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Via Electronic Submission (www.regulations.gov)

August 31, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Re: CY 2013 Outpatient PPS Proposed Rule, File Code CMS-1589-P

Dear Ms. Tavenner:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS' or the Agency's) Proposed Rule entitled *Medicare and Medicaid Programs: Hospital Outpatient and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*. . . .77 *Fed. Reg.* 45061 (July 30, 2012). The AAMC represents all 138 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

Our comments focus on the following areas:

- Use of Geometric Mean to Set APC Relative Payment Weights;
- Inpatient Status;
- Inpatient Only Procedures;
- Hospital Outpatient Quality Reporting Program;
- Proposed Payment Rate for Separately Payable Drugs and Biologicals;
- Proposed Adjustment for Cancer Hospitals;
- Proton Beam Therapy;
- Transitional Care Management;
- Payment Adjustment for Technetium-99; and
- Status Indicator for Molecular Pathology CPT Codes.

USE OF GEOMETRIC MEAN TO SET APC RELATIVE PAYMENT WEIGHTS

Since the inception of the Outpatient Prospective Payment System (OPPS), CMS has calculated ambulatory payment classification (APC) weights based on the median cost of services within an APC. For a variety of reasons including a belief that a new method could allow CMS to more accurately capture variation in costs, stabilize payments, and be consistent with Inpatient Prospective Payment System (IPPS) methodology, CMS now proposes to use the geometric mean instead of the median to determine APC relative weights.

While the AAMC supports CMS' efforts to improve the accuracy and stability of OPPS payments, the Association has several concerns about the overall effects of this proposal. First, although CMS states that the proposal is budget neutral, the AAMC has not been able to replicate CMS' budget neutrality calculations using FY 2012 data. Based both on CMS' calculations and our own calculations, the AAMC is also particularly concerned that the negative impact on major teaching hospitals is more than double the impact on non-teaching hospitals. However, CMS does not explain what causes this difference in impact. For these reasons, the AAMC urges CMS to explain its budget neutrality and impact calculations and to study the differential impacts of this proposal in greater detail before moving forward with this new policy. The AAMC also requests that CMS clarify why the Agency selected a policy that uses geometric mean, rather than the arithmetic mean currently used in determining payment weights for MS-DRGs under the IPPS.

Given that this proposal would mark a fundamental change to the calculation of APC relative payment weights, if CMS decides to finalize a geometric mean-based calculation, the AAMC urges CMS to act cautiously and transparently to ensure there are no unintended consequences for hospitals or patients. If CMS finalizes this proposal, the Agency should carefully monitor resulting changes in the frequency and distribution of services provided in the outpatient setting and patient access to any services affected by payment reductions. Additionally, given that community mental health centers (CMHCs) would likely experience large reductions under this proposal, AAMC also encourages CMS to monitor the impact of this change on CMHCs to ensure patient access to these services is not harmed by the new policy.

INPATIENT STATUS

The AAMC is pleased that CMS asked for public comment on the issue of inpatient versus outpatient status in this year's proposed rule. The Agency notes that hospitals have raised concerns that the current outpatient status policy "provides inadequate payment for resources that they have expended to take care of the beneficiary in need of medically necessary hospital care, although not necessarily at the inpatient level." 76 *Fed. Reg.* at 45156. Compounding this, "hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review, by electing to treat beneficiaries as outpatients receiving observation services...rather than admit them." 76 *Fed. Reg.* at 45156. Resource consumption and costs vary with the amount of time a patient is in the hospital, and providers need a payment methodology that is sensitive to resources actually consumed. Additionally, hospitals face ongoing criticism from patients and CMS for a perceived use of

observation services as a substitute for inpatient admission. Significant problems emerge when patients face unanticipated restrictions in allowable covered benefits and unanticipated financial obligations for services. These conflicting forces put providers in a challenging position when determining how to provide the best and most appropriate care to beneficiaries.

The AAMC and our members are extremely concerned about this issue and would welcome participation in a larger discussion of policy options going forward as further discussion and analysis clearly are needed. We would be interested in engaging CMS about such options as establishing a point in time during an encounter when a beneficiary becomes an inpatient; more specific clinical criteria (including point of service and patient safety decisions for clinical teams in the emergency department); and/or prior authorization. While the AAMC does not have a specific recommendation at this time, we encourage CMS to look toward establishing principles that enable providers to make concrete decisions that are not open to questioning upon review. Furthermore, we support CMS' establishment of clear rules that both hospitals and Recovery Audit Contractors (RACs) follow and do not allow for the individual interpretation that currently occurs.

