

CMS Finalizes Hospital Outpatient and Ambulatory Surgical Center Policy and Payment Changes, Including Changes to the Two-Midnight Rule and Quality Reporting for 2016

The Centers for Medicare & Medicaid Services (CMS) released the Calendar Year (CY) 2016 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System policy changes, quality provisions, and payment rates final rule with comment period [CMS-1633-FC] on October 30, 2015.

The CY 2016 OPPS/ASC final rule updates Medicare payment policies and rates for hospital outpatient departments (HOPDs), ASCs, and partial hospitalization services provided by community mental health centers (CMHCs), and refinements to programs that encourage high-quality care in these outpatient settings. Approximately 4,000 hospitals and 60 CMHCs are paid under the OPPS, while approximately 5,300 ASCs are paid under the ASC payment system. The OPPS provides payment for most HOPD services, including partial hospitalization services furnished by HOPDs and CMHCs. OPPS payment amounts vary according to the Ambulatory Payment Classification (APC) group to which a service or procedure is assigned. The final rule also includes important changes to the Two Midnight Rule effective beginning in CY 2016.

The OPPS/ASC final rule is one of several rules for CY 2016 that reflect a broader Administration-wide strategy to create a health care system that results in better care, smarter spending, and healthier people.

Policy and Payment Changes

Payment Update

CMS is updating OPPS rates based on the projected hospital market basket increase of 2.4 percent minus both a 0.5 percentage point adjustment for multi-factor productivity and a 0.2 percentage point adjustment required by law. As described below, there is an 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) for hospitals paid under the OPPS in CY 2016.

Beneficiary co-insurance for OPPS services is projected to decrease from 19.9 percent in CY 2015 to 19.3 percent in CY 2016.

OPPS Spending for Laboratory Services

CMS finalized a proposal to reduce the CY 2016 conversion factor to account for approximately \$1 billion in inflation in the OPPS payments resulting from excess packaged payment under the OPPS. Specifically, CMS estimated that its policy to classify laboratory services as packaged would result in a \$2.4 billion shift in CY 2014 OPPS spending for laboratory tests previously paid at the Clinical Laboratory Fee Schedule payment rates outside the OPPS. However, the CMS Office of the Actuary (OACT) found that about \$1 billion in laboratory tests payments that were projected to be packaged into OPPS payment rates continued to be paid separately in CY 2014. To prevent the excess payment from carrying through to the CY 2016 OPPS rates, CMS is reducing the CY 2016 conversion factor by 2.0 percent to account for the approximately \$1 billion inflation in OPPS payments.

CMS is also finalizing changes to the laboratory test packaging policy. CMS is creating a new conditional packaging status indicator for laboratory tests that will make it easier for hospitals to receive separate payment for laboratory tests that are provided without other OPPS services.

Chronic Care Management (CCM) Services

In CY 2015, CMS adopted separate payment codes for CCM services, which are non-face-to-face care management services for Medicare beneficiaries who have multiple, significant, chronic conditions (two or more). Examples of services included in CCM are regular development and maintenance of a plan of care, communication with other treating health professionals, and medication management.

Although CMS finalized payment for CCM services in the hospital outpatient setting for CY 2015, some hospitals have found implementing certain aspects of the policy confusing. For CY 2016, CMS responded to hospital requests for clarification of their role in furnishing CCM services and defined scope of service elements for the hospital outpatient setting that are analogous to the scope of service elements finalized as requirements to bill for CCM services in the CY 2015 Medicare Physician Fee Schedule final rule with comment period. CMS also worked with the Office of the National Coordinator for Health Information Technology to address technical questions on the Electronic Health Record criteria.

Payment for CCM is one part of a multi-faceted CMS initiative to improve Medicare beneficiaries' access to primary care. Models being tested through the Innovation Center will continue to explore innovation in primary care delivery.

Restructuring of Ambulatory Payment Classifications (APC)

By law, CMS must annually review and revise the OPPS APC groups and relative payment weights and make other adjustments taking into account changes in medical practices and technologies and the addition of new services, new cost data, and other relevant information and factors. CMS conducted a comprehensive review of all of the OPPS clinical APCs and had proposed to restructure, reorganize, and consolidate many of them, resulting in fewer APCs overall for nine clinical APC families, which include various surgical and diagnostic procedures. **CMS is finalizing the restructuring of the nine clinical families with modifications for certain services and procedures in response to public comments.**

Comprehensive Ambulatory Payment Classifications (C-APCs)

A C-APC is an APC that provides for an encounter-level payment for a designated primary procedure(s) and generally, all adjunctive and secondary services provided in conjunction with the primary procedure. In CY 2015, CMS implemented the C-APC policy with 25 C-APCs, which mostly include procedures for the implantation of costly medical devices. For CY 2016, CMS is finalizing nine new C-APCs, including some surgical APCs and a new C-APC for comprehensive observation services that is described below.

