



**Association of
American Medical Colleges**
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0460 F 202 862 6161
www.aamc.org

Darrell G. Kirch, M.D.
President and Chief Executive Officer

Via Electronic Submission (www.regulations.gov)

August 31, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS-1601-P
7500 Security Boulevard
Baltimore, MD 21244-8013

Dear Mr. Slavitt:

Re: CY 2016 Outpatient Prospective Payment System Proposed Rule, File Code CMS-1633-P.

The Association of American Medical Colleges (AAMC or Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS' or the Agency's) proposed rule entitled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System," 80 *Fed. Reg.* 39200 (July 8, 2015). The AAMC is a not-for-profit association representing all 144 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The proposed calendar year (CY) 2016 Outpatient Prospective Payment System (OPPS) rule makes significant changes to the Two-Midnight policy. While several additional revisions are needed, including a commitment by CMS to adequately monitor the impact of the use of Quality Improvement Organizations (QIOs), the proposals hold the promise of a more equitable system that relies on a physician's medical judgment and documentation in the medical record rather than a time-based approach that was inequitable to providers and beneficiaries alike.

Of concern to the AAMC is that since 2014 CMS has implemented a myriad of significant changes to the OPPS, including packaging of lab tests and certain ancillary services, and creating comprehensive Ambulatory Payment Classifications (APCs). Again, for CY 2016, CMS proposes a number of major changes to the OPPS, such as the expansion of lab packaging and the large consolidation and

restructuring of the APC system. In general, the AAMC supports CMS' vision of a true prospective payment model in OPSS, but the Association is very concerned that the rapid pace of these changes exceeds both hospitals' adaptive capacity and the Agency's ability to accurately model and sufficiently explain the impact of either past or current proposals. In most cases, these changes interact with each other. Also of concern is that the rapidity with which new policies are being adopted leaves inadequate time to identify and address implementation issues and that the data collection requirements imposed since 2014 impose a significant administrative burden. The Association urges CMS to delay finalizing the 2016 proposals, thereby allowing time to consider the overall impact of these changes that have been imposed since 2014 and to address the implementation issues that have been identified.

As CMS moves to a payment system that bundles more services together and accounts less for individual patient complexity, the AAMC urges the Agency to take a fresh look at the overall adequacy of OPSS payments to major teaching hospitals. The AAMC is concerned that the burden of these changes may fall disproportionately on major teaching hospitals primarily because they care for more complex patients. Therefore, the AAMC encourages CMS to propose a patient risk adjustment and/or teaching adjustment to the OPSS to ensure that the payment system does not penalize hospitals for serving those Medicare beneficiaries who are in need of more services than an average patient.

Our comments focus on the following major areas:

- Revisions to the Two-Midnight policy for short inpatient hospital stays
- Recovery Audit Contractor (RAC) reforms
- 2 percent reduction on conversion factor
- Data collection for non-primary Services in Comprehensive – Ambulatory Procedure Codes (C-APCs)
- New C-APC 8011 for observation stays
- Expansion of lab packaging
- Changes to the hospital Outpatient Quality Reporting (OQR) program

TWO-MIDNIGHTS

CMS Should Finalize its Proposal to Defer to an Admitting Physicians' Clinical Judgment Regarding Short Inpatient Stays

The AAMC welcomes and appreciates CMS' recognition of the longstanding stakeholder concerns regarding the Two Midnight policy for determining which hospitalizations may be categorized as inpatient for purposes of billing under Medicare Part A. After two years of open dialogue and deliberation between the AAMC and the Agency, we applaud CMS' proposal to allow physicians' clinical judgment to determine the instances in which short inpatient stays are necessary. The current proposal is closely aligned with AAMC's consistent position: individual patient characteristics, comorbidities, and complications may necessitate an inpatient stay lasting fewer than two midnights and CMS should defer

to physicians to identify and document those cases for inpatient payments. Further, stays for which the physician expects the patient to be inpatient for at least two midnights following formal admission will continue to be presumed appropriate and will be paid under Part A.

The AAMC also supports the three factors CMS proposes to consider in determining whether an individual admission lasting fewer than two midnights is appropriate for Part A payment: 1) the severity of the signs and symptoms exhibited by the patient; 2) the medical predictability of something adverse happening to the patient; and 3) the need for diagnostic studies that appropriately are outpatient services. These factors are generalizable and adaptable to complex and unique patients' circumstances, which our members agree, necessitate short inpatient stays. There will be a continuation of this dialogue with the AAMC's membership and the Agency as the new policy is implemented to determine whether additions or clarifications are necessary.

CMS has struck a reasonable balance in its expectation that hospital stays lasting only a few hours, and not overnight, can reasonably be presumed to be appropriate for outpatient care. The AAMC appreciates that even alongside this revised guideline, CMS acknowledges that there still may be rare circumstances in which a hospital stay shorter than one midnight is appropriately designated as inpatient and billed under Medicare Part A. The Association understands the rationale for targeting short inpatient stays lasting less than one midnight for additional review, and expects that the medical reviews of those cases will still consider the three clinical judgment factors listed above.

In the paragraphs that follow, the AAMC identifies modifications to the Agency's implementation strategy that will strengthen the overall proposal to revive a role for physician clinical judgment in inpatient determinations.

CMS Should Finalize its Proposal to Shift Medical Review of Short Inpatient Stays to Quality Improvement Organizations (QIOs)

The AAMC welcomes the CMS proposal to shift medical review responsibilities for short inpatient stays from Medicare Administrative Contractors (MACs) to QIOs. The individual case-by-case review policy that CMS has proposed requires clinical expertise, experience working with hospitals on clinical decision-making, and a willingness to collaborate to understand unique patient circumstances. Though their performance in this specific arena is yet untested, the AAMC is hopeful that QIOs will prove more effective partners than have the MACs.

