Issue Brief

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KEY POINTS

- Hospitals paid through the outpatient PPS system should expect a payment decrease of 0.4 percent in 2016, while ASC payments will increase by 0.3 percent.
- The calendar year 2016 OPPS rule maintains the benchmark established by the original "Two-Midnight" rule and permits greater flexibility for determining when an admission that does not meet the benchmark should be considered inpatient.

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

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

CMS says that the 1,221-page rule (which is twice as long as the proposed rule) will update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and ASCs beginning Jan. 1, 2016.

Further, CMS is making certain changes relating to the hospital inpatient prospective payment system: changes to the two-midnight rule under the short inpatient hospital stay policy; and a payment transition for hospitals that lost their MDH status because they are no longer in a rural area due to the implementation of the new OMB delineations in FY 2015 and have not reclassified from urban to rural under 42 CFR 412.103 before Jan. 1, 2016.

In addition, the rule updates and refines requirements for the Hospital Outpatient Quality Reporting Program and the ASC Quality Reporting Program.

A copy of the document is available at: https://www.federalregister.gov/articles/2015/11/13/2015-27943/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment. Publication in the Federal Register is scheduled for November 13.

COMMENT

The rule becomes longer and longer every year. Its table of contents alone is now some 21 pages. Nonetheless, it does have a well-organized and very good executive summary.

One of the most striking items is CMS' requirement that will reduce the OPPS update by 2.0 percent 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 says this decision will decrease CY 2016 payments by approximately $133 million compared to CY 2015 payments, excluding estimated changes in enrollment, utilization and case-mix.

To put it simply, this reduction is outrageous and should open the door to all types of errors in forecasting. Of course, this is another adjustment that will benefit the government. What about all the years'

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that CMS has understated, for example, inpatient PPS outlier payments without any adjustments? Underpayments for outliers that mostly accrue to the benefit to providers.

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."

A second major issue involves the so-called two-midnight rule. The two-midnight rule was adopted effective Oct. 1, 2013. Under the two-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 two 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 two midnights of care in the hospital, the services furnished should generally be billed as outpatient services.

CMS is modifying the existing "rare and unusual" exceptions policy under which the only exceptions to the 2-midnight benchmark to also allow exceptions to the two-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 two-midnight benchmark. In addition, CMS is revising the medical review strategy and announcing that no later than Oct. 1, 2015, it is changing the medical review strategy and have quality improvement organization contractors conduct reviews rather than the Medicare administrative contractors.

Based on this material, it seems that very little is being done to truly change CMS' position on the subject.

SUMMARY OF MAJOR PROVISIONS

OPPS Update

CMS is updating the OPPS rates based on a projected hospital market basket increase of 2.4 percent minus both a 0.5 percentage point adjustment for the multi-factor productivity and a 0.2 percentage point adjustment both required by the Affordable Care Act. There is the additional finalized 2.0 percentage point adjustment to the payment update to "redress inflation in the OPPS payment rates resulting from excess packaged payment for laboratory tests that continue to be paid separately outside of the OPPS." The final rate update will be -0.3 percent. After all other policy changes finalized under the OPPS, including estimated spending for pass-through payments, CMS estimates a -0.4 percent change in spending (before taking into account changes in volume and case mix).

Rural Adjustment

CMS will continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals, including essential access community hospitals.

Cancer Hospital Payment Adjustment

CMS will continue to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio after the additional payments is equal to the weighted average PCR for other OPPS hospitals using the most recently submitted or settled cost report data. Based on those data, a target PCR of 0.92 will be used to determine the CY 2016 cancer hospital payment adjustment to be paid at cost report settlement.

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Payment of Drugs, Biologicals and Radiopharmaceuticals

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 will pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. CMS also is extending 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.

Payment of Skin Substitutes

Payment for skin substitutes will utilize a high/low cost APC structure based on exceeding a threshold based on mean unit cost or per day cost. Further, for CY 2016, skin substitutes with pass-through payment status will be assigned to the high cost category. Skin substitutes with pricing information but without claims data to calculate either an MUC or PDC will be assigned to either the high cost or low cost category based on the product's ASP+6 percent payment rate. Moreover, any new skin substitutes without pricing information will be assigned to the low cost category until pricing information is available.

Packaging Policies

For CY 2016, CMS is expanding the set of conditionally packaged ancillary services to include three new APCs.

Conditionally Packaged Outpatient Laboratory Tests

CMS is conditionally packaging 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 establishing 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 will be made. The "L1"modifier will still be used for "unrelated" laboratory tests.

Comprehensive APCs

CMS is creating nine new C-APCs.

APC Restructuring

CMS says it conducted a comprehensive review of the structure of the APCs and codes and is restructuring the OPPS 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 long-standing APCs; and (4) greater simplicity and improved understandability of the OPPS APC structure.

