CY 2016 Outpatient Prospective Payment System/

Overview

On July 1, 2015, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2016 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Payment System proposed rule. Comments will be accepted through **August 31, 2015**. The final rule is expected for release in early November 2015.

Below is a summary of this rule. Please note that page numbers correspond to the display version of the rule, available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-16577.pdf.

OPPS Payment Provisions

CMS has proposed to reduce the OPPS CY 2016 conversion factor to $73.929 (p. 175). This is the result of several factors. ***CMS has proposed to increase CY 2016 OPPS payments by 1.9 percent. This is based on the proposed inpatient market basket increase of 2.7 percent minus a productivity adjustment of 0.6 percent, as well as a 0.2 percent reduction required by the Patient Protection and Affordable Care Act (ACA) (p. 163). However, CMS is also proposing to apply a 2.0 percent conversion factor reductions "to redress the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests that are excepted" from the finalized CY 2014 laboratory packaging policy*** (p. 38; 170-171).[1] In total, CMS estimates that 2016 OPPS payments will decrease by approximately $43 million from CY 2015. 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.165; 173).

Recalibration of APC Relative Payment Weights (p. 58)

CMS has used the same annual process to update the APC relative weights and payments for CY 2016. 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 2016 rates are based on data submitted from claims processed after January 1, 2014 and before January 1, 2015. CMS is also proposing to continue its policy of establishing OPPS relative payment rates based on geometric mean costs as it has done since CY 2013. CMS is also proposing to continue its policy of using hospital cost-to-charge ratios to estimate costs for rate setting purposes (p. 69).

Comprehensive APCs (p. 108). 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

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[1] This is based on CMS' analysis that it overestimated costs in previous years and inappropriately added $1 billion in excess packaged payments in CY 2014, which it is now seeking to recoup (p. 171).

[2] Comprehensive APC 8011 (Comprehensive Observation Services) is being proposed to pay for "all qualifying extended

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").

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. **Table 5** lists the services excluded from Comprehensive APC payment packaging for CY 2016 (p. 113).

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

- *Complexity Adjustments*. ***CMS is proposing to continue its methodology for assessing Comprehensive APCs to qualify for a complexity adjustment***. 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. The add-on code and complexity adjustment methodology are discussed beginning on p. 115. 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 2016 Comprehensive APCs*. ***CMS is proposing to continue the Comprehensive APC payment methodology implemented in CY 2015 and to add nine (9) additional Comprehensive APCs***. **Table 6** (p.120) lists all proposed CY 2016 Comprehensive APCs. Below is a table of the newly proposed Comprehensive APCs for CY 2016.

New Comprehensive APCs Proposed for CY 2016	
ENT Procedures	
Comprehensive APC 5165	Level 5 ENT Procedures
Ophthalmic Surgery	
Comprehensive APC 5492	Level 2 Intraocular Procedures
Gynecologic Procedures	
Comprehensive APC 5416	Level 6 Gynecologic Procedures
Laparoscopic Procedures	
Comprehensive APC 5361	Level 1 Laparoscopy
Comprehensive APC 5362	Level 2 Laparoscopy
Orthopaedic Surgery	
Comprehensive APC 5123	Level 3 Musculoskeletal Procedures
Urologic Procedure	
Comprehensive APC 5375	Level 5 Urology and Related Services
Non-Clinical Family Specific	
Comprehensive APC 5881	Ancillary Outpatient Services When Patient Expires
Comprehensive APC 8011	Comprehensive Observation Services[2]

[2] Comprehensive APC 8011 (Comprehensive Observation Services) is being proposed to pay for "all qualifying extended assessment and management encounters." Using the rate setting formula for Comprehensive APCs, CMS estimates it will result in a geometric mean hospital payment of $2,111. In addition, CMS is proposing to eliminate Composite APC 8009, which had previously

- *Specific Comprehensive APC Proposals*.
    - Stereotactic Radiosurgery (p. 126): 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. CMS separately notes that the American Taxpayer Relief Act (ATRA) requires that Cobalt-60 based SRS (or gamma knife) payments be reduced to equal payments for robotic linear accelerator-based (LINAC) SRS. The relevant Comprehensive APC is Comprehensive APC 5631[3] (Single Session Cranial Stereotactic Radiosurgery).

      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.

      To address CMS' concern that claims are being submitted for services that are packaged into the Comprehensive APC, CMS is proposing to change payment for SRS Comprehensive APC 5631 "by identifying any services that are differentially billed for HCPCS codes 77371 and 77372 on the same claim and on claims 1 month prior to delivery of SRS services . . . , including planning and preparation services," and then removing them from the geometric mean calculation for CY 2016 and 2017. CMS plans to collect data on those services by requiring use of a modifier (*See*, "Data Collection for Adjunctive Services" in the next section). For those services that ***CMS is proposing to remove from Comprehensive APC 5631, hospitals are able to receive separate payment even when they appear on a claim with the SRS treatment in CY 2016 and 2017***. CMS notes that its goal remains to create a "single encounter payment" for services by eventually repackaging all planning and preparation services, but in the meantime ***CMS is inviting public comment on its proposal, including the list of codes that would be separately payable from Comprehensive APC 5631***:

Proposed Separately Payable APC 5631 Codes	
Service Description	**HCPCS Codes**
CT Localization	77011, 77014
MRI Imaging	70551, 70552, 70553
Clinical Treatment Planning	77280, 77285, 77290, 77295
Physics Consultation	77336

been used for qualifying extended assessment and management encounters. CMS also notes that by creating a single payment via a Comprehensive APC, beneficiaries are helped by only having to pay a single copayment for the services received. A discussion of the proposal for Comprehensive APC 8011 can be found on pp. 121-125.

[3] Comprehensive APC 5631 is a proposed new number for what has been Comprehensive APC 0067 in CY 2015.

- Data Collection for Adjunctive Services[4] (p. 129). In order to better identify adjunctive services that are provided *prior* to a primary service, ***CMS is proposing the creation of a HCPCS modifier to report adjunctive services that are billed on a different claim from the primary service***. Based on the data it receives, CMS would create a "single encounter payment" and ensure that payment for adjunctive services are included as part of the Comprehensive APC payment regardless of whether they appear on the same claim as the primary service. In addition, ***CMS is seeking comment on whether it should replace the modifier with a new condition code (as early as CY 2017)***.

- Claims for Inpatient Only Services on Patients Who Die Before Admission (p. 130). CMS is proposing to convert previous APC 0357 to Comprehensive APC 5881 (Ancillary Outpatient Services When Patient Expires) to comprehensively pay "for all services reported on the same claim as the inpatient only procedure billed with modifier –CA."

Composite APCs (p. 131). 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 is proposing to continue its policy for the following existing Composite APCs:

- Low dose rate (LDR) prostate brachytherapy (Composite APC 8001);
- Mental health services (Composite APC 0034); and
- Multiple imaging services (Composite APCs 8004, 8005, 8006, 8007, and 8008) (**Table 7**, p. 140).

CMS is proposing to discontinue policy for existing Composite APC:

- Extended assessment and management services (APC 8009) as part of its proposal to create Comprehensive APC 8011 (Comprehensive Observation Services).

Packaging Policies (p. 144). CMS has relied on packaging policies in the OPPS to ensure that incentives exist for hospitals to "furnish services most efficiently and to manage their resources with maximum flexibility." ***CMS is proposing to package the costs of selected "newly identified ancillary services into payment with a primary service . . . [when] the proposed packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code."*** (p. 146).

CMS is proposing the following changes for CY 2016:

- *Ancillary Services (p. 147)*. In CY 2015, CMS conditionally packaged ancillary services by listing a limited set of APCs that will conditionally package the ancillary services for those ancillary services in APCs with a geometric mean costs that is less than or equal to $100.00 (prior to the application of the conditional packaging status indicator). Exclusions to the ancillary packaging policy include preventive services, certain psychiatric and counseling-related services, and certain low-cost drug administration services. Proposed preventive services that would continue to be exempt from the ancillary packaging policy can be found in **Table 9** on p. 150.

[4] Again defined as "integral, ancillary, supportive, dependent or adjunctive" to the primary service (p. 129).

CMS noted that the "$100 geometric mean cost target . . . adopted in CY 2015 was not intended to be a threshold above which ancillary services will not be packaged, but was a basis for selecting the initial set of APCs under the conditional packaging policy for ancillary services, which would likely be updated and expanded in the future." For CY 2016, ***CMS is proposing to expand the set to evaluate ancillary services that are "clinically similar" to those that have already been determined to be "integral, ancillary, supportive, dependent, or adjunctive to a primary service" without applying the $100 geometric mean criteria***. The ancillary service APCs proposed for packaging in CY 2016 are

- APC 5734 (Level 4 Minor Procedures)
- APC 5673 (Level 3 Pathology)
- APC 5674 (Level 4 Pathology)

The proposed new APCs for ancillary packaging can be found in **Table 8** on p. 150.

- *Drugs and Biologicals That Function as Supplies When Used in A Surgical Procedure (p. 151)*. CMS unconditionally packages all drugs and biologicals that function as supplies[5] in a surgical procedure. ***CMS proposes to unconditionally package payment for the following drugs***:

Drugs Proposed for Unconditional Packaging			
HCPCS	**Descriptor**	**Surgical Procedure**	**Proposed 1st Year for Packaging**
J0583	Injection, bivalirudin, 1 mg	Percutaneous Coronary Intervention (PCI)/Percuntaneous Transluminal coronary angioplasty (PCTA) procedures	2016
J7315	Mitomycin, ophthalmic, 0.2 mg	Glaucoma Surgery	2016
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	Cataract Surgery	2018[6]
J0130	Injection, abciximab, 10 mg	PCI procedure	2016

More details are available in **Table 10** on p. 152.

- *Clinical Diagnostic Laboratory Tests (p. 153)*. CMS conditional packages lab tests and only pays separately for lab tests when "(1) it is the only service provided to a beneficiary on a given date of service; or (2) it is conducted on the same date of the primary service, but is ordered for a different purpose that the primary service ordered by a practitioner different than the practitioner who ordered the other OPPS services." CMS also excludes selected molecular pathology tests. CMS made several proposals related to their laboratory packaging policy:
  - ***CMS is proposing to alter its exclusion for selected molecular pathology tests under its current policy to exclude all molecular pathology tests from the packaging policy (p. 155)***.

[5] CMS defines "functions as a supply in a surgical procedure" as a "drug or biological [that] is integral to, dependent on, or supportive of a surgical procedure." (p. 152).

[6] CMS is proposing an implementation date of 2018 to allow for the drug's pass through status to expire prior to packaging.

