

Issue Brief

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KEY POINTS

- The proposed rule would reduce outpatient PPS payments by a net of 0.2 percent and increase ambulatory surgical center payments by 1.1 percent
- The rule includes the continuation of the 7.1 percent OPPS payment adjustment for sole community hospitals and essential access community hospitals
- Revisions to the 2-midnight rule focuses on short inpatient hospital stays

CMS Proposes Hospital Outpatient PPS and Ambulatory Surgical Centers Policy and Payment Changes for CY 2016

The Centers for Medicare and Medicaid Services has issued a proposed rule to update the Hospital Outpatient Prospective Payment System and the Ambulatory Surgical Center payment system for calendar year 2016.

CMS says that the 697-page proposed rule, which contains a 60-day comment period ending August 31st, would update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and ASCs beginning Jan. 1, 2016.

In addition, the proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting Program and the ASC Quality Reporting Program.

Further, CMS is proposing certain changes relating to the hospital inpatient prospective payment system: proposed changes to the 2-midnight rule under the short inpatient hospital stay policy and a discussion of 2.0 percent payment adjustment.

A copy of the document is available at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-16577.pdf>. Publication in the *Federal Register* is scheduled for July 8.

COMMENT

One of the most striking items is CMS' proposal to reduce the OPPS update by a 2.0 percent reduction to "redress an inflation in payment rates resulting from excess packaged payment under the OPPS for laboratory tests that are excepted from the final CY 2014 laboratory packaging policy."

CMS is making the reduction on the grounds that "in order to eliminate the effect of the coding and classification changes for payment for laboratory tests that resulted in changes in aggregate payments, but which did not result in real changes in service-mix under the OPPS."

CMS estimates that total payments for CY 2016, including beneficiary cost-sharing, to the approximate 3,800 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers, would decrease by approximately \$43 million compared to CY 2015 payments, excluding estimated changes in enrollment, utilization, and case-mix.

A second major issue involves the two-midnight rule. The 2-midnight rule was

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adopted effective October 1, 2013. Under the 2-midnight rule, an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the expectation that the patient will need hospital care that crosses at least 2 midnights. In assessing the expected duration of necessary care, the physician (or other practitioner) may take into account outpatient hospital care received prior to inpatient admission. If the patient is expected to need less than 2 midnights of care in the hospital, the services furnished should generally be billed as outpatient services.

CMS is proposing to modify the existing “rare and unusual” exceptions policy under which the only exceptions to the 2-midnight benchmark were cases involving services designated by CMS as inpatient only, and those rare and unusual circumstances published on the CMS Web site or other sub-regulatory guidance, to also allow exceptions to the 2-midnight benchmark to be determined on a case-by-case basis by the physician responsible for the care of the beneficiary, subject to medical review.

Nonetheless, CMS says it continues to expect that stays under 24 hours would rarely qualify for an exception to the 2-midnight benchmark. In addition, CMS is revising the medical review strategy and announcing that no later than October 1, 2015, it is changing the medical review strategy and have Quality Improvement Organization contractors conduct reviews rather than the Medicare administrative contractors.

SUMMARY OF MAJOR PROVISIONS

OPPS Update

For CY 2016, CMS is proposing to increase the payment rates by an Outpatient Department fee schedule increase factor of 1.9 percent. This proposed increase is based on the proposed hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system, minus the proposed multifactor productivity adjustment of 0.6 percentage point, and minus a 0.2 percentage point adjustment both of which are

required by the Affordable Care Act. Further, CMS will reduce the update by an additional 2.0 percent to account for a so-called error it made in CY 2014 update pertaining to laboratory excess packaged payments. CMS’ error is assumed to be 1 billion. As a result, CMS estimates a net -0.2 percent update

Rural Adjustment

CMS is proposing to continue the adjustment of 7.1 percent to OPPS payments to certain rural sole community hospitals, including essential access community hospitals. This adjustment will apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, and devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

Cancer Hospital Payment Adjustment

CMS is proposing to continue the policy to provide additional payments to 11 cancer hospitals so that the hospital’s payment-to-cost ratio with the payment adjustment would equal the weighted average PCR for other OPPS hospitals using the most recent submitted or settled cost report data. Based on those data, a target PCR of 0.90 will be used to determine the proposed CY 2016 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments will be the additional payments needed to result in a PCR equal to 0.90 for each cancer hospital.

Payment of Drugs, Biologicals, and Radiopharmaceuticals

Proposed payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that

do not have pass-through status are set at the statutory default of average sales price plus 6 percent.

Payment of Biosimilar Biological Products

For CY 2016, CMS is proposing to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. CMS also is proposing to extend pass-through payment eligibility to biosimilar biological products and to set payment at the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product as determined under section 1847A of the Act) and the otherwise applicable HOPD fee schedule amount.

Packaging Policies

Beginning in CY 2015, CMS conditionally packaged certain ancillary services when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service. For CY 2016, CMS is proposing to expand the set of conditionally packaged ancillary services to include three new APCs.

Conditionally Packaged Outpatient Laboratory Tests

CMS is proposing to conditionally package laboratory tests (regardless of the date of service) on a claim with a service that is assigned status indicator “S,” “T,” or “V” unless an exception applies or the laboratory test is “unrelated” to the other HOPD service or services on the claim. CMS is proposing to establish a new status indicator “Q4” for this purpose. When laboratory tests are the only services on the claim, a separate payment at Clinical Laboratory Fee Schedule payment rates would be made. The “L1” modifier would still be used for “unrelated” laboratory tests.

Comprehensive APCs

CMS implemented comprehensive APCs for CY 2015 with a total of 25 C-APCs. CMS is proposing to create nine new C-APCs.

APC Restructuring

For CY 2016, CMS says it conducted a comprehensive review of the structure of the APCs and codes and is proposing to restructure the OPSS APC groupings for nine APC clinical families based on the following principles: (1) improved clinical homogeneity; (2) improved resource homogeneity; (3) reduced resource overlap in longstanding APCs; and (4) greater simplicity and improved understandability of the OPSS APC structure.

New Process for Device Pass-Through Payment

CMS is proposing to add a rulemaking component to the quarterly device pass-through payment application process. Specifically, CMS is proposing to supplement the quarterly process by including a description of applications received (whether they are approved or denied) as well as the rationale for approving or denying the application in the next applicable OPSS proposed rule. This proposed change is intended to help achieve the goals of increased transparency and stakeholder input. In addition, CMS says the proposal would align a portion of the OPSS device pass-through payment application process with the already established IPPS application process for new medical services and new technology add-on payments. Further, CMS is proposing that a device that requires FDA premarket approval or clearance is eligible to apply for device pass-through payment only if it is “new,” meaning that the pass-through payment application is submitted within 3 years from the date of the applicable FDA premarket

approval, clearance, or investigational device exemption.