New Process for Device Pass-Through Payment

CMS is adding a rulemaking component to the current quarterly device pass-through payment application process. Specifically, CMS is supplementing the quarterly process by including a description of applications received as well as its rationale for approving the application in the next applicable OPPS proposed rule. Applications that are not approved based on the evidence available during the quarterly review process will be described in the next applicable OPPS proposed rule, unless

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the applicant withdraws its application.

CMS is establishing policy 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 three years from the date of the initial FDA premarket approval or clearance, or, in the case of a delay of market availability, within three years of market availability.

Advanced Care Planning

CMS is conditionally packaging payment for the service described by CPT code 99497 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate).

Consequently, this code is assigned to a conditionally packaged payment status indicator of "Q1." When this service is furnished with another service paid under the OPPS, payment will be packaged; when it is the only service furnished, payment will be made separately.

Chronic Care Management

CMS is adding 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 January 1, 2016, section 218(a) of the Protecting Access to Medicare Act of 2014 Act amended section 1834 of the Act by establishing a new subsection 1834(p), which 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 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 establishing a new modifier that will be reported with specific CPT codes, effective Jan. 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 finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that will be effective January 1. Specifically, CMS stated that it would include the 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 AMA provides CMS with the codes in time for the OPPS/ASC

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proposed rule. For the CY 2016 OPPS update, CMS received the CY 2016 CPT codes from AMA for inclusion in the CY 2016 OPPS/ASC proposed rule.

Ambulatory Surgical Center Payment Update

CMS is increasing payment rates under the ASC payment system by 0.3 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a projected CPI–U update of 0.8 percent minus a multifactor productivity adjustment required by the ACA of 0.5 percentage point. Based on this update, CMS estimates that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2016 will be approximately $4.221 billion, an increase of approximately $128 million compared to estimated CY 2015 Medicare payments.

Hospital Outpatient Quality Reporting Program

For CY 2017 and subsequent years, CMS is: (1) removing the OP-15: Use of Brain Computed Tomography in the Emergency Department for Atraumatic Headache measure, effective January 1, 2016 (no data for this measure will be used for any payment determination); (2) changing the deadline for withdrawing from the Hospital OQR Program from November 1 to August 31 and revising the related regulations to reflect this change; (3) transitioning to a new payment determination timeframe that will use only three quarters of data for the CY 2017 payment determination; (4) making conforming changes to the validation scoring process to reflect changes in the APU determination timeframe; (5) changing the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet website) to Jan. 1 through May 15; (6) fixing a typographical error to correct the name of an extension and exception policy to extension and exemption policy; (7) changing the deadline for submitting a reconsideration request to the first business day on or after March 17 of the affected payment year; and (8) amending 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 (1) adding a new measure: OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822) with a modification to the proposed manner of data submission, and (2) shifting the quarters on which CMS bases payment determinations to again include four quarters of data.

In addition, CMS is exploring use of electronic clinical quality measures and whether, in future rulemaking, CMS will propose that hospitals have the option to voluntarily submit data for the OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients measure electronically possibly beginning with the CY 2019 payment determination.

Ambulatory Surgical Center Quality Reporting Program

CMS is aligning its policies regarding paid claims to be included in the calculation for all claims-based measures, modifying the submission date for reconsideration requests, modifying policies for the facility identifier for public reporting of ASCQR Program data, and finalizing the policy to not consider Indian Health Service hospital outpatient departments that bill as ASCs to be ASCs for purposes of the ASCQR Program. In addition, CMS is continuing to use the existing submission deadlines for data submitted via an online data submission tool. CMS also is codifying a number of existing and new policies.

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Information Sites

The Addenda relating to the OPPS 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 OPPS PAYMENTS

A. Recalibration of APC Relative Weights

The CY 2016 APC relative weights and payments are in Addenda A and B (which are available on CMS' website) were calculated using claims from CY 2014 that were processed through Dec. 31, 2014.

Calculation and Use of Cost-to-Charge Ratios

For CY 2016, CMS is continuing 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.

Calculation of Single Procedure APC Criteria-Based Costs

1. Blood and Blood Products

CMS is continuing 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 CY 2016 payment rates for blood and blood products (which are identified with status indicator "R").

- New HCPCS Codes for Pathogen-Reduced Blood Products

The HCPCS Workgroup established three new HCPCS P-codes for new pathogen-reduced blood products, effective Jan. 1, 2016, as follows:

- P9070 (Plasma, pooled multiple donor, pathogen reduced, frozen, each unit);
- P9071 (Plasma (single donor), pathogen reduced, frozen, each unit); and
- P9072 (Platelets, pheresis, pathogen reduced, each unit).

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The table below list the new pathogen reduced blood products HCPCS P-codes and their payment crosswalks.