- ***CMS is proposing to make separate payment for preventive lab tests (which will be giving a status indicator of "A")*** (p. 156).
- ***CMS is proposing to "consider laboratory tests provided during the same outpatient stay (rather than specifically provided on the same date of service as the primary service) as integral, ancillary, supportive, dependent, or adjunctive to a primary service or services, except when a laboratory test is ordered for a different purpose by a different practitioner than the practitioner who ordered the other OPPS services."*** *(p. 156).*

OPPS Payments to Certain Cancer Hospitals (p. 189)

The 11 PPS-exempt cancer hospitals, while exempted from the Inpatient Prospective Payment System, are paid under the OPPS for covered outpatient services. The Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) required that designated cancer (as well as children's) hospitals receive OPPS payments based on their pre-Balanced Budget Act of 1997 (BBA) payment amounts so as to be "held harmless" from otherwise mandated cuts. This means that these cancer hospitals are paid for covered outpatient services at rates that they would have received prior to the implementation of the OPPS.

- The ACA required the Secretary to conduct a study to determine whether the 11 cancer hospitals did, in fact, have outpatient costs that exceeded other hospitals' costs. The ACA required that the Secretary take into consideration of drugs and biologicals. If the Secretary determined that the costs were indeed greater, then the Secretary should provide an appropriate adjustment to reflect those higher costs.
- The Secretary conducted the requisite study in 2011 and found that the 11 cancer hospitals did have greater outpatient costs than other OPPS hospitals. Based on this information, in CY 2012, CMS finalized a policy to provide additional payments to these cancer hospitals.
- CMS is continuing its policy to provide these additional payments to these cancer hospitals.
- For CY 2016, CMS estimates that other OPPS hospitals are approximately 90 percent of those of the 11 cancer hospitals (defined as the "percent of reasonable cost."). However each hospital receives a separate adjustment factor based on a cost report settlement and the hospital's actual CY 2015 payments and costs.
- The payments to ensure the cancer hospitals are reimbursed at pre-BBA levels are applied separately.
- ***CMS is proposing that cancer hospital payment adjustments "to be determined at cost report settlement would be the additional payment needed to result in a proposed target [payment-to-cost ratio] PCR equal to 0.90 for each cancer hospital.***" (p. 193)
- CMS describes its methodology for calculating the CY 2016 additional payments beginning on p. 192.

Hospital Outpatient Outlier Payments (p. 195)

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 2015 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 $2,775. 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 2016 outlier payments will be approximately 1.0 percent of total OPPS payments.
- CMS proposes that .049 percent of the planned CY 2016 outlier payments be allocated to Community Mental Health Centers (CMHCs) for Partial Hospitalization Programs (PHPs).
- 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 $3,650 (p. 197).

APC Group Policies (p. 213)

New CPT and Level II HCPCS Codes. Upon creation of new CPT codes (Catergory I and III) as well as Level II HCPCS codes, CMS will assign these 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 13** (p. 215) 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 2015 (**Table 14** on p. 217)
- New Category III CPT and Level II HCPCS Codes Implemented in July 2015 (**Table 15** on p. 219)
- New and Revised CY 2016 Category I and III CPT Codes that will be effective January 1, 2016 (p. 222). 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).

CMS will be soliciting comments on the following categories of codes in the CY 2016 OPPS/ASC *Final* Rule:

- New Level II HCPCS Codes that will be effective October 1, 2015 and January 1, 2016 (p. 221)

Two Times Rule (p. 226). 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.

- CMS lists the reassignments to avoid violation of this rule on its Web site in Addendum B with the "CH" comment indicator.
- When reassignments are necessary, in some cases, CMS proposes to change the status indicators for some procedure codes, rename existing APCs, or create new clinical APCs to reflect the new APCs due to the reassignments.
- CMS often makes exceptions when the 2 Times Rule has been violated, typically in cases of low-volume items or services. CMS is proposing to apply the exception in 3 cases for CY 2016. Table 16 (p. 231) lists the APCs where the exception is being made.

New Technology APCs (p. 233). CMS currently has 37 new technology APCs. ***CMS is proposing to add 9 more levels of New Technology APCs by adding "Levels 38 through 46."*** The levels refer to dollar amounts with the lowest of the proposed additional New Technology APCs running from APC 1575

$10,000 to $15,000 (Level 38) to APC 1593 at $70,000 to $80,000 (Level 46). The proposed payment rates for the proposed New Technology APCs can be found in Addendum A.

- *Transprostatic Urethral Implant* Procedure (p. 236). There is currently one procedure that is receiving payment through a New Technology APC (APC 1564; Level 27; $4,500 – $5,000): HCPCS C9740 (*Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants*). ***CMS has not yet retained enough claims data, CMS is proposing to maintain assignment of this procedure to New Technology APC 1564 for CY 2016***.
- *Retinal Prosthesis Implant Procedure (p. 236)*. CPT 0100T (*Placement of a subconjunctival retinal prosthesis receive and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy*) is currently assigned to APC 0673 (Level III Intraocular Procedures) with a payment rate of $3,123. Because the procedure utilizes a device that has expiring pass-through status, the cost of the device becomes packaged in the procedures APC. Because the procedure is so new and because of the limited number of claims, ***CMS proposes reassigning CPT 0100T from existing APC 0673 to newly established New Technology APC 1593 (Level 46; $70,000 - $80,000) with a payment rate of $75,000***.

Proposed OPPS APC-Specific Policies (p. 240). CMS is proposing to restructure nine APC clinical families. Because of the restructuring CMS has renumbered many APCs, CMS has provided a crosswalk of the CY 2015 APC numbers to the proposed CY 2016 APCs in Addendum Q. CMS includes 2 tables in the proposed rule for each of the nine clinical families proposed for restructuring: the CY 2015 APCs and the proposed CY 2016 APCs.

- Airway Endoscopy APCs (**Tables 18 and 19**, p. 241)
- Diagnostic Tests and Related Services (**Tables 20 and Table 21**, p. 243)
- Excision/Biopsy and Incision and Drainage Procedures (**Tables 22 and 23**, p. 246)
- Gastrointestinal Procedures[7] (**Tables 24 and 25**, p. 248)
- Imaging Services (**Tables 27 and 28**, p. 252)
- Orthopedic Procedures (**Tables 29 and 30**, p. 256)
- Skin Procedures (**Tables 31 and 32**, p. 258)
- Urology and Related Services (**Tables 33 and 34**, p. 260)
- Vascular Procedures (Excluding Endovascular Procedures) (**Tables 35 and 36**, p. 262).

OPPS Payment for Devices (p. 263)

Expiration of Transitional Pass-Through Payments for Certain Devices (p. 263). Devices eligible for a transitional pass-through payment are eligible for at least 2, but not more than 3 years. One current device eligible for pass through payments will lose its pass-through status on December 31, 2015:

- HCPCS C1841 (Retinal prosthesis, includes all internal and external components)

CMS has proposed packaging the device into an appropriate APC (*See*, discussion of New Technology APCs above).

The following devices with pass-through status that will retain their payment status in CY 2016:

[7] CMS restructuring of gastrointestinal APCs was, in part, based on a Hospital Outpatient Payment Advisory Panel recommendation that CPT codes 44384, 44402, 45347, and 45389 be moved from their current respect APCs into Comprehensive APC 5331 (Complex GI procedures). More information is available on p. 249 and in **Table 26** on p. 250.

- HCPCS C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) (effective January 1, 2015)
- HCPCS C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) (effective April 1, 2015)
- HCPCS C2613 (Lung biopsy plug with delivery system) (effective July 1, 2015).

Device Pass-Through Payment Application Process (p. 264). CMS is proposing several changes related to the pass-through payment application process:

- ***CMS proposes to align a portion of the application process with the already established Inpatient Prospective Payment System (IPPS) process for new technology add-on payments***.
- ***CMS proposes to add a rulemaking component to the current quarterly device pass-through application process by including a description of applications received as well as CMS' rationale for approving or denying the application in the next applicable OPPS proposed rule*** (p. 269), which would create an informal reconsideration process for applications denied in the middle of the year.
- In order address concerns about whether the devices are "new," ***CMS is proposing that "not only must a device, if required, receive FDA premarket approval or clearance . . .or meet [an] . . . appropriate FDA exemption from premarket approval or clearance, but also that beginning with applications received on or after January 1, 2016, any such device must have received such approval or clearance, as applicable, within 3 years from the date of the application for transitional pass-through payment."*** (p. 273).

Proposed Provisions for Reducing Transitional Pass-Through Payments to Offset Costs Packaged into APC Groups (p. 274). CMS has a policy and methodology to estimate the portion of an APC payment amount attributable to the cost of associated devices eligible for pass-through payments (the "device APC offset amount'). Since 2010, this also includes the costs related to implantable biologicals (that are surgically inserted or implanted through a surgical incision or a natural orifice) that are approved for pass-through status. CMS notes that beginning January 1, 2015, skin substitutes are also evaluated under the device pass-through process. ***CMS proposes to continue its methodology for determining the device APC offset amount*.** The device APC offset amounts are available on the CMS Web site for us in developing device pass-through payment applications.

Device-Intensive Procedures (p. 277). CMS defines Device-Intensive Procedures as those with a device offset amount greater than 40 percent. CMS finalized a policy in CY 2015 that required "any of the device codes used in previous device-to procedure edits to be present on the claim whenever a procedure code assigned to any of the [applicable] APCs . . . is reported on a claim." (p. 278).[8] ***CMS is proposing to remove 10 APCs from the list of applicable APCs because the device offsets no longer exceed 40 percent. CMS also proposes that the requirement that a claim include a device code no longer be restricted to only those APCs that had previously been Device Dependent APCs.*** The resulting proposed list of CY 2016 Device-Intensive APCs can be found in **Table 38** on p. 280.

[8] The relevant CY 2015 APCs are listed in **Table 37** on p. 278)

Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices (p. 280). 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 proposing to continue its previous policies for reporting and paying for devices in these situations***. However, in previous years, CMS would list costly devices to which this payment adjustment would apply. ***For CY 2016, CMS is proposing "to no longer specify a list of devices to which the OPPS payment adjustments for no cost/full credit and partial credit devices would apply," and CMS is instead proposing "to apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device" (pp. 283-284)***. Therefore, the APCs to which the full/partial credit offset policy would apply is the list of Device-Intensive APCs found in **Table 38** on p. 280.

