CMS Releases Two Final Rules for CY 2016: Hospital Outpatient/ASC Payment Systems and Physician Fee Schedule

On Oct. 30, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2016 outpatient prospective payment system (PPS)/ambulatory surgical center (ASC) final rule. In addition to changes to the outpatient PPS and ASC payment systems, the rule makes changes to CMS’s two-midnight policy for inpatient admissions. The same day, the agency also released the CY 2016 physician fee schedule final rule.

Highlights of the rules follow, beginning with an overview of the changes related to the two-midnight policy. This bulletin is eight pages.

Two-midnight Policy Changes

Revisions to the Two-midnight Policy: CMS finalizes its proposed updates to the two-midnight policy regarding when inpatient admissions are appropriate for payment under Medicare Part A. The agency originally 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 final 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.

The AHA is very pleased that, as a result, CMS finalizes its proposal 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).

Therefore, an inpatient admission may be payable under Part A if the documentation in the medical record supports either the admitting physician’s reasonable expectation that the patient will require hospital care spanning at least two midnights, or the physician’s determination, based on the factors identified above, that the patient requires formal admission to the hospital on an inpatient basis. CMS indicates that inpatient cases that are not expected to last two midnights will be subject to medical review and the clinical judgment of the medical reviewer, who would review all submitted medical record information (e.g., progress notes, diagnostic findings, medications, nursing notes and other supporting documentation).

Notwithstanding this 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 make any changes to the two-midnight presumption or for stays that are expected to last more than two midnights.

The AHA is pleased that the agency finalized its revisions to the two-midnight policy. We appreciate that these changes maintain the certainty that stays of two midnights or longer are appropriate as inpatient cases; with stays of less than two midnights also considered inpatient based on physician judgment.

Changes to CMS’s Medical Review Strategy: CMS also restates the changes it announced to its medical review and enforcement strategy in the outpatient PPS proposed rule. Specifically, starting Oct. 1, CMS requires 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 indicates that 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.

CMS indicates that it will address technical medical review questions related to this transition to its new medical review and enforcement strategy in subregulatory guidance no later than Dec. 31, 2015.

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. We look forward to working with the QIOs and to a more fair auditing process.

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 final rule, CMS deferred discussion of the 0.2 percent reduction until later this year. If the reduction remains, the AHA will continue to pursue a robust critique of CMS’s justification for the unlawful 0.2 percent cut.

**Highlights of the Outpatient PPS Final Rule**

**Payment Update:** The rule includes a market-basket update of 2.4 percent, as well as a productivity cut of 0.5 percentage point and an additional reduction of 0.2 percentage point, as required by the Affordable Care Act (ACA). In addition, the agency finalizes its proposal 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 (CLFS). 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 0.4 percent (approximately $133 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 CMS finalized its negative update for hospital outpatient services for patient care. It is unfortunate that hospitals and the patients they serve are now left to deal with the consequences of CMS’s faulty math. We continue to be troubled by CMS’s actuaries’ lack of transparency, which is untenable.
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 creates 10 new C-APCs, including C-APCs for ear, nose and throat procedures, intraocular procedures, gynecologic procedures, laparoscopy, musculoskeletal procedures, urology and related procedures, ancillary outpatient procedures when a patient expires and comprehensive observation services.

Of particular note, the new comprehensive observation services APC (C-APC 8011) will replace the current composite extended assessment and management APC 8009. In the final rule, CMS adopted the AHA’s recommendation to exclude claims containing surgical procedure with status indicator “T” from qualifying for the new observation C-APC. Further, CMS will include all emergency department visits as eligible services paid through C-APC 8011, rather than only the high-level ED visits.

In addition, the AHA is pleased that CMS decided not to implement a burdensome policy that would have required hospitals to report a modifier with every Healthcare Procedure Coding System (HCPCS) code for a service that is adjunctive to a C-APC primary service, but reported on different claim. Instead, the agency will only require the use of the modifier in CY 2016 to identify specified planning and preparation services furnished in advance of stereotactic radiosurgery (SRS) C-APC primary procedures.