New CY 2016 HCPCS P-Code	New HCPCS P-Code Long Descriptor	Crosswalked HCPCS P-Code	Crosswalked HCPCS P-Code Long Descriptor	Final CY 2016 OPPS Payment Amount
P9070	Plasma, pooled multiple donor, pathogen reduced, frozen, each unit	P9059	Fresh frozen plasma between 8-24 hours of collection, each unit	$73.08
P9071	Plasma (single donor), pathogen reduced, frozen, each unit	P9017	Fresh frozen plasma (single donor), frozen within 8 hours of collection, each unit	$72.56
P9072	Platelets, pheresis, pathogen reduced, each unit	P9037	Platelets, pheresis, leukocytes reduced, irradiated, each unit	$641.85

2. Brachytherapy Sources
The CY 2016 final payment rates for brachytherapy sources are found in Addendum B (which is available on CMS' website).

Comprehensive APCs for CY 2016

CMS is adding 10 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 newly adopted for CY 2016, are displayed in the table below with the new C-APCs denoted with an asterisk.

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

CY 2016 C-APCs			
CY 2016 C-APC+	CY 2016 APC Group Title	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	*

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CY 2016 C-APCs			
CY 2016 C-APC+	CY 2016 APC Group Title	Clinical Family	New C-APC
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	
5125	Level 5 Musculoskeletal Procedures	ORTHO	*
5471	Implantation of Drug Infusion Device	PUMPS	
5627	Level 7 Radiation Therapy	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 this final rule with comment period for a discussion of the overall restructuring and renumbering of APCs.

**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

Observation Comprehensive APC (C-APC 8011)

CMS will pay for all qualifying extended assessment and management encounters through

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a newly created "Comprehensive Observation Services" C-APC (C-APC 8011) and to assign the services within this APC to new status indicator "J2."

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

- The claims do not contain a procedure described by a HCPCS code to which CMS has assigned status indicator "T";
- The claims contain eight or more units of services described by HCPCS code G0378 (observation services, per hour);
- The claims contain services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by 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 99281 (emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (emergency department visit for the evaluation and management of a patient (Level 3)); 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 G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); 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); and
- The claims do not contain a service that is described by a HCPCS code to which CMS has assigned status indicator "J1."

The final CY 2016 geometric mean cost for C-APC 8011 resulting from this methodology is approximately $2,275, based on 1,338,889 claims used for rate setting.

CMS is deleting APC 8009, as it will be replaced with new C-APC 8011 (Comprehensive Observation Services).

CY 2016 Policies for Specific C-APCs

1. Stereotactic Radiosurgery

CMS is finalizing its proposal to remove planning and preparation services (identified by the following 10 specific HCPCS codes: 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) from the geometric mean cost calculations for proposed C-APC 5631 which, beginning in CY 2016, will be C-APC 5627 (Level 7 Radiation Therapy).

In addition, for CY 2016 and CY 2017, CMS will separately pay for planning and preparation services adjunctive to the delivery of the SRS treatment through either modality, regardless of whether they are furnished on the same date of service as the primary "J1" SRS service.

2. Data Collection for Non-Primary Services in C-APCs

Effective Jan. 1, 2016, hospitals must use the HCPCS code modifier "CP" (Adjunctive service related to a

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procedure assigned to a comprehensive ambulatory payment classification (C-APC) procedure, but reported on a different claim) to report adjunctive service(s) related to a primary "J1" SRS services that is reported on a separate claim than the primary "J1" service. With respect to other C-APCs, CMS is not adopting a policy to require the use of the HCPCS code modifier to identify adjunctive services that are reported separately at this time, but may consider doing so in the future.

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

CMS will provide comprehensive payment through renumbered C-APC 5881 for all services reported on the same claim as an inpatient only procedure billed with modifier "–CA."

Calculation of Composite APC Criteria-Based Costs

(1) Low Dose Rate Prostate Brachytherapy Composite APC

CMS will continue to use the payment rate for composite APC 8001 to pay for LDR prostate brachytherapy services for CY 2016.

(2) Mental Health Services Composite APC

When the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be assigned to renumbered composite APC 8010 (Mental Health Services Composite) (existing APC 0034) for CY 2016. For CY 2016, CMS also will continue to set the payment rate for renumbered composite APC 8010 (existing APC 0034) at the same payment rate established for renumbered APC 5862 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) (existing APC 0176), which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital will continue to be paid the payment rate for renumbered composite APC 8010.

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

CMS will 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 10 lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2016.

Changes to Packaged Items and Services

(1) Ancillary Services

CMS is finalizing its proposal to conditionally packaged ancillary services assigned to APCs 5734, 5673, and 5674 for CY 2016. The three APCs and their CY 2016 final status indicators and payment rates are displayed below.

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APCs for Conditionally Packaged Ancillary Services for CY 2016			
Renumbered CY 2016 APC*	CY 2016 APC Title	CY 2016 OPPS Status Indicator	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

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

Preventive Services Exempted		
HCPCS Code	Short Descriptor	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

(2) Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure
Based on clinical review, for CY 2016, CMS will 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 for Unconditional Packaging				
HCPCS Code	Descriptor	CY 2015 Status Indicator	Primary Use in Surgical Procedure	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) CMS will standardize all of the relative payment weights to APC 0632 to which HCPCS code G0463 will now be assigned.
For CY 2016, CMS will renumber APC 0632 as APC 5012 (Level 2 Examination and Related Services).

