of Facility***
None	OP-37e: OAS CAHPS – Recommendation of Facility***

[†] NQF endorsement for this measure was removed.

[°] OP-26: Procedure categories and corresponding HCPCS codes are located at:

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244>

* Measure name was revised to reflect NQF title.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period

*** Proposed to delay measure reporting beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this proposed rule.

Hospital OQR Program Measure Set Proposed for the CY 2021 Payment Determination and Subsequent Years	
NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0289	OP-5: Median Time to ECG [†]
0514	OP-8: MRI Lumbar Spine for Low Back Pain
None	OP-9: Mammography Follow-up Rates
None	OP-10: Abdomen CT – Use of Contrast Material
0513	OP-11: Thorax CT – Use of Contrast Material
None	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT
0491	OP-17: Tracking Clinical Results between Visits [†]
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen [†]
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use*
1536	OP-31: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery**
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
1822	OP-33: External Beam Radiotherapy for Bone Metastases
None	OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff***
None	OP-37b: OAS CAHPS – Communication About Procedure***
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery***
None	OP-37d: OAS CAHPS – Overall Rating of Facility***
None	OP-37e: OAS CAHPS – Recommendation of Facility***

† NQF endorsement for this measure was removed.

‡ OP-26: Procedure categories and corresponding HCPCS codes are located at:

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244>

* Measure name was revised to reflect NQF title.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period

*** Proposed to delay measure reporting beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this proposed rule.

Hospital OQR Program Measures and Topics for Future Consideration (p. 482)

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

CMS also seeks comment on the future development of [OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival](#) as an electronic clinical quality measure (eCQM) in order to reduce the administrative burden on hospitals. Since OP-2 is not yet developed as an eCQM, electronic measure specifications are not available at this time.

Public Display of Quality Measures (p. 485)

- **OP-18c: Median Time from ED Arrival to ED Departure for Discharged ED Patients - Psychiatric/Mental Health Patients.** This measure addresses ED efficiency in the form of the median time from ED arrival to time of departure from the ED for patients discharged from the ED (i.e., ED throughput). As discussed in the measure specifications and [Measure Information Form \(MIF\)](#),²¹ OP-18 measure data is stratified into four separate calculations: (1) OP-18a is defined as the overall rate; (2) OP-18b is defined as the reporting measure; (3) OP-18c is defined as assessing Psychiatric/Mental Health Patients; and (4) OP-18d is defined as assessing Transfer Patients. Currently, the OP-18 measure publicly reports data only for the calculations designated as OP-18b, which excludes psychiatric/mental health patients and transfer patients. CMS believes it is important to publicly report data for OP-18c to address a behavioral health gap in the publicly reported Hospital OQR Program measure set. **Thus, CMS proposes to also publicly report OP-18c beginning as early as July of 2018 using data from patient encounters during the third quarter of 2017.** CMS also would make corresponding updates to its MIF to reflect these proposals. CMS also considered publicly reporting around July 2019, but felt this would create a delay in its efforts to address the behavioral health data gap in the publicly reported measure set.

Administrative Requirements (p. 488)

CMS proposes, beginning with the CY 2020 payment determination, to revise the Notice of Participation (NOP) submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet website, rather than by the deadlines specified previously. For example, a hospital submitting data for Q1 2019 encounters would be required to submit the NOP only prior to registering on the QualityNet website, which must be done prior to the data submission deadline of August 1, 2019.

²¹ The MIF provides detail on the rationale for a measure as well as the relevant numerator statements, denominator statements and measure calculations.

Form, Manner & Timing of Data Submitted (p. 491)

Hospital OQR Program Annual Payment Determinations (p. 491)

CMS previously finalized a policy to shift the quarters upon which the Hospital OQR Program payment determinations are based, beginning with the 2018 payment determination. The finalized deadlines for the 2020 payment determination and subsequent years are illustrated below.