The AAMC appreciates CMS' willingness to open a dialogue on this topic through the solicitation of policy suggestions. However, the AAMC does not believe a 60-day comment period is adequate time to formulate and assess an entirely new policy and thus urges CMS not to finalize any particular suggestion received during this comment period. This year's OPSS rulemaking process should simply be the first step in resolving this issue. Any changes to the definitions of inpatient and outpatient status should be made through the rulemaking process with adequate time for public comment.

PROPOSED INPATIENT-ONLY PROCEDURES

For CY 2013, CMS proposes to remove two CPT codes from the "inpatient list": codes 22856 (total disc arthroplasty) and 27447 (total knee arthroplasty). As the proposed rule explains, the Agency considers a variety of factors when recommending and deciding to remove procedures from the inpatient list, including whether most outpatient departments are equipped to perform the procedure on Medicare beneficiaries and whether the procedure is already commonly performed in the outpatient setting.

While the AAMC believes that hospitals and providers, not CMS, should make decisions as to which setting is most clinically appropriate to perform specific procedures, the Association disagrees with CMS' proposal to remove CPT 27447 from the inpatient only list. Our primary concern arises from AAMC members, who have raised questions about the clinical appropriateness of performing this procedure on Medicare beneficiaries in the outpatient setting. The AAMC supports the American Hospital Association's (AHA) discussion, as put forth in its comment letter on the proposed rule, of the clinical justification for keeping CPT 27477 as an inpatient-only procedure. For this reason, we urge CMS not to remove this procedure from the inpatient only list.

The AAMC also is concerned about the effects of CMS' proposed removal of CPT 27447 on participants in the CMS Innovation Center's (CMMI's) Bundled Payments for Care Improvement (BPCI) initiative. The AAMC applied to BPCI as a facilitator-convener of ten academic medical centers and would be thrilled to have the opportunity to participate in this innovative program through the unique convener role. Total joint replacement, encompassing both joint replacement and revisions (with four designated awardees across two models), is one of the AAMC's proposed bundles. Total joint replacement is anticipated to be one of the most commonly-bid clinical conditions across the country, so the significance of the following concerns extends much further than our convened group.

The removal of CPT 27447 from the inpatient-only list would have an impact on the total joint replacement bundle in a number of ways. Under the current BPCI episode definitions, the initiation of the bundle is triggered by the inpatient hospitalization. As cases move to the outpatient setting, healthier patients who are able to be treated without an inpatient stay are removed from the population. This movement of cases from the inpatient to the outpatient setting would likely leave the more complex cases in bundles, thus skewing both a participant's ability to meet its target price and any year-to-year comparisons. The movement to the outpatient setting also will hamper CMMI's ability to assess the influence of clinical care redesign on outcomes, quality, and cost-efficiency because costs could be shifting due to a changing patient population in bundles, not changes in inpatient care.

Beyond BPCI, the removal of CPT 27477 has additional hospital payment implications. Removing CPT 27477 from the inpatient-only list would require an adjustment to Medicare's benefit design to allow beneficiaries who receive such surgical procedures in the outpatient setting to qualify for any necessary post-acute care (such as a SNF stay) without a prequalifying hospital stay. Without the necessary benefit adjustments, providers may be discouraged from performing such procedures on an outpatient basis, even when doing so would be medically appropriate.

The AAMC urges CMS to consider addressing this issue more broadly than simply in the context of the inpatient-only list. We would be happy to work with CMS to find a solution to these problems, particularly given our role as a BPCI applicant. The removal of CPT 27477 from the inpatient-only list could be considered in the future. The AAMC believes that, given current circumstances, the code should not be removed at this time, so that hospitals are not disadvantaged when trying to provide care in the most clinically appropriate setting for beneficiaries, while at the same time participate in innovative (and cost-saving) payment models.

REPORTING QUALITY DATA FOR ANNUAL PAYMENT RATE UPDATE

The AAMC applauds CMS for not proposing any additional measures for the Outpatient Quality Reporting (OQR) program in CY 2013. The Association thanks the Agency for taking a balanced approach to measure adoption in the proposed rule that recognizes the additional burden placed on hospitals with the inclusion of new measures. The AAMC also appreciates that for purposes of displaying a consistent time period on Hospital Compare CMS is proposing to align the OPSS Medicare FFS claims data periods with the IPPS program starting with CY 2015 payment

determination. Yet, the AAMC has specific concerns with certain aspects of the proposed rule as outlined below.