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B. Conversion Factor Update

For CY 2016, CMS is using a conversion factor of $73.725 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. That is, the OPD fee schedule increase factor of 1.7 percent for CY 2016, a required wage index budget neutrality adjustment of 0.9992, a cancer hospital payment adjustment of 0.9994, the negative 2.0 percent adjustment to the conversion factor to eliminate the effects of classification changes that would otherwise result in an increase in aggregate OPPS payments (due to excess packaged payment under the OPPS for laboratory tests), and an adjustment of -0.13 percentage point of projected OPPS spending for the difference in the pass-through spending result in a conversion factor for CY 2016 of $73.725.

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points — $72.251.

Conversion factor to redress the inflation in the OPPS payment rates

CMS will 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.

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 OPPS by approximately $1 billion. This $1 billion effectively resulted in inflation in the OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests for all OPPS services and duplicate payments for certain laboratory tests packaged payment incorporated into the OPPS payment rates as well as through separate payment at the CLFS payment rates outside the OPPS.

COMMENT

This and other similar reductions throughout the various Medicare PPS programs is cause for much alarm. Without saying so, CMS is making reductions where it can to reduce payments. Without a corresponding system to fix all forecast errors, the program may no longer be sincere in setting accurate and appropriate rates.

CMS needs to address all forecast errors, no matter how small, and account for them in a prospective measure going forward. To do otherwise would seem to corrupt the basics of the system.

C. Wage Index Changes

The OPPS labor-related share remains at 60 percent of the national OPPS 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 will use the FY 2016 hospital IPPS wage index for urban and rural areas as the wage index for the OPPS hospital to determine the wage adjustments for the OPPS payment rate and the copayment standardized amount for CY 2016.

CMS is referring readers to its for the OPPS at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. At this link, readers will find a link to the final FY 2016 IPPS wage index tables and Addendum L.

D. Statewide Average Default CCRs

The rule's table 14 lists the final CY 2016 default urban and rural CCRs by State.

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

CMS will 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 OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. OPPS Payment to Certain Cancer Hospitals

For CY 2016, CMS will 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 OPPS hospitals using the most recent submitted or settled cost report data that are available.

The table below indicates the estimated percentage increase in OPPS 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 OPPS Payments for CY 2016
050146	City of Hope Comprehensive Cancer Center	21.6%
050660	USC Norris Cancer Hospital	21.9%
100079	Sylvester Comprehensive Cancer Center	25.1%
100271	H. Lee Moffitt Cancer Center & Research Institute	27.3%
220162	Dana-Farber Cancer Institute	51.1%
330154	Memorial Sloan-Kettering Cancer Center	46.9%
330354	Roswell Park Cancer Institute	31.4%
360242	James Cancer Hospital & Solove Research Institute	35.4%
390196	Fox Chase Cancer Center	23.7%
450076	M.D. Anderson Cancer Center	50.9%
500138	Seattle Cancer Care Alliance	57.3%

G. Hospital Outpatient Outlier Payment

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

CMS now estimates that a fixed-dollar threshold of $3,250, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of aggregated total OPPS payments to outlier payments.

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

COMMENT

CMS says that it paid 0.1 percentage points below the CY 2014 outlier target of 1.0 percent of total aggregated OPPS payments. Once again, nothing is said or done to make up this shortfall.

III. OPPS AMBULATORY PAYMENT CLASSIFICATION GROUP POLICIES

A. OPPS Treatment of New CPT and Level II HCPCS Codes

Treatment of New CY 2015 Level II HCPCS and CPT Codes Effective April 1, 2015 and July 1.

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

New Level II HCPCS Codes Implemented in April 2015			
CY 2015 HCPCS Code	**CY 2015 Long Descriptor**	**CY 2016 Status Indicator**	**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	G	9448
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 C9136 (Injection, factor viii, fc fusion protein (recombinant), per i.u.) was deleted on March 31, 2015 and replaced with HCPCS code Q9975.

The following CPT and Level II HCPCS codes were implemented on July 1, 2015.

New Category III CPT and Level II HCPCS Codes Implemented in July 2015				
CY 2015 CPT/HCPCS Code	CY 2016 CPT/HCPCS Code	CY 2016 Long Descriptor	Final CY 2016 Status Indicator	Final CY 2016 APC
C2613	C2613	Lung biopsy plug with delivery system	H	2613
C9453	J9299	Injection, nivolumab, 1 mg	G	9453
C9454	J2502	Injection, pasireotide long acting, 1 mg	G	9454
C9455	J2860	Injection, siltuximab, 10 mg	G	9455
Q5101*	Q5101*	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	G	1822
Q9976	J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron	E	N/A
Q9977	Q9977**	Compounded Drug, Not Otherwise Classified	D	N/A
Q9978	J8655	Netupitant 300 mg and palonosetron 0.5 mg	G	9448
0392T	0392T	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band)	J1	5362
0393T	0393T	Removal of esophageal sphincter augmentation device	Q2	5361

*HCPCS code Q5101, which described the drug Zarxio, was approved by the FDA on March 6, 2015.Separate payment for Zarxio was effective September 3, 2015, the date the drug was marketed.