- C-APC for Comprehensive Observation Services: Currently, when making payment for observation services, CMS makes a single payment for non-surgical encounters with a high-level visit and 8 or more hours of observation and then also makes separate payment for most other services reported on the claim. CMS proposed to create a C-APC to provide comprehensive payment for all services furnished during a non-surgical outpatient encounter where the patient receives 8 or more hours of observation with a high level outpatient hospital visit.

CMS is finalizing the C-APC for Comprehensive Observation Services, but will exclude all surgical procedures from being bundled into the observation C-APC, regardless of date of service. This means that if a surgical procedure code appears on a claim that would otherwise qualify for the Comprehensive Observation C-APC, the surgical APC payment would be made in lieu of the observation C-APC payment. CMS will also include all emergency department visits, not just high-level ED visits, in the criteria used to qualify for the observation C-APC, as this is more consistent with a comprehensive payment policy.

- C-APC for Stereotactic Radiosurgery (SRS): With the advent of comprehensive APCs, the OPPS consists of a wide array of payment methodologies, ranging from separate payment for a single service to a C-APC payment for an entire outpatient encounter with multiple services. Sometimes, services that should be included as a part of an encounter payment are furnished prior to a primary service and billed separately. Practice patterns associated with the linear accelerator (LINAC) type of cranial single session Stereotactic Radiosurgery (SRS) are a good example of disconnected adjunctive services.

CMS finalized a proposal to separately pay for certain adjunctive services related to the SRS C-APC as a data collection strategy to improve comprehensive payment for SRS services. In addition, CMS proposed to collect data through the use of a HCPCS modifier on all services related to a C-APC primary procedure that are reported on a separate claim. The purpose of this data collection is to assess the costs of all adjunctive services related to C-APC services, even when they are reported on a separate claim. **However, in response to public comments, CMS is not finalizing its proposal to require hospitals to report C-APC adjunctive services for CY 2016, with the exception of services related to cranial single session SRS.**

Packaged Services

CMS believes that a basic tenet of a prospective payment system is the packaging of all integral, ancillary, supportive, dependent, or adjunctive services into primary services. In CY 2015, CMS conditionally packaged many ancillary services. For CY 2016, CMS is finalizing its proposal to conditionally package a limited number of additional ancillary services, in particular certain minor procedures and pathology services, except for cochlear implant and auditory implant programming services. CMS will also package payment for a few drugs that function as supplies in a surgical procedure.

Change in OPPS Device Pass-through Process

Device pass-through payments are intended to enable initial access to certain new medical devices. CMS currently accepts and reviews applications for device pass-through on a quarterly basis through a subregulatory process. CMS is finalizing its proposal to evaluate device pass-through applications through annual rulemaking in addition to the quarterly subregulatory review process.

In addition, CMS is implementing a newness criterion for device pass-through applications under which applications must be submitted within three years of FDA approval/clearance or the date of market availability if there is a documented, verifiable delay in market availability after FDA approval or clearance.

Skin Substitutes

In the CY 2014 OPPS final rule, CMS unconditionally packaged skin substitutes (meaning skin substitutes are never separately paid in the OPPS) into their associated surgical procedures as part of a broader proposal to package drugs and biologicals that function as supplies when used in a surgical procedure.

This policy also included a methodology that classifies each skin substitute into either a high cost group or a low cost group in an effort to improve resource homogeneity among APC assignments for the skin substitute application procedures. For CY 2016, CMS is finalizing a policy to calculate the high/low cost group threshold based on either mean unit cost or per patient per day costs with assignment of skin substitute products to the high cost group being determined by a product exceeding the threshold under either methodology. This is consistent with CMS' overall goal to promote stability in the group assignments.

Payment for Biosimilar Biological Products under the OPPS

Under the OPPS, CMS packages drugs and biologicals into the OPPS payment below a specified threshold cost per day. Above that amount, CMS pays separately at ASP plus six percent.

Accordingly, CMS is adopting a policy to pay biosimilars based on ASP, using six percent of the reference biological product as the add-on percentage and to allow drug pass-through payment for biosimilars using the same amount. We are also finalizing our proposal that coding and modifiers for biosimilar biological products will be based on the policy established under the CY 2016 Medicare Physician Fee Schedule final rule.