Outpatient Quality Reporting Program

While CMS did not propose to add any new quality measures, the Association is concerned that seven measures that were previously recommended for removal by the Measure Applications Partnership (MAP) still remain in the OQR program. In its February 2012 report,¹ the MAP recommended that HHS remove these seven measures because they were not NQF endorsed, or the measures' NQF endorsement was scheduled to be removed. At this time, none of the measures in the following chart are NQF-endorsed:

Measure Name/Title
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
OP-22: ED-Patient Left Without Being Seen
OP-9: Mammography Follow-Up Rates
OP-10: Abdomen CT-Use of Contrast Material: For Diagnosis Of Calculi In The Kidneys, Ureter, And/Or Urinary Tract—Excluding Calculi Of The Kidneys, Ureter, And/Or Urinary Tract
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache
OP-25: Safe Surgery Checklist

While the MAP supported the concept of these measures, the Partnership did not recommend them for inclusion in the OQR program without additional development. The AAMC urges CMS to only use measures that meet the NQF's standards for scientific soundness, importance, and usability. The AAMC had previously advocated for the removal of the imaging measures and agrees with the MAP that they should be removed from the OQR program.

Suspension of Data Collection for OP-19 Transition Record with Specified Elements Received by Discharged Patients

CMS originally proposed OP-19 for inclusion in the OQR program for CY 2013 payment determination with data collection for this measure starting on January 1, 2012. After receiving concerns regarding potential patient privacy issues and following an internal Agency review, CMS decided to suspend data collection of this measure in January 2012 until further notice. While OP-19 is not being publicly reported or used for payment determination at this time, CMS

¹ "Input on Measures Under Consideration by HHS for 2012 Rulemaking." MAP Pre-Rulemaking Report: Final Report. Retrieved from: http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx. Feb 2012. Pg 72.

² The AAMC's most recent analyses, for example, indicate that in Fiscal Year (FY) 2009, aggregate major teaching hospitals (defined as hospitals with an intern and resident to bed (IRB) ratio of greater than 0.25) had a Medicare outpatient PCR of approximately 82 percent.

continues to require hospitals to submit a meaningless populated value for this measure. Such data abstraction is burdensome for hospitals that are unable to insert a default value for this measure. Similar to our colleagues at the Federation of American Hospitals, the AAMC believes that hospitals should not be forced to submit meaningless data and strongly urges CMS to correct the Agency's data systems to ensure that a hospital following all the OQR program requirements will not be found out of compliance as a result of limitations in the CMS data systems.

After release of the OPPS proposed rule, CMS also announced that data collection would be suspended for OP-16: Troponin results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) received within 60 minutes of arrival due to patient safety concerns. We believe that the removal of this measure is appropriate. However, as is the case for OP-19, hospitals are being asked to submit meaningless data for OP-16. Providers should not be burdened with reporting these measures simply due to the limitations of the CMS data warehouse. While hospitals expect to manage the burden associated with reporting data on quality measures, the burden of continuing to report meaningless data on a measure that is suspended is a waste of resources in our health care system. This burden of handling the suspension of data collection on a measure should not fall on hospitals or their quality data vendors.

On a related matter, the AAMC is concerned with CMS' procedures for notifying providers of significant changes to quality measures and general changes to the OQR program. The AAMC believes that email blasts, CMS' preferred method of communicating, are problematic due to the fact that emails do not always reach the correct quality measurement personnel in hospitals. Furthermore, we urge CMS to be consistent in its communications to hospitals, vendors and Quality Improvement Organizations (QIOs). Messages on the same topic are sometimes different and lead to different interpretations of needed actions. Especially in light of the CMS decision to rely on subregulatory processes for communicating certain changes in measures, CMS should ensure that communications are clear, consistent, timely, and directed at the correct audience. CMS should consider options for informal industry communication to facilitate transparency and to seek real-time information on operational costs and burdens associated with changing measure specifications.

Structural Measures Deadline Submission

CMS proposes to extend the data submission deadline for structural measures an additional two and a half months starting in CY 2014. As proposed, hospitals would be able to submit data from July 1, 2013, to November 1, 2013, with respect to the time period January 1 to December 31, 2012. This change includes OP-22: ED-Patient Left Without Being Seen. Although this is a chart abstracted measure, data is collected via a web tool and therefore is treated as a structural measure. The AAMC supports this change in the submission deadline.

Electronic Reporting Pilot

CMS proposes to continue the EHR Incentive Program Electronic Reporting Pilot that was previously finalized in the CY 2012 OPPS Rule, and which can be used to satisfy Meaningful

Use (MU) Stage 2 requirements. Hospitals also will continue to have the option of submitting quality data via attestation for CY 2013. According to our member hospitals, the burden for submitting all the necessary data for all Medicare patients is significant, which may point to the current lack of participation.