In response to a recent survey, AAMC members reported mixed experiences with their regional QIOs, ranging from very engaged and responsive relationships to very little interaction at all. Some reported minor concerns about QIO readiness, responsiveness, and technological capabilities – which are detailed in subsequent sections of this letter. All AAMC members who responded to the survey, however, expressed support for QIO medical reviews, indicating a sincere desire for improvement over the current process. Given that these reviews will be a new responsibility for QIOs, the AAMC urges CMS to closely

monitor them, including soliciting frequent feedback from hospitals, to ensure that the QIO process avoids the many issues that were caused by the RACs.

CMS Should Align Implementation of QIO Medical Review with the Effective Date of the Final Outpatient Prospective Payment System Rule

CMS proposes to shift medical review responsibilities to the QIOs beginning in October 2015, even though the final rule itself will not be released until November 2015 and will not be effective until January 2016. While the AAMC shares the Agency's sense of urgency regarding improvements to the medical review and recovery auditor process, failure to align these implementation dates will be unfair to those hospitals that are audited under rules that will change soon. If QIOs begin sampling post payment claims of short inpatient stays in October, before an exception for clinical judgment is finalized, QIOs may find themselves educating hospitals on a rigid standard that will change in a matter of few months.

Postponing the implementation of QIO medical reviews until at least January 2016 has the additional benefit of providing the QIOs more time to prepare for their new role, one that seems difficult to undertake effectively by October 1. A delay will also allow CMS to issue more specific guidance to QIOs about taking samples, reviews, and referrals to recovery auditors. Hospitals will have more time to understand the new rules and educate staff, rather than being asked to adopt new medical review protocols in October only to have the rules change again three months later. The Association is concerned that this element of confusion could undermine the new relationships between hospitals and QIOs which should be focused on collaboration and education. Before the QIOs begin their work, CMS should assure the hospital community that it has taken all necessary steps to prepare the QIOs for their new role.

CMS Should Ensure QIOs have Adequate Resources to Assume Their New Medical Review Responsibilities

The AAMC is concerned that despite their noted clinical and quality expertise, the QIOs may not have sufficient staff capacity and resources to undertake this new role efficiently. While we laud the collaborative oversight process CMS envisions in the proposed rule, we urge the Agency to provide additional resources to the QIOs as may be necessary to conduct medical reviews and work with hospitals in a timely and responsive manner. The AAMC also requests that CMS formally monitor response times by QIOs and seek regular feedback from both the QIOs and hospitals about the staff, expertise, and resources necessary to improve the process as it is implemented.

Of specific concern is the QIOs' reliance on paper copies of medical records and their general inability to receive relevant records and documentation electronically. Over the past several years, hospitals nationwide have begun (and in many cases completed) transitioning to electronic health records (EHRs). Major teaching hospitals have led the way and invested millions in newer and more efficient systems. In many teaching hospitals, few paper records remain, and staff once tasked with maintaining paper records have been retrained.

To now be required to print/mail/fax paper records will introduce a significant administrative burden for hospitals and will lead to a slower and inefficient medical review process. This is of particular concern because a number of AAMC members already cite difficulty in exchanging medical records for the purposes of quality improvement initiatives – having to send medical records multiple times or the QIO being unable to verify receipt of documents.

In spite of this technological deficiency, the AAMC supports CMS' proposal to transition medical review of short inpatient stays to QIOs but implores the Agency to quickly provide the QIOs with the resources to implement technologies capable of receiving medical records electronically.

CMS Should Provide Additional Guidance to QIOs Regarding Referrals to Recovery Auditors to Mitigate Bias Against Hospitals Performing High-Risk Procedures on Complex Patients

CMS proposes that Recovery auditor patient status reviews will be conducted for those hospitals that have consistently high denial rates based on QIO medical review outcomes. The AAMC urges CMS to specify the methodology that will be used to categorize a hospital as having a high denial rate and ensure that such methodology is based on the proportion of denials relative to both inpatient and outpatient procedures. Without this clarity we are concerned that the referral process will be biased against institutions performing procedures for complex patients.

For example, one AAMC member institution (referred to here as Hospital A) performs approximately 1,000 Medicare FFS Percutaneous Coronary Intervention (PCI) cases per year. 60 percent – the majority of these cases – are performed as ambulatory procedures while 40 percent require, based on the physician's judgment regarding the signs and symptoms of the patient and the likelihood of adverse outcomes, inpatient admission (largely one day stays). Through CMS data shared with this hospital in the quarterly PEPPER reports (Program for Evaluating Payment Patterns Electronic Report) it is clear that compared with peers Hospital A is consistently well below the 80th percentile in terms of the ratio of inpatient to outpatient PCI cases, and therefore, should not be a target for audit. On the other hand, consider that a hypothetical "Hospital B" performs 50 PCIs per year, 90 percent as one-day inpatient stays and only 10 percent as ambulatory procedures.

The AAMC is very concerned that if the QIO compares the 400 one-day inpatient stays at Hospital A to the 45 at Hospital B, it will refer Hospital A for the Recovery auditor review although the difference in the two hospitals is attributed to volume. The AAMC urges CMS to instruct the QIOs to base referrals to recovery auditors on hospitals' denied claims relative to their percentages of inpatient v. outpatient claims for each category of ambulatory or observation-amenable procedures or conditions. Without the necessary context provided by that information, larger academic medical centers are likely to be inappropriately referred to recovery auditors due simply to volume of one day inpatient stays rather than appropriateness of patient status. In addition, consideration should be given to the complexity of the patients who have one-day inpatient stays that, too, is an important factor.

