**CMS Releases Two Proposed Rules for CY 2016: Hospital Outpatient/ASC Payment Systems and End-Stage Renal Disease Payment System**

On July 1, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2016 outpatient prospective payment system (PPS)/ambulatory surgical center (ASC) proposed rule. In addition to changes to the outpatient PPS and ASC payment systems, the rule proposed changes to CMS’s two-midnight policy for inpatient admissions. On June 26, CMS issued the End-Stage Renal Disease System (ESRD) PPS proposed rule. Highlights of the proposed rules follow, beginning with an overview of the proposed changes related to the two-midnight policy. This bulletin is five pages.

**Proposed Two-midnight Policy Changes**

**Proposed Revision to the Two-midnight Policy:** CMS proposes updates to its two-midnight policy regarding when inpatient admissions are appropriate for payment under Medicare Part A. CMS finalized its two-midnight policy in the fiscal year (FY) 2014 inpatient PPS final rule. Under this policy, CMS generally considers hospital admissions spanning at least two midnights as appropriate for payment under the inpatient PPS. In contrast, hospital stays of less than two midnights are generally considered outpatient cases, regardless of clinical severity.

In the proposed rule, CMS indicates that it continues to believe that the use of the two-midnight threshold is appropriate. However, the agency 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.

As a result, CMS proposes to modify its “rare and unusual” exceptions policy so that certain hospital inpatient services that do not cross two midnights may be appropriate for payment under Medicare Part A if a physician determines and documents in the patient’s medical record that the patient requires reasonable and necessary admission to the hospital as an inpatient. The agency indicates that the following factors, among others, would be relevant in determining whether an inpatient admission where the patient stay is expected to be less than two midnights is appropriate for Part A payment:
• 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 appropriately are outpatient services (that is, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more).

Notwithstanding this proposed exception, CMS does note that cases for which the physician determines that an inpatient admission is necessary, but that do not span at least one midnight, will be prioritized for medical review. In addition, CMS states that minor surgical procedures or treatments that keep a beneficiary for only a few hours (less than 24 hours) should continue to be billed as outpatient Medicare Part B services, regardless of the hour the beneficiary comes to the hospital, whether the beneficiary uses a bed or remains in the hospital past midnight. CMS does not propose any changes for stays that are expected to last more than two midnights.

The AHA believes this proposed revision to the two-midnight policy is a good first step. We appreciate that this proposal maintains the certainty that patient stays of two midnights or longer are appropriate as inpatient cases and agree that stays of less than two midnights should be paid on an inpatient basis based on the medical judgment of a physician. Finally, we remain concerned about the timing of potential changes to the two-midnight policy, given that the partial enforcement delay expires Oct. 1, 2015 but CMS’s proposed changes would not take effect until Jan. 1, 2016. Therefore, we continue to believe CMS must extend the partial enforcement delay past Oct. 1.

Proposed Changes to CMS’s Medical Review Strategy: Regardless of whether the proposed changes discussed above are finalized, CMS also will make changes to its patient status medical review and enforcement strategy. Specifically, no later than Oct. 1, 2015, CMS will use Quality Improvement Organizations (QIOs), rather than Medicare Administrative Contractors (MACs) or Recovery Audit Contractors (RACs), to conduct first-line medical reviews of the majority of patient status claims and to educate hospitals about claims denied under the two-midnight policy. CMS believes that QIO contractors are well-suited to conduct these reviews because they fit within the scope of the QIO statutory functions and because their quality improvement programs are aligned with the Department of Health and Human Services’ National Quality Strategy objective to provide “better care and better health at lower cost.”

RACs will focus only on those hospitals with consistently high denial rates. Specifically, under the QIO short-stay inpatient review process, those hospitals that are found to exhibit a pattern of practices including, but not limited to having high denial rates and consistently failing to adhere to the two-midnight policy (including having frequent inpatient hospital admissions for stays that do not span one midnight), or failing to improve their performance after QIO educational intervention, will be referred to the RACs for further payment audit.
The AHA is pleased that CMS will be using QIOs as the first line of medical review instead of the RACs, which will prevent RACs from making inappropriate denials of patient status determinations. At the same time, however, it is still unclear how CMS’s recent changes to the RAC program will interface with this new review process. We believe that these efforts to address short inpatient stays and the two-midnight policy will continue to fail if they are not combined with meaningful reform and management of the RAC program.

Payment Reduction: As part of the FY 2014 inpatient PPS final rule, CMS unlawfully imposed a permanent prospective 0.2 percent reduction to the operating PPS standardized amount, the Puerto Rico specific standardized amount, the hospital-specific payment rates and the capital Federal rate to offset what the agency claimed would be an increase of $220 million in inpatient PPS expenditures resulting from implementation of the two-midnight policy. In this rule, CMS states it will maintain the 0.2 percent reduction because the agency continues to believe the assumptions used by its actuaries to develop the calculation are consistent with the data thus far. As indicated in our comment letter for the FY 2016 inpatient PPS proposed rule, AHA’s analysis shows that this reduction is inappropriate and unwarranted. We continue to believe that the agency should fully reverse its unlawful 0.2 percent payment reduction for FY 2014 and subsequent years.