Chronic Care Management

CMS is proposing additional requirements for hospitals to bill and receive OPPS payment for CCM services described by CPT code 99490. These requirements include scope of service elements analogous to the scope of service elements finalized as requirements in the CY 2015 Medicare Physician Fee Schedule final rule.

National Electrical Manufacturers Association Modifier

Effective for services furnished on or after Jan. 1, 2016, section 218(a) of the Protecting Access to Medicare Act of 2014 reduces payment for the technical component (and the TC of the global fee) under the MPFS and the OPPS (5 percent in 2016 and 15 percent in 2017 and subsequent years) for applicable computed tomography services identified by certain CPT HCPCS codes furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013, entitled “Standard Attributes on CT Equipment Related to Dose Optimization and Management.” The provision requires that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable CT service was furnished that was not consistent with the NEMA CT equipment standard. To implement this provision, CMS is proposing to establish a new modifier that would be reported with specific CPT codes, effective January 1, 2016.

New Process for Requesting Comments on New and Revised Category I and III CPT Codes

In the CY 2015 OPPS/ASC final rule CMS stated that it would include proposed APC and status indicator assignments for the vast majority of new and revised CPT codes before they are used for payment purposes under the OPPS if the American Medical Association provides CMS with the codes in time for the OPPS/ASC proposed rule. CMS has received CY 2016 CPT codes from AMA in time for inclusion to this CY 2016 OPPS/ASC proposed rule.

The new and revised CY 2016 Category I and III CPT codes can be found in OPPS Addendum B and assigned to new comment indicator “NP” to indicate that the code is a new code for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.

Ambulatory Surgical Center Payment Update

CMS is proposing to increase payment rates under the ASC payment system by 1.1 percent, based on a projected CPI-U update of 1.7 percent minus a multifactor productivity adjustment required by the ACA that is projected to be 0.6 percentage point. CMS estimates that proposed total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for

CY 2016 would be approximately \$4.293 billion, an increase of approximately \$186 million compared to estimated CY 2015 Medicare payments.

CMS is proposing to include the proposed ASC payment indicator assignments in the OP-34: Emergency Department Transfer Communication (NQF #0291).

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Hospital Outpatient Quality Reporting Program

For CY 2017 and subsequent years, CMS is proposing to: (1) remove OP-15: Use of Brain Computed Tomography in the Emergency Department for Atraumatic Headache measure, effective Jan. 1, 2016 (no data for this measure will be used for any payment determination); (2) change the deadline for withdrawing from the Hospital OQR Program from November 1 to August 31; (3) shift the quarters on which it bases payment determinations; (4) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet website) from July 1 through Nov. 1 to Jan. 1 through May 15; (5) rename the extension and exception policy to extension and exemption policy; (6) 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; and (7) amend 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term “fiscal year” with the term “calendar year.”

For CY 2018 and subsequent years, CMS is proposing a new measure: OP-33: External Beam Radiotherapy for Bone

Metastases (NQF #1822). For CY 2019 and subsequent years, CMS is proposing a new measure: OP-34: Emergency Department Transfer Communication (NQF #0291).

In addition, CMS is exploring electronic clinical quality measures and whether, in future rulemaking, CMS would 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 electronically beginning with the CY 2019 payment determination.

Ambulatory Surgical Center Quality Reporting Program

CMS is proposing to align data submission end dates for data submitted using a Web-based tool, to align policies regarding paid claims to be included in the calculation for all claims-based measures, to modify the submission date for reconsideration requests, to modify the policy for the facility identifier for public reporting of ASCQR Program data, and to not consider Indian Health Service hospital outpatient departments that bill as ASCs to be ASCs for purposes of the ASCQR Program. CMS is proposing to codify a number of existing and proposed policies and is soliciting public comments on the possible inclusion of two measures in the ASCQR Program measure set in the future.

Information Sites

The Addenda relating to the OP-33 are available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

The Addenda relating to the ASC payment system are available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-payment/ASCPayment/index.html>.

COMMENT

The discussion below follows the rule's order and is not reflective of major versus minor changes.

II. PROPOSED UPDATES AFFECTING OPPTS PAYMENTS

A. Recalibration of APC Relative Weights

The proposed APC relative weights and payments for CY 2016 are in Addenda A and B (which are available via the Internet on the CMS Web site) were calculated using claims from CY 2014 that were processed through Dec. 31, 2014.

Proposed Calculation and Use of Cost-to-Charge Ratios

For CY 2016, CMS is proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. The crosswalk is available for review and continuous comment on CMS' website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

CMS is proposing to continue to use data from the "Implantable Devices Charged to Patients" and "Cardiac Catheterization" cost centers to create distinct CCRs for use in calculating the OPPTS relative payment weights for the CY 2016 OPPTS. For the "Magnetic Resonance Imaging" and "Computed Tomography Scan" APCs are identified in the rule's Table 3, CMS is proposing to continue its policy of removing claims from cost modeling for those providers

using "square feet" as the cost allocation statistic for CY 2016.

Proposed Calculation of Single Procedure APC Criteria-Based Costs

1. Blood and Blood Products

CMS is proposing to continue to establish payment rates for blood and blood products using its blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs.

CMS refers readers to Addendum B for the proposed CY 2016 payment rates for blood and blood products (which are identified with status indicator "R").

2. Brachytherapy Sources

CMS is proposing to use the costs derived from CY 2014 claims data to set the proposed CY 2016 payment rates for brachytherapy sources.

CMS refers readers to Addendum B for the proposed CY 2016 payment rates for brachytherapy sources, which are identified with status indicator "U."

Proposed Comprehensive APCs for CY 2016

CMS is proposing nine additional C-APCs to be paid under the existing C-APC payment policy beginning in CY 2016. All C-APCs, including those effective in CY 2016 and those being proposed for CY 2016, are displayed in the table below with the proposed new C-APCs denoted with an asterisk.

Addendum J (which is available via the Internet on the CMS Web site) contains all of the data related to the C-APC payment policy methodology, including the list of proposed complexity adjustments.