Proposed Adjustment to OPPS Payment for Discontinued Device-Intensive Procedures (p. 285). CMS has required hospitals to use a modifier[9,10,11] to indicate if a procedure has been discontinued, partially reduced, or cancelled. CMS assumes that a procedure that is assigned to a Device-Intensive APC that is discontinued (either prior to administration of anesthesia or for a procedure that does not require anesthesia) that the device was no used. To avoid paying for an unused device, CMS is proposing that for procedures involving implantable devices that are assigned to a device-intensive APC, ***CMS would reduce the payment amount for discontinued device-intensive procedures by 100 percent of the device offset amount (in addition to any other payment adjustments that would otherwise be applied when a procedure is discontinued)*** (p. 287). ***CMS notes that it is seeking comments on its decision to limit the policy to Device Intensive APCs, to not apply the policy after anesthesia has been administered (Modifier ~74), and comments on how often devices become ineligible for use in subsequent cases in Modifier ~74 scenarios and whether CMS should deduct the device offset amount from those cases as well***.

OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices (p. 288)

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.

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[9] Modifier 73: for a procedure requiring anesthesia was terminated due to extenuating circumstances or to circumstances that threatened the well-being of the patient after the patient had been prepared for the procedure and been taken to the room where the procedure was to be performed, but prior to the administration of anesthesia (p. 285).

[10] Modifier 73: for a procedure requiring anesthesia was terminated after the induction of anesthesia or after the procedure was started due to extenuating circumstances or to circumstances that threatened the well-being of the patient (p. 286).

[11] Modifier 52: to indicate partial reduction, cancellation or discontinuation of services for which anesthesia is not planned.

Proposed Drugs and Biologicals with Expiring Pass-Through Status in CY 2014 (p. 290). CMS is proposing that 12 drugs and biologicals' pass-through status would expire on December 31, 2015. The list of these drugs and biologicals is available in **Table 39** (p. 291).

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2015 (p. 292).

- CMS is proposing to continue pass through status for 32 drugs and biologicals. They can be viewed on the CMS Web site in Addenda A and B (and will be listed with the status indicator of "G"). They are also available in Table 40 (p. 296).
- CMS is proposing to continue to pay for pass-through drugs and biologicals at the Average Sales Price plus 6 (ASP+6) percent level.
- CMS is proposing to continue to update pass-through payment rates on a quarterly basis during CY 2016 if later quarter ASP submissions indicate that adjustments are necessary.
- CMS is also proposing 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).
- CMS proposes to continue its policy of setting the beneficiary copayment for pass-through drugs and biologicals at zero given that the statute requires that the amount of the copayment associated with pass-through items is "equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied." (p. 295)

Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups (p. 324). 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.

- For CY 2016, there will be a single diagnostic radiopharmaceutical with pass-through status: HCPCS A9586 (Florbetapir fl8, diagnostic, per study dose, up to 10 millicuries); **Table 41** (p. 300) lists the nuclear medicine APCs for which CMS expects that an APC offset for diagnostic radiopharmaceuticals with pass-through status could be expected.
- There are currently no contrast agents with pass-through status under the OPPS. However, CMS still proposes to identify APCs where it would expect an offset if a contrast agent was later approved for pass through payment. Those APCs can be found in **Table 42** on page 302.
- In CY 2014, CMS finalized a policy that skin substitutes and stress agents used in myocardial perfusion imaging (MPI) be packaged into APCs. Therefore, CMS also developed a policy and methodology to deduct from the pass-through payment the portion of the APC payment associated with predecessor skin substitutes and stress agents in the event a skin substitute or stress agent used in MPI received pass-through status (p. 304). CMS is proposing to continue its policy and methodology in CY 2016.
- For CY 2016, CMS states that there will be two (2) skin substitutes with pass-through status (Q4121 and C9349). **Table 43** (p. 305) lists the APCs to which CMS believes the skin substitutes offset would be applicable.

- There are currently no stress agents with pass-through status. However, CMS still proposes to identify APCs where it would expect an offset if a stress agent was later approved for pass through payment. Those APCs can be found in **Table 44** on page 305.

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals (without Pass-Through Payment Status) (p. 306)

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 for CY 2016 to set the threshold at $100 (the CY 2015 threshold was $90). Therefore, using its standard methodology to set the threshold, CMS proposes to package items with a per day cost less than or equal to $100 and separately pay for these items if they have a per day cost greater than $100.

Proposed High/Low Cost Threshold for Packaged Skin Substitutes (p.312). In CY 2014, CMS unconditionally packaged skin substitute products into their associated procedures. CMS also finalized a methodology to divide skin substitutes into high and low cost groups with the goal of ensuring adequate resource homogeneity among APC assignments for the skin substitute application procedures. In response to stakeholder concerns about the CMS methodology for assigning skin substitutes to high and low cost categories, in CY 2015 CMS finalized basing the high/low cost assignments on the weighted average mean unit cost (MUC) rather than ASP as it had done previously. In CY 2015, CMS also finalized a policy that skin substitutes with pass-through payment status would be assigned to the high cost category. CMS also stated in the CY 2015 Final Rule that it would also calculate the per day cost (PDC) and compare it to the MUC methodology in CY 2016.

- Based on the methodology, ***CMS is proposing the weighted average MUC threshold for CY 2016 is $25 per cm^2 and a PDC of $1,050***: Skin substitutes that exceed the MUC threshold of $25 per cm^2 or the PDC of $1,050 will be classified as high cost.
- CMS will continue its policy that skin substitutes without claims data to calculate the MUC will be assigned to the high or low cost category based on the product's ASP+6 percent payment rate (if not ASP, then WAC+6, if not WAC, then 95 percent of AWP).
- Any new skin substitute without pricing information will continue to be assigned to the low cost category until pricing information is available.
- For CY 2016, ***CMS is also proposing to remove all implantable biologicals from the skin substitute cost group list*** because "these products are typically used in internal surgical procedures to reinforce or repair soft tissue, and are not typically used to promote healing of wounds on the skin." (p. 317). These products are listed in **Table 45** on page 318.
- ***CMS also proposes that a skin substitute assigned to the high cost group in CY 2015 and exceeds either the MUC or PDC threshold in this proposed rule would be assigned to the high cost group for CY 2016 "even if it no longer exceeds the MUC or PDC CY 2016 thresholds based on updated claims data and pricing information used in the CY 2016 final rule with comment period."*** (p. 318)
- **Table 46** (p. 319) lists skin substitutes and their CY 2015 high/low cost classification and their proposed CY 2016 classifications (by both MUC and PDC). CMS also posted the data utilized for its analysis on the CMS Web site.

Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages (p. 320). CMS is proposing 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.[12] Table 47 (p. 322) lists the proposed HCPCS codes to which the CY 2016 drug specific packaging methodology would apply.

Proposed Payment for Items without Pass-Through Status That Are Not Packaged (p. 324). CMS applies the same payment policy to all separately payable drugs and biologicals and the statutorily defined "specific covered outpatient drugs" or SCODs. In the proposed rule, CMS reiterated past concerns about the use of the standard drug payment methodology and it "might not appropriately account for average acquisition and pharmacy overhead cost, and therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be." (p. 327), and CMS will continue to look for ways to collect data to verify payment appropriateness and accuracy.

For CY 2016, ***CMS proposes to continue its policy of paying for those separately payable drugs and biologicals at a rate of ASP+6 percent noting that they believe that this methodology represents the combined acquisition and pharmacy overhead payments***. Separately payable drug and biological proposed CY 2016 payment rates are listed in Addenda A and B. CMS is also proposing to continue the ASP+6 percent payment methodology for separately payable radiopharmaceuticals (p. 331) and blood clotting factors (p. 334). CMS would also continue to pay at the ASP+6 percent rate for those new drugs and biologicals that have HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data (if not available, WAC+6; if WAC not available, 95 percent of the product's most recent AWP) (pp. 336-337).

Drugs and biologicals without 2014 claims data for packaging are listed in **Table 48** (p. 341); Drugs and biologicals without claims data and without pricing information for ASP methodology are listed in **Table 49** (p. 341).

Self-Administered Drug Technical Correction (p. 342). ***CMS is proposing to amend regulatory language to better reflect the statutory definition of Medicare Part B self-administered drugs (SADs)***. CMS proposes to delete the phrase "any drug or biological that can be self-administered" and add the phrase, "any drug or biological which is usually self-administered by the patient." (p. 343).

OPPS Proposed Payments for Biosimilar Biological Products (p. 343). CMS refers to the abbreviated pathway for licensing of biosimilars created by the ACA.[13] The ACA also defined a "biosimilar biological product" and created a payment methodology for biosimilars. In 2010, CMS implemented regulations via the Medicare Physician Fee Schedule for office visit administered biosimilars even though CMS was not sure about the implementation of the pathway for biosimilars by the FDA. At the time, CMS did

[12] CMS did not have pricing information for the ASP methodology and therefore use the mean unit cost available from CY 2014 claims data to make the packaging determinations for the following drugs: HCPCS J3471 (Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); HCPCS J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units) (p. 322).

[13] "Under this abbreviated pathway, a proposed biological product that is demonstrated to be biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure." (p. 343).

not, however, issue guidance about how biosimilars would be paid under the OPPS. CMS approved its first biosimilar under the new pathway on March 6, 2015.

- ***CMS is proposing to utilize the same payment methodology for biosimilars that it uses for "specific covered outpatient drugs" or SCODs.***
- ***CMS believes that biosimilars are eligible to apply for transitional pass-through payments where appropriate and is proposing to apply the current transitional pass-through payment process to biosimilars (p. 346)***.

Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals and Devices (p. 166; 346). Statute limits pass through payment spending at 2.0 percent of total OPPS payments. CMS estimates that pass-through spending in CY 2016 would equal approximately $146.6 ($136.8 million for devices and $9.8 million for drugs and biologicals) or 0.25 percent of total projected CY 2016 OPPS spending, and would therefore not cross the 2.0 percent program spending limit.

OPPS Payment for Hospital Outpatient Visits (p. 355)

Proposed Payment for Hospital Outpatient Clinic and Emergency Department Visits. It had been previous CMS policy for hospitals to use CPT E/M codes to report clinic and emergency department (ED) hospital outpatient visits. In addition, CMS directed hospitals to develop internal guidelines for reporting the appropriate visit level. CMS has attempted to create a national set of guidelines but has found it difficult to create a policy that would accurately capture hospital relative costs (and no approach has been broadly endorsed by the stakeholder community).