Laboratory Test Packaging: CMS creates a new “Q4” conditional packaging status indicator for laboratory tests. The AHA supports the new status indicator because it will make it easier for hospitals to receive separate payment under the CLFS for laboratory tests that are provided without other outpatient PPS services. We also support CMS’s decision to exclude all molecular pathology tests and preventive laboratory tests from packaging.

However, the AHA is disappointed that CMS finalized its proposal to expand its laboratory test packaging to the claims level, rather than maintaining its current policy of date-of-service packaging. We believe that this decision was based on an incorrect interpretation of CY 2014 claims data. Further, claims-level laboratory packaging will increase operational burden and require manual claims handling for hospitals seeking separate payment under the CLFS for unrelated laboratory tests (using the “L1” modifier) furnished on a different date of service, but on the same claim, as other outpatient PPS services.

In addition, CMS expands its packaging policies for ancillary service APCs and for drugs that function as supplies when used in surgical procedures.

APC Restructuring: CMS finalizes, with modifications, its restructuring of the APC groupings for nine APC clinical categories. 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. The agency argues that this restructuring will improve clinical and resource homogeneity, reduce resource overlap in longstanding APCs, and improve the understandability and simplicity of the outpatient PPS APC structure. As part of this restructuring, CMS renumbers several families of APCs to provide consecutive APC numbers for consecutive APC levels within the clinical family. The AHA is pleased that, as part of its final restructuring of the imaging APCs, CMS assigned positron emission tomography (PET) procedures to a new higher-paying APC. This is appropriate because PET imaging services involve higher resource costs than non-PET imaging services.

Changes for Payment for Computed Tomography (CT): CMS implements a non-budget neutral provision of the Protecting Access to Medicare Act of 2014 that will reduce outpatient PPS payment by 5 percent in CY 2016 (and 15 percent in CY 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, titled “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 establishes a new modifier “CT” to be reported with claims for certain CPT codes for such services.

Lung Cancer Screening with Low-dose CT: As the AHA requested, CMS clarifies that the effective date for the two new HCPCS G-codes for lung cancer screening with low-dose CT is retroactive to Feb. 5, 2015, the date that CMS’s National Coverage Determination for these services was approved.

Advance Care Planning Services: Consistent with the AHA’s recommendation, CMS will make a separate payment under the outpatient PPS for advance care planning services (CPT 99497) furnished by hospital staff in an outpatient department when these services are the only services furnished to patients. CMS assigned CPT 99497 to APC 5011 (Level 1 Examinations and Related Services). We are pleased that Medicare will now cover these services, which will help ensure that Medicare beneficiaries will be able to develop advanced care plans in conjunction with their medical care providers.

Outpatient Quality Reporting (OQR) Program Changes: CMS finalizes the removal of OP-15: Use of Brain Computed Tomography from the OQR program because it is no longer consistent with clinical practice guidelines. For the CY 2018 OQR, CMS adds one new measure, 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. As urged by the AHA, CMS chose not to finalize OP-34: Emergency Department Transfer Communication Measure for the CY 2019 OQR program. The agency acknowledges that OP-34 is duplicative of many Medicare Electronic Health Record Incentive Program requirements and is overly burdensome to collect.
HIGHLIGHTS OF THE MEDICARE ASC PPS FINAL 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 0.8 percent. As required by the ACA, this update is reduced by a productivity adjustment, which is 0.5 percentage point, resulting in a 0.3 percent update for CY 2016.

HIGHLIGHTS OF THE PHYSICIAN FEE SCHEDULE FINAL RULE

Payment Update: CMS increased payment rates for CY 2016 by 0.5 percent, as required by the Medicare Access and CHIP Reauthorization Act 2015 (MACRA).

Advanced Care Planning (ACP): As urged by the AHA, CMS finalizes its proposal to pay for advanced care planning (ACP) services. In the CY 2015 PFS final rule, CMS created two new Current Procedural Terminology (CPT) codes (99497 and 99498) that describe ACP services, which include the explanation and discussion of advance directives by a physician or other qualified health professional. However, CMS assigned the codes an inactive status, which means they are not payable under Medicare. We are pleased that Medicare will now cover these services, which will help ensure that Medicare beneficiaries will be able to develop advanced care plans in conjunction with their medical care providers.