Proposed CY 2016 C-APCs			
Proposed CY 2016 C-APC+	Proposed CY 2016 APC Descriptor	Clinical Family	New C-APC
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5165	Level 5 ENT Procedures	ENTXX	*
5166	Level 6 ENT Procedures	ENTXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5492	Level 2 Intraocular Procedures	EYEXX	*
5493	Level 3 Intraocular Procedures	EYEXX	
5494	Level 4 Intraocular Procedures	EYEXX	
5331	Complex GI Procedures	GIXXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	*
5361	Level 1 Laparoscopy	LAPXX	*
5362	Level 2 Laparoscopy	LAPXX	*
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5123	Level 3 Musculoskeletal Procedures	ORTHO	*
5124	Level 4 Musculoskeletal Procedures	ORTHO	
5471	Implantation of Drug Infusion Device	PUMPS	
5631	Single Session Cranial Stereotactic Radiosurgery	RADTX	
5375	Level 5 Urology and Related Services	UROXX	*
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5191	Level 1 Endovascular Procedures	VASCX	
5192	Level 2 Endovascular Procedures	VASCX	
5193	Level 3 Endovascular Procedures	VASCX	
5881	Ancillary Outpatient Services When Patient Expires	N/A	*
8011	Comprehensive Observation Services	N/A	*

+CMS refers readers to section III.D. of the proposed rule for a discussion of the proposed overall restructuring and renumbering of APCs and to Addendum Q (which is available via the Internet on the CMS Web site) for a complete crosswalk of the existing APC numbers to the proposed new APC numbers.

*Proposed New C-APC for CY 2016.

Clinical Family Descriptor Key:
 AICDP = Automatic Implantable Cardiac
 Defibrillators, Pacemakers, and Related
 Devices
 BREAS = Breast Surgery
 ENTXX = ENT Procedures
 EPHYS = Cardiac Electrophysiology
 EYEXX = Ophthalmic Surgery
 GIXXX = Gastrointestinal Procedures
 GYNXX = Gynecologic Procedures
 LAPXX = Laparoscopic Procedures
 NSTIM = Neurostimulators
 ORTHO = Orthopedic Surgery
 PUMPS = Implantable Drug Delivery Systems
 RADTX = Radiation Oncology
 UROXX = Urologic Procedures
 VASCX = Vascular Procedures

Proposed Observation Comprehensive APC

For CY 2016, CMS is proposing to pay for all qualifying extended assessment and management encounters through a newly created “Comprehensive Observation Services” C-APC (C-APC 8011) and to assign the services within this APC to proposed new status indicator “J2.”

Payments through the proposed new C-APC 8011 are for claims that meet the following criteria:

- The claims do not contain a HCPCS code to which CMS has assigned status indicator “T” that is reported with a date of service on the same day or 1 day earlier than the date of service associated with HCPCS code G0378;
- The claims contain 8 or more units of services described by HCPCS code G0378 (Observation services, per hour);
- The claims contain one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code

99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) provided on the same date of service or 1 day before the date of service for HCPCS code G0378;

- The claims do not contain a HCPCS code to which CMS has have assigned status indicator “J1.”

The proposed CY 2016 geometric mean cost resulting from this methodology is approximately \$2,111.

CMS is proposing to delete APC 8009, as it would be replaced with proposed new C-APC 8011 (Comprehensive Observation Services).

Proposed CY 2016 Policies for Specific C-APCs

1. Stereotactic Radiosurgery

Section 634 of the American Taxpayer Relief Act of 2012 amended section 1833(t)(16) of the Act by adding a new subparagraph (D) to require that OPSS payments for Cobalt-60 based SRS (also referred to as gamma knife) be reduced to equal that of payments for robotic linear accelerator-based (LINAC) SRS, for covered OPD services furnished on or after April 1, 2013. This payment reduction does not apply to hospitals in rural areas, rural referral centers, or SCHs.

Because Cobalt-60 based and LINAC based technologies are assigned to proposed renumbered C-APC 5631, the

costs of both technologies are reflected in the APC payment rate.

2. Proposed Data Collection for Non-primary Services in C-APCs

CMS is proposing to establish a HCPCS modifier to be reported with every code that is adjunctive to a comprehensive service, but is billed on a different claim.

CMS is seeking additional public comment on whether to adopt a condition code as early as CY 2017, which would replace this modifier to be used for CY 2016 data collection, for collecting this service-level information.

3. Proposed Policy Regarding Payment for Claims Reporting Inpatient Only Services Performed on a Patient Who Dies Before Admission

CMS is proposing to renumber APC 0375 to APC 5881 for CY 2016. For CY 2016, CMS is proposing to provide comprehensive payment through proposed renumbered C-APC 5881 for all services reported on the same claim as an inpatient only procedure billed with modifier “-CA.”

Proposed Calculation of Composite APC Criteria-Based Costs

(1) Low Dose Rate Prostate Brachytherapy Composite APC

CMS is proposing to use CY 2014 claims reporting charges for both CPT codes 55875 and 77778 on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the proposed payment rate for composite APC 8001.

CMS says that using 226 claims that contained both CPT codes 55875 and 77778 it proposes geometric mean cost of approximately \$3,807 for these procedures upon which the proposed CY 2016 payment rate for composite APC 8001 is based.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

CMS is proposing to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology.

The rule’s table 7 lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2016.

Proposed Changes to Packaged Items and Services

CMS is proposing to package the costs of selected newly identified ancillary services into payment with a primary service where the agency believes that 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.

Proposed Packaging Policies for CY 2016

(1) Ancillary Services

In the CY 2015 OP/ASC final rule CMS conditionally packaged payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to \$100 (prior to application of the conditional packaging status indicator).

CMS says there are some ancillary services that are assigned to APCs with a geometric mean cost above \$100, but for which conditional packaging is appropriate, given the context in which the service is performed.

CMS is proposing to expand the set of conditionally packaged ancillary services to include services in the three APCs listed in the table below.

Proposed APCs for Conditionally Packaged Ancillary Services for CY 2016			
Proposed Renumbered CY 2016 APC*	Proposed CY 2016 APC Title	Proposed CY 2016 OPPS Status Indicator	Proposed CY 2016 Payment Rate
5734	Level 4 Minor Procedures	Q1	\$119.58
5673	Level 3 Pathology	Q2	\$229.13
5674	Level 4 Pathology	Q2	\$459.96

*Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed APC renubmers for CY 2016.

Preventable services that would continue to be exempted from the ancillary service packaging policy for CY 2016 are listed below.

Proposed Preventive Services Exempted		
HCPCS Code	Short Descriptor	Proposed Renumbered CY 2016 APC*
76977	Us bone density measure	5732
77078	Ct bone density axial	5521
77080	Dxa bone density axial	5522
77081	Dxa bone density/peripheral	5521
G0117	Glaucoma scrn hgh risk direc	5732
G0118	Glaucoma scrn hgh risk direc	5732
G0130	Single energy x-ray study	5521
G0389	Ultrasound exam aaa screen	5531
G0404	Ekg tracing for initial prev	5731
Q0091	Obtaining screen pap smear	5731

*Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed APC renubmers.