- ***Outpatient Clinic Visits***. In CY 2014, CMS finalized a new policy in which they created new HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) for any and all OPPS clinic visits. G0463 was assigned to APC 0634 (Hospital Clinic Visits). The APC payment was based on 2012 data and the geometric mean cost of the 5 levels of CPT E/M codes for clinic visits (99201 – 99205) as previously utilized under the OPPS. The new policy also no longer distinguished between new and established patient clinic visits.
- ***Type A ED Visits***. In the CY 2014 final rule, CMS stated its intention to continue its existing methodology of recognizing the existing CPT codes for Type A ED visits.
- ***Type B ED Visits.*** In the CY 2014 final rule, CMS also stated that it would recognize the five HCPCS codes that apply to Type B ED visits.
- ***For CY 2016, CMS proposes to continue its current policy for paying for outpatient clinic and ED visits***.
- As part of APC restructuring, ***CMS proposes to move HCPCS G0463 from existing APC 0635 to renumbered APC 5012 (Level 2 Examinations and Related Services) (former APC 0632)***.
- CMS continues to believe that additional study is needed to assess the most appropriate method for paying ED visits and there for ***CMS does not propose any changes for ED visits***. However, CMS continues to state that it could propose changes to the coding and APC assignments for ED visits in future rulemaking.

Proposed Payment for Critical Care Services (p. 358). CMS proposes to continue its policy for hospitals to utilize the critical care CPT codes (99291, 99292) to bill for critical care services. CMS will continue to calculate the payment rate based on historical claims data. CMS also plans to continue its

policy of conditionally packaging ancillary services reported on the same date of service as critical care services.

Payment for Chronic Care Management Services (p. 359)

CMS reviewed its policies from the CY 2015 OPPS/ASC Final Rule for assigning CPT 99490 (*Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) to APC 0631 (Level 1 Examinations and Related Services). While CMS discussed some of the Medicare Physician Fee Schedule (MPFS)-related issues related to CPT 99490, CMS also stated that it has received several questions about the criteria beyond the MPFS requirements for hospitals to be able to appropriately bill the code.

- CMS noted that it addressed many of the issues through a CCM FAQ posted in May 2015.
- After reviewing the questions received, ***CMS is also proposing to add additional guidance for purposes of the OPPS for CY 2016 (in addition to what it already believes was required in CY 2015)***:
    - While CMS assumed the requirement previously, it is now formalizing through notice and comment that "the hospital must have an established relationship with the patient as a requirement for billing and OPPS payment." CMS continued that "a hospital would be able to bill CPT code 99490 for CCM services only when furnished to a patient who has been either admitted to the hospital as an inpatient or has been a registered outpatient of the hospital within the last 12 months and for whom the hospital furnished therapeutic services." (p. 361).
    - CMS is adopting OPPS rules to align with the MPFS requirement and proposing that:
        - Hospitals must document in the hospital's medical record the patient's agreement to have the CCM services provided or alternatively to have the patient's agreement to have the CCM services provided documented in a beneficiary's medical record that the hospital can access.
        - Hospitals must document in the hospital medical record (or beneficiary medical record that the hospital can access) that all elements of the CCM services were explained and offered to the beneficiary, including a notation of the beneficiary's decision to accept or decline the services.
        - Only one hospital can furnish and be paid for CCM services during the calendar month service period.
    - CMS is also adopting OPPS rules to align with the MPFS scope of service rules. These requirements are listed on p. 364.
    - CMS is proposing to adopt OPPS rules to align with the MPFS requirements related to use of EHRs in order to be able to bill the codes. These requirements are outlined on pp 365-367.

Inpatient Only Procedures (p. 403)

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 bases.
- 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 2016, CMS has identified seven (7) procedures that could be **removed** from the Inpatient Only list.

CPT 0312T: Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming

CPT 20936 Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from the same incision;

CPT 20937 Autograft for spine surgery only (includes harvesting the graft); morselized (through s separate skin or fascial incision)

CPT 20938 Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricotical (through separate skin or fascial incision)

CPT 22552 Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace;

CPT 54411 Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including the irrigation and debridement of infected tissue)

CPT 54417 Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative sessions, including irrigation and debridement of infected tissue

The codes and their long descriptors are also available for review in **Table 54** on p. 406.

CMS did not propose any procedures for addition to the Inpatient Only list.

ASC Payment System Provisions (p. 417)

For CY 2016, CMS is proposing to increase ASC payment rates by 1.1 percent (for those ASCs who meet the quality reporting requirements). This is based on an estimate of a Consumer Price Index-Urban (CPI-U) update of 1.7 percent minus a productivity adjustment of 0.6 percent. For those ASCs that do not meet the ASC quality reporting requirements, CMS will add an additional 2.0 percent reduction resulting in a total update for those ASCs of -0.9 percent (p. 497).

Overview

- CMS is proposing to finalize the payment indicators and payment rates for 13 new Level II HCPCS codes and new Category III CPT codes that were not addressed in the CY 2015 OPPS/ASC final rule with comment period, in the CY 2016 OPPS/ASC final rule with comment period.
- CMS is proposing to make changes in the process it uses to establish ASC payment indicators for new and revised Category I and Category III CPT codes, similar to revisions the agency made last year under the MPFS and the OPPS for establishing payment indicators for new and revised CPT codes that take effect each January 1. Several codes would be affected by this proposed policy, which can be found in ASC Addendum AA and Addendum BB, with the proposed new comment indicator of "NP".
- CMS is proposing to permanently designate three procedures as office-based; maintain its temporary office-based designations for five procedures; and, designate four new CY 2016 codes for ASC covered surgical procedures as temporarily office-based.
- CMS is proposing to continue its CY 2015 policies to update the ASC list of covered surgical procedures that are eligible for payment according to CMS' device-intensive procedure payment methodology, consistent with CMS' proposed modified definition of device-intensive procedures. In addition, CMS is soliciting public comments for alternative methodologies for establishing device-intensive status for ASC covered surgical procedures, in light of stakeholder concerns regarding situations where procedures with high-cost devices are not classified as device-intensive under the ASC payment system (*See* related discussion in OPPS section of the summary above).
- CMS is proposing to update the list of ASC covered device-intensive procedures, based on the revised device-intensive definition finalized last year, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2016. For partial credit, CMS is proposing to reduce the payment for implantation procedures listed in the table below 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.
- CMS is proposing to modify the calculation of OPPS payment when modifiers indicating that the procedure was discontinued appear on the claim (modifiers 52 and 73). The alternative payment calculation would remove the device offset before applying any standard downward payment adjustments because a full procedure was not performed, for device-intensive procedures. CMS is soliciting public comments on how often the device becomes ineligible for use in a subsequent case and whether CMS should deduct the device offset amount from claims with modifier 74 as well (*See* related discussion in OPPS discussion above).

- CMS is proposing to update the list of ASC covered surgical procedures by adding 11 procedures to the list for CY 2016, and inviting public comment on the continued exclusion of seven codes from the ASC list of covered surgical procedures.
- CMS is proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2016 OPPS (see Addendum BB), which would include removing three codes from the list of covered ancillary services.
- CMS is proposing to continue its methodologies for paying for covered ancillary services established for CY 2015.

Proposed Treatment of New Codes (p. 421)

Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2015 and July 2015 for Which CMS is Soliciting Public Comments in This Proposed Rule (p. 423). CMS made effective for April 1, 2015 and July 1, 2015, respectively, a total of 13 new Level II HCPCS codes and two new Category III CPT codes that describe covered ASC services that were not addressed in the CY 2015 OPPS/ASC final rule with comment period. The table below lists the new Level II HCPCS codes that were implemented during 2015, along with their proposed payment indicators for CY 2016. ***CMS invites public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2015 and July 2015 through the quarterly updates. CMS is proposing to finalize their payment indicators and their payment rates in the CY 2016 OPPS/ASC final rule with comment period***.

NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2015 AND JULY 2015, AND NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2015

CY 2015 HCPCS Code	CY 2015 Long Descriptor	Proposed CY 2016 Payment Indicator
C2623	Catheter, transluminal angioplasty, drug-coated, nonlaser	J7
C9445	Injection, c-1 esterase inhibitor (recombinant), Ruconest, 10 units	K2
C9448*	Netupitant 300mg and palonosetron 0.5 mg, oral	D5
C9449	Injection, blinatumomab, 1 mcg	K2
C9450	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	K2
C9451	Injection, peramivir, 1 mg	K2
C9452	Injection, ceftolozane 50 mg and tazobactam 25 mg	K2
Q9975	Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu	K2
C2613	Lung biopsy plug with delivery system	J7
C9453	Injection, nivolumab, 1 mg	K2
C9454	Injection, pasireotide long acting, 1mg	K2
C9455	Injection, siltuximab, 10 mg	K2
Q9978**	Netupitant 300 mg and Palonosetron 0.5 mg, oral	K2

**HCPCS code C9448 was deleted June 30, 2015 and replaced with HCPCS code Q9978 effective July 1, 2015.*
***HCPCS code Q9978 replaced HCPCS code C9448 effective July 1, 2015.*

Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2016 (p. 426). ***CMS is proposing to include in the OPPS/ASC proposed rule the proposed ASC payment indicators for the vast majority of new and revised CPT codes before they are used for payment purposes under the ASC payment system***. CMS would address new and revised CPT codes for the upcoming year that are available in time for the proposed rule by proposing ASC payment indicators for the codes. Otherwise, CMS would delay adoption of the new and revised codes for a year while using the methods described below to maintain the existing ASC payment indicators until the following year when CMS would include proposed assignments for the new and revised codes in the proposed rule. CMS is also proposing to make changes in the process it uses to establish ASC payment indicators for new and revised Category I and Category III CPT codes, similar to revisions the agency made last year under the MPFS and the OPPS for establishing payment indicators for new and revised CPT codes that take effect each January 1.

The proposed revised process would:

- ***Eliminate*** CMS' current practice of assigning interim payment indicators for the vast majority of new and revised CPT codes that take effect on January 1 each year;
- ***Delay*** adoption of new and revised codes for that year and, instead, ***adopt*** coding policies and payment rates that conform, to the extent possible, to the policies and payment rates in place for the previous year; and,
- ***Adopt*** these conforming coding and payment policies on an interim basis pending the result of CMS' specific proposals for new and revised codes through notice-and-comment rulemaking in the OPPS/ASC proposed rule for the following year.

Process for revised codes. ***CMS is proposing to create HCPCS G-codes to describe the predecessor codes for any codes that were revised (or deleted) as part of annual CPT coding changes. Exception:*** CPT codes that are revised in a manner that would not affect the cost of inputs (such as a grammatical change to the code descriptors), in which case CMS would use the revised codes and continue to assign the codes to their current ASC payment indicator.