Telehealth Services: CMS finalizes its proposal to add to the list of Medicare-payable telehealth services the codes for prolonged service in the inpatient or observation setting, and for end-stage renal disease related services for home dialysis.

Physician Quality Measurement: CMS finalizes several updates to the physician quality reporting system (PQRS) and value-based payment modifier (VM) programs that would affect payment in CY 2018. As required by the MACRA, CY 2018 is the final year for both PQRS and the VM, which will be supplanted by a new Merit-Based Incentive Payment System (MIPS) beginning with CY 2019 payments.

PQRS. As required by the ACA, individual eligible professionals (EPs) and group practices are required to meet PQRS requirements to avoid a 2.0 percentage point payment penalty in CY 2016. For the CY 2018 PQRS program, CMS will allow, as required by the MACRA, group practices to use the qualified clinical data registry (QCDR) reporting option that is currently available to individual EPs. As urged by the AHA, CMS does not finalize its proposal to require reporting of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey by group practices of 25-99 EPs. However, CMS will require CAHPS reporting by all group practices of 100 or more EPs, except those groups using the QCDR reporting option.

VM. For CY 2018, CMS will continue placing up to 4 percent of PFS payment at risk for upward or downward adjustment under the VM. The agency also will exercise its discretion
under the ACA to apply the CY 2018 VM to several non-physician EPs – physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. As urged by the AHA, CMS also will exempt individual EPs and group practices from the 2017 and 2018 VM if they participate in certain Center for Medicare and Medicaid Innovation (CMMI) initiative, including the Pioneer Accountable Care Organization (ACO) model and Comprehensive Primary Care Initiative. However, CMS will continue to apply the VM to individual EPs and group practices participating in the Medicare Shared Savings Program (MSSP).

Physician Compare. CMS will continue to expand the measures and information reported on Physician Compare. Beginning in CY 2017, the agency will begin to report the results of some individual measures using a five-star rating approach.

MSSP: CMS finalizes its proposal to add one quality measure, Statin Therapy for the Prevention and Treatment of Cardiovascular Disease, to assess ACO quality starting in 2016. In response to feedback, CMS will implement the measure as pay-for-reporting in all agreement years, rather than transitioning to pay-for-performance in the third year, as proposed.

CMS also finalizes its proposed changes to the services it considers primary care when assigning Medicare beneficiaries to an ACO under the MSSP. The agency will exclude certain evaluation and management services provided in skilled nursing facilities and other nursing facility settings, but will include certain services provided by Elective Teaching Amendment hospitals, which are hospitals that have elected to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in lieu of Medicare PFS payments.

Physician Self-referral: The AHA is pleased that CMS finalizes its proposal to create a new exception to self-referral regulations that will allow payments to physicians for the purpose of recruiting non-physician practitioners. The agency also finalizes a new exception that would permit timeshare arrangements for the use of office space, equipment, personnel, supplies and other services when they are used predominately for the evaluation and management of patients. Further, the agency finalizes a number of changes intended to clarify terminology and provide policy guidance to reduce perceived or technical noncompliance with self-referral rules.

Physician-owned Hospitals (POH): CMS finalizes its proposed amendments to a requirement that POHs must disclose on any public hospital website and in any public advertising that the hospital is owned or invested in by physicians. The agency defines more specifically what constitutes a public website and public advertising. The agency also finalizes its proposal to include all physician owners or investors – not just those that self-refer – when calculating the percentage of physician ownership.
**NEXT STEPS**

The [outpatient PPS/ASC final rule](#) will be published in the Nov. 13 *Federal Register*, while the [PFS final rule](#) will be published in the Nov. 16 *Federal Register*. The rules take effect Jan. 1, 2016. Watch for AHA Regulatory Advisories with further details in the coming weeks.