(2) *Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure*
Based on clinical review, for CY 2016, CMS is proposing to package payment for the four drugs based on their primary function as a supply in a surgical procedure, which typically means that the drug or biological is integral to, dependent on, or supportive of a surgical procedure.

Separately Payable Drugs Proposed for Unconditional Packaging

HCPCS Code	Descriptor	CY 2015 Status Indicator	Primary Use in Surgical Procedure	Proposed First Calendar Year to be Packaged
J0583	Injection, bivalirudin, 1 mg	K	Percutaneous Coronary Intervention[PCI]/PCTA [percutaneous transluminal coronary angioplasty] procedures	2016
J7315	Mitomycin, ophthalmic, 0.2 mg	G	Glaucoma surgery	2016
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	Cataract surgery	2018
J0130	Injection abciximab, 10 mg	K	PCI procedure	2016

(3) Clinical Diagnostic Laboratory Tests

First, for CY 2016 and subsequent years, CMS is proposing a few revisions to its current laboratory packaging policy.

CMS is proposing to assign all laboratory tests that describe molecular pathology tests status indicator “A” in Addendum B, which means that they are separately paid at the CLFS rates outside of the OPSS.

Second, CMS is proposing for CY 2016 to make separate payment for preventive laboratory tests and assign them a status indicator “A” in Addendum B.

Third, CMS is proposing to package laboratory tests that are reported on the same claim with a primary service, regardless of the date of service.

This proposal does not affect existing policy to provide separate payment for laboratory tests: (1) if they are the only services furnished to an outpatient and are the only services on a claim and have a payment rate on the CLFS; or (2) if they are ordered for a different purpose than another OPSS service by a practitioner different than the practitioner who ordered the primary service. CMS also plans to continue to have hospitals report the “L1” modifier to identify any clinically “unrelated” laboratory tests that are furnished on the same claim as OPSS services, but are ordered by a different practitioner and for a different purpose than the primary OPSS services.

(4) Proposed Calculation of OPSS Scaled Payment Weights

For CY 2016 and subsequent years, CMS is proposing to standardize all of the relative payment weights to APC 0632 to which HCPCS code G0463 will now be assigned.

For CY 2016, CMS is proposing to renumber APC 0632 as APC 5012 (Level 2 Examination and Related Services).

B. Conversion Factor Update

CMS is proposing to apply an OPD fee schedule increase factor of 1.9 percent for the CY 2016 OPPS (which is 2.7 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less a proposed 0.6 percentage point MFP adjustment, and less an ACA -0.2 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points

To set the OPPS conversion factor for CY 2016, CMS is proposing to increase the CY 2015 conversion factor of \$74.173 by 1.9 percent. CMS is proposing to calculate an overall proposed budget neutrality factor of 0.9993 for wage index changes. CMS is proposing to maintain the current rural adjustment policy. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000.

CMS estimates that proposed pass-through spending for drugs, biologicals, and devices for CY 2016 would equal approximately \$136.8 million, which represents 0.25 percent of total projected CY 2016 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.13 percent estimate of pass-through spending for CY 2015 and the 0.25 percent estimate of proposed pass-through spending for CY 2016, resulting in a proposed adjustment for CY 2016 of -0.12 percent. Proposed estimated payments for outliers would be 1.0 percent of total OPPS payments for CY 2016. CMS currently estimates that outlier payments will be 0.95 percent of total OPPS payments in CY 2015; the 1.0 percent for proposed outlier payments in CY 2016 would constitute a 0.05 percent

increase in payment in CY 2016 relative to CY 2015.

Conversion factor to redress the inflation in the OPPS payment rates

CMS is proposing to exercise its authority in section 1833(t)(3)(C)(iii) of the Act to further adjust the conversion factor to eliminate the effect of coding and classification changes that it believes resulted in a change in aggregate payments that do not reflect real changes in service-mix related to final policy to package certain clinical diagnostic laboratory tests in the CY 2014 OPPS/ASC final rule.

Under current policy, payment for a laboratory test is not packaged when: (1) a laboratory test is the only service provided to the beneficiary on that date of service; or (2) a laboratory test is conducted on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service. The laboratory tests falling under these two exceptions continue to be paid separately at the CLFS payment rates outside the OPPS.

CMS says it estimated that it spent approximately \$2.4 billion on laboratory services on 13X type bill claims, and it incorporated this aggregate amount of weight into the estimate of the 2013 relative weight when calculating the budget neutral weight scaler to scale all relative weights for CY 2014, except those with a fixed payment amount such as drugs paid at ASP+6 percent. An adjustment to the overall weight scaler has a comparable effect on final payment as an adjustment to the conversion factor. CMS says it also assumed that separate payment would continue for laboratory services billed on 14X bill type claims

for referred specimens and for select inpatient Part B claims billed on a 12X bill type claim.

CMS says it overestimated the adjustment necessary to account for the new policy to package laboratory tests and underestimated the amount of spending that would continue for laboratory tests paid at the CLFS rates outside the OPSS by approximately \$1 billion. This \$1 billion effectively resulted in inflation in the OPSS payment rates resulting from excess packaged payment under the OPSS for laboratory tests for all OPSS services and duplicate payments for certain laboratory tests packaged payment incorporated into the OPSS payment rates as well as through separate payment at the CLFS payment rates outside the OPSS.

CMS is proposing a reduction of 2.0 percentage points to the proposed CY 2016 conversion factor to redress inappropriate inflation in the OPSS payment rates and remove the \$1 billion in excess packaged payment.

In sum

For CY 2016, CMS is proposing to use a conversion factor of \$73.929 and a CF of \$72.478 for hospitals that fail to meet the Hospital OQR requirements

C. Wage Index Changes

The OPSS labor-related share remains at 60 percent of the national OPSS payment.

Frontier State hospitals will receive a wage index of 1.0000 if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality) is less than 1.0000.

CMS is proposing to use the proposed FY 2016 hospital IPPS wage index for urban and rural areas as the wage index

for the OPSS hospital to determine the wage adjustments for the OPSS payment rate and the copayment standardized amount for CY 2016.

CMS is referring readers to CMS' website for the OPSS at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. At this link, readers will find a link to the proposed FY 2016 IPPS wage index tables.

D. Statewide Average Default CCRs

The rule's table 11 lists the proposed CY 2016 default urban and rural CCRs by State.