CMS Should Clarify that Recovery Auditor Patient Status Reviews are to be Limited to Only Those Institutions Referred by QIOs

The AAMC supports CMS' proposal to instruct QIOs to collaborate with hospitals found to have high denial rates of short inpatient stay claims. An educational process, quality improvement activities, and review of organizational systems may prove useful to hospitals in understanding expectations for medical reviews. Additionally, the educational process may also allow QIOs unaccustomed to the complexities of hospital admitting decisions to be better informed. It is appropriate that this collaboration take place prior to Recovery auditor patient status reviews and that hospitals be given an opportunity to lower their denial rates before being referred for audits.

The AAMC requests that CMS explicitly state that the recovery auditors will only conduct patient status reviews after the aforementioned collaborative process with the QIOs has taken place. This appears to be consistent with the Agency's intent.

CMS proposes that "recovery auditors will conduct patient status reviews *focused* on those providers that are referred from the QIOs and have high denial rates. The number of claims that a recovery auditor will be allowed to review for patient status will be based on the claim volume of the hospital and the denial rate identified by the QIO"¹(emphasis added). The number of claims a recovery auditor will be allowed to review is contingent in part on the denial rate identified by the QIO. CMS' proposal would be more precise if the word "focused" were replaced with "only," and the AAMC requests that the Agency make this minor clarifying change.

CMS Should Repeal the 0.2 Percent Reduction to the Standardized Amount That Was Implemented in FY 2014

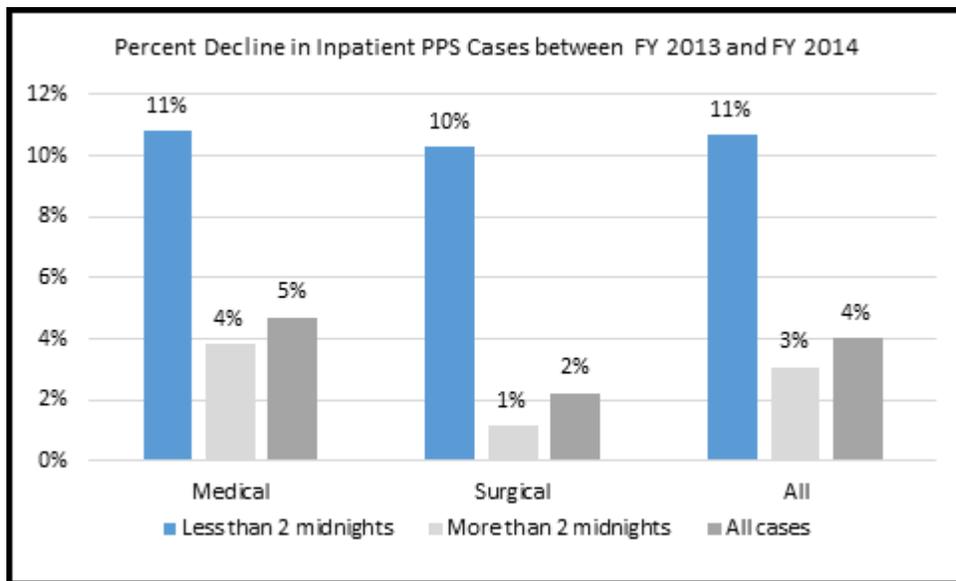
In the FY 2014 IPPS final rule,² CMS finalized a 0.2 percent reduction to IPPS payments to offset expected shifts in utilization between inpatient and outpatient settings. To justify this reduction, CMS stated that its actuaries projected an increase in IPPS expenditures resulting from the Two Midnight rule. Specifically, CMS estimated \$220 million in additional expenditures that would result from an expected net increase of 40,000 hospital inpatient encounters. As a result, CMS applied a -0.2 percent adjustment to all FY 2014 rates (the operating IPPS standardized amount, the hospital-specific rates, the Puerto Rico-specific operating standardized amount, as well as the national capital Federal rate and the Puerto Rico-specific capital rate).

The AAMC appreciates that CMS revisits the issue in the proposed rule and explains the rationale behind original assumptions made by the Office of the Actuary (OACT or Actuary); however, the explanation provided by CMS was incomplete and failed to provide sufficient

¹ 80 Fed. Reg. 39353 (July 8, 2015)

² [2013 IPPS Final Rule](#), 77 Fed. Reg. 53258, 50746 (Aug. 31, 2012).

evidence to support the 0.2 percent reduction. The Association urges the Actuary to reexamine and adjust their assumptions in light of more recent data and feedback from stakeholders. For example, the Actuary’s original projection was limited to net shifting between inpatient surgical short stays and outpatient observation stays with major procedures. As the Two Midnight Rule applies to all inpatient short stays, surgical and medical, the AAMC suggests the Actuary to reevaluate the impact based on net shifting of all inpatient cases. AAMC and peer hospital associations’ data analysis shows that declines in medical short stays from FY 2013 to FY 2014 as much as that in surgical short stays.



Source: FY 2013 and 2014 MedPAR (December proposed rule updates).

Given that this negative adjustment was based on the Actuary’s assumptions of a net increase in inpatient cases, the adjustment is not justified if this projected increase in inpatient cases is unsubstantiated. Analysis base on MedPAR data (March final rule updates) shows there was a net decline (-4 percent) in inpatient encounters and an 10 percent decline in encounters of less than two midnights from FY 2013 to FY 2014 after implementation of the Two Midnight Rule.

Comparison of FY 2013 and FY 2014 Inpatient Encounters³

Length of Stay	FY 2013	FY 2014	% Change
Less than 2 days	1,173,783	1,059,254	-10%
2-4 days	4,641,536	4,571,074	-2%
5 or more days	3,751,453	3,559,706	-5%

³ *Id.* Source: FY 2013 and FY 2014 MedPAR (March final rule updates).

