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

The Centers for Medicare & Medicaid Services (CMS) released the Calendar Year (CY) 2016 Hospital Outpatient Prospective Payment System (HOPPS) and Ambulatory Surgical Center (ASC) Payment System policy changes, quality provisions, and payment rates proposed rule (CMS-1633-P) on July 1, 2015.

The CY 2016 HOPPS/ASC proposed rule proposes updates to 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 3,800 hospitals and 60 CMHCs are paid under the HOPPS, while approximately 5,300 ASCs are paid under the ASC payment system. The HOPPS provides payment for most HOPD services, including partial hospitalization services furnished by HOPDs and CMHCs. HOPPS payment amounts vary according to the Ambulatory Payment Classification (APC) group to which a service or procedure is assigned.

The proposed rule also includes important proposed changes to the Two Midnight Rule for CY 2016. See related fact sheet for detailed information http://cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-07-01.html

The HOPPS/ASC proposed 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

Proposed Payment Update

CMS proposes to update HOPPS rates by -0.1 percent. The change is based on the projected hospital market basket increase of 2.7 percent minus both a 0.6 percentage point adjustment for multi-factor productivity and a 0.2 percentage point adjustment required by law. As described below, there is an additional proposed 2.0 percentage point adjustment to the payment update to redress inflation in the HOPPS payment rates resulting from excess packaged payment under the HOPPS for laboratory tests that continue to be paid separately outside of the HOPPS. After considering all other policy changes proposed under the HOPPS, including estimated spending for pass-through payments, CMS estimates a -0.2 percent adjustment for hospitals paid under the HOPPS in CY 2016.

HOPPS Spending for Laboratory Services

CMS is proposing to reduce the CY 2016 conversion factor to account for roughly \$1 billion in inflation in the HOPPS payments resulting from excess packaged payment under the HOPPS. For CY 2014, in monitoring aggregate spending for Part B services, the CMS Office of the Actuary (OACT) observed a 14 percent increase in CY 2014 HOPPS spending as compared to the typical 6 to 8 percent annual growth. The primary source of this 14 percent increase in

HOPPS spending was identified as estimates related to the policy to package laboratory tests into HOPPS payment for related services, beginning in CY 2014.

Specifically, CMS estimated a \$2.4 billion shift in CY 2014 spending to be packaged into the HOPPS payment rates to account for hospital outpatient claims for laboratory tests previously paid at the Clinical Laboratory Fee Schedule payment rates outside the HOPPS. However, OACT found that about \$1 billion in laboratory tests payments that were projected to be packaged into HOPPS payment rates continued to be paid separately in CY 2014. Therefore, in CY 2014, CMS overestimated the amount of laboratory test packaging that would result from this new packaging policy by \$1 billion. To adjust for this, CMS is proposing to reduce the CY 2016 conversion factor by 2.0 percent to account for the roughly \$1 billion inflation in HOPPS payments.

CMS is also proposing changes to the laboratory test packaging policy. One key proposal is for 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 related HOPPS services.

Chronic Care Management (CCM) Services

In CY 2015, CMS adopted separate payment codes for CCM services – non-face-to-face care management services for Medicare beneficiaries who have multiple, significant, chronic conditions (two or more). Some 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, stakeholders have found implementing certain aspects of the policy confusing. For CY 2016, CMS is responding to hospital requests for clarification of their role in furnishing CCM services and defining the 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.

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 HOPPS Ambulatory Payment Classification (APC) groups, 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 has conducted a comprehensive review of all of the HOPPS clinical APCs and proposes to restructure, reorganize, and consolidate many APCs, resulting in fewer APCs overall for nine clinical APC families.** The nine clinical APC families include various surgical and diagnostic procedures.

Proposed Comprehensive Ambulatory Payment Classifications (C-APCs) for 2016

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. There are currently 25 C-APCs, which mostly include procedures for the implantation of costly medical devices. For CY 2016, CMS is proposing nine new C-APCs, including some surgical APCs and a new C-APC for comprehensive observation services that is described below.

In addition, CMS is proposing 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.

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 primary services reported on the claim. CMS is proposing to create a C-APC for observation services to provide comprehensive payment for all services received when receiving comprehensive observation services, defined as a non-surgical encounter with a high level outpatient hospital visit and 8 or more hours of observation. Copayments under the HOPPS for any service are capped at the inpatient deductible amount.

Proposed 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 proposing to conditionally package a limited number of additional ancillary services, in particular certain minor procedures and pathology services. CMS is also proposing to package payment for a few drugs that function as supplies in a surgical procedure.

Proposed Change in HOPPS Device Pass-through Process

Device pass-through payments are intended to enable 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 proposes to continue to accept and review device pass-through applications on a quarterly basis but would include discussions of the preliminary decisions on pass-through applications (both approvals and denials) in the next HOPPS proposed rule. CMS would accept public comments on the preliminary decisions and could change the decisions in the final rule in consideration of public comment. This change is in response to stakeholder requests for greater transparency and it also better aligns with the process used for evaluating New Technology Add-On payment requests under the Inpatient Prospective Payment System (IPPS).

CMS is also proposing a newness criterion for device pass-through applications. Under the proposal, a device that requires FDA approval or clearance would be considered "new" as evidenced by a FDA approval/clearance that is no more than 3 years old. This proposed newness criterion is similar to the IPPS New Technology Add-On payment newness requirement.

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 projected to be 1.7 percent. The multifactor productivity (MFP) adjustment is projected to be 0.6 percent, resulting in an MFP-adjusted CPI-U update factor of 1.1 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 items and services that are integral to a covered surgical procedure. CMS is proposing to exclude codes for services on the covered ancillary services list that are not used as ancillary and integral to a covered ASC surgical procedure. Specifically, radiation treatment using Co-60 stereotactic radiosurgery (SRS) is only provided in the HOPD or freestanding radiation centers and is not provided in ASCs. Therefore, CMS is proposing to remove these SRS 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 proposed rule 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 HOPPS. PHP services are furnished to patients as an alternative to inpatient psychiatric hospitalization, or as a step-down program to shorten an inpatient stay and transition a patient to a less intensive level of care.

CMS is proposing a methodology for addressing aberrant costs in the rate-setting process for PHPs, which would result in more accurate rates that better align with actual costs and would further CMS' goal of better managing medical costs. In addition, CMS is clearly articulating the PHP rate-setting process in the proposed rule to make it clearer for providers.

Quality Reporting Program Changes

Hospital Outpatient Quality Reporting (OQR) Program: Proposed Changes for 2017, 2018, and 2019 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 proposes to add two new measures to the program. Both measures are NQF endorsed, supported by the Measure Applications Partnership (MAP), and address the Making Care Safer and Effective Communication and Care Coordination National Quality Strategy goals.

The two measures are:

- 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.
- For the CY 2019 payment determination and subsequent years-OP34: 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.

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

CMS is also proposing several policy changes. To align with the Ambulatory Surgical Center Quality Reporting Program (ASCQR), CMS is proposing to: (1) change the deadline for withdrawing from the program from November 1 to August 31; (2) shift the quarters on which payment determinations are based and make conforming changes to the validation process to reflect proposed changes in the payment determination timeframes, requiring a one-time change in the payment determination timeframe to cover three quarters instead of four quarters; (3) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Website) from July 1 through November 1 to January 1 through May 15; and (4) change the deadline for submitting a reconsideration request from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year. CMS also proposes to correct a typographical error in its extensions and exceptions policy, and change paragraphs 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term "fiscal year" with the term "calendar year."

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 failure to meet the requirements of the ASCQR Program. The CY 2018 ASCQR Program measure set includes 12 measures—11 required and 1 voluntary.

CMS is not proposing to add any new measures to the program in this proposed rule, but is requesting 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).

Additionally, CMS proposes to exclude Indian Health Service hospital outpatient departments from the ASCQR Program because, while these entities bill Medicare for ASC services and are paid based on the ASC rates for services under the ASC payment system, they are required to meet the conditions of participation for hospitals – not the conditions of coverage for ASCs – and therefore should not be included in the ASCQR Program. CMS also proposes to display data by the National Provider Identifier (NPI) if data are submitted by NPI or by CMS Certification Number (CCN) if data are submitted by CCN. Additionally, CMS proposes to codify a number of existing and proposed policies.

CMS will accept comments on the proposed rule until August 31, 2015 and will respond to comments in a final rule to be issued on or around November 1, 2015. The proposed rule will appear in the July 8, 2015 Federal Register and can be downloaded from the Federal Register at: http://www.federalregister.gov/inspection.aspx.