Regulatory Update

Final Rule Summary

Medicare Outpatient Prospective Payment System

Calendar Year 2016

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Florida Hospital Association

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OVERVIEW

The final calendar year (CY) 2016 payment rule with comment period for the Medicare outpatient prospective payment system (OPPS) was published in the *Federal Register* on November 13, 2015. The final rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates as well as finalized regulations that implement new policies:

- Renumbering of APCs in order to better group clinical families;
- Implementation of 10 new Comprehensive Ambulatory Payment Classifications (C-APCs) that bundle all payments for certain device-dependent procedures;
- Expansion of the list of services to be packaged into APCs as opposed to separately paid;
- Under inpatient prospective payment system (IPPS), revision of the "Two-Midnight Rule" for reasonable expectation requirement and use of Quality Improvement Organizations (QIOs) as the first line for auditing; and
- Updated payment rates and policies for Ambulatory Surgical Centers (ASCs).

A copy of the *Federal Register* and other resources related to the OPPS are available on the Centers for Medicare & Medicaid Services (CMS) Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending. Comments on payment classifications assigned to HCPCS codes identified by CMS in Addenda B, AA, and BB with the "NI" indicator, and other areas of the final rule with comment period, are due to CMS by December 29, 2015, and can be submitted electronically at http://www.regulations.gov by using the Web site's search feature to search for file code "1633-FC".

An online version of the rule is available at https://federalregister.gov/a/2015-27943. Page numbers noted in this summary are from the version of the final rule published in the *Federal Register*. A summary of the major hospital OPPS sections of the final rule is provided below.

OPPS PAYMENT RATE

Federal Register pages 70351-70357

The tables below show the final CY2016 conversion factor compared to CY2015 and the components of the update factor:

	Final CY2015 (CN)	Final CY2016	Percent Change
OPPS Conversion Factor	$74.173	$73.725	-0.60

Final CY2016 Update Factor Component	Value (Percent)
Market Basket Update	+2.4 (proposed at 2.7)
Patient Protection and Affordable Care Act (PPACA)-Mandated Productivity Market Basket Reduction	-0.5 percentage points (proposed at -0.6 percentage points)
PPACA-Mandated Pre-Determined Market Basket Reduction	-0.2 percentage points
Wage Index Budget Neutrality Adjustment	-0.08
Pass-through Spending Budget Neutrality Adjustment	-0.13
Cancer Hospital Budget Neutral Adjustment	-0.06
Inflation Adjustment for Excess Packaged Payments for Laboratory Tests	-2.0
Overall Final Rate Update	**-0.60**

Inflation Adjustment for Excess Packaged Payments Due to Laboratory Tests

OPPS spending for CY2014 experienced double-digit growth, compared to a typical annual increase of 6-8 percent. This was due to CMS' policy of packaging laboratory services into OPPS payment weights, without implementing a comparable reduction in spending for laboratory services that continued to be paid at the clinical laboratory fee schedule (CLFS). In order to address the increased payments resultant of this, CMS is adopting a prospective reduction of 2.0 percent to the CY2016 OPPS conversion factor.

ADJUSTMENTS TO THE OUTPATIENT RATE AND PAYMENTS

Wage Indexes

Federal Register pages 70357-70359

As in past years, for CY2016 OPPS payments, CMS will use the federal fiscal year (FY) 2016 IPPS wage indexes, including all reclassifications, add-ons, rural floors, and budget neutrality adjustment. Regarding the new Core-Based Statistical Area (CBSA) delineations adopted in FY2015, in some very limited circumstances (i.e., urban to rural changes that affect geographic location or Lugar status), this is the second year of the three-year transition to the new wage index. Hospitals affected by this transition will receive a wage index based on their prior geographic CBSA. The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor-related. For CY2016, CMS will continue to use a labor-related share of 60 percent.

Payment Increase for Rural SCHs and EACHs

Federal Register pages 70361-70362

CMS will continue to apply a 7.1 percent payment increase for rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs). This payment add-on excludes separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

Cancer Hospital Payment Adjustment and Budget Neutrality Effect

Federal Register pages 70362-70363

CMS will continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals in a budget neutral manner. As a result of this policy, CMS has adopted a -0.06 percent budget neutrality change to the CY2016 conversion factor.

Outlier Payments

Federal Register pages 70363-70365

To maintain total outlier payments at 1.0 percent of total OPPS payments, CMS has set a final CY2016 outlier fixed-dollar threshold of $3,250. This is an increase compared to the current threshold of $2,775. Outlier payments will continue to be paid at 50 percent of the amount by which the hospital's cost exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold are met.