All Cases	9,566,772	9,190,034	-4%
-----------	-----------	-----------	-----

Even taking into account the recent downward trend in inpatient volume between 2009 and 2013, there was still a net decrease in inpatient volume in FY 2014 after implementation of the Two Midnight Rule. Further data analysis was conducted using FY 2009 - FY 2013 IPPS final rule MedPAR data sets to calculate counts for stays less than and greater than two midnights. Different compound annual growth rates (CAGRs) were then created and used to project what the numbers would have been in FY 2014 without the Two Midnight rule (using FY 2013 IPPS final rule numbers).⁴ Next, these projected numbers were compared to actual FY 2014 IPPS final rule numbers that take into account the effect of the Two Midnight Rule. The actual case counts for FY 2013 and FY 2014 and the projected case counts without the Two Midnight Rule (using the longer term 2009 - 2013 CAGR) are included in the table below. The data shows a net **decrease** of almost 200,000 inpatient encounters attributable to the Two Midnight rule. The data also shows differences between the actual FY 2014 case counts with the Two Midnight rule in effect and projected FY 2014 inpatient case counts without the Two Midnight Rule. The projected inpatient case counts without the Two Midnight Rule are substantially higher.

Difference between Actual and Expected Inpatient Cases Using 2009- 2013 CAGR⁵

Length of Stay	Actual FY 2013 Case Counts	Actual FY 2014 Case Counts (With 2 MN Policy in Effect)	2009-2013 CAGR	Projected FY 2014 Case Counts Absent 2 Midnight Policy Using 2009-2013 CAGR	Difference between Actual and Projected FY 2014
Less than 2 days	1,173,783	1,059,254	-4.2%	1,124,831	-65,577
2-4 days	4,641,536	4,571,074	-0.8%	4,603,040	-31,966
5 or more days	3,751,453	3,559,706	-2.6%	3,652,292	-92,586
All Cases	9,566,772	9,190,034	-2.0%	9,380,163	-190,129

The analysis shows a nearly 200,000 stay decrease in inpatient volume that would not have occurred absent the Two Midnight Rule, thus demonstrating that OACT’s estimated increase in inpatient volume attributable to the Two Midnight Rule is unsupported. While many factors influence inpatient volume, no scenario justifies the net increase of 40,000 inpatient cases projected by CMS. These data directly counter

⁴ CAGRs were created for each of the following time periods: FY 2009-2013, FY 2009-2011 (the time period used by OACT in the FY 2014 final rule); and FY 2011-2013 (a more recent period used for the sake of comparison).

⁵ *Id.*, Source: FY 2013 – FY 2014 Case Counts by Length of Stay and Expected Cases Using 2009-2013 CAGR.

the original estimate that was used by CMS to justify the 0.2 percentage point negative adjustment to the update factor starting FY 2014, and instead could justify an increase to the update factor to restore the budget neutrality of the IPPS.

There are many reasons why CMS' assumptions may have been inaccurate. Without more details about the assumptions CMS used, it is not possible to determine the part of the Agency's methodology that is flawed. This is why the AAMC and other stakeholders have repeatedly requested additional information. The AAMC and other stakeholders have also applied numerous methodologies to model the shift in volume between inpatient and outpatient settings that could be attributable to the Two Midnight Rule. There is not a single methodology or reasonable scenario that supports the net increase in 40,000 inpatient cases that CMS uses to justify the negative adjustment finalized in conjunction with the Two Midnight Rule. Accordingly, the AAMC strongly urges CMS to revisit the Agency's original assumptions, remove the 0.2 percentage point reduction, and restore the offset that was taken in FYs 2014 and 2015.

CMS Should Remove the Sub-regulatory Countersignature Requirement for Resident Orders for Inpatient Admission

The AAMC continues to have significant concerns related to CMS' sub-regulatory guidance implementing the physician order requirements finalized in conjunction with the Two Midnight Rule that requires that resident inpatient admission orders be countersigned by an attending physician. In our June 16 comment letter to CMS on the FY 2016 Inpatient Prospective Payment System Proposed Rule (<https://www.aamc.org/download/434704/data/aamccommentsonfy2016ippsproposedrule.pdf>), the Association provided information about the unreasonable burden this requirement has placed on teaching hospitals and gave a detailed analysis that shows that the requirement is not supported by the Conditions of Participation. The Agency has not responded to our request that the sub-regulatory guidance be modified as follows:

Certain non-physician practitioners and residents working within their residency program are authorized by the state in which the hospital is located *to practice* medicine, and are allowed by hospital by-laws or policies to *furnish orders*. The admitting practitioner may allow these individuals to write inpatient admission orders on his or her behalf, if the admitting practitioner approves and accepts responsibility for the admission decision as demonstrated by documentation in the medical record, *such as progress notes*. *In this case a countersignature of the order is not needed unless required by state law or hospital by-laws.*

As the Two Midnight Rule is undergoing substantial revisions, there is an opportunity to make these changes in the sub-regulatory guidance. The AAMC urges CMS to do so expeditiously to avoid a situation in which QIO oversight process may be overwhelmed with teaching hospital claims that are flagged on the basis of resident ordering rather regulatory criteria.