On a related note, the AAMC has serious concerns with the level of accuracy and reliability of the electronically reported data. If CMS can gain participation in the pilot, the AAMC believes it be an ideal opportunity to undertake an analysis comparing the accuracy of electronically reporting data to manually abstracted data, and ultimately determine the reliability of electronically reported data prior to its inclusion in performance-based payment programs.

PROPOSED PAYMENT FOR SEPARATELY PAYABLE DRUGS AND BIOLOGICALS

For many years, the AAMC has urged CMS to pay for separately payable drugs and biologicals at the average sales price (ASP) plus six percent until the Agency establishes a more precise methodology for determining the acquisition and overhead costs of these products. This rate is the same as the physician office setting payment rate and is consistent with the ASP plus six percent payment level set forth in the Medicare statute.

CMS now proposes to pay for these drugs at the statutory default rate of ASP plus six percent. The AAMC applauds CMS for this proposal and urges the Agency to finalize the proposal to pay for separately payable drugs and biological at the rate of ASP plus six percent. The AAMC agrees with CMS' assessment that using the statutory default of ASP plus six percent will improve the predictability in payment for these drugs and believes the policy will improve the adequacy of payment for these drugs as well.

PROPOSED ADJUSTMENT FOR CANCER HOSPITALS

Section 3138 of the ACA instructed the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals exceed the costs incurred by other hospitals, and if they do, directs the Secretary to provide an appropriate adjustment to reflect these higher costs. The ACA also required this adjustment to be budget neutral and effective for outpatient services provided at cancer hospitals on or after January 1, 2011.

CMS conducted the required study and reported the Agency's findings in the CY 2011 OPPS proposed rule. In the study, CMS observed that cancer hospitals' cost per discounted unit standardized for service mix is higher than the standardized cost per discounted unit of all other hospitals. In addition, cancer hospitals' volume-weighted average payment-to-cost (PCR) is lower than the volume-weighted PCR of other hospitals paid under the OPPS. This led the Agency to conclude that cancer hospitals are more costly than other hospitals paid under the OPPS and to propose a hospital-specific payment adjustment for cancer hospitals to reflect these higher costs, effective January 1, 2011, as mandated by the ACA. Based on public comments and acknowledging the need for further study and deliberation, CMS did not finalize the Agency's proposed adjustments in the CY 2011 final rule.

CMS instead finalized a payment policy for cancer hospitals in the CY 2012 OPPS final rule. Under this policy, CMS provides additional payments to each of the eleven cancer hospitals so that each hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (or "target PCR") for other hospitals paid under the OPPS. Under this policy, payment adjustments are made on an aggregate basis at cost report settlement.

For CY 2013, CMS proposes to continue the policies adopted in last year's final rule, including adopting a target PCR of 0.91. The AAMC believes CMS adopted final policies last year that addressed many provider and beneficiary concerns. The Association therefore supports CMS' proposal to continue the same policies for payment adjustments to cancer hospitals in CY 2013.

Finally, the AAMC urges CMS to examine the adequacy of OPPS payments to teaching hospitals to determine whether, like cancer hospitals, major teaching hospitals' PCRs are consistently lower than those of other hospitals and, if they are, the reasons for any systematic differences.² If such analyses reveal that differences are due to the unique missions of teaching hospitals or other characteristics typical of such hospitals, the AAMC believes a teaching adjustment should be included in the OPPS to ensure equitable payments for all classes of hospitals.

PROTON BEAM THERAPY

In the CY 2013 OPPS proposed rule, CMS notes that the estimated cost of APC 0667 (Level II Proton Beam Radiation Therapy), which includes intermediate and complex Proton treatment delivery, has decreased substantially. To improve resource homogeneity within the proton beam APCs, CMS proposes to reassign CPT code 77522 (Proton treatment delivery; simple, with compensation) to APC 0667 and CPT code 77525 (Proton treatment delivery, complex) to APC 0664 (Level I Proton Beam Radiation Therapy).

The AAMC is concerned about CMS' placement of both simple and complex proton beam therapy codes in the same APC (APC 0667), because these services are not clinically homogenous. The AAMC encourages CMS to conduct further analyses to determine the reason for the significant cost decreases rather than reconfiguring the relevant APCs as proposed.

TRANSITIONAL CARE MANAGEMENT

In the CY 2013 Medicare Physician Fee Schedule (MPFS) proposed rule, CMS discusses a multiple year strategy to encourage the provision of primary care and care coordination services to Medicare beneficiaries. Specifically, CMS proposes to introduce a new Healthcare Common Procedure Coding System (HCPCS) G-code for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's physician or qualified nonphysician practitioner in the community. The

² The AAMC's most recent analyses, for example, indicate that in Fiscal Year (FY) 2009, aggregate major teaching hospitals (defined as hospitals with an intern and resident to bed (IRB) ratio of greater than 0.25) had a Medicare outpatient PCR of approximately 82 percent.