E. Proposed Adjustment for Rural SCHs and EACHs under Section 1833(t)(13)(B) of the Act

CMS is proposing to continue its policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPSS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Proposed OPSS Payment to Certain Cancer Hospitals

For CY 2016, CMS is proposing to continue its policy to provide additional payments to 11 cancer hospitals so that each cancer hospital's final payment to cost ratio is equal to the weighted average PCR (or "target PCR") for the other OPSS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of this proposed rule.

The table below indicates the estimated percentage increase in OPSS payments to each cancer hospital for CY 2016 due to the cancer hospital payment adjustment policy. The actual amount of the CY 2016 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2016 payments and costs.

Estimated CY 2016 Hospital-Specific Payment Adjustment for Cancer Hospitals To Be Provided at Cost Report Settlement		
Provider Number	Hospital Name	Estimated Percentage Increase in OPSS Payments for CY 2016
050146	City of Hope Comprehensive Cancer Center	19.0
050660	USC Norris Cancer Hospital	19.3
100079	Sylvester Comprehensive Cancer Center	22.3
100271	H. Lee Moffitt Cancer Center & Research Institute	24.5
220162	Dana-Farber Cancer Institute	47.8
330154	Memorial Sloan-Kettering Cancer Center	42.4
330354	Roswell Park Cancer Institute	19.2
360242	James Cancer Hospital & Solove Research Institute	32.5
390196	Fox Chase Cancer Center	21.0
450076	M.D. Anderson Cancer Center	47.7
500138	Seattle Cancer Care Alliance	53.9

G. Proposed Hospital Outpatient Outlier Payment

For CY 2016, CMS is proposing to continue its policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. CMS is proposing that a portion of that 1.0 percent, an amount equal to 0.49 percent of outlier payments (or 0.0049 percent of total OPSS payments) would be allocated to CMHCs for PHP outlier payments.

To ensure that the estimated CY 2016 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS, CMS is proposing that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus \$3,650.

For CY 2014, CMS estimates that it paid 0.1 percent below the CY 2014 outlier target of 1.0 percent of total aggregated OPSS payments. Using CY 2014 claims data and CY 2015 payment rates, CMS currently estimates that the aggregate outlier payments for CY 2015 will be approximately 0.95 percent of the total CY 2015 OPSS payments.

For CMHCs, CMS is proposing that, if a CMHC's cost for partial hospitalization services, paid under either proposed renumbered APC 5851 (existing APC 0172) or proposed renumbered APC 5852 (existing APC 0173), exceeds 3.40 times the payment rate for proposed renumbered 5852, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed renumbered APC 5852 payment rate.

III. PROPOSED OPPTS AMBULATORY PAYMENT CLASSIFICATION GROUP POLICIES

A. Proposed OPPTS Treatment of New CPT and Level II HCPCS Codes

Proposed Treatment of New CY 2015 Level II HCPCS and CPT Codes Effective April 1, 2015 and July 1, 2015 for which CMS is Soliciting Public Comments

Effective April 1, 2015, CMS made effective eight new Level II HCPCS codes and also assigned them to appropriate interim OPPTS status indicators and APCs.

New Level II HCPCS Codes Implemented in April 2015			
CY 2015 HCPCS Code	CY 2015 Long Descriptor	Proposed CY 2016 Status Indicator	Proposed CY 2016 APC**
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	H	2623
C9445	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
C9448#	Netupitant 300mg and palonosetron 0.5 mg, oral	N/A	N/A
C9449	Injection, blinatumomab, 1 mcg	G	9449
C9450	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
C9451	Injection, peramivir, 1 mg	G	9451
C9452	Injection, ceftolozane 50 mg and tazobactam, 25 mg	G	9452
Q9975*	Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu	G	1656

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

*HCPCS code Q9975 was replaced with HCPCS code C9136 (Injection, factor viii, fc fusion protein, (recombinant), per i.u.), effective April 1, 2015.

**Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

CMS is soliciting public comments on the proposed APC and status indicator assignments, where applicable, for the CPT and Level II HCPCS codes implemented on July 1, 2015.

New Category III CPT and Level II HCPCS Codes Implemented in July 2015			
CY 2015 CPT/HCPCS Code	CY 2015 Long Descriptor	Proposed CY 2016 Status Indicator	Proposed CY 2016 APC****
C2613	Lung biopsy plug with delivery system	H	2613
C9453	Injection, nivolumab, 1 mg	G	9453

New Category III CPT and Level II HCPCS Codes Implemented in July 2015

CY 2015 CPT/HCPCS Code	CY 2015 Long Descriptor	Proposed CY 2016 Status Indicator	Proposed CY 2016 APC****
C9454	Injection, pasireotide long acting, 1 mg	G	9454
C9455	Injection, siltuximab, 10 mg	G	9455
Q5101*	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	E	N/A
Q9976	Injection, Ferric Pyrophosphate Citrate Solution, 0.1 mg of iron	E	N/A
Q9977	Compounded drug, not otherwise classified	N	N/A
Q9978**	Netupitant 300 mg and Palonosetron 0.5 mg, oral	G	9448
0392T***	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band)	Q2	5362
0393T	Removal of esophageal sphincter augmentation device	Q2	5361

*HCPCS code Q5101, Zarxio, was approved by the FDA on March 6, 2015. As the biosimilar is currently not being marketed, pricing information is not yet available. Once Zarxio is marketed CMS will make pricing information available at the soonest possible date on the OPPS payment files and payment for Zarxio will be retroactive to the date the product is first marketed.

**HCPCS code C9448 (Netupitant 300 mg and palonosetron 0.5 mg, oral) was deleted June 30, 2015, and replaced with HCPCS code Q9978, effective July 1, 2015.

***HCPCS code C9737 (Laparoscopy, surgical, esophageal sphincter augmentation with device (eg, magnetic band) was deleted June 30, 2015 and replaced with CPT code 0392T, effective July 1, 2015.

****CMS refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

B. OPPS Changes – Variations within APCs

The following table lists 3 APCs that CMS is proposing to exempt from the 2 times rule for CY 2016.

Proposed APC Exceptions to the 2 Times Rule for CY 2016	
Proposed CY 2016 APC*	Proposed CY 2016 APC Title
5221	Level 1 Pacemaker and Similar Procedures
5673	Level 3 Pathology
5731	Level 1 Minor Procedures

C. Proposed New Technology APCs

Currently, there are 37 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of “S” and the other set with a status indicator of “T.” CMS is proposing to establish a new set of New Technology APCs 1575 through 1583 (for Levels 38 through 46) with OPSS status indicator “S” and a new set of New Technology APCs 1585 through 1593 (for Levels 38 through 46) with OPSS status indicator “T.”