RECOVERY AUDIT CONTRACTORS REFORM

CMS Should Move Quickly to Implement Meaningful RAC Reform

Overly aggressive RAC denials are a major source of the problems surrounding short inpatient stays and longer observation stays. The AAMC is hopeful that a new role for QIOs in conducting medical reviews of short inpatient stays will diminish RAC's broad denial of claims which contributed to the still-large appeals back-log. The AAMC appreciates the December 30, 2014 changes to the Recovery Audit Program that CMS announced and supports the much-needed revisions to the program. However, the AAMC hopes that CMS will incorporate these improvements into RAC contracts as soon as possible rather than waiting for the next Recovery Audit Program contract awards. In addition, other reforms are needed, such as those described here:

- **Hold RACs Accountable for Excessive Overturn Rates.** Until the problematic contingency fee structure is replaced, RACs' contingency fees should be subject to a penalty if their overturn rate exceeds a certain threshold. This MedPAC recommendation is an important step towards reforming the misplaced RAC incentives to broadly deny inpatient claims, exacerbating the appeals backlog.
- **Require Expert Review for Complex Services.** RACs often do not have the necessary clinical expertise to audit complex services, such as radiation therapy. Many hospitals find that when hospital staff and specialized physicians can explain the codes and documentation to the RAC auditors, it becomes clear that the claim should not be denied. Requiring RACs to have a Contractor Medical Director consult with physician specialists and communicate with providers about coding and documentation would reduce improper denials.
- **Maintain Separate Limits for Inpatient and Outpatient Reviews.** The current methodology results in a disproportionate share of acute inpatient records being audited, because the contingency fees are more lucrative. When oversight is biased in this way, policy makers also get a biased perspective regarding where providers are "overbilling" – simply because RACs are looking for overbilling in inpatient settings more frequently.
- **Improve RAC / Provider Communication.** Requiring RACs to contact providers throughout the review process could clear up simple misunderstandings and prevent appeals. For example, if a RAC identifies an unusually large error rate, the RAC should be required to contact the hospital/physician group to determine if the cause is a misunderstanding rather than a billing problem.
- **Extend the Rebilling Window.** Misalignment between the RAC look back period and the Part B rebilling window prevents Part B rebilling from ever being an effective recourse for hospitals to be paid for claims that will not be paid under Part A. Shortening the RAC look back period would

be a step in the right direction but would not remedy the problem, because it is nearly impossible for RACs to complete audits and for the hospital to rebill within this timeframe. To resolve this issue, CMS should extend the one-year rebilling window so that it starts after the RAC denies the inpatient stay rather than the date of service and remain open until appeals are exhausted.

2 PERCENT REDUCTION ON CONVERSION FACTOR

More Analysis and Transparency Is Needed Before CMS Implements the Proposed Reduction in the Conversion Factor

CMS proposes to apply a 2.0 percent reduction to the conversion factor as an offset to estimated payment inflation resulting from the implementation of the lab packaging policy in 2014. In 2014 CMS finalized the policy to conditionally package lab tests that are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services ordered on the same date as primary services by the same practitioner. At that time the Agency estimated that \$2.4 billion in spending on lab tests that originally was paid under the Clinical Lab Fee Schedule (CLFS) would be packaged into the OPSS. In the proposed rule CMS explained that to maintain budget neutrality the weight scaler in 2014 was increased by an amount that was equivalent to \$2.4 billion to the aggregate OPSS payment. In reviewing aggregate payment for 2014, CMS observed \$1 billion more than expected spending on lab tests that were exempted from the lab packaging policy and were paid separately under CLFS. To account for this error by the Agency, CMS now proposes a 2.0 percent reduction (\$1 billion) to eliminate potential overpayments in 2016 and future years.

The AAMC believes it is premature to reduce payments and urges CMS to not adopt the proposal. When the CY 2014 final rule was released, CMS neither mentioned nor explained the projected \$2.4 billion spending on lab services that would be packaged into the OPSS, even though AAMC raised concerns in the comment letter about the lack of data and information. This year, the AAMC engaged a data consultant, Watson Policy Analysis (WPA), to help verify the \$1 billion overpayment estimated by CMS. Among the problems identified by WPA were two key issues that prevented them from fully replicating CMS' projection: lack of data and lack of transparency in methodology. The spreadsheet released with the CY 2016 proposed rule shows the shifts of volume by bill type. CMS noted the analysis was based on claims processed through May 31st, 2015. In contrast, the OPSS data released to the public only contains claims processed through December 31st, 2014, which according to CMS is estimated to include only approximately 90% of the CY 2014 claims. CMS provided limited technical details and left unexplained many methodological decisions, assumptions, and logic. For example, CMS acknowledged that projecting how much the packaged lab tests would be paid under the CLFS in 2014 without the lab packaging policy required certain assumptions to be made, yet the Agency failed to explain those assumptions.

The AAMC is extremely concerned about the use of 2014 claims data to project a payment offset in 2016. Changes in billing instructions on lab services in the middle of 2014 render 2014 claims data an unrepresentative sample of future years. To implement the lab packaging policy in 2014, CMS instructed hospitals to use 14X bill type codes for lab tests that should be separately paid. This was an inappropriate

use of the 14X bill type, as indicated in the letter sent to CMS by the National Uniform Billing Committee (NUBC). CMS' instruction to use the 14X bill type caused confusion among the hospital community. In July 2014, CMS instructed hospitals to continue using the 14X bill type but to use an "L1" modifier to indicate separately billable lab tests. Once again, it took time for hospitals to absorb and comply with the new guidance. It is possible that what CMS observed in the 2014 data is a reflection of hospitals' confusion and the learning curve they experienced, thereby rendering 2014 claims an unreliable source to project utilization of lab services in 2016. The Association strongly urges CMS to delay the implementation of the 2 percent payment reduction until more reliable data are available.

In addition, CMS' projection of lab use in 2016 should consider other proposed policy changes. For example, CMS proposes to expand the lab packaging policy in 2016 by including lab tests that are on different dates from the primary services but ordered by the same practitioner for the same purpose. If implemented, such a policy expansion would reduce spending on separate billable lab tests in 2016 and hence reduce the projected payment inflation attributed to implementation of the lab packaging policy in 2014. It is incumbent on CMS to provide an estimate of the impact of the lab packaging expansion and a discussion regarding the net effect of new policy proposals on projected payment inflation in the proposed rule.

