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Via Electronic Submission (www.regulations.gov)

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Donald Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Re: CY 2012 Outpatient PPS Proposed Rule, File Code CMS-1525-P

Dear Dr. Berwick:

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 Prospective Payment*. . . .76 *Fed. Reg.* 42170 (July 18, 2011). The AAMC represents all 135 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 125,000 faculty members, 75,000 medical students, and 106,000 resident physicians.

Our comments focus on the following areas:

- Hospital Quality and Value Based Purchasing Programs;
- Proposed Payment Rate for Separately Payable Drugs and Biologicals;
- Proposed Adjustment for Cancer Hospitals;
- Physician Supervision Proposal;
- Partial Hospitalization Program;
- Inpatient Only Procedures; and
- Wage Index Proposals.

REPORTING QUALITY DATA FOR ANNUAL PAYMENT RATE UPDATE

Before calendar year (CY) 2011, the OPSS rules included measures required for the hospital outpatient quality data reporting program (HOP QDRP) one calendar year at a time. In CY 2011, CMS changed the Agency's reporting procedures and began proposing measures for three calendar years, CY 2012 through CY 2014. While CMS finalized measures for CY 2012 and CY 2013, the Agency also reserved the right to add additional measures in future rulemaking. In the current rule, CMS proposes to add new measures for CY 2013 through CY 2015.

Proposed Measure Expansion

CY 2014

For the CY 2014 payment determination, CMS proposes six chart-based measures (five diabetes and one cardiac rehabilitation referral), two structural measures (safe surgery checklist and volume data on selected surgical procedures), and one NHSN HAI measure (surgical site infection). Specific comments on these measures are as follows.

Hemoglobin A1c Poor Control; Low Density Lipoprotein Control; High Blood Pressure Control; Dilated Eye Exam; Urine Screening for Microalbumin or Medical Attention for Nephropathy.

CMS had previously proposed the above diabetic measures for the CY 2014 payment determination in the OPSS CY 2011 proposed rule, but withdrew them in the final rule, as CMS was still in the process of refining the measures' numerator definitions. The AAMC's concern with these measures has not changed. The AAMC does not support the inclusion of the proposed diabetes measures in the outpatient reporting program. While these measures are appropriate for measuring diabetes care, we believe they are inappropriate for the hospital outpatient setting.

First, the proposed rule does not define the patient population for which these measures apply. It is unclear if these measures are meant to capture those patients who seek primary care services in provider-based clinics or whether those patients seeking care in an outpatient department, such as those participating in physical therapy, would be included as well. These measures address care managed by a primary care provider and therefore, it would seem illogical to include those patients receiving care outside of the ambulatory setting. Not all institutions have provider-based clinics, therefore comparisons across institutions would be limited to that subset of facilities. Conversely, including patients who receive care both in provider-based clinics as well as in hospital outpatient departments would lead to large variation in patient populations and ultimately inaccurate comparisons across institutions.

Second, the care delivered in provider-based clinics is often episodic, making ongoing management of diabetes patients a challenge. Certain patients seek care from multiple providers or do not return for follow-up care. One of our member institution's data revealed that in its internal medicine clinic, 58 percent of patients seek care two or fewer times per year. As several

of the proposed measures evaluate patient outcomes over a calendar year period, the AAMC believes there should be some minimum number of visits before the provider-based clinic is tasked as responsible for these outcomes. CMS has already established a precedent in this arena. Both for the Physician Group Practice (PGP) Demonstration as well as the Group Reporting Option I in the Physician Quality Reporting Initiative (PQRI), patients must have a minimum of two visits with a specific provider to be assigned to that provider.

Third, appropriate attribution of these and other patients is also a key concern with these measures, as not all provider-based clinics provide primary care services including diabetes care. The diabetes measures are not relevant to all specialties practicing in provider-based clinics and therefore reporting these measures may not be appropriate.