CY 2020 Payment Determination and Subsequent Year

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2018 (April 1 - June 30)	11/1/2018
Q3 2018 (July 1 – September 30)	2/1/2019
Q4 2018 (October 1 - December 31)	5/1/2019
Q1 2019 (January 1 - March 31)	8/1/2019

In this rule, for the 2020 payment determination and subsequent years, CMS proposes to revise the data submission requirements for hospitals that did not participate in the previous year's Hospital OQR Program. Specifically, it would align the timeline specifying the initial quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program, rather than specifying different timelines for hospitals with Medicare acceptance dates before versus after January 1 of the year prior to an affected annual payment update.

Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2020 Payment Determination and Subsequent Years (p. 498)

In this section, CMS clarifies the hospital selection process previously finalized for validation and proposes to formalize and update its educational review process.

Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2018 Payment Determination (p. 509)

Section 1833(t)(17) of the Act states that hospitals that fail to report required data will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction.

CMS proposes to continue its established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full 2018 annual payment update factor. For the 2018 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of 74.953 by the proposed full conversion factor of 76.483. CMS proposes to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor.

ASC Quality Reporting (ASCQR) Reporting Program ([p. 515](#))

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

This section includes a discussion on accounting for social risk factors in the ASCQR Program that mirrors the discussion provided earlier regarding the [Hospital OQR Program](#).

Proposed Measure Removal ([p. 519](#))

CMS proposes to remove/delay the following measures for the 2019 payment determination and subsequent years:

- **Remove ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing Beginning with the CY 2019 Payment Determination.** This measure assesses whether intravenous antibiotics given for prevention of surgical site infection were administered on time. This measure has been found to be topped out. Also, NQF endorsement was removed in February 2015. As such, CMS believes the burden outweighs the benefit of maintaining this measure. A similar measure was removed from the Hospital OQR Program in the 2015 OPPS/ASC final rule.
- **Remove ASC-6: Safe Surgery Checklist Use Beginning with the 2019 Payment Determination.** This structural measure of facility process assesses whether an ASC employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period. Due to topped out status, this measure is also being proposed for removal. In this rule, the Hospital OQR Program also proposes to remove a similar measure.
- **Remove ASC-7: ASC Facility Volume Data on Selected Procedures Beginning with the 2019 Payment Determination.** This structural measure of facility capacity collects surgical procedure volume data on six categories of procedures frequently performed in the ASC setting. CMS adopted this measure based on evidence that volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality (76 FR 74507). However, over time, CMS has adopted and continues to propose assessing ASCs' performance on specific procedure types (e.g. ASC-14: Unplanned Anterior Vitrectomy and ASC-16: Toxic Anterior Segment Syndrome). CMS believes these procedure-type-specific measures will provide patients with more valuable ASC performance data than the ASC-7 measure.
- **Delay ASC-15a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures Beginning with the CY 2020 Payment Determination.** These measures assess patients' experience with care following a procedure or surgery in an ASC by rating patient experience as a means for empowering patients and improving the quality of their care. See section above on [delay of OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems \(OAS CAHPS\) Survey-Based Measures](#) for the rationale for delaying these measures.

Proposed New ASCQR Program Quality Measures for the CY 2021 and CY 2022 Payment Determinations and Subsequent Years ([p. 528](#))

- **Proposed adoption of ASC-16: Toxic Anterior Segment Syndrome Beginning with the CY 2021 Payment Determination ([p. 529](#)),** targeting an acute, noninfectious inflammation of the anterior segment of the eye, is a complication of anterior segment eye surgery that typically develops within 24 hours after surgery.
- **Proposed adoption of ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures Beginning with the CY 2022 Payment Determination ([p. 536](#)).** The measure outcome is all-cause, unplanned hospital visits within seven days of an orthopedic procedure performed at an ASC. CMS

clarifies that “hospital visits” here include emergency department visits, observation stays, and unplanned inpatient admissions.