Effect of Sequestration

No *Federal Register* page reference

The final rule does not specifically address the 2.0 percent sequester reductions to all Medicare payments (authorized by Congress and currently in effect through FY2025). Sequester is not applied to the payment rate; instead, it is applied to Medicare claims after determining co-insurance, any applicable deductibles, and any applicable Medicare secondary payment adjustments. Other Medicare payment lines such as graduate medical education (GME), bad debt, and electronic health record (EHR) incentives are also affected by the sequester reductions. Payments from Medicare Advantage (MA) plans should not be automatically impacted by sequestration.

UPDATES TO THE APC GROUPS AND WEIGHTS

Federal Register pages 70309-70351, 70368-70448, and 70473-70474

As required by law, CMS must review and revise the APC relative payment weights annually. CMS must also revise the APC groups each year to account for drugs and medical devices that no longer qualify for pass-through status, new and deleted Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, advances in technology, new services and new cost data.

The adopted payment weights and rates for CY2016 are available in Addenda A and B of the final rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.

For CY2016, CMS is finalizing two new status indicators: "J2" to identify certain combinations of services that will be paid through C-APC 8011 (Comprehensive Observation Services) and "Q4" to identify conditionally packaged laboratory tests.

In order to better identify and group consecutive APC levels within a clinical family, CMS will renumber 220 APCs for CY2016. CMS had provided a crosswalk of current APC numbers to the new 2016 numbers in Addendum Q of the proposed rule, but states in the final rule that they "now do not believe that Addenda O and Q are necessary for this CY2016 OPPS/ASC final rule with comment period. Therefore, we are not including them in the files available on the CMS Web site for this final rule with comment period."

The table below shows the shift in the number of APCs per category from CY2015 to CY2016:

APC Category	Status Indicator	Final CY2015	Final CY2016
Clinic or Emergency Department Visit	V	15	13
Procedure or Service, Multiple Reduction Applies	T	129	65
Procedure or Service, No Multiple Reduction	S	134	78
Pass-Through Devices Categories	H	2	4
OPD Services Paid through a Comprehensive APC	J1	25	34
Observation Services	J2	0	1
Non-Pass-Through Drugs/Biologicals	K	289	304
Partial Hospitalization	P	4	4
Blood and Blood Products	R	34	37
Brachytherapy Sources	U	17	17
Pass-Through Drugs and Biologicals	G	35	38
New Technology	S/T	82	104
Total		**766**	**699**

New Comprehensive APCs

Federal Register pages 70326-70339

In CY2014, CMS began adopting a number of refinements to the APC assignments in an effort to create larger payment bundles. For CY2016, CMS is continuing to create larger payment bundles by expanding its packaging policies and implementing new comprehensive APCs (C-APCs).

C-APCs are applicable for certain medical device implantation procedures. A C-APC covers payment for all Part B services that are related to the device-dependent procedure (including items currently paid under separate fee schedules). The C-APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure, visits and evaluations performed in association with the procedure, coded and un-coded services and supplies used during the service, outpatient department services delivered by therapists as part of the comprehensive service, durable medical equipment as well as the supplies to support that equipment, and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products are included in the C-APCs.

The C-APCs do not include payments for services that are not covered by Medicare Part B or are not payable under OPPS such as: certain mammography and ambulance services, brachytherapy sources, pass-through drugs and devices, and charges for self-administered drugs (SADs). A full list of excluded services is provided in Table 7 of the final rule (70326-70327).

For CY2016, CMS will add 10 new C-APCs, bringing the total to 35 C-APCs within 14 clinical families, as listed in Table 9 of the final rule (pages 70332-70333). The list of the 10 new C-APCs are:

Final New CY2016 C-APCs	Final New CY2016 APC Descriptors	Clinical Families
5165	Level 5 ENT Procedures	ENTXX
5492	Level 2 Intraocular Procedures	EYEXX
5416	Level 6 Gynecologic Procedures	GYNXX
5361	Level 1 Laparoscopy	LAPXX
5362	Level 2 Laparoscopy	LAPXX
5123	Level 3 Musculoskeletal Procedures	ORTHO
5125	Level 5 Musculoskeletal Procedures	ORTHO
5375	Level 5 Urology and Related Services	UROXX
5881	Ancillary Outpatient Services When Patient Expires	N/A
8011	Comprehensive Observation Services	N/A

Included in these new C-APCs is the newly created "Comprehensive Observation Services" C–APC (C–APC 8011), which will be used for all qualifying extended assessment and management non-surgical encounters with a high-level visit and eight or more hours of observation.

Composite APCs

Federal Register pages 70339-70343

Composite APCs are another type of packaging to provide a single APC payment for groups of services that are typically performed together during a single outpatient encounter. Currently, there are eight composite APCs for:

- Low-Dose Rate (LDR) Prostate Brachytherapy (APC 8001);
- Mental Health Services (APC 0034);
- Multiple Imaging Services (APCs 8004, 8005, 8006, 8007 and 8008); and
- Extended Assessment and Management (EAM) Services (APC 8009).