**HCPCS code Q9977 will be deleted December 31, 2015, and a replacement code will not be established.

B. OPPS Changes – Variations Within APCs

The following table lists three APCs that CMS will exempt from the two times rule for CY 2016.

APC Exceptions to the 2 Times Rule for CY 2016	
CY 2016 APC*	CY 2016 APC Title
5165	Level 5 ENT Procedures
5731	Level 1 Minor Procedures
5841	Psychotherapy

C. 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 will establish a new set of New Technology APCs 1575 through 1583(for Levels 38 through 46) with OPPS status indicator "S" and a new set of New Technology APCs1585 through 1593 (for Levels 38 through 46) with OPPS status indicator "T." In addition, CMS is adding two additional levels, New Technology Levels 47 and 48.

The rule's Table 21 contains the complete list of the Technology APC groups.

Transprostatic Urethral Implant Procedure
CMS is reassigning HCPCS code C9740 from New Technology APC 1564 to New Technology APC 1565, and reassigning HCPCS code C9739 from clinical APC 5374 to APC 5375. CMS notes that the APC to which HCPCS code C9740 is assigned is designated as a device-intensive APC, which will require reporting the appropriate device code (in this case, HCPCS code L8699) when the surgical procedure describing HCPCS C9740 is reported on the claim.

Retinal Prosthesis Implant Procedure
CPT code 0100T (Placement of a subconjunctival 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 assigning CPT code 0100T to New Technology APC 1599, which has a final payment of $95,000. This payment rate includes the payment for the retinal prosthesis system as well as all other items and supplies used in the surgical procedure to implant the device. Because payment for retinal prosthesis is included in CPT code 100T, CMS is finalizing its proposal to assign HCPCS code C1841 to OPPS status indicator "N" to indicate that this code is packaged under the hospital OPPS.

D. OPPS Ambulatory Payment Classification Group Policies

CMS will restructure nine APC clinical families. The final payment rates for the nine individual clinical family APCs are included in Addendum A

The nine families are:

- Airway Endoscopy Procedures
- Diagnostic Tests and Related Services
- Excision/Biopsy and Incision and Drainage Procedures
- Gastrointestinal Procedures
- Imaging Services
- Orthopedic Procedures
- Skin Procedures
- Urology and Related Services Procedures
- Vascular Procedures (Excluding Endovascular Procedures)

COMMENT

While CMS says it is adopting refinement to nine families, its discussion addresses the following:

- Airway Endoscopy Procedures
- Cardiovascular Procedures and Services
- Diagnostic Tests and Related Services
- Excision/Biopsy and Incision and Drainage Procedures
- Eye Surgery and Other Eye-Related Procedures
- Gastrointestinal Procedures
- Gynecologic Procedures and Services
- Imaging Services
- Orthopedic Procedures
- Pathology Services
- Radiology Oncology Procedures and Services
- Skin Procedures
- Urology and Related Services
- Vascular Procedures (Excluding Endovascular Procedures)
- Other Procedures and Services

The rule's tables 22-40 reflect the current (2015) APC assignments and the CY 2016 assignments.

This material is detailed and coding intensive. The discussion extends for some 121 pages.

IV. OPPS PAYMENT FOR DEVICES

A. Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices
There currently are four device categories eligible for pass-through payment: HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) was established effective October 1, 2013. HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) was established effective January 1, 2015. HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) was established effective April 1, 2015. HCPCS code C2613 (Lung biopsy plug with delivery system) was established effective July 1, 2015.

The pass-through payment status of the device category for HCPCS code C1841 will end on December 31, 2015. Therefore, the costs of the HCPCS code C1841 devices will be packaged into the costs related to the procedures with which the device is reported in the hospital claims data.

2. Provisions for Reducing Transitional Pass-through Payments to Offset Costs Packaged into APC Groups
CMS is updating 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. Device-Intensive Procedures

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

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

CY 2016 Device-Intensive APCs	
Renumbered CY 2016 APC	**CY 2016 APC Title**
1565	New Technology - Level 28 ($5,000-$5,500)
1599	New Technology - Level 48 ($90,000-$100,000)
5125	Level 5 Musculoskeletal Procedures
5166	Level 6 ENT Procedures
5192	Level 2 Endovascular Procedures
5193	Level 3 Endovascular Procedures
5222	5222 Level 2 Pacemaker and Similar Procedures
5223	5223 Level 3 Pacemaker and Similar Procedures