CMS notes here that 60% of all medical or surgical procedures performed in 2006 were performed at ASCs, which represents a three-fold increase from the late 1990s. In 2015, more than 3.4 million fee-for-service Medicare beneficiaries were treated at 5,475 Medicare-certified ASCs, and spending on ASC services by Medicare and its beneficiaries amounted to \$4.1 billion. The patient population served at ASCs has increased not only in volume, but also in age and complexity. According to Medicare claims data, approximately 7% of surgeries performed in ASCs in 2007 were orthopedic in nature, which reflects a 77% increase in orthopedic procedures performed at ASCs from 2000 to 2007. As such, CMS believes measuring and reporting seven-day unplanned hospital visits following orthopedic ASC procedures will incentivize ASCs to improve care and care transitions. Patients that have hospital visits that occur at or after discharge from the ASC and may not be readily visible to clinicians because such patients often present to alternative facilities, such as emergency departments where patient information is not linked back to the ASC. Furthermore, many of the reasons for hospital visits following surgery at an ASC are preventable; patients often present to the hospital for complications of medical care, including infection, post-operative bleeding, urinary retention, nausea and vomiting, and pain.

This measure was included on the “List of Measures under Consideration for December 1, 2016.” The MAP reviewed it (MUC16-152) and recommended it be refined and resubmitted prior to adoption, stating that testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting. The MAP also recommended that this measure be submitted to NQF for review and endorsement. At the time, this measure was still undergoing field testing. Since then, CMS has completed testing for this measure and refinements in response to the MAP’s recommendations. These results will be presented to the MAP during the MAP feedback loop meeting in fall 2017. Facility-level testing showed variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care and opportunities for quality improvement; and reliability testing showed fair measure score reliability. Detailed testing results are available in the technical report for this measure, located [here](#). The proposed ASC-17 measure is not currently NQF-endorsed. However, CMS intends to submit it for review and endorsement by NQF once an appropriate NQF project has a call for measures. CMS cites its authority to adopt non-NQF-endorsed measures.

CMS believes this measure is appropriate for the measurement of quality care furnished by ASCs, because surgeries are becoming increasingly common in ASCs and can signify unanticipated admissions after care provided in ASCs. It also believes this proposed measure reflects consensus among affected parties because it was developed with stakeholder input from a Technical Expert Panel convened by a CMS contractor as well as from the measure development public comment period.

This measure is claims-based and uses Part A and Part B Medicare administrative claims and Medicare enrollment data to calculate the measure, which means ASCs will not need to submit any additional data directly to CMS. CMS proposes that the data collection period would be the two calendar years ending two years prior to the applicable payment determination year.

Starting on [p. 542](#), CMS discusses the calculation of this measure.

Starting on [p. 543](#), CMS discusses the patient cohort, which includes all Medicare beneficiaries ages 65 and older undergoing outpatient orthopedic surgery at an ASC who have 12 prior months of Medicare fee-for-service Parts A and B enrollment.

Starting on [p. 545](#), CMS also discusses the risk adjustment methodology and public reporting strategy for this measure.

For more information on these methodologies, including additional cohort details, CMS also refers readers [here](#) (the cohort procedures are available for download under “Version 1.0_Hospital Visits_Orthopedic ASC Procedures_Supplemental Files”). Note that the cohort includes therapeutic procedures on muscles and tendons, as well as spine procedures.

- **Proposed Adoption of ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures Beginning with the CY 2022 Payment Determination ([p. 548](#))** This measure evaluates all-cause, unplanned hospital visit occurring within seven days of the urology procedure performed at an ASC. The measure cohort includes beneficiaries ages 65 and older undergoing outpatient urology procedures at an ASC who have 12 prior months of Medicare fee-for service Parts A and B enrollment. The target group of procedures are those that: (1) are routinely performed at ASCs; (2) involve increased risk of post-surgery hospital visits; and (3) are routinely performed by urologists.