AAMC refers CMS to the Association's response to the MPFS for detailed comments on the new, proposed HCPCS G-code.

In the CY 2013 OPFS proposed rule, CMS recognizes that some elements of the transitional care coordination services described by the proposed G-code could be provided to a hospital outpatient as an ancillary or supportive service with a primary diagnostic or therapeutic service that is payable under the OPFS. For this reason, CMS proposes to assign a status indicator of "N" (Items and Services Packaged into APC Rates) to the new G-code, to signify that payment for transitional care coordination services is packaged with the primary service. The AAMC appreciates CMS' recognition of the use of care coordination services in the outpatient setting and supports the use of a new HCPCS G-code to identify the work involved in discharge care coordination.

PAYMENT ADJUSTMENT FOR TECHNETIUM-99

The Obama Administration announced a goal of reducing reliance on radioisotopes produced in legacy reactors outside the United States that use highly enriched uranium (HEU). Acknowledging that this change in supply source for radioisotopes, specifically Technetium-99 (Tc-99m) which is used widely in diagnostic imaging services, will likely increase costs for providers, CMS proposes to make an additional payment of \$10 per dose so long as the Tc-99m the hospital uses can be certified as coming from non-HEU sources.

Given the current unavailability of non-HEU source Tc-99m in the United States, the AAMC does not believe this proposed payment adjustment actually will promote hospitals' conversion to non-HEU sources of Tc-99m. Our member hospitals indicate they are simply not able to obtain Tc-99m from non-HEU sources. In the best case scenario, one hospital was told it *may* be possible to obtain a product produced from a mix of HEU and low enriched uranium (LEU), but that it would be impossible to determine which tracers use an unknown mixture of high and low energy uranium. For this reason, we recommend that this policy be deferred and reexamined in next year's rulemaking cycle.

When and if CMS adopts a payment adjustment for Tc-99m, the AAMC is concerned about the adequacy of a \$10/dose payment adjustment. CMS does not explain in the proposed rule exactly how this proposed adjustment was calculated, and in the estimation of our member hospitals, \$10 would not nearly cover the cost of using LEU-source Tc-99m, even if it were available. The AAMC recommends that CMS conduct a thorough study of the actual costs, at a time when non-HEU Tc-99m actually is available to hospitals, and propose an adjustment that will better reflect both the marginal additional costs of the non-HEU sources and the administrative and compliance burden on hospitals. If and when CMS adopts a payment adjustment for Tc-99m, the AAMC also recommends a phase-in process that allows hospitals to receive an adjustment when at least some of the Tc-99m is derived from LEU sources.

STATUS INDICATOR FOR MOLECULAR PATHOLOGY CPT CODES

For CY 2012, the CPT Editorial Panel began creating new CPT codes to replace the current codes used to bill for molecular pathology services. CMS recently advised contractors (see Transmittal 2365, Change Request 7654, December 9, 2011) that providers should concurrently bill both the old “stacked” CPT codes and the new single CPT codes, a recommendation that providers currently find to be an extreme administratively burden. In the CY 2013 OPSS proposed rule, CMS did not specify whether CPT codes 81200-81299, 81300-81383, and 81400-81408 will continue to be assigned status indicator “E” under the OPSS. The AAMC requests that, given the recent recommendation, CMS clarify the status indicator for these codes.

SUMMARY

Teaching hospitals’ outpatient departments are critical to providing needed services to beneficiaries as well as fulfilling the missions of teaching hospitals. Medicare outpatient payments are essential for teaching hospitals to continue their missions in the outpatient setting, including serving important access roles for outpatient services that range from clinic and emergency room visits to technically-advanced innovations. We would be pleased to work with CMS as the Agency continues to refine and improve this important Medicare payment system.

If you have questions concerning comments on the quality reporting program, please contact Jennifer Faerberg at jfaerberg@aamc.org or 202-862-6221. For all other issues, please contact Lori Mihalich-Levin, at lmlevin@aamc.org, 202-828-0599.

Sincerely,

A handwritten signature in black ink, appearing to read 'J Conroy', with a stylized flourish at the end.

Joanne Conroy, MD
Chief Health Care Officer

cc: Ivy Baer, JD, MPH, AAMC
Jennifer Faerberg, AAMC
Lori Mihalich-Levin, JD, AAMC