Process for new codes. ***CMS is proposing to establish the initial ASC payment indicator assignments for wholly new codes (such as for a new technology or new surgical procedure that has not been previously addressed under the ASC payment system) as interim final assignments, and to follow the current process to solicit and respond to public comments and finalize the ASC payment indicator assignments in the subsequent year.***

CMS invites public comment on these proposals.

In addition, the new and revised Category I and III CPT codes that were received in time for the CY 2016 ASC update can be found in ASC Addendum AA and Addendum BB, with the proposed 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 current calendar year with a proposed ASC payment indicator and that comments will be accepted on the proposed payment indicator. ***CMS is soliciting public comments on the proposed CY 2016 ASC payment indicators for the new and revised Category I and III CPT codes that would be effective January 1, 2016.***

Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2015 and January 1, 2016 for Which CMS Will Be Soliciting Public Comments in the CY 2016 OPPS/ASC Final Rule with Comment Period (p. 433). Although CMS is proposing to revise its process for requesting public comments on the new and revised Category I and III CPT codes, CMS is not proposing any change to the process for requesting public comments on the new and revised Level II HCPCS codes that would be effective October 1and January 1. ***Specifically, the Level II HCPCS codes that will be effective October 1, 2015 and January 1, 2016 will continue to be flagged with comment indicator "NI" in Addendum AA and BB to the CY 2016 OPPS/ASC final rule with comment period to indicate that CMS has assigned the codes an interim ASC payment status for CY 2016.*** CMS will invite public comments on the proposed payment indicators and payment rates for these codes, if applicable, that would be finalized in the CY 2017 OPPS/ASC final rule with comment period.

The table below summarizes the CY 2016 process for updating codes through its ASC quarterly update change requests (CRs), seeking public comments, and finalizing the treatment of these new and revised codes under the ASC payment system. ***CMS invites public comment on this proposed process.***

PROPOSED COMMENT TIMEFRAME FOR CY 2016 FOR NEW OR REVISED CATEGORY I AND III CPT CODES AND LEVEL II HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 1, 2015	Level II HCPCS Codes	April 1, 2015	CY 2016 OPPS/ASC proposed rule	CY 2016 OPPS/ASC final rule with comment period
July 1, 2015	Level II HCPCS Codes	July 1, 2015	CY 2016 OPPS/ASC proposed rule	CY 2016 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2015	CY 2016 OPPS/ASC proposed rule	CY 2016 OPPS/ASC final rule with comment period
October 1, 2015	Level II HCPCS Codes	October 1, 2015	CY 2016 OPPS/ASC final rule with comment period	CY 2017 OPPS/ASC final rule with comment period
January 1, 2016	Level II HCPCS Codes	January 1, 2016	CY 2016 OPPS/ASC final rule with comment period	CY 2017 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2016	CY 2016 OPPS/ASC proposed rule	CY 2016 OPPS/ASC final rule with comment period

Proposed Update to Lists of ASC Covered Surgical Procedures and Covered Ancillary Services (p. 436)

Proposed Covered Surgical Procedures Designated as Office-Based. Each year, CMS designates covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that CMS have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or non-office-based, after taking into account updated volume and utilization data.

CMS' review of the CY 2014 volume and utilization data resulted in its identification of two covered surgical procedures (see table below) that CMS believes meet the criteria for designation as office-based; they are performed more than 50 percent of the time in physicians' offices and are of a level of complexity consistent with other procedures performed routinely in physicians' offices. ***CMS is proposing to permanently designate these two procedures as office-based. CMS invites public***

comment on this proposal.

ASC COVERED SURGICAL PROCEDURES NEWLY PROPOSED AS PERMANENTLY OFFICE-BASED FOR CY 2016

Proposed CY 2016 CPT Code	Proposed CY 2016 Long Descriptor	CY 2015 ASC Payment Indicator	Proposed CY 2016 ASC Payment Indicator*
43197	Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	G2	P3
43198	Esophagoscopy, flexible, transnasal; with biopsy, single or multiple	G2	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 2016. For a discussion of the MPFS rates, CMS refer readers to the CY 2016 MPFS proposed rule.

CMS also reviewed CY 2014 volume and utilization data and other information for six procedures finalized for temporary office-based status in the CY 2015 OPPS/ASC final rule with comment period. ***For five of the procedures (see table below), CMS is proposing to maintain its temporary office-based designations for CY 2016, as there were very few claims or no claims data available.*** **Note:** HCPCS code 0099T was assigned payment indicator R2* in the CY 2015 OPPS/ASC final rule with comment period, but this code is being replaced with a new CPT code currently identified with a CMS 5-digit placeholder code of 657XG.

CMS is also proposing to make permanent the office-based designation for CPT code 64617 (Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed), as its review of the claims data indicated that this procedure is performed more than 50 percent of the time in physicians' offices and is of a level of complexity consistent with other procedures performed routinely in physicians' offices.

PROPOSED CY 2016 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2015 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2015 CPT Code	CY 2015 Long Descriptor	CY 2015 ASC Payment Indicator	Proposed CY 2016 ASC Payment Indicator**
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2*	R2*
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	R2*	R2*
10030	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity abdominal wall, neck), percutaneous	P2*	P2*
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed	P3*	P3*
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm	R2*	R2*

	infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy		

* 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 2016. For a discussion of the MPFS rates, CMS refer readers to the CY 2016 MPFS proposed rule.

Finally, ***CMS is proposing to designate four new CY 2016 codes for ASC covered surgical procedures as temporarily office-based (see table below),*** because the clinical characteristics, utilization, and volume of related codes were determined to be predominantly performed in physicians' offices. CMS will reevaluate the procedures for office-based designation when data become available. ***CMS invites public comment on these proposals.***

PROPOSED CY 2016 PAYMENT INDICATORS FOR NEW CY 2016 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

Proposed CY 2016 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code***	Proposed CY 2016 Long Descriptor	Proposed CY 2016 ASC Payment Indicator**
6446A	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed)	R2*
6446C	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)	R2*
03XXB	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)	R2*
657XG	Implantation of intrastromal corneal ring segments	P2*

* 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 2016. For a discussion of the MPFS rates, CMS refer readers to the CY 2016 MPFS proposed rule.
***New CPT codes (with CMS 5-digit placeholder codes) that will be effective January 1, 2016. The proposed ASC payment rate for this code can be found in ASC Addendum AA, which is available via the Internet on the CMS Web site.

Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2016. ***CMS is proposing to continue its CY 2015 policies to update the ASC list of covered surgical procedures that are eligible for payment according to CMS' device-intensive procedure payment methodology, consistent with CMS' proposed modified definition of device-intensive procedures.*** The ASC covered surgical procedures that CMS is proposing to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2016 are listed in the table below (see table on page 8 of this summary). **CMS invites public comment on these proposals.**

Solicitation of Comments on Device-Intensive Policy for ASCs. In 2015, CMS implemented the comprehensive APC policy that included eliminating device-dependent APCs under the OPPS. CMS redefined ASC device-intensive procedures for CY 2015 as those procedures that are assigned to any APC with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology.

As it stands, payment rates for ASC device-intensive procedures are based on a modified payment

methodology. Under that modified payment methodology, CMS applies the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the non-comprehensive OPPS unadjusted payment rate for a device-intensive ASC covered surgical procedure, which CMS then sets as equal to the device portion of the national unadjusted ASC payment rate for the procedure. CMS then calculates the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure, which is then scaled for ASC budget neutrality. Finally, CMS sums the ASC device portion and the ASC service portion to establish the full payment for the device-intensive procedure under the revised ASC payment system.

CMS recognizes that, in some instances, there may be a procedure that contains high-cost devices but is not assigned to a device-intensive APC. Where an ASC covered surgical procedure is not designated as device-intensive, the procedure would be paid under the ASC methodology established for that covered surgical procedure, through either an MPFS nonfacility PE RVU-based amount or an OPPS relative payment weight based methodology, depending on the ASC status indicator assignment.

In response to stakeholder concerns regarding the situation where procedures with high-cost devices are not classified as device-intensive under the ASC payment system***, CMS is soliciting public comments for alternative methodologies for establishing device-intensive status for ASC covered surgical procedures.***

Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices. ***CMS is proposing to update the list of ASC covered device-intensive procedures, based on the revised device-intensive definition finalized last year, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2016.***

Table 62 (beginning on page 451) displays the ASC covered device-intensive procedures that CMS is proposing would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2016. Specifically, when a procedure listed the table below 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 with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that CMS estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. CMS continues to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

For partial credit, CMS is proposing to reduce the payment for implantation procedures listed in the table below 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 surgical procedure listed in Table 62 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. In order to report that they 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 continue to be based on the reduced payment amount.

As finalized in the CY 2015 OPPS/ASC final rule with comment period, in order to ensure that 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 it's FB/FC policy to all device-intensive procedures. ***CMS is inviting public comment on these proposals.***

Proposed Adjustment to ASC Payments for Discontinued Device-Intensive Procedures. CMS is proposing to modify the calculation of OPPS payment when modifiers indicating that the procedure was discontinued appear on the claim.

When a procedure assigned to a device-intensive APC is discontinued either prior to administration of anesthesia or for a procedure that does not require anesthesia, CMS presumes that, in the majority of cases, the device was not used and remains sterile such that it could be used for another case. In these circumstances, under current policy, providers are being paid twice by Medicare for the same device; once for the initial procedure that was discontinued, and again when the device is actually used. CMS believes that in cases where the procedure was not performed, that it would be appropriate to remove the estimated cost of the device, since it would have presumably not been used.

CMS believes these same issues exist in the ASC setting, and thus is proposing that this alternative payment calculation where the device offset is removed before applying any standard downward payment adjustments because a full procedure was not performed would also apply to device-intensive procedures in the ASC system beginning in CY 2016, with modifiers 52 (reduced services) and 73 (Discontinued outpatient procedure prior to anesthesia administration), which are the same modifiers proposed in the OPPS**.**

Under this proposed methodology, any adjustment policies reducing payment would only apply to the procedural portion of the service, based on ASC payment after the device offset is removed. Use of modifiers 52 or 73 would thus result in 50 percent of ASC payment for the service, after the device offset has first been subtracted from the standard ASC payment amount. CMS is proposing to restrict the policy to ASC device-intensive procedures so that the adjustment would not be triggered by the use of an inexpensive device whose cost would not constitute a significant portion of the total payment rate.

Similar to the OPPS, CMS is not proposing to deduct the device offset amount from a procedure that was discontinued after anesthesia was administered (modifier 74) as CMS believes that it may be more likely that devices involved with such procedures are more likely to no longer be sterile such that they could be restocked and used for another case. However, ***CMS is soliciting public comments on how often the device becomes ineligible for use in a subsequent case and whether CMS should deduct the device offset amount from claims with modifier 74 as well.*** CMS is proposing to revise its regulations to reflect this proposal. CMS is inviting public comment on this proposal and this proposed codification.