The rule’s Table 17 contains the complete list of the proposed additional 18 New Technology APC groups.

Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a sub-conjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis.

CMS is proposing to reassign CPT code 0100T from existing APC 0673 (Level III Intraocular Procedures) to proposed newly established New Technology APC 1593 (New Technology - Level 46 (\$70,000-\$80,000)). CMS is proposing a CY 2016 OPSS payment of approximately \$75,000 for proposed new APC 1593, which would be the payment for CPT code 0100T (not including the retinal prosthesis), plus the proposed maximum FY 2016 IPPS new technology add-on payment for a case involving the Argus® II Retinal Prosthesis System of \$72,028.75.

D. Proposed OPSS Ambulatory Payment Classification Group Policies

CMS is proposing to restructure nine APC clinical families. CMS notes that, in conjunction with the proposed

restructuring, it is proposing to renumber several families of APCs to provide consecutive APC numbers for consecutive APC levels within a clinical family for improved identification of APCs and ease of understanding the APC groupings.

The nine families are as follows.

1. Airway Endoscopy Procedures
2. Diagnostic Tests and Related Services
3. Excision/Biopsy and Incision and Drainage Procedures
4. Gastrointestinal Procedures
5. Imaging Services
6. Orthopedic Procedures
7. Skin Procedures
8. Urology and Related Services Procedures
9. Vascular Procedures (Excluding Endovascular Procedures)

The rule’s tables 18-36 reflect the current APC assignments and the proposed CY 2016 assignments.

IV. PROPOSED OPSS PAYMENT FOR DEVICES

A. Proposed Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

There currently is one device category eligible for pass-through payment that will end on Dec. 31, 2015: HCPCS code C1841 (Retinal prosthesis, includes all internal and external components).

CMS is proposing to package the costs of the HCPCS code C1841 devices into the costs related to the procedures with which the device is reported in the hospital claims data.

2. Proposed Provisions for Reducing Transitional Pass-through Payments to Offset Costs Packaged into APC Groups

CMS is proposing to update the list of all procedural APCs with the final CY 2016 portions of the APC payment amounts that it determines are associated with the cost of devices on CMS' website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

B. Proposed Device-Intensive Procedures

Under the OPSS, device-intensive APCs are defined as those APCs with a device offset greater than 40 percent.

CMS is proposing for CY 2016 that only the procedures that require the implantation of a device that are assigned to a device-intensive APC would require a device code on the claim. The list of device-intensive APCs is listed in the table below.

Proposed CY 2016 Device-Intensive APCs	
Proposed Renumbered CY 2016*	Proposed CY 2016 APC Title
0039	Level III Neurostimulator & Related Procedures
0061	Level II Neurostimulator & Related Procedures
0089	Level III Pacemaker & Similar Procedures
0090	Level II Pacemaker & Similar Procedures
0105	Level I Pacemaker & Similar Procedures
0107	Level I ICD & Similar Procedures
0108	Level II ICD & Similar Procedures
0227	Implantation of Drug Infusion Device
0229	Level II Endovascular Procedures
0259	Level VI ENT Procedures
0293	Level III Intraocular Procedures
0318	Level IV Neurostimulator & Related Procedures
0319	Level III Endovascular Procedures
0351	Level IV Intraocular Procedures
0386	Level VII Urology & Related Procedures
0425	Level IV Musculoskeletal Procedures
0655	Level IV Pacemaker & Similar Procedures
1564	New Technology – Level 27
1593	New Technology – Level 46

C. Proposed Adjustment to OPSS Payment for Partial or Full Credit Devices

CMS is proposing to no longer specify a list of devices to which the OPSS payment adjustment for no cost/full credit and partial credit devices would apply. Instead,

CMS is 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 specified device that is 50 percent or greater than the cost of the device.

V. PROPOSED OPPTS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

A. Proposed OPPTS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

Proposed Drugs and Biologicals with Expiring Pass-Through Status in CY 2015

CMS is proposing that the pass-through status of 12 drugs and biologicals would expire on Dec. 31, 2015, as listed in the table below.

Proposed Drugs and Biologicals for which Pass-Through Status Will Expire Dec. 31, 2015			
CY 2015 HCPCS Code	CY 2015 Long Descriptor	CY 2015 SI	CY 2015 APC
A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	N	N/A
C9132	Prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activity	K	9132
J1556	Injection, immune globulin (Bivigam), 500 mg	K	9130
J3060	Injection, taliglucerase alfa, 10 units	K	9294
J7315	Mitomycin, ophthalmic, 0.2 mg	N	N/A
J7316	Injection, Ocriplasmin, 0.125mg	K	9298
J9047	Injection, carfilzomib, 1 mg	K	9295
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	K	9297
J9354	Injection, ado-trastuzumab emtansine, 1 mg	K	9131
J9400	Injection, Ziv-Aflibercept, 1 mg	K	9296
Q4122	Dermacell, per square centimeter	N	N/A
Q4127	Talymed, per square centimeter	N	N/A

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2016

CMS is proposing to continue pass-through payment status in CY 2016 for 32 drugs and biologicals, and to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2016.

The 32 drugs are displayed in the rule's Table 40. The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator "G" in Addenda A and B.

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

CMS is proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals. For CY 2016, there will be one diagnostic radiopharmaceutical with pass-through status under the OPSS, HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries).

Proposed Payment Offset Policy for Contrast Agents

There are currently no contrast agents with pass-through status under the OPSS.

Proposed Payment Offset Policy for Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure (Other Than Diagnostic Radiopharmaceuticals and Contrast Agents and Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure)

For CY 2016, as CMS did in CY 2015, CMS is to continue to apply the skin substitute and stress agent offset policy to payment for pass-through skin substitutes and stress agents. For 2016, there will be two skin substitutes (HCPCS codes Q4121 and C9349) with pass-through payment status under the OPSS.

B. Proposed OPSS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status

CMS is proposing to package items with a per day cost less than or equal to \$100, and identify items with a per day cost greater than \$100 as separately payable.

Proposed High/Low Cost Threshold for Packaged Skin Substitutes

CMS has posted a file on the CMS Web site that provides details on the CY 2016 high/low cost status for each skin substitute product based on a measure under consideration threshold (rounded to the nearest \$1) of \$25 per cm² and a per day cost threshold (rounded to the nearest \$1) of \$1,050.

The rule's Table 46 shows the current high/low cost status for each skin substitute product.

Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

CMS will continue to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages.

The rule's table 47 contains the list of these proposed HCPCS codes.

Proposed Payment for Specified Covered Outpatient Drugs and Other Separately Payable and Packaged Drugs and Biologicals

For CY 2016 and subsequent years, CMS is proposing to continue its CY 2015 policy and pay for separately payable drugs and biologicals at ASP+6 percent.