CY 2016 Device-Intensive APCs	
Renumbered CY 2016 APC	**CY 2016 APC Title**
5224	5224 Level 4 Pacemaker and Similar Procedures
5231	5231 Level 1 ICD and Similar Procedures
5232	5232 Level 2 ICD and Similar Procedures
5377	5377 Level 7 Urology and Related Services
5462	Level 2 Neurostimulator and Related Procedures
5463	Level 3 Neurostimulator and Related Procedures
5464	Level 4 Neurostimulator and Related Procedures
5471	Implantation of Drug Infusion Device
5493	Level 3 Intraocular Procedures
5494	Level 4 Intraocular Procedures

C. Adjustment to OPPS Payment for Partial or Full Credit Devices

CMS is finalizing its proposal, without modification, to continue to reduce the OPPS payment, for the device intensive APCs by the full or partial credit a provider receives for a replacement device.

CMS is also finalizing its proposal, without modification, to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead, 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.

COMMENT

CMS provides a lengthy discussion regarding adjustments to the OPPS payment for this continued device–intensive procedures. The discussion centers on the use of modifiers 73, 74 and 52.

V. OPPS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

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

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

CMS will discontinue pass-through status of 12 drugs and biologicals on Dec. 31, 2015, as listed in the table below.

Drugs and Biologicals for Which Pass-Through Status Will Expire Dec. 31, 2015			
CY 2016 HCPCS Code	CY 2016 Long Descriptor	Final CY 2016 Status Indicator	Final CY 2016 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

Drugs, Biologicals and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2016
CMS will provide pass-through payment status in CY 2016 for 38 drugs and biologicals, and to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals will receive in the physician's office setting in CY 2016.

The 38 drugs are displayed in the rule's Table 44. The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator "G" in Addenda A and B.

Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups
CMS will continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

There will be three diagnostic radiopharmaceuticals with pass-through payment status under the OPPS: (1) HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries); (2) HCPCS code C9458 (Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries); and (3) HCPCS code C9459 (Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries).

Payment Offset Policy for Contrast Agents
There is currently one contrast agent with pass-through payment status under the OPPS. HCPCS code Q9950 (Injection, sulfur hexafluoride lipid microsphere, per ml) was granted pass-through payment status beginning Oct. 1, 2015.

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, CMS will 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 OPPS.

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

CMS will 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.

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 cm^2 and a per day cost threshold (rounded to the nearest $1) of $1,050.

The rule's Table 50 shows the current high/low cost status for each skin substitute product.

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 51 contains the list of these HCPCSs codes.

Payment for Specified Covered Outpatient Drugs and Other Separately Payable and Packaged Drugs and Biologicals
For CY 2016 and subsequent years, CMS will continue its policy and pay for separately payable drugs and biologicals at ASP+6 percent.

Payment Policy for Therapeutic Radiopharmaceuticals
For CY 2016 CMS will pay all non-pass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent.

Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources
For CY 2016, CMS will continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

Payment for Blood Clotting Factors
For CY 2016, CMS will pay for blood clotting factors at ASP+6 percent.

Payment for Non-pass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but without OPPS Hospital Claims
CMS will make payments for new drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at ASP+6 percent.

For CY 2016, CMS will assign status indicator "E" to drugs and biologicals that lack CY 2014 claims data and pricing information for the ASP methodology.

The rule's tables 52 and 53 contain a list of the drugs being affected.

C. OPPS Payment for Biosimilar Biological Products

CMS will 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 OPPS.

VI. ESTIMATE OF OPPS 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 OPPS furnished for that year.

CMS estimates that 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 will be approximately $160.8 million (approximately $136.8 million for device categories and approximately $24 million for drugs and biologicals), which represents 0.26 percent of total projected OPPS payments for CY 2016. Therefore, CMS estimates that pass-through spending in CY 2016 will not amount to 2.0 percent of total projected OPPS CY 2016 program spending.

VII. OPPS PAYMENT FOR HOSPITAL OUTPATIENT VISITS

Payment for Hospital Outpatient Clinic and Emergency Department Visits

CMS will use HCPCS code G0463 (for hospital use only) to represent any and all clinic visits under the OPPS for CY 2016. In addition, CMS is finalizing its proposal to reassign HCPCS code G0463 from existing APC 0634 to renumbered APC 5012 and to use CY 2014 claims data to develop the CY 2016 OPPS payment rate for HCPCS code G0463 based on the total geometric mean cost of HCPCS code G0463, as CY 2014 is the first year for which claims data are available for this code.

CMS is finalizing its proposals, without modification, to continue to use existing methodology to recognize the existing CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits.

Payment for Chronic Care Management Services

A hospital will 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.

For CY 2016 and subsequent years, hospitals furnishing and billing services described by CPT code 99490 under the OPPS will 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.

COMMENT

There are a number of other requirements that hospitals must observe to bill for CCM.

VIII. 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 renumbering the four PHP APCs, that is, APCs 0172, 0173, 0175, and 0176, as APCs 5851, 5852, 5861, and 5862, respectively.