Proposed Additions to the List of ASC Covered Surgical Procedures. CMS conducted a review of HCPCS codes currently paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, ***CMS is proposing to update the list of ASC covered surgical procedures by adding 11 procedures to the list for CY 2016 (see table below).*** CMS determined that these 11 procedures 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 is inviting public comment on this proposal.***

PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2016

Proposed CY 2016 HCPCS Code	Proposed CY 2016 Long Descriptor	Proposed CY 2016 ASC Payment Indicator
0171T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level	J8
0172T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level	N1
57120	Colpocleisis (Le Fort type)	J8
57310	Closure of urethrovaginal fistula	J8
58260	Vaginal hysterectomy, for uterus 250 g or less	J8
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	J8
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g	J8
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	J8
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g	J8
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	J8
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	J8

ASC Treatment of Surgical Procedures Proposed for Removal from the OPPS Inpatient List for CY 2016. Previously, CMS adopted a policy to include, in CMS' annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. CMS evaluated each of the seven procedures proposed for removal from the OPPS inpatient list for CY 2016 according to the criteria for exclusion from the list of covered ASC surgical procedures. CMS believes that these seven procedures (see table below) should continue to be excluded from the ASC list of covered surgical procedures for CY 2016 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs. ***CMS is inviting public comment on the continued exclusion of these codes from the ASC list of covered surgical procedures.***

PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED SURGICAL PROCEDURES FOR CY 2016 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2016 OPPS INPATIENT LIST

CPT Code	Long Descriptor
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision)
20938	Autograft for spine surgery only (includes harvesting the graft); structural bicortical or tricortical (through separate skin or fascial incision)
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue

Covered Ancillary Services (p. 462)

Proposed List of Covered Ancillary Services. Consistent with the established ASC payment system policy, ***CMS is proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2016 OPPS.*** To maintain consistency with the OPPS, ***CMS is proposing that these services also would be packaged under the ASC payment system for CY 2016. CMS is proposing to continue this reconciliation of packaged status for subsequent calendar years.*** All ASC covered ancillary services and their proposed payment indicators for CY 2016 are included in Addendum BB of the proposed rule. ***CMS is inviting public comment on this proposal.***

Proposal to Remove Certain Services from the Covered Ancillary Services List That Are Not Used as Ancillary and Integral to a Covered Surgical Procedure. ***CMS is proposing to remove, from the list of ASC covered ancillary services for CY 2016 and subsequent years, CPT codes***

- ***77371 (Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source cobalt 60 based);***
- ***77372 (Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of***

treatment of cranial lesion(s) consisting of 1 session; linear accelerator based); and,

- ***77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions).***

While CMS is proposing to remove these three codes from the list of ancillary covered services for CY 2016 and subsequent years, CMS will continue to monitor the claims data to identify services for which clinical practice patterns indicate they are not provided in the ASC setting. ***CMS is inviting public comment on this proposal***.

Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services (p. 464)

Proposed ASC Payment for Covered Surgical Procedures (pg. 464). CMS is proposing to update ASC payment rates for CY 2016 and subsequent years using the established rate calculation methodologies and established modified definition of device-intensive procedures, as discussed above. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2016 and subsequent years, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology.

CMS is proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2." CMS is proposing that payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") and device-intensive procedures (payment indicator "J8") be calculated according to CMS' established policies and, for device-intensive procedures, using CMS' established modified definition of device-intensive procedures, as discussed above. Therefore, ***CMS is proposing to update the payment amount for the service portion of the device-intensive procedures using the ASC standard ratesetting methodology and the payment amount for the device portion based on the proposed CY 2016 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology***. Payment for office-based procedures is at the lesser of the proposed CY 2016 MPFS nonfacility PE RVU-based amount or the proposed CY 2016 ASC payment amount calculated according to the ASC standard ratesetting methodology.

CMS is proposing 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 is inviting public comment on these proposals.

Payment for Cardiac Resynchronization Therapy Services. CMS is not proposing any changes to its payment policies for cardiac resynchronization therapy (CRT) for CY 2016. However, CMS is proposing to renumber APC 0108 as APC 5232.

Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite. CMS is not proposing any changes to CMS' current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2016.

Proposed Payment for Covered Ancillary Services (p. 471). For CY 2016 and subsequent years, ***CMS is proposing 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 2016 OPPS and ASC payment rates and subsequent year payment rates. CMS is also proposing to continue to set the CY 2016 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the proposed OPPS payment rates for CY 2016.

Consistent with established ASC payment policy, ***CMS is proposing that the CY 2016 payment for separately payable covered radiology services be based on a comparison of the proposed CY 2016 MPFS nonfacility PE RVU-based amounts and the CY 2016 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two*** amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). CMS would make this same proposal for subsequent years.

For CY 2016 and subsequent years, ***CMS is also proposing that payment for a radiology service would be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS.*** The payment indicators in Addendum BB to this proposed rule indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator "N1").

Radiology services that CMS is proposing to pay based on the ASC standard ratesetting methodology in CY 2016 and subsequent years are assigned payment indicator "Z2" (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight), and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator "Z3" (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

Payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services and that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment for these procedures will be based on the OPPS relative payment weight (rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower) and, therefore, will include the cost for the diagnostic radiopharmaceutical. ***CMS is proposing to continue this modification to the payment methodology for CY 2016 and subsequent years and, therefore, is proposing to assign the payment indicator "Z2" to***

nuclear medicine procedures. Payment indicators for radiology services that use contrast agents are set to "Z2" so that payment for these procedures will be based on the OPPS relative payment weight and, therefore, will include the cost for the contrast agent. ***CMS is proposing to continue this modification to the payment methodology for CY 2016 and subsequent years and, therefore, is proposing to assign the payment indicator "Z2" to radiology services that use contrast agents.***

CMS is proposing to not make separate payment as a covered ancillary service for procurement of corneal tissue when used in any nontransplant procedure under the ASC payment system. CMS is proposing, for CY 2016 ASC payment purposes, to continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant.

Consistent with CMS' established ASC payment policy, ***CMS is proposing that the CY 2016 payment for devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and would be contractor-priced.*** Currently, the three devices that are eligible for pass-through payment in the OPPS are described by:

- HCPCS code C1841 (Retinal prosthesis, includes all internal and external components)
- HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) and, beginning on July 1
- HCPCS code C2613 (Lung biopsy plug with delivery system).

As finalized in the CY 2015 OPPS/ASC final rule with comment period, HCPCS code C1841 will no longer be eligible for pass-through payment in the OPPS for CY 2016 (79 FR 66870 through 66871), and thus the costs for devices described by HCPCS code C1841 would be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish ASC payment rates for CY 2016. Payment amounts for HCPCS codes C2623 and C2613 under the ASC payment system would be contractor-priced for CY 2016. Consistent with CMS' current policy, ***CMS is proposing that payment for the surgical procedure associated with the pass-through device is made according to CMS' standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight, if the APC weight for the procedure includes similar packaged device costs.***

Consistent with CMS' current policy, ***CMS is proposing that certain diagnostic tests within the medicine range of CPT codes (that is, all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT) for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure.*** CMS would pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology.

CMS previously identified one diagnostic test that is within the medicine range of CPT codes and for which separate payment is allowed under the OPPS: CPT code 91035 (Esophagus, gastroesophageal

reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation). CMS added this code to the list of ASC covered ancillary services and finalized separate ASC payment as a covered ancillary service for this code beginning in CY 2015 when the test is integral to an ASC covered surgical procedure. CMS stated that CMS would expect the procedure described by CPT code 91035 to be integral to the endoscopic attachment of the electrode to the esophageal mucosa. There are no additional codes that meet this criterion for CY 2016.

In summary, for CY 2016, ***CMS is proposing to continue its methodologies for paying for covered ancillary services established for CY 2015.*** Most covered ancillary services and their proposed payment indicators for CY 2016 are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

Calculation of the Proposed ASC Conversion Factor and Proposed ASC Payment Rates (p. 485)

Updating the ASC Relative Payment Weights for CY 2016 and Future Years. Consistent with CMS' established policy, CMS is proposing to scale the CY 2016 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2014, CMS is proposing to compare the total payment using the CY 2015 ASC relative payment weights with the total payment using the CY 2016 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2015 and CY 2016. CMS is proposing to use the ratio of CY 2015 to CY 2016 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2016. The proposed CY 2016 ASC scaler is 0.9180 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.

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

For any given year's ratesetting, CMS typically uses the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, CMS had available 98 percent of CY 2014 ASC claims data. To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), CMS summarized available CY 2014 ASC claims by ASC and by HCPCS code. CMS used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2014 claims data. CMS used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for this proposed rule, is posted on the CMS web site.

Updating the ASC Conversion Factor. For CY 2016, CMS is proposing to reduce the Consumer Price Index – Urban (CPI-U) update of 1.7 percent by the multifactor productivity (MFP) adjustment of 0.6 percentage point, resulting in an MFP-adjusted CPI-U update factor of 1.1 percent for ASCs meeting the quality reporting requirements. Therefore, CMS is proposing to apply a 1.1 percent MFP-adjusted CPI-U update factor to the CY 2015 ASC conversion factor for ASCs meeting the quality reporting requirements.

The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the CPI-U for ASCs that fail to meet the ASCQR Program requirements. CMS is proposing to reduce the CPI-U update of 1.7 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.6 percentage point MFP reduction. Therefore, CMS is proposing to apply a –0.9 percent quality reporting/MFP-adjusted CPI-U update factor to the CY 2015 ASC conversion factor for ASCs not meeting the quality reporting requirements. CMS is also proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 2016 CPI-U update and MFP adjustment), CMS would use such data, if appropriate, to determine the CY 2016 ASC update for the final rule with comment period.

For CY 2016, CMS is also proposing to adjust the CY 2015 ASC conversion factor ($44.058) by the proposed wage index budget neutrality factor of 1.0014 in addition to the MFP-adjusted CPI-U update factor of 1.1 percent discussed above, which results in a proposed CY 2016 ASC conversion factor of $44.605 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, CMS is proposing to adjust the CY 2015 ASC conversion factor ($44.058) by the proposed wage index budget neutrality factor of 1.0014 in addition to the quality reporting/MFP-adjusted CPI-U update factor of -0.9 percent discussed above, which results in a proposed CY 2016 ASC conversion factor of $43.723.