HIGHLIGHTS OF THE OUTPATIENT PPS PROPOSED RULE

Payment Update: The proposed rule includes a market-basket update of 2.7 percent, as well as a productivity cut of 0.6 percentage point and an additional reduction of 0.2 percentage point, as required by the Affordable Care Act (ACA). In addition, the agency proposes to apply a 2.0 percentage point reduction to the CY 2016 conversion factor to account for the Office of the Actuary’s previous overestimation of the amount of packaged laboratory payments in the outpatient PPS for laboratory tests. CMS alleges that these laboratory tests were, instead, separately paid under the Clinical Laboratory Fee Schedule. These payment adjustments, in addition to other proposed changes in the rule, are estimated to result in a net decrease in outpatient PPS payments of 0.2 percent (approximately $43 million) compared to CY 2015 payments. For those hospitals that do not publicly report quality measure data, CMS would continue to impose the statutory 2.0 percentage point additional reduction in payment.

The AHA is deeply disappointed that the agency has proposed a negative update for hospital outpatient services. We are dismayed that miscalculations by the CMS actuaries are resulting in penalties to hospitals and the patients they care for.

Proposed New Comprehensive Ambulatory Payment Classifications (APCs): In the CY 2015 final rule, CMS implemented 25 comprehensive APCs (C-APCs) that package an expanded number of related items and services contained on the same claim into a single payment for a comprehensive primary service under the outpatient PPS. For CY 2016, CMS
proposes to create nine new C-APCs. Among these is a proposed new comprehensive observation services APC (C-APC 8011), which would replace the current composite extended assessment and management APC 8009. CMS also proposes to create new C-APCs for ENT procedures, intraocular procedures, gynecologic procedures, laparoscopy, musculoskeletal procedures, urology and related procedures, and for ancillary outpatient procedures when a patient expires.

**Packaging Proposals:** In CY 2015, CMS conditionally packaged the costs of certain ancillary services into the primary service with which they are furnished. For CY 2016, CMS proposes to expand the set of conditionally packaged ancillary services to include three new APCs. Specifically, CMS proposes to package levels 3 and 4 pathology services that are billed with a surgical service as well as level 4 minor procedures. The agency also proposes changes to its current packaging policies for clinical diagnostic laboratory tests and for drugs and biologicals that function as supplies when used in a surgical procedure.

**APC Restructuring:** CMS proposes to restructure the APC groupings for nine APC clinical categories in order to improve clinical and resource homogeneity, reduce resource overlap in longstanding APCs, and improve the understandability and simplicity of the outpatient PPS APC structure. These include airway endoscopy procedures, diagnostic tests, excision/biopsy and incision and drainage procedures, gastrointestinal procedures, imaging services, orthopedic procedures, skin procedures, urology procedures and vascular procedures. As part of this restructuring, CMS also proposes to renumber several families of APCs to provide consecutive APC numbers for consecutive APC levels within the clinical family.

**Changes for Payment for Computed Tomography (CT):** CMS proposes to implement a non-budget neutral provision of the Protecting Access to Medicare Act of 2014 that will reduce outpatient PPS payment by 5 percent in 2016 (and 15 percent in 2017 and subsequent years) for certain CT services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) 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 proposes to establish a new modifier that would be reported with claims for certain CPT codes for such services.

**Proposed Changes in Quality Measurement and Reporting for the Outpatient PPS:** CMS proposes to add two new measures to the program. For the CY 2018 payment determination and beyond, CMS proposes to require reporting of OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases, which examines the percentage of patients with painful bone metastases and no history of radiation who receive EBRT on an acceptable dosing schedule. For CY 2019, CMS proposes to add OP34: Emergency Department Transfer Communication Measure, which assess the percentage of patients who are transferred to another facility and for whom there is documentation that administrative and clinical information was
communicated to the receiving hospital in an appropriate timeframe. CMS proposes to remove OP-15: Use of Brain Computed Tomography because it is no longer consistent with clinical practice guidelines. CMS had previously suspended data collection for this measure, so this proposed removal of the measure will have no discernable impact on hospital operations.

**Highlights of the Medicare ASC PPS Proposed Rule**

**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). For CY 2016, the CPI-U update is projected to be 1.7 percent. As required by the ACA, this update is reduced by a productivity adjustment, which is projected to be 0.6 percentage point, resulting in a 1.1 percent update for CY 2016.

**Highlights of the ESRD PPS Rule**

**Payment Update:** For CY 2016, CMS proposes an ESRD PPS base rate of $230.20. This rate includes the Protecting Access to Medicare Act of 2014-required reduced ESRD bundled market-basket update for CY 2016 of 0.15 percent, as well as productivity and wage index budget-neutrality adjustments. Including all policy changes in the rule, overall Medicare payments to ESRD facilities are proposed to increase by 0.3 percent in CY 2016. Hospital-based facilities would see a 0.5 percent increase.

**ESRD Quality Incentive Program (QIP):** CMS proposes three new measures for the ESRD QIP for payment year 2019. Specifically, the rule would replace four dialysis adequacy measures with a single clinical measure and adopt new quality reporting measures for ultrafiltration rate and flu vaccination.

**Next Steps**

The [outpatient PPS/ASC proposed rule](https://www.cms.gov) will be published in the July 8 *Federal Register*. The [ESRD PPS proposed rule](https://www.cms.gov) was published in the July 1 *Federal Register*.

Comments for the outpatient/ASC proposed rule must be submitted to CMS on or before Aug. 31. Comments for the ESRD PPS must be submitted to CMS on or before Aug. 25. The rules will be finalized in November and take effect Jan. 1, 2016.

Watch for AHA Regulatory Advisories with further details in the coming weeks.