CMS cites multiple study findings in its rationale for proposing this measure:

- Urology procedures accounted for 4.8% of unanticipated admissions, and that urology surgery patients were almost twice as likely as orthopedics, plastic surgery, or neurosurgery to be admitted following surgery;
- Outpatient urology surgery has an overall 3.7% readmission rate;
- Using a 5% national sample of Medicare beneficiaries ages 65 and older who underwent one of 22 common outpatient urologic procedures at ASCs from 1998 to 2006, there was a 7.9% 30-day risk-adjusted rate of inpatient admission following surgery, with more frequent same-day admissions following outpatient surgery at ASCs than at hospitals.

The ASC-18 measure was included on the “List of Measures under Consideration for December 1, 2016.” The MAP reviewed this measure (MUC16-153) and recommended that it be refined and resubmitted prior to adoption by the ASCQR Program because, at the time of the MAP’s review, this measure was still undergoing field testing. The Workgroup stated testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting, and recommended this measure be submitted to NQF for review and endorsement. Since the MAP’s review and recommendation of ‘Refine and Resubmit’ in 2016, CMS has completed testing for this measure and continued to refine this proposed measure in response to the MAP’s recommendations. Results of continued development activities, including stakeholder feedback from the public comment period and pilot test findings will be presented to the MAP during its feedback loop meeting in fall 2017. CMS also intends to submit this measure for review and endorsement by the NQF once an appropriate measure endorsement project has a call for measures.

Facility-level testing showed significant variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care. CMS testing also found moderate measure score reliability for this measure, which is consistent with existing measures of patient outcomes in the ASC setting. Validity testing demonstrated that the measure scores identify differences in quality across facilities. Detailed testing results are available in the technical report for this measure, available [here](#).

This measure is claims-based and uses Part A and Part B Medicare administrative claims and Medicare enrollment data to calculate the measure, which means ASCs will not need to submit any additional data

directly to CMS. ***CMS proposes that the data collection period would be the two calendar years ending two years prior to the applicable payment determination year***

Starting on [p. 553](#), CMS discusses the calculation of this measure. Again, the measure outcome is all-cause, unplanned hospital visit occurring within seven days of the urology procedure performed at an ASC. CMS clarifies that “hospital visits” here include emergency department visits, observation stays, and unplanned inpatient admissions.

Starting on [p. 555](#), CMS discusses the patient cohort.

Starting on [p. 557](#), CMS also discusses the risk adjustment methodology and public reporting strategy for this measure. The risk-adjustment model includes nine clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following ASC urology surgery.

For more information on these methodologies, including additional cohort details, CMS also refers readers [here](#) (the cohort procedures can be found in Appendix A of the Version 1.0 Hospital Visits Urology ASC Procedures Measure Technical Report).

If these proposals are finalized, the measure set for the ASCQR Program CY 2021 payment determination and subsequent years would be as listed below:

ASCQR Program Measure Set Previously Finalized and Proposed for the CY 2021 Payment Determination and Subsequent Years		
ASC #	NQF #	Measure Name
ASC-1	0263	Patient Burn
ASC-2	0266	Patient Fall
ASC-3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265 [†]	All-Cause Hospital Transfer/Admission
ASC-8	0431	Influenza Vaccination Coverage among Healthcare Personnel
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use
ASC-11	1536	Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff**
ASC-15b	None	OAS CAHPS – Communication About Procedure**
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery**
ASC-15d	None	OAS CAHPS – Overall Rating of Facility**
ASC-15e	None	OAS CAHPS – Recommendation of Facility**
ASC-16	None	Toxic Anterior Segment Syndrome***

† NQF endorsement for this measure was removed.

* Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66984 through 66985).

**Measure proposed for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) and until further action in future rulemaking, as discussed in section XIV.B.4. of this proposed rule.
 *** New measure proposed for the CY 2021 payment determination and subsequent years.