The AAMC suggests that in the future, when CMS estimates that proposals will result in a significant payment reduction, the Agency provide a transition period to lessen the impact on hospitals. For example, a 2 percent payment reduction would mean a revenue shortfall of millions of dollars for many AAMC member hospitals. Such a significant deficit is hard to absorb in one year, particularly since these reductions come at a time when many hospitals have finalized their budgets for the coming year.

DATA COLLECTION FOR NONPRIMARY SERVICES IN COMPREHENSIVE APC

The Proposal for Data Collection of Non-primary Services in Comprehensive APC Should Not Be Implemented

CMS states that the Agency is interested in collecting data on "adjunctive services" that are delivered prior to a comprehensive service and billed in a separate claim. Once these data are available, CMS envisions packaging adjunctive services into the payment rate of comprehensive APCs (C-APCs), instead of providing a separate payment. To achieve this objective, CMS proposes to establish a Healthcare Common Procedure Coding System (HCPCS) modifier to be reported with every code that is adjunctive to a comprehensive service (with status indicator "J1"), but is billed on a different claim. CMS also seeks comment on whether to adopt a conditional code as early as CY2017 to replace this proposed modifier for collecting this service-level information.

The AAMC urges CMS not to implement this data collection proposal that will require hospitals to identify and report non-primary services in C-APCs. Even though the AAMC is generally supportive of CMS' vision to improve payment accuracy through increased packaging of adjunctive services, the Association is extremely concerned about the administrative burden associated with such a data collection

and the short timeline for implementation. It will require a substantial effort for hospitals to identify related non-primary services billed in different claims. At a minimum, the implementation of this proposal will require trained staff to review physician orders and medical records to identify related services, all of which will delay claims processing, affect cash flow, and reduce resources available for planned uses.

Before this proposal is implemented, CMS must provide clear instructions, a longer period for preparation, and a way to identify the information that is not burdensome. For example, CMS needs to specify adjunctive services for each J1 code and also define a look-back period. Once the instructions are available, it may take years of preparation for hospitals to be able to start reporting the data. Preparation includes, but is not limited to, modifications to the IT system to automatically extract potentially related orders based on CMS' instructions, changes to the flow of the billing process by adding a manual claim review step, and recruiting and training staff that are capable of determining related services based on documentation in physician orders and medical records.

NEW C-APC 8011 FOR OBSERVATION STAYS

High Cost and Low Frequency Procedures and Services Should be Excluded from C-APC 8011

CMS proposes to create a new C-APC 8011 (Comprehensive Observation Services) to replace C-APC 8009 (Extended Assessment & Management Composite) for observation stays. Under this policy, once the comprehensive observation APC is activated with a specific combination of service codes, all other services and items reported on the same claim (excluding preventive services and certain Medicare Part B inpatient services) will be paid under the single comprehensive APC rate.

Even though the AAMC is generally supportive of the creation of a new C-APC 8011 for observation stays, the Association is concerned when low volume but relatively costly procedures and services are packaged into the C-APC. The AAMC's data analyst, WPA, has identified a group of cardiac procedures (with status indicator T), such as Coronary Arteriogram with Ventriculography (HCPCS code 93458 and 93459), that are among the services packaged into the C-APC. The geometric mean cost of HCPCS code 93458 or 93459 is higher than the geometric mean cost of the APC 8011. Even though under the C-APC policy, C-APC 8011 will not be activated if a T code is reported on the same day or one day earlier than when the observation stay (HCPCS code G0378) starts, a T code will be packaged into the observation stay if it is reported after the observation stay starts, as long as it is on the same claim. The AAMC recommends that CMS exclude procedures with a status indicator T from being packaged into C-APC 8011, regardless of the date of service.

The AAMC also encourages CMS to establish a cost threshold to further exclude relative high cost but low frequency services from being packaged into C-APC 8011. For example, WPA's analysis also finds that a few relatively expensive procedures or services with status indicator S are also included in the C-APC package, such as Stereotactic Body Radiation Therapy (HCPCS code 77373) and PET image

(HCPCS 78492). The geometric mean cost of each of these codes is more than half of the geometric mean cost of the APC 8011. Establishing a cost threshold will help mitigate the financial risk associated with high-cost and complex patients within the APC system. Failure to do so may result in more outlier observation stays and an increase to the outlier payment fixed-dollar amount threshold, which has already risen substantially this year.

In addition, the AAMC encourages CMS to evaluate the issue of long observation stays. It is not uncommon in many AAMC member hospitals, especially among safety net hospitals, that patients with special needs (especially dual-eligibles) are kept in observation stays for extended periods of time. The reasons for this can be attributed to multiple factors, many of which are related to the difficulty of finding an appropriate place to release the patient due to the patient's unstable housing situation, lack of support at home, and lack of appropriate services within the community. The AAMC encourages CMS to evaluate the burden of long observation stays on hospitals and to consider how to address this issue, such as by the creation of a separate observation APC for long observation stays.