As part of its overall APC restructuring and renumbering, CMS will change APC 0034 to APC 8010. In addition, to ensure alignment with the C-APC policies, CMS will discontinue composite APC 8009, which will be replaced by C-APC 8011 (Comprehensive Observation Services). Table 10 on pages 70341-70343 of the *Federal Register* shows the HCPCS codes that are eligible for composite APC assignment.

Packaged Services

Federal Register pages 70343-70350

For CY2016, CMS is continuing its efforts to create more complete APC payment bundles by expanding its packaging policies to the following services/items:

- Ancillary Services – CMS' stated intention, over time, is to package more ancillary services when they occur on a claim with another service, and only pay for them

separately when performed alone. There are three additional ancillary services (Table 11, page 70345) currently paid separately under the OPPS that CMS will package in CY2016 under certain conditions. Other ancillary services will remain separately paid (assigned a status indicator of S or T) because CMS has identified them as not being clinically similar to those services currently packaged, or as services that are preventative or psychiatry/counseling-related. A list of HCPCS codes that will be conditionally packaged are displayed in Addendum B of the final rule.

- Drugs and Biologicals Functioning as Supplies for a Surgical Procedure – CMS will package payment for four drugs (Table 13, page 70348), that are currently paid separately, based on their primary function as a supply in surgical procedures. CMS will also package an additional drug (HCPCS code C9447) in CY2018, once its pass-through payment status expires.
- Clinical Diagnostic Laboratory Tests – CMS will exclude from the packaging policy all current and future codes that describe molecular pathology tests as these are considered to be less tied to other primary outpatient services. CMS also finalized its proposal to make separate payments for preventative laboratory tests in order to maintain alignment with the exclusions for ancillary services. Finally, CMS adopted an expansion of the current conditional payment policy to laboratory tests provided during an outpatient stay, rather than specifically provided on the same date as the primary service, except when ordered for a different purpose and by a different practitioner.

Payment for Medical Devices with Pass-Through Status

Federal Register pages 70415-70421

CMS will remove HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) from the list of medical devices currently provided pass-through payment status. As a result, the costs of these devices will be packaged into the costs related to the procedures with which HCPCS code C1841 is reported. The HCPCS codes for devices still on the pass-through payment list are:

- C2613 - Lung biopsy plug with delivery system;
- C2623 - Catheter, transluminal angioplasty, drug-coated, non-laser; and
- C2624 - Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components.

Payment Adjustment for No Cost/Full Credit and Partial Credit Devices

Federal Register pages 70422-70424

For outpatient services that include certain medical devices, CMS reduces the APC payment if the hospital received a credit from the manufacturer. The offset can be 100 percent of the device amount when a hospital attains the device at no cost or receives a full credit from the manufacturer, or 50 percent when a hospital receives partial credit of 50 percent or more. For CY2016, CMS is adopting a policy that hospitals must continue to report any credits received if they are 50 percent or more of the cost of the device. CMS will also no longer specify lists of devices to which this payment adjustment would apply. Instead, CMS will apply

this 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."*

Payment for Drugs, Biologicals and Radiopharmaceuticals

Federal Register pages 70426-70444

CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately. The determination is based on a price threshold. For CY2016, CMS has adopted a packaging threshold of $100. Drugs, biologicals and radiopharmaceuticals that are above the $100 threshold are paid separately using individual APCs. The payment rate for CY2016 is the average sales price (ASP) + 6 percent. CMS will allow pass-through status to expire for 12 drugs and biologicals, listed in Table 43 and is continuing pass-through status for 38 others, shown in Table 44 of the *Federal Register*.

Payment for Chronic Care Management Services

Federal Register pages 70450-70453

CMS is adopting additional requirements for hospitals to bill and receive payment for CPT code 99490 ("Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month"). The primary points of this change are:

- The patient must have registered at the hospital as either an inpatient or outpatient within the last 12 months and received therapeutic services;
- The hospital is required to have documented in the medical record that the services were explained and offered to the beneficiary, and that the beneficiary either agreed to or declined the services or that this agreement is provided in a medical record accessible to the hospital;
- That during a single calendar month service period, only one hospital may furnish and be paid for those services described by CPT code 99490; and
- That additional requirements listed on page 70452 of the *Federal Register* be provided, including the recording of demographics and potential complications, full-time access to care management services, that there be continuity of care for any routine appointments to follow, and a requirement for the use of EHR technology.

Other OPPS Policies

Partial Hospitalization Program (PHP) Services

Federal Register pages 70453 – 70467

The PHP is an intensive outpatient psychiatric program to provide outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding Community Mental Health Center (CMHC). PHP providers are paid on a per

diem basis with payment rates calculated using CMHC-level or hospital-specific data. The table below compares the CY2015 and final CY2016 PHP payment rates.