If these proposals are finalized, the measure set for the ASCQR Program CY 2022 payment determination and subsequent years would be as listed below:

ASCQR Program Measure Set with Previously Finalized and Newly Proposed Measures for the CY 2022 Payment Determination and Subsequent Years		
ASC #	NQF #	Measure Name
ASC-1	0263	Patient Burn
ASC-2	0266	Patient Fall
ASC-3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265	All-Cause Hospital Transfer/Admission
ASC-8	0431	Influenza Vaccination Coverage among Healthcare Personnel
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use
ASC-11	1536	Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff**
ASC-15b	None	OAS CAHPS – Communication About Procedure**
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery**
ASC-15d	None	OAS CAHPS – Overall Rating of Facility**
ASC-15e	None	OAS CAHPS – Recommendation of Facility**
ASC-16	None	Toxic Anterior Segment Syndrome***
ASC-17	None	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures***
ASC-18	None	Hospital Visits after Urology Ambulatory Surgical Center Procedures****

† NQF endorsement for this measure was removed.

* Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66984 through 66985).

**Measure proposed for delay beginning with CY 2018 reporting until further action in future rulemaking as discussed in section XIV.B.4. of this proposed rule

*** New measure proposed for the CY 2022 payment determination and subsequent years.

ASCQR Program Measures and Topics for Future Consideration (p. 560)

CMS invites public comment on the possible inclusion of the Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure in ASCQR Program measure set in the future. This measure is used to assess the risk-adjusted Standardized Infection Ratio (SIR) for all SSIs following breast procedures conducted at ASCs among adult patients and reported to the CDC’s National Healthcare Safety Network. The measure compares the reported number of SSIs observed at an ASC with a predicted value based on nationally aggregated data. The numerator for this measure is all SSIs during the 30-day and 90-day postoperative periods following breast procedures in ASCs. The denominator for this measure is all adult patients (defined as patients ages 18 to 108

years) undergoing breast procedures, as specified by the operative codes that comprise the breast procedure category of the NHSN Patient Safety Component Protocol, at an ASC. This measure cohort excludes hospital inpatient and outpatient departments, pediatric patients (patients younger than 18 years) and very elderly patients (older than 108 years), and brain-dead patients whose organs are being removed for donor purposes. The specifications can be found [here](#) after searching “Ambulatory Breast Procedure Surgical Site Infection Outcome Measure.”

According to CMS, breast SSIs represent a substantial proportion of SSIs overall in inpatient settings, and have one of the highest infection risks of any procedure type in outpatient settings. While SSI rates following breast procedures vary from 1% to over 30% depending on procedure type, the trend in surgery transitioning to outpatient and ambulatory surgery settings due to advances in surgical techniques and economic incentives for ambulatory surgery make these events an outcome of interest for the ASCQR Program. Although standardized metrics have been developed to measure SSI rates for inpatient surgeries in the hospital setting, these have not yet been developed for outpatient surgeries in ASCs, which comprise a fast-growing proportion of all surgeries performed in the U.S.

This measure was included on the 2016 MUC list and reviewed by the MAP. The MAP conditionally supported the measure (MUC16-155), noting the rapid shift of care to the ambulatory surgery setting and the need to ensure transparency about the safety of ASCs. The MAP further noted that this measure should be submitted for NQF review and endorsement. This measure subsequently received NQF endorsement in January 2017.

Form, Manner, and Timing of Data Submitted ([p. 568](#))

The only significant proposal in this section is to expand the CMS online tool to also allow for batch submission of measure data beginning with data submitted during CY 2018.

Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements Administrative Requirements ([p. 578](#))

Under the ASCQR Program, ***any annual update will be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program.*** This reduction applied beginning with the CY 2014 payment rates. CMS is not proposing any changes to these policies.

Requests for Information ([p. 583](#))

Request for Information on CMS Flexibilities and Efficiencies ([p. 583](#))

CMS seeks ideas from the public on regulatory, subregulatory, policy, practice, and procedural changes to better accomplish the agency's goals of reducing burden for hospitals, physicians and patients; increasing quality of care; lowering costs; improving program integrity; and making the health care system more effective, simple and accessible. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this RFI could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS's authority is welcome for CMS's consideration.

CMS is particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. CMS requests commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

CMS will not respond to comments or questions related to the issues raised in this RFI in the 2018 OPPI/ASC final rule. Rather, CMS will actively consider all input as it develops future regulatory proposals or subregulatory guidance.