EXPANSION OF LAB PACKAGING

CMS Should Withdraw the Proposal to Expand the Lab Packaging Policy to Include Lab Tests Provided on Different Dates

CMS proposes to expand the laboratory packaging policy by including laboratory tests provided during the same outpatient stay (versus on the same date as primary services under current policy) because CMS believes such tests are “integral, ancillary, supportive, dependent, or adjunctive to a primary service or services.” An exception is provided when the test is ordered for a different purpose and by a different practitioner. To implement this policy, CMS plans to continue to have hospitals report the “L1” modifier to identify any clinically “unrelated” laboratory tests that are furnished on the same claim as the primary services, but are ordered by a different practitioner for a different purpose. The proposal relies on CMS’ observation of CY 2014 claims data, in which the L1 modifier is infrequently reported along with lab tests on different days than a primary service. This led the Agency to conclude that “hospitals generally do not view laboratory tests occurring on a different day than the primary service during an outpatient stay as a reason for separate payment.”⁶

The AAMC suggests that CMS formed an incorrect conclusion from its data observation and that what the Agency observed reflects implementation issues related to reporting of the L1 code. The L1 code was introduced in the middle of CY 2014 to report unrelated lab tests provided on the same date of primary services, causing uncertainty regarding whether the code could be used on lab tests ordered on different dates than primary services. The lack of reporting of L1 codes with lab tests on different dates in CY 2014 also reflects the inability of hospitals to track lab tests ordered on different dates. CMS has not provided a

⁶ 80 *Fed. Reg.* 39236

persuasive reason for this proposed packaging policy. Therefore, the AAMC urges the Agency to withdraw this proposal.

Should the proposal be finalized, the AAMC is concerned about the administrative burden it will impose on hospitals and the short timeline for implementation. In discussing this proposal, AAMC members raised granular issues, such as the definition of “related” lab tests: will the definition be based on diagnostic codes or disease? For example, will a lab test be viewed as related if it has the same diagnostic code as a primary service? Or should lab tests ordered to examine different symptoms related to the same disease be all viewed as related? Without this level of specification, it is impossible to develop an automatic process to report unrelated lab tests, leaving hospitals with no option but to use manual interventions. The Agency should work with hospital stakeholders to identify the most accurate and least burdensome way of reporting unrelated lab tests before finalizing an expansion of the lab packaging policy and provide sufficient time for providers to implement these changes.

PAYMENT POLICY FOR LUNG CANCER SCREENING WITH LOW DOSE CT (LDCT)

The Billing Period for Lung Cancer Screening with LDCT Should be Extended and Retroactive Billing Should be Allowed

In February 2015, CMS provided Medicare coverage for lung cancer screening with LDCT. CMS now proposes to pay for the services under two existing APCs starting in 2016. The AAMC commends CMS for providing the much-needed coverage for Medicare beneficiaries. As the payment policy will not be effective until January 1, 2016, CMS should temporarily extend the billing period and allow hospitals to retroactively bill or rebill for the screening services provided in 2015.

PAYMENT REDUCTION TO DISCONTINUED DEVICE-INTENSIVE PROCEDURES

It Is Premature for CMS to Implement the Proposed Payment Reduction for Device-Intensive Procedures

CMS proposes to deduct 100 percent of the amount of a device from the APC payment amount when a device-intensive procedure is discontinued either prior to administration of anesthesia (HCPCS modifier 73) or for a procedure that does not require anesthesia (HCPCS modifier 52). CMS explains this proposal by presuming that in most cases when the procedure is discontinued under the scenarios described above, the device was not used and could be used for another case. The Agency believes that without this change Medicare would pay twice for the same device.

The AAMC recommends that CMS not finalize the proposed policy; rather, the Agency should reexamine the issue based on complete information. According to AAMC members, when a device is unpacked/used, a hospital reports a charge for the device using revenue code 0278. No charge will be

reported when the device is not unpacked/used. Analysis by WPA shows that out of the approximately 1500 claims with device-intensive procedures and also HCPCS modifier 73 or 52, more than 1000 of the claims also reported revenue code 0278. The data suggests that in two thirds of the cases the device was unpacked/used even though the procedure was canceled. As the payment is based on the average cost of all cases, the Association also recommends that CMS evaluate whether the APC weights for device-intensive APCs already reflect the fact that not all cases reported device costs.

CHRONIC CARE MANAGEMENT (CCM) SERVICES

Support and Recommend Simplifying Billing Requirements for CCM Services

CMS proposes additional requirements for hospitals to bill and receive OPSS payment for CCM services described by CPT code 99490. AAMC is grateful that the Agency has proposed a series of requirements to allow hospitals to bill for the CCM code. Additionally, the AAMC is pleased that the OPSS CCM requirements successfully align with the Physician Fee Schedule requirements. However, there are still many concerns regarding the administrative complexity for billing the CCM code that may be a barrier to billing for services. The Association highly encourages CMS to continue to actively engage key stakeholders to ensure that the implementation of these codes will not be administratively burdensome.

HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

In the CY 2016 rule, CMS outlines changes to the hospital OQR program which would take effect starting CYs 2018 and 2019. The Agency proposes two new measures, *External Beam Radiotherapy for Bone Metastases* (OP-33) and *Emergency Department Transfer Communication* (OP-34) for inclusion in OQR, and the removal of *Use of Brain Computed Tomography in the Emergency Department for Atraumatic Headache* (OP-15) from public reporting.

CMS Must Take Steps to Reduce Measure Burden for Hospitals

Under the most recent proposal, by CY 2019 hospitals will collect data on and report nearly 30 measures as a requirement for the OQR program. These measures are in addition to the multitude of quality measures providers currently report to CMS under the Inpatient Quality Reporting (IQR) Program, and to The Joint Commission, states and private insurers. Reporting and transmitting these quality measures requires intensive staff training, labor, and resources – and ultimately limits the time clinicians spend with their patients. The AAMC recognizes the importance of quality measurement to ensure that hospitals and physicians are providing high quality care. The Association was a founding member of the Hospital Quality Alliance, which pushed hospitals to publicly report core process measures and later worked closely with CMS on the creation and development of the Hospital Compare website, where all federal inpatient and outpatient measures are reported. The AAMC, however, has serious concerns that the recent

explosion in quality measurement has become unmanageable for providers and must be addressed by CMS.