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

CY 2016 PHP APC Geometric Mean Per Diem Costs For CMHC PHP Services		
Renumbered CY 2016 APC	Group Title	PHP APC Geometric Mean Per Diem Costs
5851	Level 1 Partial Hospitalization (3 services) for CMHCs	$98.88
5852	Level 2 Partial Hospitalization (4 or more services) for CMHCs	$149.64

CY 2016 PHP APC Geometric Mean Per Diem Costs for Hospital-Based PHP Services		
Renumbered CY 2016 APC	Group Title	PHP APC Geometric Mean Per Diem Costs
5861	Level 1 Partial Hospitalization (3 services) for hospital-based PHPs	$191.91
5862	Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs	$222.54

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

For CY 2016, CMS will 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 tricotical (through separate skin or fascial incision));
- CPT code 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 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 following two codes have been added since the proposed rulemaking.

- CPT code 27477 (Arrest epiphyseal, any method (eg, epiphysiodesis); tibia and fibula, proximal
- CPT code 27485 (Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus).

The complete list of codes to be paid by Medicare in CY 2016 only as inpatient procedures is included as Addendum E.

X. 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 establishing 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 January 1, 2016, hospitals and suppliers will 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 modifier will 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

CMS is finalizing its proposal to assign HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening using low dose CT scan (service is for eligibility determination and shared decision making)), to APC 5822 (Level 2 Health and Behavior Services) and HCPCS code G0297 (Low dose CT scan for lung cancer screening), to APC 5570 (Computed Tomography without Contrast).

Payment for Corneal Tissue in the HOPD and the ASC

Corneal tissue will be separately paid when used in procedures performed in the HOPD and the ASC only when the corneal tissue is used in a corneal transplant procedure described by one of the following CPT codes: 65710 (Keratoplasty (corneal transplant); anterior lamellar); 65730 (Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)); 65750 (Keratoplasty (corneal transplant); penetrating (in aphakia)); 65755 (Keratoplasty (corneal transplant); penetrating (in pseudophakia)); 65756 (Keratoplasty (corneal transplant); endothelial); 65765 (Keratophakia); 65767 (Epikeratoplasty); and any successor code or new code describing a new type of corneal transplant procedure that uses eye banked corneal tissue.

XI. CY 2016 OPPS PAYMENT STATUS AND COMMENT INDICATORS

The 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. 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 this rule.

Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2015 and July 2015

New Level II HCPCS Codes for Covered Ancillary Services Implemented in April 2015			
CY 2015 HCPCS Code	CY 2016 HCPCS Code	CY 2016 Long Descriptor	Final CY 2016 Payment Indicator
C2623	C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	J7
C9445	J0596	Injection, c1 esterase inhibitor (recombinant), Ruconest, 10 units	K2
C9448*	J8655	Netupitant 300 mg and palonosetron 0.5 mg	K2
C9449	J9039	Injection, blinatumomab, 1 microgram	K2
C9450	J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	K2
C9451	J2547	Injection, peramivir, 1 mg	K2
C9452	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	K2
Q9975	J7205	Injection, factor viii fc fusion (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 2016 HCPCS Code	CY 2016 Long Descriptor	Final CY 2016 Payment Indicator
C2613	C2613	Lung biopsy plug with delivery system	J7
C9453	J9299	Injection, nivolumab, 1 mg	K2
C9454	J2502	Injection, pasireotide long acting, 1 mg	K2
C9455	J2860	Injection, siltuximab, 10 mg	K2
Q9978*	J8655	Netupitant 300 mg and palonosetron 0.5 mg	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 2016 CPT Code	CY 2016 Long Descriptor	Final CY 2016 Payment Indicator
0392T	0392T	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band)	G2
0393T	0393T	Removal of esophageal sphincter augmentation device	G2

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

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.

CMS is finalizing its proposal, without modification, to designate the procedures described by CPT codes 43197 and 43198 as permanently office-based for CY 2016, CMS also is designating four new CY 2016 codes for ASC covered surgical procedures as temporary office-based.

Final CY 2016 OPPS/ ASC Proposed Rule 5-Digit CMS Placeholder Code***	CY 2016 CPT Code	Final CY 2016 Long Descriptor	Final CY 2016 ASC Payment Indicator**
6446A	64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed)	P3*
6446C	64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)	P3*
03XXB	0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)	R2*
657XG	65785	Implantation of intrastromal corneal ring segments	R2*

*If designation is temporary.
**Final payment indicators are based on a comparison of the final rates according to the ASC standard rate setting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2016. For a discussion of the MPFS rates.
***New CPT codes (with CMS 5-digit placeholder codes) that will be effective Jan. 1, 2016. The final ASC payment rate for this code can be found in ASC Addendum AA, which is available via the Internet on CMS' website.