Eliminating Inappropriate Medicare Payment Differentials for Similar Services in the Inpatient and Outpatient Settings ([p. 585](#))

CMS is committed to eliminating inappropriate Medicare payment differentials for similar services in the inpatient and outpatient settings in order to execute its responsibility to taxpayers to prudently pay for high quality care. CMS has recognized that, even when particular hospital inpatient services and hospital outpatient services are similar, Medicare payment differentials may exist because different statutory provisions and different payment methodologies apply. Furthermore, CMS is concerned that, to the extent Medicare payment differentials exist (and may be inappropriate), there is a corresponding effect on financial liability of patients.

CMS' most recent solicitation for public comments on these issues occurred in the CY 2016 OPPI/ASC final rule with comment period. CMS notes that both hospitals and CMS have had the opportunity to gain experience under the various policy changes that have occurred with respect to short inpatient hospital stays since that time. ***In this context, CMS believes it is an appropriate time to seek public comment again on transparent ways to identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings.***

Physician Owned Hospitals ([p. 586](#))

CMS is seeking public comments on the appropriate role of physician-owned hospitals in the delivery system. CMS would like to explore whether physician-owned hospitals could play a more prominent role in the delivery system. In addition, CMS seeking public comments on the impact of the current requirements of the physician self-referral law regarding physician-owned hospitals. In particular, CMS is interested in comments on the impact on Medicare beneficiaries.

Regulatory Impact Analysis (p. 609)

CMS estimates that the OPPS provisions included in this proposed rule would redistribute more than \$100 million in one year, thus making this rulemaking “economically significant” and a major rule under the Congressional Review Act.

Specifically, CMS estimates that the total increase in Federal government expenditures under the OPPS for CY 2018, compared to CY 2017 due to the changes in this proposed rule, will be approximately \$897 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, CMS estimates that the OPPS expenditures for CY 2018 will be approximately \$5.7 billion higher relative to expenditures in CY 2017. [Table 38](#) displays the distributional impact of the proposed CY 2018 changes in OPPS payment to various groups of hospitals and for CMHCs.

CMS also estimates the proposed total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment system for CY 2018 compared to CY 2017 to be approximately \$67 million. [Table 39](#) and [Table 40](#) display the redistributive impact of the proposed CY 2018 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

On the [proposal to reduce payment for separately payable drugs purchased under the 340B drug pricing program](#), CMS estimates that OPPS payments for separately payable drugs, including beneficiary copayment, could decrease by as much as \$900 million under this proposal. Because CMS is proposing to implement this payment reduction in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B drug pricing program would increase payment rates (and by extension, beneficiary coinsurance liabilities) for other items and services paid under the OPPS by an offsetting aggregate amount by approximately 1.4 percent in CY 2018. However, because data on drugs that are purchased with a 340B discount are not publicly available, and because there may be potential offsetting factors, including possible changes in provider behavior and overall market changes that would likely lower the impact of the payment reduction, CMS notes that – if this policy is finalized – it may need to make an adjustment in future years to revise the conversion factor once more accurate data on drugs purchased with a 340B discount within the OPPS are available, similar to the adjustment we made for clinical diagnostic laboratory test packaging policy in the CY 2017 OPPS/ASC final rule with comment period.

CMS notes that the proposed payment rates and estimated impacts included in this proposed rule do not reflect the effects of the 340B proposal, which CMS notes could change in the final rule based on several factors. ***CMS is seeking public comment on its estimate and are especially interested in whether commenters believe there are other publicly available data sources or proxies that can be used for determining which drugs billed by hospitals paid under the OPPS were acquired under the 340B program.***

In addition, CMS is soliciting public comment on whether to apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018, rather than imply increasing the conversion factor. In particular, CMS is seeking public comment on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. Finally, CMS seeking public comment on whether the redistribution of savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section [1833\(t\)\(2\)\(F\)](#) of the Act.

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