Finally, the AAMC has concerns with the data collection methods specified in these measures. As stated earlier, these measures were designed for use in the ambulatory/clinician office setting, not for an outpatient department. There are significant challenges for a hospital outpatient department (HOPD) to collect the necessary data to populate these ambulatory-specific measures. These measures rely on CPT II codes, which are not routinely collected in the HOPD. To utilize the data that is collected through CPT II codes, there would need to be additional modifications to the billing process, which would needlessly impose a significant reporting burden on hospitals.

Cardiac Rehabilitation Patient Referral from an Outpatient Setting

This cardiac rehabilitation measure calculates the percentage of patients evaluated in an outpatient setting who in the previous twelve months experienced a major cardiac event, such as a heart attack, and received treatment for the event in an inpatient setting. The AAMC does not support the inclusion of this measure in the outpatient reporting program. We are concerned that the measure denominator would require clinical information from the previous twelve months in order to identify the appropriate patient population. Due to the typical structure of a hospital outpatient clinic, this information is not likely to be available. Furthermore, this measure only focuses on the referral for rehabilitation, and not whether the patient actually enrolled in the program.

Last, this is a stand-alone measure. This outpatient measure is meant to be used along with a corresponding inpatient measure for the cardiac event. However, the corresponding inpatient measure has not been proposed for use in the Inpatient Quality Program (IQR). The AAMC believes that both measures need to be implemented simultaneously to truly drive quality improvement.

Safe Surgery Checklist Use

The AAMC is very supportive of widespread use of surgical checklists. The AAMC has taken the lead in enlisting approximately 240 medical schools, hospitals, and health systems to implement best practices to improve health care at their institutions. This initiative, known as Best Practices for Better Care (BPBC), includes the utilization of a surgical checklist. Under the

BPBC initiative, institutions will create policies requiring the use of surgical checklists in operating rooms for all procedures, document the use of checklists in patient charts, report compliance rates, and demonstrate that medical students and residents understand the importance of standard processes and improved communication.

While we would generally support the inclusion of a safe surgical checklist in HOP QDRP, we have several concerns. First, this is not an NQF-endorsed quality measure with a specified numerator and denominator. Perhaps more importantly, this measure would only assess whether a surgical checklist is in place, which could result in a “check the box” process. We urge CMS to focus on how the measure should be implemented, including specifying standardized criteria to be followed instead of whether the checklist is simply in place. We also urge CMS to submit this measure for NQF endorsement before it is implemented.

Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures

For the CY 2014 payment determination, CMS proposes that hospitals submit all-patient surgical volume data for the following selected outpatient procedures: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. The AAMC does not support this proposal. While we understand CMS’ interest in reporting high volume procedures, this is not a quality measure with a specified numerator and denominator, and therefore should not be required as part of a quality pay-for-reporting program. Requiring hospitals to submit volume data would create an added burden with no clear link to quality improvement. Similar to volume data for inpatient procedures, we recommend that these data be publicly reported, but not for payment purposes.

Surgical Site Infection

Under the proposed rule, CMS proposes to assess the percentage of outpatient surgical site infections (SSI) that occur after a National Healthcare Safety Network (NHSN)-defined operative procedure. While the AAMC supports including an SSI measure in a quality reporting program, we do not support this measure for the Outpatient Quality Reporting (OQR) program. The SSI measure listed in the proposed rule was endorsed by the NQF and approved by the Hospital Quality Alliance as an inpatient measure. Because this measure has not been specified for outpatient use, it should go through the NQF endorsement process before being considered for implementation in the OQR program. Moreover, we are concerned that a surgical site infection rate will not accurately capture infections that result from care provided in the outpatient setting. Patients are constantly moving through outpatient departments (and clinics that are covered under the OQR program) and therefore it is difficult to ascertain which person or entity is responsible for any infections.