CMS invites public comment on these proposals.

Hospital Outpatient Quality Reporting Program Updates (p. 500)

Proposed Hospital OQR Measure for Removal for CY 2017 Payment Determination and Subsequent Years (p. 509). The Hospital OQR Program measure set previously adopted for the 2017 payment determination is listed beginning on p. 505.

Beginning with the 2017 payment determination, CMS proposes to remove: OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache. This measure has consistently generated concerns from stakeholders since its adoption in 2011. As such, public reporting of the measure has been deferred while CMS continues to evaluate the measure. Despite conducting a dry run and refining the measure to address some stakeholder concerns, CMS is proposing to remove this measure given the continued inconsistency of current clinical practice guidelines on which the measure is based. In peer-reviewed literature, headache guidelines have either excluded older adults or recommended a lower threshold for the use of CT scans. Furthermore, stakeholders have expressed concern that this measure is influenced significantly by case mix, patient severity, and clinician behavior, and thus, fails to represent appropriateness or efficiency accurately.

Proposed New Quality Measures for the CY 2018 and 2019 Payment Determinations and Subsequent Years (p. 511)/ To address concerns associated with unnecessary exposure to radiation and a desire for shorter and less painful treatment options, CMS proposes to add the following web-based quality measure to the Hospital OQR Program starting with the 2018 payment year: OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822). This measure is NQF-endorsed and was recommended for use in the program by the MAP. The numerator includes all patients with painful bone metastases and no previous radiation to the same site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns; 24Gy/6fxns; 20Gy/5fxns; or 8Gy/1fxn. The measure denominator includes all patients (all-payer) with painful bone metastases and no previous radiation to the same site who receive EBRT. The following patients are excluded from the denominator: patients who have had previous radiation to the same site; patients with femoral axis cortical involvement greater than 3 cm in length; patients who have undergone a surgical stabilization procedure; and patients with spinal cord compression, cauda equina compression, or radicular pain. Detailed specifications for this proposed measure may be found at: https://www.qualityforum.org/QPS/1822. The PPS-Exempt Hospitals Quality Reporting (PCHQR) Program previously adopted this measure starting with the 2017 payment year.

The newly proposed and previously finalized OQR Program measure set for the 2018 payment determination is listed on p. 515.

Proposed New Hospital OQR Program Quality Measure for the CY 2019 (p. 516). CMS proposes to add the following web-based quality measure to the OQR Program starting with the 2019 payment determination: OP-34: Emergency Department Transfer Communication (EDTC) (NQF #0291). This measure is NQF-endorsed and supported by the MAP. CMS notes in this section that the highest percentage of preventable and negligent adverse events within a hospital occur in the Emergency Department and that *performance measures for Emergency Department care are lacking*. CMS proposes to begin using this measure starting with the 2019 payment determination, rather than 2018, to give hospitals time to familiarize themselves with the implementation protocol and tools related to the measure and to make associated improvements prior to the first reporting deadline.

This measure has been rigorously peer reviewed and extensively tested with field tests from 2004 to 2014 across 16 states in 249 hospitals. It captures the percentage of patients transferred to another healthcare facility whose medical record documentation indicated that administrative and clinical information was communicated to the receiving facility in an appropriate time frame. The measure consists of seven subcomponents: (a) administrative data; (b) patient information; (c) vital signs; (d) medication; (e) physician information; (f) nursing information; and (g) procedure and test results. The subcomponents are further comprised of a total of twenty-seven elements, illustrated in a table on p. 519. The EDTC measure does not require hospitals to submit patient data on each of these elements; but rather, hospitals would be required to answer yes or no as to whether these clinical indicators were recorded and communicated to the receiving facility prior to departure or within 60 minutes of transfer.

CMS also proposes a scoring methodology for this measure, described on p. 520.

Additional information about this measure, including specifications, can be found at:

- http://rhrc.umn.edu/2012/02/ed-transfer-submission-manual and
- http://www.qualityforum.org/QPS/0291

The newly proposed and previously finalized measures for the CY 2019 Hospital OQR Program payment determination and subsequent years are listed on p. 527.

Hospital OQR Program Measures and Topics for Future Consideration (p. 528). For future payment determinations, CMS is considering exploring electronic clinical quality measures (eCQMs) and whether to, at a later date, propose that hospitals have the option to voluntarily submit data for OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF # 0496) electronically beginning with the 2019 OQR Program payment determination.

CMS notes its commitment to accelerate health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health IT across the broader care continuum. CMS points out that the Hospital IQR Program previously allowed hospitals to voluntarily report any 16 of 28 eCQMs that align with the Medicare EHR Incentive Program as long as those measures span three different NQS priority areas. More recently, in the 2016 IPPS proposed rule, the Hospital IQR Program proposed to make reporting of eCQMs required rather than voluntary. Hospitals would be required to submit both Q3 and Q4 of 2016 data for 16 eCQMs.

OP-18 was finalized in the 2011 OPPS/ASC final rule and is the only measure in the OQR measure set that is e-specified. The e-specification for this measure is available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2014_eCQM_Specs_for_EH.zip in the folder entitled: EH_CMS32v2_NQF0496_ED3_MedianTime.

This measure was also adopted by the Medicare and Medicaid EHR Incentive Program for Eligible Hospitals as one of 29 clinical quality measures available for reporting beginning with FY2014. CMS feels that allowing submission of OP-18 as an eCQM will begin to align the Hospital OQR Program with the Medicare EHR Incentive Program. Hospitals that chose not to submit electronically would still be required to submit data though chart abstraction.

Maintenance of Technical Specifications for Quality Measures (p. 532). Specifications for the previously adopted measures can be found on the QualityNet Web site at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244

Public Display of Quality Measures (p. 533) . CMS is not proposing any changes to its public display policy, previously finalized in the 2014 OPPS/ASC final rule.

Administrative Requirements (p. 533). To align with the Ambulatory Surgical Center Quality Reporting Program (ASCQR), CMS is proposing to:

- (p. 533) Change the deadline for withdrawing from the program from November 1 to August 31 of the year prior to the affected payment update, beginning with the 2017 payment

determination.

- (p. 535) Shift the quarters on which payment determinations are based and make conforming changes to the validation process to reflect these proposed changes to the timeframes. CMS currently bases APU determinations on chart-abstracted data from patient encounter quarter 3 of 2 years prior to the payment determination through patient encounter quarter 2 of the year prior to the payment determination. CMS proposes to change that timeframe to patient encounter quarter 2 of the 2 years prior to the payment determination through patient encounter quarter 1 of the year prior to the payment determination beginning with the CY 2018 payment determination. Because the deadline for hospitals to submit chart-abstracted data for quarter 1 is August 1, this will afford both CMS and hospitals additional time to review the APU determinations before they are implemented in January. To accommodate the transition to this timeframe, CMS will rely only on three quarters of data for determining the CY 2017 payment determination as illustrated on p. 536. Data submission deadlines will not change.
- (p. 540) Change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Website) from July 1 through November 1 to January 1 through May 15 of the year prior to the payment determination with respect to the encounter period of January 1 to December 31 of 2 years prior to the payment determination year. This proposal aims to streamline hospital data submissions by ensuring consistency with proposed data submission deadlines for the ASCQR Program in this rule and to align with the submission deadline for OP-27: Influenza Vaccination Coverage among Healthcare Personnel (reported via the CDC NHSN Web site). This proposal would affect the following OQR Web-based and chart-abstracted measures, which must be reported through the CMS Web-based tool, starting with the CY 2017 payment determination:
    - OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data (via CMS' QualityNet Web site);
    - OP-17: Tracking Clinical Results between Visits (via CMS' QualityNet Web site);
    - OP-22: ED – Left Without Being Seen (via CMS' QualityNet Web site);
    - OP-25: Safe Surgery Checklist Use (via CMS' QualityNet Web site);
    - OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (via CMS' QualityNet Web site);
    - OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (chart abstracted);* and
    - OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (chart abstracted).*

      **Although CMS categorizes OP-29 and OP-30 as chart-abstracted measures, unlike other chart-abstracted measures, they are submitted through a Web-based tool (CMS' QualityNet Web site).*
- (p. 547) Change the deadline for submitting a reconsideration request from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year.

Proposed Data Submission Requirements for Web-Based Measure OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) for the CY 2018 Payment Determination and Subsequent Years (p. 543). For this newly proposed Web-based measure, CMS proposes that hospitals can either: (1) report the measure beginning with services furnished on January 1, 2016 via the QualityNet Web site or (2) submit an aggregate data file for this measure through a vendor (via QualityNet infrastructure) containing aggregated data at the hospital level. The data submission deadline for either method would be May 15. Detailed information about format and submission requirements will be posted on QualityNet at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1191255879384

Proposed Data Submission Requirements for Web-Based Measure OP-34: Emergency Department Transfer Communication (EDTC) Measure for the CY 2019 Payment Determination and Subsequent Years (p. 544). For this newly proposed Web-based measure, CMS proposes that hospitals can either: (1) report it beginning with January 1, 2017 outpatient encounter dates via the QualityNet Website or (2) submit an aggregate data file for this measure through a vendor (via QualityNet infrastructure) containing aggregated data at the hospital level. The data submission deadline for either method would be May 15.

Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2016 Payment Determination (p. 548). Outpatient hospitals are subject to a reduction of 2.0 percentage points to their OPD fee schedule increase factor for failure to meet requirements for the Hospital OQR Program. CMS proposes to maintain all previously finalized policies related to payment reductions under this program, including the policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2016 annual payment update factor.

ASC Quality Reporting (ASCQR) Reporting Program (p. 553)

ASCQR Program Quality Measures Adopted in Previous Rulemaking (p. 557). CMS discusses ASCQR Program quality measures adopted via previous rulemaking starting on p. 557. A table of these measures previously finalized for CY 2017 and subsequent years is included on p. 559.

On p. 558, CMS discusses how most ASCQR measures are NQF endorsed, although endorsement is not a requirement for inclusion under this program. However, two measures previously adopted for the ASCQR Program are not currently NQF-endorsed, and were not endorsed when adopted for the program (ASC-6: Safe Surgery Checklist Use and ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures). Further, ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) was not NQF-endorsed at the time it was adopted for the ASCQR Program, but now is NQF-endorsed. Also, the NQF recently removed endorsement from ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing (formerly NQF #0264). CMS continues to believe that ASC-5 is appropriate for measurement of the quality of care furnished by ASCs and should be retained by the ASCQR Program since the measure is supported by clinical evidence and the measure steward will be continuing to support the measure.