Proposed Payment Policy for Therapeutic Radiopharmaceuticals

CMS is proposing for CY 2016 to pay all non-pass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent.

Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

For CY 2016, CMS is proposing to

continue to provide an additional \$10 payment for radioisotopes produced by non-HEU sources.

Payment for Blood Clotting Factors

For CY 2016, CMS is proposing to pay for blood clotting factors at ASP+6 percent.

Proposed Payment for Non-pass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but without OPSS Hospital Claims

For CY 2016, CMS is proposing to provide payment for new drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at ASP+6 percent.

For CY 2016, CMS is proposing to continue to assign status indicator “E” to drugs and biologicals that lack CY 2014 claims data and pricing information for the ASP methodology.

C. Proposed OPSS Payment for Biosimilar Biological Products

CMS is proposing to extend the application of the methodology for determining the amount of payment applicable to separately covered outpatient drugs to biosimilar biological products provided under the OPSS.

VI. PROPOSED ESTIMATE OF OPSS TRANSITIONAL PASS-THROUGH SPENDING FOR DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND DEVICES

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an “applicable percentage” (currently 2.0 percent) of total program payments estimated to be made for all covered

services under the hospital OPSS furnished for that year.

CMS estimates that proposed total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2016 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2016 would be approximately \$146.6 million (approximately \$136.8 million for device categories and approximately \$9.8 million for drugs and biologicals), which represents 0.25 percent of total projected OPSS payments for CY 2016. Therefore, CMS estimates that proposed pass-through spending in CY 2016 would not amount to 2.0 percent of total projected OPSS CY 2016 program spending.

VII. PROPOSED OPSS PAYMENT FOR HOSPITAL OUTPATIENT VISITS

Proposed Payment for Hospital Outpatient Clinic and Emergency Department Visits

CMS is proposing to continue the current policy, adopted in CY 2014, for clinic and ED visits. CMS is proposing to reassign HCPCS code G0463 from existing APC 0634 to proposed renumbered APC 5012 (Level 2 Examinations and Related Services), former APC 0632. Proposed renumbered APC 5012 includes other services that are clinically similar with similar resource costs to HCPCS code G0463, such as HCPCS code G0402 (Initial preventive physical examination).

Proposed Payment for Chronic Care Management Services

CMS is proposing 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.

CMS is proposing, for CY 2016 and subsequent years, that hospitals furnishing and billing services described by CPT code 99490 under the OPPTS would be required to have documented in the hospital’s medical record the patient’s agreement to have the 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. In addition, for CY 2016 and subsequent years, CMS is proposing to require hospitals furnishing and billing for the CCM services described by CPT code 99490 under the OPPTS to have documented 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.

VIII. PROPOSED PAYMENT FOR PARTIAL HOSPITALIZATION PROGRAM SERVICES

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness.

CMS is proposing to renumber the four PHP APCs, that is, APCs 0172, 0173, 0175, and 0176, as APCs 5851, 5852, 5861, and 5862, respectively.

The proposed CY 2016 geometric mean per diem costs for the PHP APCs are shown in the tables below.

Proposed CY 2016 PHP APC Geometric Mean Per Diem Costs For CMHC PHP Services		
Proposed Renumbered CY 2016 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5851	Level 1 Partial Hospitalization (3 services) for CMHCs	\$105.82
5852	Level 2 Partial Hospitalization (4 or more services) for CMHCs	\$147.51

Proposed CY 2016 PHP APC Geometric Mean Per Diem Costs for Hospital-Based PHP Services		
Proposed Renumbered CY 2016 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5861	Level 1 Partial Hospitalization (3 services) for hospital-based PHPs	\$195.73
5862	Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs	\$218.93

IX. PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

For CY 2016, CMS is proposing to remove the following procedures from the inpatient only list:

- CPT code 0312T (Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction, with implantation of pulse generator, includes programming);
- CPT code 20936 (Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from the same incision);
- CPT code 20937 (Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision));
- CPT code 20938 (Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision));
- CPT code 22552 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophy-tectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace);
- CPT code 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); and
- CPT code 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 complete list of codes that CMS is proposing to be paid by Medicare in CY 2016 only as inpatient procedures is included as Addendum E.

X. PROPOSED NONRECURRING POLICY CHANGES

Changes for Payment for Computed Tomography

Effective for services furnished on or after January 1, 2016, new section 1834(p) of the Act reduces payment for the technical component of applicable computed tomography services paid under the MPFS and applicable CT services paid under the OPPS (a 5-percent reduction in 2016 and a 15-percent reduction in 2017 and subsequent years).

CMS is proposing to establish a new modifier to be used on claims that describes CT services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR-29-2013. Beginning Jan. 1, 2016, hospitals and suppliers would be required to use this modifier on claims for CT scans described by any of the CPT codes (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scans. The use of this proposed modifier would result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

The applicable CT services are identified by HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574.

Lung Cancer Screening with Low Dose Computed Tomography

For the CY 2016 OPPIs, CMS is proposing to assign HCPCS code GXXX1 to proposed renumbered APC 5822 (Level 2 Health and Behavior Services) (existing APC 0432) and HCPCS code GXXX2 to proposed renumbered APC 5570 (Computed Tomography without Contrast) (existing APC 0332).

Payment for Corneal Tissue in the HOPD and the ASC

CMS is proposing to limit the separate payment policy for corneal tissue acquisition costs in the HOPD and the ASC to only corneal tissue that is used in a corneal transplant procedure.

XI. PROPOSED CY 2016 OPPI PAYMENT STATUS AND COMMENT INDICATORS

The proposed CY 2016 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, which are available on CMS' website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

XII. PROPOSED UPDATES OF THE REVISED AMBULATORY SURGICAL CENTER PAYMENT SYSTEM

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. The tables that follow identify codes that CMS is addressing in the proposed rule.

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

New Level II HCPCS Codes for Covered Ancillary Services Implemented in April 2015		
CY 2015 HCPCS Code	CY 2015 Long Descriptor	Proposed CY 2016 Payment Indicator
C2623	Catheter, transluminal angioplasty, drug-coated, non- laser	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

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

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
C2613	Lung biopsy plug with delivery system	J7
C9453	Injection, nivolumab, 1 mg	K2
C9454	Injection, pasireotide long acting, 1 mg	K2
C9455	Injection, siltuximab, 10 mg	K2
Q9978*	Netupitant 300 mg and Palonosetron 0.5 mg, oral	K2

*HCPCS code Q9978 replaced HCPCS code C9448 effective July 1, 2015.