The AAMC also has concerns with the capability of the NHSN to handle the influx of data from the more than 4,000 outpatient facilities that would report this measure. In addition to outpatient facilities, inpatient PPS hospitals, long-term care hospitals, inpatient rehabilitation facilities, and ESRD facilities may soon be reporting NHSN measures. With such a steep increase in facilities reporting through the NHSN, we have serious concerns that it will be able to adequately handle

the data. We urge CMS to take the necessary steps to ensure that the NHSN is capable of such an increase, and that sufficient technical assistance be available should problems occur.

CY 2015

For the CY 2015 payment determination, CMS proposes an additional NHSN HAI measure: *Influenza Vaccination Coverage among Healthcare Personnel (HCP)*.

The AAMC supports efforts to increase influenza vaccination rates among health care personnel, as they are at significantly greater risk for acquiring and transmitting the influenza virus. However, the proposed HAI measure, as specified, will be extremely burdensome and difficult to report. The current specifications require hospitals to report detailed information on every employee to the Centers for Disease Control and Prevention (CDC) through the NHSN rather than reporting the overall percentage of vaccination rates. Collecting and reporting this information would require the involvement of hospital departments and other individuals and organizations that are not typically involved in hospital quality data reporting, such as the medical staff, residents, and human resources departments. The proposed measure would also require reporting of vaccinations obtained outside of the hospital. Such a process would involve transferring data that are currently based on separate and inconsistent systems.

Additionally, the proposed rule is unclear whether hospitals are responsible for ensuring that their vendors are complying with the vaccination requirement. At this point, there are no defined methods for monitoring their compliance. Would hospitals be required to offer the vaccine to their vendors, if the vendors do not already provide it? Are there exclusions for manufacturing shortages or increased consumer demand for the vaccination, which may lead to workers not being inoculated? The AAMC urges CMS to resolve these underlying issues before implementing this measure.

The Hospital Inpatient Value-Based Purchasing Program

The proposed rule includes a section on the Hospital Inpatient Value-Based Purchasing (VBP) program. In the proposed rule, CMS discusses measures that were proposed in the inpatient PPS rule, such as a Medicare spending per beneficiary (MSPB) measure, and makes additional proposals, including a domain scoring methodology for FY 2014 that includes the MSPB measure. While the inpatient prospective payment system (IPPS) final rule addresses VBP, we believe that because these issues were also included in the OPSS proposed rule, they may still be viewed as proposals that CMS can choose to modify in the OPSS final rule. We urge CMS to take this view. The VBP program is new and untested. Consequently, modifications that improve the program and avert unintended consequences should be accepted and implemented by CMS in any regulatory vehicle that includes a discussion of the VBP program, including this proposed rule.

Timeframe for Data Publication

In the FY 2012 IPPS final rule, CMS asserted that the Agency was finalizing the inclusion MSPB measure in the VBP program in FY 2014. Similarly, in the VBP final rule, CMS attempted to finalize the inclusion of Hospital Acquired Conditions (HACs) and AHRQ Patient Safety Composites. We do not believe these measures can be included in the FY 2014 VBP program due to timing reasons.

As stated in section 3001 of the Affordable Care Act (ACA), a quality measure is only eligible for inclusion in the VBP program after it has been publicly reported on Hospital Compare for at least one year. It is critical that these measures be posted for this length of time so that both hospitals and CMS have time to review the data to ensure its reliability and accuracy before the measure is used for payment purposes. Moreover, we believe the requirement is predicated on the fact that hospitals need to have real-world experience with a measure prior to its incorporation into the VBP program. This review period also provides the opportunity to monitor for unintended consequences prior to implementation.

From conversations with CMS staff, it appears the Agency believes the MSPB and AHRQ PSI Indicators reporting requirements have been met, because these measures are on the Hospital Compare website in a list of “potential” future measures to be included in the VBP (MSPB since April 2011 and AHRQ Patient Safety Composites since March 2011). The AAMC believes the mere inclusion of these measures in a glossary does not meet the one year requirement, and we are particularly disturbed that CMS would even suggest this rationale.