Former APC	New APC	Group Title	CY2015 Payment Rate	Final CY2016 Payment Rate	Percent Change
0175	5861	Hospital-Based PHPs-Level I PHP (three services)	$179.11	$191.91	+7.1
0176	5862	Hospital-Based PHPs-Level II PHP (four or more)	$195.62	$222.54	+13.8
0172	5851	CMHCs-Level I PHP (three services)	$96.51	$98.88	+2.5
0173	5852	CMHCs-Level II PHP (four or more)	$114.23	$149.64	+31.0

For CMHCs, for APCs 5851 and 5852, CMS will continue to make outlier payments for 50 percent of the amount by which the cost for the PHP service exceeds 3.4 times the payment rate of APC 5852.

Updates to the Inpatient-Only List

Federal Register pages 70467-70469

The inpatient-only list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY2016, CMS will remove the following nine services 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 (EGJ), with implantation of pulse generator, includes programming;
- CPT code 20936 – Autograft for spine surgery only (includes harvesting the graft); local (e.g., 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 27477 – Arrest epiphyseal, any method (e.g., epiphysiodesis); tibia and fibula, proximal;
- CPT code 27485 – Arrest hemiepiphyseal, distal femur or proximal tibia or fibula (e.g., genu varus or valgus);
- 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 full list of inpatient-only procedures is available in Addendum E.

UPDATES TO THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

Federal Register pages 70502-70526

The OQR program is mandated by law. Hospitals that do not successfully participate are subject to a 2.0 percentage point reduction to the OPPS market basket update for the applicable year. The required OQR measures for CY2016 payment determinations were established in prior years' rulemaking and the 27 required quality measures are listed in the final rule CY2015 *Federal Register* (page 66944). A table that lists the 25 measures CMS is currently collecting for the CY2017 payment determinations is available on page 70505 of the final rule *Federal Register*.

The CY2016 OPPS final rule establishes OQR program changes for CYs 2017, 2018, and 2019 payment determinations. The changes to the measures are as follows:

Elimination of one chart-abstracted process measure:

- OP-15 – Use of Brain Computed Tomography (CT) in the ED for Atraumatic Headache (CY2017).

Addition of two new web-based measures:

- OP-33 – External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) **(**CY2018); and
- OP-34 – Emergency Department Transfer Communication (EDTC) (NQF #0291) **(**CY2019).

A table listing the 26 measures CMS is collecting for CY2018 payment determinations is available on page 70510 of the final rule *Federal Register*.

TWO-MIDNIGHT POLICY FOR INPATIENT STAYS

Federal Register pages 70538-70549

CMS is not making any changes to the two-midnight presumption – meaning hospital stays that are expected to be two midnights or longer will continue to be presumed appropriate for inpatient admission and will not be subject to medical necessity reviews. However, CMS acknowledges that certain procedures may have intrinsic risks, recovery impacts or complexities that would cause them to be appropriate for inpatient coverage under Medicare Part A, regardless of the length of hospital time the admitting physician expects a particular patient to require.

For stays expected to last less than two midnights, CMS has adopted the following:

- For stays which the physician expects the patient to need less than two midnights of hospital care (and the procedure is not on the inpatient-only list or otherwise listed as a national exception), an inpatient admission would be payable under Medicare Part A on a case-by-

case basis based on the judgment of the admitting physician. The documentation in the medical record must support that an inpatient admission is necessary, and is subject to medical review.

    - CMS states that it would be rare and unusual for a beneficiary to require inpatient hospital admission for a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for a period of time that is only for a few hours and does not span at least overnight. CMS will monitor the number of these types of admissions and plans to prioritize these types of cases for medical review.

- In addition, CMS states that it has changed the medical review strategy and QIO contractors are now responsible for conducting reviews of short inpatient stays in place of the Medicare Audit Contractors (MACs) by October 1, 2015. Under the QIO process, claim denials will be referred to the MACs, followed by the QIO providing education about the claims denied and collaborating with hospitals to improve organizational processes. Hospitals that consistently have high denial rates, fail to adhere to the two-midnight rule, or fail to improve their performance after QIO educational intervention will then be referred to the Recovery Auditors (RAs) for further auditing.

In the proposed rule, CMS had requested comments regarding the establishment of medical review criteria for inpatient admissions not expected to span two midnights. In the final rule, CMS states that although commenters were largely supportive, the unique circumstances of individual Medicare beneficiaries makes it difficult to suggest specific criteria. As a result, CMS is not yet adopting medical review criteria regarding the two-midnight rule. CMS will address technical medical review questions related to this transition to the new medical review and enforcement strategy in subregulatory guidance no later than December 31, 2015.