The AAMC urges the Agency to consider the recommendations included in the Institute of Medicine (IOM)'s April 2015 Vital Signs report on Core Metrics for Health and Health Care Progress.⁷ The IOM noted that the "sheer number [of measures], as well as their lack of focus, consistency, and organization, limits their overall effectiveness in improving performance of the health system." In addition, the organization cited the "significant burden" on providers to collect and examine this data. A committee convened by the IOM proposed 15 core measure areas, along with 39 additional priority measures, in which to provide benchmarks and improve overall health system performance. CMS should take steps to reduce overall measure burden across all programs by creating a streamlined measure set that provides the most value for patients and providers.

MEASURES PROPOSED FOR THE OQR PROGRAM

CMS has proposed two new measure for the OQR program starting CY 2018 & 2019:

Payment Year	Identifier	Measure name
CY 2018	OP-33	External Beam Radiotherapy for Bone Metastases
CY 2019	OP-34	Emergency Department Transfer Communication (EDTC)

AAMC Supports Inclusion of the External Beam Radiotherapy for Bone Metastases Measure

OP-33 is a web-based measure that assesses the percentage of all payer patients with painful bone metastases and no history of previous radiation who receive External Beam Radiotherapy Treatment (EBRT) with an acceptable dosing schedule. The recommended fractionation schemes are included in the proposed rule. The measure was developed by the American Society for Radiation Oncology (ASTRO), endorsed by the National Quality Forum (NQF) and was supported by the Measure Applications Partnership (MAP) for inclusion in the OQR program.

The AAMC supports the adoption of this measure as proposed. Standardizing dosing schedules will address variation in treatment plans and help reduce EBRT overuse. That being said, the Association remains concerned with the high number of quality measures currently required under the OQR program. Submission of web-based quality measures requires considerable clinician time and resources. As stated

⁷ Vital Signs: Core Metrics for Health and Health Care Progress. April 2015. Retrieved from: http://iom.nationalacademies.org/~media/Files/Report%20Files/2015/Vital_Signs/VitalSigns_RB.pdf

at the start of this section, we ask that CMS holistically examine the quality measurement portfolio, and remove those measures from the OQR and IQR programs that are overly burdensome while focusing on a subset of measures that provide the most value for both patients and hospitals.

CMS Should Revise the Emergency Department Transfer Communication (EDTC) Measure

OP-34 is a web-based measure that assesses the percentage of patients who were transferred from the emergency department (ED) to another healthcare facility, and whose medical record included documentation noting that certain clinical and administrative details were communicated to the receiving facility prior to departure or within 60 minutes of transfer. The EDTC measure requires documentation of 27 distinct data elements, categorized into 7 subcomponents. The EDTC measure was endorsed by the NQF and was supported by the MAP.

While the AAMC supports efforts to ensure that critical patient data is accurately and promptly transferred to receiving healthcare facilities, we have serious concerns that the measure is overly burdensome as constructed. CMS is proposing a requirement that all 27 elements must be captured, but the Agency has not given sufficient consideration regarding patients who are incapacitated or otherwise unable to convey the necessary information when they arrive in the ED. We have also heard concerns from providers that certain subcomponents, including the Administrative Communication, Physician or Practitioner Generated Information, and elements of the Patient Information (specifically insurance), would be particularly difficult to capture from the electronic health record and would therefore require time-intensive manual data abstraction for each transferred patient.

Of even more concern is that CMS' proposed scoring methodology for this measure is not the same as the methodology outlined in the NQF specifications.^[1] The Agency's scoring methodology would require that all 27 elements be documented and communicated across all for a hospital to receive complete credit for a case. A hospital's score, as will be displayed on Hospital Compare, will be the percentage of cases where all 27 elements are documented and communicated divided by the total number of eligible cases. The EDTC measure developer, however, stated that the measure should be "reported as an average of the patient observations scores from the facility. The individual average score is the sum of the **subsection scores** which use an all-or-none approach." The proposed scoring methodology has not been tested or reviewed, so it should not be described as "endorsed" by the NQF. CMS should utilize the scoring methodology that was endorsed by the NQF.

Measures Proposed for Removal from the OQR Program

CMS has proposed one measure for removal starting CY 2017:

^[1] National Quality Forum Measure Information Document: #0291 Emergency Transfer Communication Measure, updated 10 Feb 2015

Payment Year	Identifier	Measure name
CY 2017	OP-15	Use of Brain Computed Tomography in the Emergency Department for Atraumatic Headache

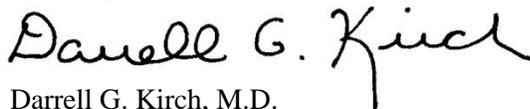
The AAMC Supports the Removal of Use of Brain Computed Tomography (CT) in the Emergency Department (ED) for Atraumatic Headache

OP-15 was originally adopted for the OQR program in CY 2012; however, reporting on this measure has been continually deferred and has not been required for payment determination. CMS recently determined that the measure no longer aligns with current clinical guidelines and has proposed its removal. The AAMC thanks CMS for reviewing this measure and supports the Agency's proposal to remove this measure from the OQR program.

CONCLUSION

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Ivy Baer, J.D., M.P.H., at 202-828-0499 or ibaer@aamc.org for two-midnights and RAC issues, Susan Xu, M.P.A., M.S., at 202-862-6012 or sxu@aamc.org regarding payment related issues, and Scott Wetzel at 202-8828-0495 or swetzel@aamc.org regarding quality issues.

Sincerely,



Darrell G. Kirch, M.D.
President and Chief Executive Officer

Cc: Janis Orlowski, M.D., AAMC
Ivy Baer, J.D., AAMC
Susan Xu, AAMC
Scott Wetzel, AAMC