In a June 7, 2011 meeting of the Hospital Quality Alliance (HQA), CMS seemingly acknowledged that inclusion in a glossary does not meet the reporting requirement. During this meeting, CMS staff indicated in a PowerPoint presentation that these measures are not scheduled to be posted to Hospital Compare until October 2011.¹

In the VBP final rule, CMS also stated the HAC rates were posted beginning March 2011. However, this information was available only via a downloadable database linked to the Hospital Compare website, rather than being included directly on the website like the other measures that are included in the IQR program. Consequently it does not meet the one-year reporting requirement.

The one year time frame is particularly important for the MSPB measure, because, as CMS states in the IPPS final rule, it is “a new type of measure for the Hospital IQR and Hospital VBP Programs.” 76 *Fed. Reg.* at 51623. Moreover, as CMS also points out in the IPPS final rule, this measure has not been endorsed by NQF or “any other consensus organizations.” 76 *Fed. Reg.* at 51619.

¹ Slide # 6

<http://www.hospitalqualityalliance.org/hospitalqualityalliance/files/HQA%20Principals%20Meeting%20June%207%202011%20CMS%20Update.pdf>

In addition, for the MSPB measure, there has yet to be any measure specifications proposed or finalized. To date, every measure included in a quality program has had these details set forth in a final rule. We believe this process must be followed for the MSPB measure before it can be included in the VBP, or any other, program. For example, while we understand that CMS is not including direct GME payments in the MSPB calculation, and we believe this is appropriate, this decision and any other specifications have never been published.

A consistent application and interpretation of the measure time frame is critical to maintaining the credibility of the VBP program for both providers and beneficiaries. This means publishing the measure, its specifications and associated data for one year prior to including it in a quality program. **CMS has not met these requirements for the MSPB, HAC and AHRQ measures and therefore they should not be included in the VBP program for FY 2014.** We believe that delaying the inclusion of these measures is permitted by the ACA, because section 3001 explicitly states that a measure may not be selected for the VBP program if it has not satisfied the one-year Hospital Compare requirement. We believe CMS has the authority to make this decision in the OPSS final rule given that these measures were addressed in the proposed rule. Moreover, for the MSPB measure, Congress specifically allowed for a later date when it stated in the ACA that an efficiency measure shall be included in “fiscal year 2014 *or a subsequent fiscal year*” (emphasis added). Social Security Act Section 1886(o)(2)(B)(ii).

Domain Weighting

CMS proposes a weighting methodology for the FY 2014 VBP that would weigh the care domains as follows:

- Process of Care – 20 percent;
- HCAHPS – 30 percent;
- Outcomes – 30 percent; and
- Efficiency – 20 percent.

The AAMC recommends that the domain weighting scale be modified to more appropriately measure the quality of care provided by hospitals. The AAMC has previously commented on the weighting of the HCAHPS domain for the FY 2013 VBP program. We believe that the proposed weight of 30 percent for the HCAHPS domain is inappropriately high. A recent HCAHPS analysis by the Cleveland Clinic, an AAMC member, indicates that this tool can produce inequitable results for subsets of hospitals, particularly those that treat severely ill or disadvantaged patient populations. Until there is more research to better understand the relationship between HCAHPS and severely ill and disadvantaged patients, we think it is imprudent to weight this domain at the 30 percent level. We believe that weighting the HCAHPS domain no greater than 10 percent recognizes the importance of patient satisfaction without unduly penalizing hospitals solely due to their patient population.

Regarding the outcomes domain, if the HAC and AHRQ measures are removed, the only measures remaining are the three mortality measures in AMI, HF, and PN. Given that the

domain would now only be calculated on three measures, we believe the domain weight should be no more than 15 percent, instead of the proposed 30 percent.

As we have previously stated, the AAMC believes that the efficiency domain should be removed from the FY 2014 VBP program. However, if CMS does decide to include the MSPB measure- since it is new and untested- we ask that the efficiency domain be weighted not more than 5 percent, at least initially.