New P Codes for Pathogen-Reduced Blood Products

The Healthcare Common Procedure Coding System (HCPCS) Workgroup is creating three new codes for pathogen-reduced blood products (one platelet product and two plasma products). CMS is creating interim payment amounts for these codes in the OPPS based on crosswalks to existing blood product codes while claims data accumulates in the system for these new products.

ASC Payment Update

ASC payments are annually updated for inflation by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). The Medicare statute specifies a multifactor productivity (MFP) adjustment to the ASC annual update. For CY 2016, the CPI-U update is 0.8 percent. The MFP adjustment is 0.5 percent, resulting in an MFP-adjusted CPI-U update factor of 0.3 percent.

Removing Certain Codes from the List of ASC Covered Ancillary Services

The ASC payment system makes a separate payment for covered ancillary services, which are certain items and services that are provided integral to a covered surgical procedure. CMS will be excluding codes for services currently on the covered ancillary services list that are not provided ancillary and integral to a covered ASC surgical procedure. **Specifically, CMS is removing the SRS treatment services CPT codes from the list of ASC covered ancillary services.**

Update of the Partial Hospitalization Program (PHP) Per Diem Amounts in Outpatient Hospital Departments and Community Mental Health Centers (CMHCs)

The final rule with comment period updates Medicare payment rates for PHP services furnished in hospital outpatient departments and CMHCs. The PHPs are structured intensive outpatient programs consisting of a group of mental health services paid on a per diem basis under the OPPS, based on PHP per diem costs.

CMS is finalizing two methodologies for trimming aberrant costs in the rate-setting process for PHPs based on provider type. This trimming should result in more stable rates and supports CMS' commitment to accurate payment and protecting the Medicare Trust Fund. CMS will review trims and may propose to revise them in future rulemaking, as needed to remove aberrant data.

Using the most recent updated data, the calculated final CMHC PHP APC geometric mean per diem costs were similar to those proposed. However, the calculated final hospital-based PHP APC geometric mean per diem costs for Level 1 and Level 2 days were inverted. CMS believes it is not appropriate or equitable to pay a lower payment rate for the hospital-based PHP APC for Level 2 days, under which four or more PHP services are provided, than for the hospital-based PHP APC for Level 1 days, under which three PHP services are provided. Therefore, under the authority in section 1833(t)(2)(E) of the Act, CMS is applying an equitable adjustment to the calculated final hospital-based PHP APC per diem costs to remove the inversion.

Payment Transition for Former Medicare Dependent, Small Rural Hospitals (MDH) under the Hospital Inpatient Prospective Payment System (IPPS)

To qualify as a Medicare-dependent, small rural hospital (MDH), a hospital must be located in a rural area, have 100 beds or fewer, and 60 percent or more of its inpatient days or discharges must be for Medicare beneficiaries. By statute, MDHs receive special payment under the IPPS based on the higher of the standard Federal rate or a blended rate calculated using the Federal rate payment plus 75 percent of the amount by which the Federal rate payment is exceeded by the MDH's hospital-specific rate payments. Following Medicare's implementation of the revised Office of Management and Budget (OMB) statistical area delineations from the 2010 Census for FY 2015, some MDHs were no longer in an area designated as rural. In order to retain their MDH status and avoid losing special MDH payment, these hospitals must be approved for urban-to-rural reclassification by meeting the criteria codified at § 412.103.

CMS originally proposed a payment transition only for those former MDHs located in all urban states following implementation of the new OMB delineations. After consideration of comments received on the proposal, CMS is extending the proposed three-year payment transition to all former MDHs that lost MDH status because they are no longer in a rural area due to the implementation of the new OMB delineations and have not reclassified from urban to rural under § 412.103 by January 1st, 2016. For discharges occurring on or after January 1, 2016, and before October 1, 2016, a former MDH will receive the Federal rate plus two-thirds of 75 percent of the amount by which the Federal rate payment is exceeded by its hospital-specific rate payment. For FY 2017, a former MDH 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. These former MDHs will be paid solely based on the Federal rate beginning FY 2018.

Appropriate Claims in Provider Cost Reports; Appeals by Providers and Judicial Review

CMS is revising cost reporting regulations by requiring a provider to include an appropriate claim for a specific item in its cost report in order to receive or potentially receive Medicare reimbursement for the specific item. If the provider's cost report does not include an appropriate claim for a specific item, then reimbursement for the item will not be included in the notice of program reimbursement issued by the contractor or in any decision or order issued by a reviewing entity in an administrative appeal filed by the provider. CMS is also finalizing proposals to revise the appeals regulations by eliminating the requirement that a provider must include an appropriate claim for a specific item in its cost report in order to meet the dissatisfaction requirement for jurisdiction before the Provider Reimbursement Review Board, and by specifying the procedures for Board review of whether the provider's cost report meets the substantive reimbursement requirement of an appropriate cost report claim for a specific item.

Quality Reporting Program Changes

Hospital Outpatient Quality Reporting (OQR) Program: Changes for 2017 and 2018 Payment Determinations

Outpatient hospitals are subject to a reduction of 2.0 percentage points to their OPD fee schedule increase factor for failure to meet requirements for the Hospital OQR Program.

CMS is finalizing one new measure to the program, which is NQF endorsed, supported by the Measure Applications Partnership (MAP), and addresses the Making Care Safer National Quality Strategy goal. The new measure is:

- **For the CY 2018 payment determination and subsequent years - OP-33: External Beam Radiotherapy for Bone Metastases (NQF# 1822)** (Web-based): Percentage of patients (all-payer) with painful bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule. **CMS is adopting the measure with a modification to the**

proposed data submission method, requiring that all hospitals submit this measure as an aggregate data file via a Web-based tool (QualityNet).

Please note that in the proposed rule for the CY 2019 payment determination and subsequent years, CMS proposed the OP-34: Emergency Department Transfer Communication (EDTC) Measure (NQF# 0291) (Web-based): Percentage of patients transferred to another healthcare facility whose medical record documentation indicated that administrative and clinical information was communicated to the receiving facility in an appropriate time frame. After considering the comments received, we are not finalizing our proposal to adopt OP-34 for the CY 2019 payment determination and subsequent years due to concerns about overlap with EHR Incentive Program requirements, burden of abstracting, and the scoring methodology.

CMS is finalizing the removal of one measure, OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache, because the measure does not align with the most updated clinical guidelines or practice.

Additionally, CMS is continuing to explore electronic clinical quality measures (eCQMs) and whether, in future rulemaking, it would propose that hospitals have the option to voluntarily submit data electronically for OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients, possibly beginning with the CY 2019 payment determination.

CMS also finalized several policy changes. To align with the Ambulatory Surgical Center Quality Reporting Program (ASCQR), the Hospital OQR Program is: (1) changing the deadline for withdrawing from the program to August 31; (2) changing the deadline for submitting a reconsideration request to the first business day on or after March 17 of the affected payment year; and (3) shifting the quarters on which payment determinations are based and making conforming changes to the validation process to reflect proposed changes in the payment determination timeframes, requiring a one-time change in the CY 2017 payment determination timeframe to cover three quarters instead of four quarters, and returning to a four-quarter payment determination in CY 2018 and subsequent years. The Hospital OQR program is aligning with the National Healthcare Safety Network (NHSN) measure deadline by changing the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Website) from July 1 through November 1 to January 1 through May 15.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program

Ambulatory Surgical Centers (ASCs) are subject to a reduction of 2.0 percentage points in their annual payment update for not meeting the requirements of the ASCQR Program. The CY 2018 ASCQR Program measure set includes 12 measures—11 required and 1 voluntary.

CMS did not propose to add any new measures to the program, but requested comment on two outcome measures for future consideration. The two measures are:

- Normothermia Outcome, which assesses the percentage of patients having surgical procedures under general or neuroaxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit.
- Unplanned Anterior Vitrectomy, which assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy (removal of the vitreous present in the anterior chamber of the eye).

CMS will consider the comments received regarding these measures for potential future rulemaking.

CMS also finalized a proposal not to consider Indian Health Service hospital outpatient departments that bill Medicare for ASC services and are paid based on the ASC rates as ASCs for purposes of the ASCQR Program. While these entities are able to bill Medicare for ASC services and be paid based on the ASC rates, they are required to meet the conditions of participation for hospitals – not the conditions of coverage for ASCs. CMS also will display ASCQR Program data by: the National Provider Identifier (NPI), if data are submitted by the NPI; or by the CMS Certification Number (CCN), if data are submitted by the CCN.

Additionally, CMS finalized to display ASCQR Program data by the National Provider Identifier (NPI) if data are submitted by the NPI or by the CMS Certification Number (CCN) if data are submitted by the CCN and will codify a number of existing and newly finalized policies.

The final rule will appear in the November 13, 2015 Federal Register