ASCQR Measures Proposed for CY 2018 Payment Determination and Subsequent Years (p. 561). CMS is not proposing any new quality measures for the CY 2018 payment determination. The previously finalized measure set for the ASCQR Program CY 2018 payment determination and subsequent years is listed in a table on p. 560. The CY 2018 ASCQR Program measure set includes 12 measures—11 required and 1 voluntary.

ASCQR Program Measures for Future Consideration (p. 561). CMS is not proposing to add any new measures to the program at this point in time, but is requesting comment on the following two outcome measures for future consideration:

- (p. 562) Normothermia Outcome, which assesses the percentage of patients having surgical procedures under general or neuroaxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. The specifications for this measure for the ASC setting can be found at: http://ascquality.org/documents/ASC_QC_ImplementationGuide_3.0_January_2015.pdf.
- (p. 563) Unplanned Anterior Vitrectomy, which assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy (removal of the vitreous present in the anterior chamber of the eye).

Both measures have received conditional support from the MAP, pending the completion of reliability testing and NQF endorsement (see 2015 MAP 2015 Final Recommendations at: http://www.qualityforum.org/setting_priorities/partnership/measure_applications_partnership.aspx)

Maintenance of Technical Specification for Quality Measures (p. 564). CMS previously finalized a policy to post technical specifications on a CMS Website in addition to posting this information on QualityNet but now believes that posting on QualityNet alone is preferable to prevent possible inconsistencies associated with accessing multiple sites for information and to reduce burden.

Public Reporting of ASCQR Program Data (p. 566). CMS previously finalized a policy to publicly display ASCQR Program data at the CMS Certification Number (CCN) level. However, it proposes to change this policy in this rule. ASCs typically report quality measure data to CMS using their National Provider Identifier (NPI) and payment determinations are made by NPI. Because an ASC CCN can have multiple NPIs, publication of data by CCN can aggregate data for multiple facilities, thereby reducing identification of individual facility information. To allow for identification of individual facility information, beginning with any public reporting that occurs on or after January 1, 2016, CMS proposes to display the data by the NPI when data are submitted by the NPI. CMS feels this would allow consumers to better distinguish between ASCs and make more informed decisions about their care. It would also help ASCs to better understand their performance on measures. CMS also proposes, beginning with any public reporting that occurs on or after January 1, 2016, to display data by the CCN when data are submitted by the CCN. When data are submitted by the CCN, all NPIs associated with the CCN would be assigned the CCN's value because CMS would not be able to parse the data by the NPI.

Requirements for Data Submitted Via a CMS Online Data Submission Tool (p. 572). CMS proposes to implement a May 15 submission deadline, in the year prior to the payment determination year, for all data submitted via a CMS Web-based tool under the ASCQR Program starting with the CY 2017 payment determination. Under previously finalized policy, these data must be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year. CMS feels that aligning all Web-based tool data submission deadlines with the newly proposed date would allow for earlier public reporting of measure data and reduce the administrative burden for ASCs associated with tracking multiple submission deadlines for these measures. This proposal would affect the following measures:

- ASC-6: Safe Surgery Checklist Use
- ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures
- ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)
- ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659)
- ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)

Claims-Based Measure Data Requirements for the ASC-12: Facility Seven-Day Risk□Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure for the CY 2018 Payment Determination and Subsequent Years (p. 574). Unlike other claims-based measures adopted for the ASCQR Program, this measure does not require any additional data submission, such as quality data codes (QDCs). CMS previously finalized the policy to use paid Medicare FFS claims from the calendar year two years before the payment determination year. In this rule, CMS proposes, beginning with the CY 2018 payment determination, to use claims for services furnished in each calendar year that have been paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the

data used for the payment determination. This would better align policies across measures using QDCs and those that do not. CMS also believes that this claim paid date would allow ASCs sufficient time to submit claims and at the same time allow CMS sufficient time to complete required data analysis and processing to make payment determinations and to supply this information to the MACs.

Proposals for Indian Health Service (IHS) Hospital Outpatient Departments to Not Be Considered ASCs for the Purpose of the ASCQR Program (p. 575). CMS proposes to exclude Indian Health Service hospital outpatient departments from the ASCQR Program because, while these entities bill Medicare for ASC services and are paid based on the ASC rates for services under the ASC payment system, they are required to meet the conditions of participation for hospitals – not the conditions of coverage for ASCs – and therefore should not be included in the ASCQR Program.

ASCQR Program Reconsideration Procedures (p. 578). Under current procedures, ASCs are required to submit reconsideration requests by March 17 of the affected payment determination year. However, CMS recognizes that in some payment years, March 17 may fall outside of the business week. Therefore, it proposes, beginning with the CY 2017 payment determination, that ASCs must submit a reconsideration request to CMS by no later than the first *business day* on or after March 17 of the affected payment year.

Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements (p. 580). CMS does not propose any changes to previously finalized policy under this section. Outpatient hospitals are subject to a reduction of 2.0 percentage points to their OPD fee schedule increase factor for failure to meet requirements for the Hospital OQR Program.

Short Inpatient Hospital Stays (p. 585)

CMS reviewed previous guidance of Medicare contractor reviews of inpatient and Critical Access Hospital (CAH) admissions. Even after guidance, CMS continued to see "large improper payment rates in short-stay hospital inpatient claims, requests to provide guidance regarding proper billing of those services, and concerns about increasingly long stays of Medicare beneficiaries as outpatients due to hospital uncertainties about payment." In response, in the FY 2014 final rule CMS implemented the "Two Midnight" guidance for inpatient admissions which generally states, "a hospital inpatient admission is considered reasonable and necessary if a physician or other qualified practitioner (collectively, "physician") orders such admission based on the expectation that the beneficiary's length of stay will exceed 2 midnights or if the beneficiary requires a procedure specified as inpatient only." CMS also finalized "a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based on that expectation." CMS also stated in the final rule that "when a beneficiary enters a hospital for a surgical procedure not specified as inpatient only . . . , a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed."

CMS also reviews its expanded guidance as to the "2 midnight benchmark" which serves as guidance to reviewers to identify when an inpatient admission is generally appropriate for coverage and payment

and the "2 midnight presumption" which serves as instructions to medical reviewers regarding the selection of claims for medical review (p. 587).

"Rare and Unusual" Circumstances. CMS has continued to accept input on "rare and unusual" circumstances under which an inpatient admission (non-Inpatient Only procedure-related) that is expected to span less than 2 midnights would still be appropriate for Part A payment. CMS has already identified "newly initiated mechanical ventilation (excluding anticipated intubations related to minor surgical procedures or other treatment)" as one such instance.

"**Probe and Educate."** Two pieces of recent legislation of placed moratoria through September 30, 2015 on Medicare contractors which precludes them from recoveries related to hospital inpatient status. During this time, CMS and the contractors have continued medical reviews to help educate hospitals on the new billing and review guidance. CMS stated that it has seen positive results from this process.

RAC Improvements. In response to stakeholder concerns, CMS also implemented changes to the Recovery Audit Contractor (RAC) program.

Part B Rebilling. CMS also noted its updated rules allowing hospitals to rebill for denied Part A services under Part B in response to hospital concerns that RACs were denying inpatient claims that could then no longer be processed under Part B because of billing restrictions.

Proposed Changes. CMS states that it continues "to believe that use of the 2-midnight benchmark gives appropriate consideration to the medical judgment of physicians and also furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A." (p. 589). CMS reiterates that it continues "to believe that the 2-midnight benchmark provides, for payment purposes, clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment," but that the continued concerns from stakeholders warrant additional consideration.

- ***CMS is proposing to modify its existing "rare and unusual" exceptions policy***. This will allow for Medicare Part A payment on a *case-by-case basis* for inpatient admissions that do not satisfy the 2-midnight benchmark. CMS provides further guidance by saying the inpatient admission is allowed " if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights." (p. 594)[14].
- ***CMS does not propose any policy changes for stays that are expected to be greater than 2 midnights.***
- ***CMS does not propose any changes to the "2 midnight presumption."***
- ***CMS requests public comment on whether specific medical review criteria should be adopted for inpatient admissions that are not expected to span at least 2 midnights and what those criteria should be.***

[14] CMS notes that important considerations are "the severity of the signs and symptoms exhibited by the patient"; "the medical predictability of something adverse happening to the patient"; and "the need for diagnostic studies that appropriately are outpatient services." (p. 594).

- ***CMS also announced that (no later than October 1, 2015) it will change the medical review strategy and plan to have Quality Improvement Organization (QIO) contractors conduct reviews of short inpatient stays rather than Medicare Administrative Contractors (MACs) (p. 600). QIOs will then refer claim denials to MACs for payment adjustments where appropriate.***
- ***CMS will continue to monitor and evaluate the 2 midnight payment policy and medical review strategy and stated that it is open to considering potential payment policy options that address the concerns that led to implementation of the 2 midnight rule, including concerns regarding the large increase in long outpatient observation stays.***

Proposed Transition for Medicare-Dependent, Small Rural Hospitals (MDHs) in All-Urban States under the IPPS (p. 606)

CMS is proposing that, effective January 1, 2016, payments to hospitals that lost their MDH status because they are no longer in a rural area due to the adoption of the new OMB delineations and are now located in all-urban States would transition from payments based, in part, on the hospital-specific rate to payments based entirely on the Federal rate. Currently, an MDH receives the higher of the Federal rate or the Federal rate payment plus 75 percent of the amount by which the Federal rate payment is exceeded by its hospital-specific rate payment. CMS is proposing that, for discharges occurring on or after January 1, 2016, and before October 1, 2016, a former MDH in an all-urban State would receive the Federal rate plus two-thirds of 75 percent of the amount by which the Federal rate payment is exceeded by its hospital-specific rate payment. For FY 2017, that is, for discharges occurring on or after October 1, 2016, and before October 1, 2017, CMS is proposing that such a former MDH would receive the Federal rate plus one-third of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate. For FY 2018, that is, for discharges occurring on or after October 1, 2018, CMS is proposing that these former MDHs would be solely paid based on the Federal rate.

CMS believes it is appropriate to apply these proposed transitional payments for hospitals formerly located in rural areas and formerly classified as MDHs that are now located in all-urban States, given the potentially significant payment impacts for these hospitals and the fact that a hospital may not reclassify from urban to rural under section 1886(d)(8)(E) of the Act in an all-urban State. Allowing a gradual transition for such hospitals from payments based, in part, on the hospital-specific rate to payments based solely on the Federal rate would minimize the negative impact of CMS' adoption of the new OMB delineations, which caused certain rural hospitals to lose their MDH status. ***CMS is inviting public comments on CMS' proposal.***

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