New Category III CPT Codes for Covered Surgical Procedures or Covered Ancillary Services Implemented Implemented in July 2015		
CY 2015 CPT Code	CY 2015 Long Descriptor	Proposed CY 2016 Payment Indicator
0392T	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band)	G2
0393T	Removal of esophageal sphincter augmentation device	G2

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

Proposed Changes for CY 2016 to Covered Surgical Procedures Designated as Office-Based

CMS' review of the CY 2014 volume and utilization data resulted in the identification of two covered surgical procedures, CPT codes 43197 (Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 43198 (Esophagoscopy, flexible, transnasal; with biopsy, single or multiple) that CMS says meets the criteria for designation as office-based.

The proposed CY 2016 payment indicator designations for the procedures that were temporarily designated as office-based in CY 2015 are displayed below.

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*

CY 2015 CPT Code	CY 2015 Long Descriptor	CY 2015 ASC Payment Indicator	Proposed CY 2016 ASC Payment Indicator**
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*
4617	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 infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2*	R2*

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard rate-setting methodology and the MPFS proposed rates.

CMS is also proposing to designate certain new CY 2016 codes for ASC covered surgical procedures as temporary office-based.

Proposed CY 2016 OP/ASC Proposed Rule 5-Digit CMS Placeholder Code***	Proposed CY 2016 Long Descriptor	Proposed CY 2016 ASC Payment Indicator**
6446A	Paravertebral block (PVB) (paraspinal block), thoracic; single injection site (includes imaging guidance, when performed)	R2*
6446C	Paravertebral block (PVB) (paraspinal 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 rate-setting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2016.

***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 CMS' website.

Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2016

The 186 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 rule's Table 62.

Proposed Adjustment to ASC Payments for Discontinued Device-Intensive Procedures

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.

CMS is proposing that where the device offset is removed 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 OPPI.

Proposed Additions to the List of ASC Covered Surgical Procedures

CMS is proposing to update the list of ASC covered surgical procedures by adding 11 procedures to the list 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

Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

For CY 2016, the proposed CY 2016 ASC wage indexes fully reflect the new OMB labor market area delineations.

The annual update to the ASC payment system is the CPI-U (referred to as the CPI-U update factor). Based on IHS Global Insight's 2015 first quarter forecast with historical data through 2014 fourth quarter, for the 12-month period ending with the midpoint of CY 2016, the CPI-U update is projected to be 1.7 percent. The MFP adjustment for the period ending with the midpoint of CY 2016 is projected to be 0.6 percent.

CMS is proposing to adjust the CY 2015 ASC conversion factor (\$44.058) by a 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 (1.1 minus 2.0), which results in a proposed CY 2016 ASC conversion factor of \$43.723.

XIII. HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM UPDATES

Proposed Hospital OQR Program Quality Measure for Removal for CY 2017 Payment Determination and Subsequent Years

CMS is proposing to remove one measure for the CY 2017 payment determination and subsequent years -- OP-15: Use of Brain Computed Tomography

in the Emergency Department for Atraumatic Headache.

Proposed New Hospital OQR Program Quality Measures for the CY 2018 and CY 2019 Payment Determinations and Subsequent Years

Proposed New Quality Measure for the CY 2018 Payment Determination and Subsequent Years: OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822)

Proposed New Hospital OQR Program Quality Measure for the CY 2019 Payment Determination and Subsequent Years: OP-34: Emergency Department Transfer Communication (NQF #0291)

The proposed and previously finalized measures for the CY 2019 payment determination and subsequent years are listed below.

Proposed Hospital OQR Program Measure Set for the CY 2019 Payment Determination and Subsequent Years

NQF #	Measure Name
N/A	OP-1: Median Time to Fibrinolysis
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0289	OP-5: Median Time to ECG
0514	OP-8: MRI Lumbar Spine for Low Back Pain
N/A	OP-9: Mammography Follow-up Rates
N/A	OP-10: Abdomen CT – Use of Contrast Material
0513	OP-11: Thorax CT – Use of Contrast Material
N/A	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non- Cardiac Low-Risk Surgery
N/A	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
N/A	OP-17: Tracking Clinical Results between Visits
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
N/A	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
0662	OP-21: Median Time to Pain Management for Long Bone Fracture
N/A	OP-22: ED- Left Without Being Seen
0661	OP-23: ED- Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival
N/A	OP-25: Safe Surgery Checklist Use
N/A	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures*
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel
0658	OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients
0659	OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use
1536	OP-31: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery**
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
1822	OP-33: External Beam Radiotherapy for Bone Metastases****
0291	OP-34: Emergency Department Transfer Communication Measure****

* OP-26: Procedure categories and corresponding HCPCS codes are located at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244>.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

*** New measure proposed for the CY 2018 payment determination and subsequent years.

**** New measure proposed for the CY 2019 payment determination and subsequent years.

COMMENT

There is much more to the issue and subject to quality than the above lists. The rule addresses issues for future considerations, Maintenance of Technical Specifications for Quality Measures, Public Display of Quality Measures, Form, and Manner, and Timing of Data Submitted for the Hospital OQR Program.

CMS has devoted some 53 page to the OQR system.

XIV. REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY-REPORTING (ASCQR) PROGRAM

ASCQR Program Quality Measures for the CY 2018 Payment Determination and Subsequent Years

CMS is not proposing to adopt any additional measures for the ASCQR Program for the CY 2018 payment determination and subsequent years in this proposed rule.

XV. SHORT INPATIENT HOSPITAL STAYS (2-MIDNIGHT RULE)

COMMENT

The issue of the 2-midnight rule and CMS proposed changes does not appear to provide real change. Below are several statements that would suggest changes are minimal.

“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 under § 419.22 of the regulations.

“Conversely, when a beneficiary enters a hospital for a surgical procedure not specified as inpatient only under § 419.22(n), 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.

“We continue 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.

“With respect to the 2-midnight benchmark, we have been clear that this instruction does not override the clinical judgment of the physician regarding the need to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital.

“We continue 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, although we acknowledge that our current payment policy and medical review policy focus on physician judgment regarding the expected duration of medically necessary hospital care.

“We are proposing to modify our existing “rare and unusual” exceptions policy to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, 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.

“We note that, under the existing rare and unusual policy, only one exception—prolonged mechanical ventilation—has been identified to date.

“We also are not proposing to change the 2-midnight presumption.

“We note that our proposed change in policy for payment of hospital care expected to last less than 2 midnights does not negate our longstanding policy, which recognizes that there are certain situations in which a hospital inpatient admission is rarely appropriate for Medicare Part A payment.”

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