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

There are 133 ASC covered surgical procedures that CMS will designate as device-intensive and that will be subject to the device-intensive procedure payment methodology for CY 2016. These are listed in the rule's table 66.

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.

For device-intensive procedures (defined as those APCs with a device offset greater than 40 percent), CMS will reduce the ASC payment amount for discontinued device-intensive procedures billed with modifier "73," where anesthesia is planned but is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before anesthesia is induced, by 100 percent of the device offset amount prior to application of any additional payment adjustments associated with discontinued procedures.

Additions to the List of ASC Covered Surgical Procedures

CMS is adding 17 ASC covered surgical procedures.

Final CY 2016 HCPCS Code	Final CY 2016 Long Descriptor	Final 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
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	J8
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	J8
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction	J8
49406	Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous	G2
57120	Colpocleisis (Le Fort type)	G2
57310	Closure of urethrovaginal fistula	G2
58260	Vaginal hysterectomy, for uterus 250 g or less	G2
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	G2
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g	G2
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g	G2
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
63046	Laminectomy, facetectomy, and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equine and/or nerve root(s), eg spinal or lateral recess stenosis, single vertebral segment; thoracic	G2
63055	Transpedicular approach with decompression of spinal cord, equine and/or nerve root(s) (eg, herniated intervertebral disc), single segment; thoracic	G2

Calculation of the ASC Conversion Factor and the ASC Payment Rates

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

Using more complete CY 2014 data CMS now calculates a wage index budget neutrality adjustment of 0.9997. Based on IGI's 2015 third quarter forecast, the CPI–U for the 12-month period ending with the midpoint of CY 2016 is now projected to be 0.8 percent, while the MFP adjustment is 0.5 percent, resulting in an MFP-adjusted CPI–U update factor of 0.3 percent for ASCs that meet the quality reporting requirements. The final ASC conversion factor is $44.177.

For ASCs that do not meet the quality reporting requirements, CMS is reducing the CPI–U update of 0.8 percent by 2.0 percentage points and then we are applying the 0.5 percentage point MFP reduction, resulting in a -1.7 percent quality reporting/MFP-adjusted CPI–U update factor. The final ASC conversion factor of $43.296 is for ASCs that do not meet the quality reporting requirements.

XIII. HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM UPDATES

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

CMS will 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.

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

CMS will adopt a new quality measure for the CY 2018 Payment Determination and Subsequent Years: OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822)

CMS will adopt a new Hospital OQR Program Quality Measure for the CY 2019 Payment Determination and Subsequent Years: OP-34: Emergency Department Transfer Communication (EDTC) (NQF #0291)

An error???

In the CY 2016 OPPS/ASC proposed rule, OP-4: Aspirin at Arrival (NQF #0286) was inadvertently omitted from tables for the CY 2018 and CY 2019 Payment Determination and Subsequent Years (80 FR 39329 and 80 FR 39334). CMS says it would "like to clarify that OP-4 has not been removed from the Hospital OQR Program measure set and data for OP-4 should be submitted for the CY 2018 payment determination and subsequent years as previously finalized."

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

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
0286	OP-4: Aspirin at Arrival
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)

Hospital OQR Program Measure Set for the CY 2019 Payment Determination and Subsequent Years	
NQF #	**Measure Name**
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****

*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 for the CY 2018 payment determination and subsequent years.

COMMENT

There is much more to the issue and subject to quality than the above lists. CMS has devoted some 88 pages to the OQR system.

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

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

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

COMMENT

Like the OPPS quality requirements, the ASCQR is long and detailed.

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

COMMENT

The two-midnight rule continues to generate much consternation among providers. CMS' changes do not appear to provide any substantive change. CMS spends some 43 pages defending its actions. One element is clear. CMS says on several occasions that an inpatient admissions that does not include a stay of two or more midnights would under "rare and unusual" circumstances be appropriate for Medicare Part A payment.

In January 2014, CMS identified newly initiated mechanical ventilation (when medically necessary and excluding anticipated intubations related to minor surgical procedures or other treatment) as the first such rare and unusual exception to the two-midnight benchmark. So far this is the one only exception.

CMS seems determined to hold the two-midnight rule valid policy.

XVI. TRANSITION FOR FORMER MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS UNDER THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM

CMS is finalizing a policy that, effective January 1, 2016, payments to hospitals that (1) lost their MDH status because they are no longer in a rural area due to the implementation of the new OMB delineations in FY 2015 and (2) have not reclassified from urban to rural under the regulations at § 412.103 before Jan. 1, 2016, will transition from payments based, in part, on the hospital-specific rate to payments based entirely on the Federal rate.

For discharges occurring on or after Jan. 1, 2016, and before Oct. 1, 2016, these former MDHs will receive the Federal rate plus two-thirds of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate payment. For FY 2017, that is, for discharges occurring on or after Oct. 1, 2016, and before Oct. 1, 2017, these former MDHs will 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 Oct. 1, 2017, these former MDHs will be paid based solely on the Federal rate.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting