MEMORANDUM

July 7, 2015

Re: CMS Releases CY 2015 Outpatient Prospective Payment System Proposed Rule

The Centers for Medicare & Medicaid Services (CMS) released July 2 the proposed Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ACS) rule for calendar year (CY) 2016. The proposed rules will be published in the Federal Register on July 8, 2014. CMS will accept comments until August 31, 2015.

The proposed rule can be downloaded from the Federal Register at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-16577.pdf

CMS is sharply accelerating its push toward moving outpatient payments from a fee-for-service model to a true prospective payment system with a number of its proposals.

The proposed outpatient PPS rule will reduce payment rates under the hospital outpatient PPS by -0.1 percent in CY 2016. This reduction is based on the projected hospital inpatient market basket increase of 2.7 percent for services paid under the hospital inpatient PPS minus a 0.6 percentage point adjustment for multi factor productivity and a 0.2 percentage point adjustment to the market basket, both of which are required by the Affordable Care Act (ACA). There is an additional proposed 2.0 percentage point adjustment to the payment update to account for excess packaged payment for laboratory tests, explained in more detail below. Overall, hospitals will receive $43 million less in outpatient PPS payments compared to CY 2015.

Highlights of the proposed rule include:

Changes to the Two-Midnight Rule: CMS introduced no changes to the 2-midnight rule in the 2016 IPPS proposed rule but acknowledged plans to address it in the OPPS rule. Accordingly, CMS released proposed updates to the "Two-Midnight" rule regarding when inpatient admissions are appropriate for payment under Medicare Part A. For stays that 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. For appropriate payment under Part A, the following factors, among others, would be relevant:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient; and
- The need for diagnostic studies that are more appropriately outpatient services (that is, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more).

CMS also announces a change in the enforcement of the standard so that Quality Improvement Organizations (QIOs) will oversee the majority of patient status audits, with the Recovery Audit program focusing on only those hospitals with consistently high denial rates.
CMS is not proposing to remove or adjust the -0.2% payment reduction to inpatient payments in light of these changes.

**Hospital Outpatient Quality Reporting (OQR) Program:** 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. 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:

- Move up the deadline for withdrawing from the program from November 1 to August 30 of the year prior to the affected annual payment update.
- Shift the quarters on which payment determination is made from Q3 two years prior to payment determination through Q2 of the year prior to payment determination to Q2 two years prior to payment determination through Q1 of the year prior to payment determination; if this change is made for CY 2018 payment determination, CY 2017 payment determination will be based on three quarters instead of four.
- Change the submission deadline for measures submitted through the CMS Web-based tool from July 1 through November 1 to January 1 through May 15.

**CMS Proposes to Align ASC Web-Based Quality Measure Reporting Dates:** CMS has proposed that all web-based measures in the ASC Quality Reporting Program be reported by May 15 each year. Currently, the deadline for ASC-8 is May 15 (although the deadline was extended only for 2015) and the deadline for ASC-6, ASC-7, ASC-9 and ASC-10 is August 15. According to CMS, aligning the dates “would allow for earlier public reporting of measure data and reduce the administrative burden for ASCs associated with tracking multiple submission deadlines for these measures.”

CMS is not proposing to add any new measures to the ASC Quality Reporting Program for the coming year.
**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 and Consolidation of Ambulatory Payment Classifications (APC):** By law, CMS must annually review and revise the OPPS 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 OPPS clinical APCs and proposes to restructure, reorganize, and consolidate many APCs, resulting in fewer APCs overall for nine clinical APC families.

The end result will be fewer APCs overall for nine clinical APC families:

- 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)

The proposed rule would combine the excision/biopsy and incision and drainage APCs and those for diagnostic radiology (x-ray, CT, MR, and ultrasound) with nuclear imaging.

CMS is also proposing to expand conditionally packaged services to include certain minor procedures and pathology services as well as proposing to package payment for “a few drugs that function as supplies in a surgical procedure.”
Payment of Part B Drugs, Biologicals, and Radiopharmaceuticals and Biosimilars in the Outpatient Setting: CMS proposes to continue payment at average sales price (ASP) plus 6 percent for non-pass-through drugs and biologicals that are payable separately under the Outpatient PPS.

CMS proposes to pay for biosimilar biological products based on the payment allowance of the product as set forth in the ACA; that is, 100% of the ASP for the biosimilar biologic and 6% of the reference biological’s ASP.

The agency also proposes to extend pass-through payment eligibility to biosimilar biological products and to set payment based on the same methodology outlined above. The proposed packaging threshold for non-pass-through drugs is $100.