PROPOSED PAYMENT FOR SEPARATELY PAYABLE DRUGS AND BIOLOGICALS

CMS proposes to pay for separately payable drugs and biologicals at the average sales price (ASP) plus four percent in CY 2012. The AAMC is concerned that the proposed payment rate does not adequately reimburse separately payable drugs and biologicals, thereby having deleterious effects on beneficiary access to certain necessary drugs provided in the hospital outpatient department. The AAMC also believes this payment rate unfairly penalizes hospitals that provide a disproportionate amount of high-cost drugs as part of the clinical care mission, many of which are major teaching hospitals.

The AAMC urges CMS to pay these drugs at 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. Under the Medicare statute (Section 1833(t)(14)(A)), CMS is to use this payment rate or the rates set under the Competitive Acquisition Program (CAP) as an alternative, if average acquisition cost for the drug – as determined by the Government Accountability Office (GAO) or CMS surveys of hospital acquisition costs – is not available.² The law also authorizes (Section 1833(t)(14)(E)) CMS to adjust payments for these drugs to pay for overhead and pharmacy service and handling costs.

CMS determined the proposed payment rate for CY 2012 using the same methodology the Agency used to determine the payment rate for separately payable drugs and biologicals in CYs 2010 and 2011. Although this methodology represents an improvement over that used in previous years, it still needs additional improvements to estimate an accurate payment rate for separately payable drugs and biologicals.

Currently, CMS first applies its standard methodology for estimating the acquisition and pharmacy overhead costs for separately payable drugs and biologicals. That is, the Agency divides the drugs and biologicals into packaged and separately payable drugs and biologicals and applies the same cost-to-charge ratio (CCR) to both groups. CMS then compares the estimated aggregate costs of separately payable drugs and biologicals in the claims data to the estimated aggregate ASP dollars for these products.

² While GAO published a report that analyzed 2004 data, there has been no subsequent update. Thus, no current data are available.

Recognizing that because of the combined effects of charge compression and the Agency's choice of a drug packaging threshold, the standard methodology can lead to a misallocation of overhead costs between separately payable drugs and biologicals and packaged drugs and biologicals, CMS proposes to redistribute \$161 million from the pharmacy overhead cost of coded packaged drugs and biologicals and \$54 million from the cost of uncoded packaged drugs and biologicals to the cost of separately payable drugs and biologicals. Charge compression is the practice of applying a lower charge markup to higher-cost services and a higher charge markup to lower-cost services. As a result, some of the pharmacy costs that should be associated with the separately payable drugs are being included with the packaged drugs, thus resulting in an estimated cost calculation for separately payable drugs that is significantly lower than it should be. The charge compression problem is exacerbated as the packaging threshold increases, because the cost value for the remaining high-cost separately payable drugs decreases, even though there is no change in the overhead costs for these items.

The AAMC believes that the proposed methodology continues to underestimate the acquisition and overhead costs of separately payable drugs and biologicals for several reasons. First, CMS continues to include claims data for hospitals that participate in the 340B drug discount program in the calculation of payment for drugs and biologicals. The 340B program allows certain hospitals that serve poor and uninsured patients to purchase drugs at discounted prices not available to other types of hospitals. Thus, incorporating claims data from these hospitals results in an underestimation of aggregate costs of drugs and biologicals. In addition, 340B hospital data are excluded from the ASP calculation. When the Agency compares aggregate costs to ASP, the result is an ASP-based rate that is too low.

Second, CMS proposes to redistribute only \$54 million in uncoded packaged drug costs to separately payable drugs and biologicals. As the Agency acknowledges, this amount is a "conservative estimate of the pharmacy overhead cost of uncoded packaged drugs and biological that should be appropriately associated with the cost of separately payable drugs and biologicals." 76 *Fed. Reg.* at 42259.

CMS' rationale for distributing only \$54 million from the cost of uncoded packaged drugs and biologicals to separately payable drugs and biologicals is that the Agency does not have sufficient data to support a larger distribution. According to CMS, this is in part because hospitals do not always report HCPCS codes for all drugs.

CMS has been urging hospitals to report charges for all items and services with HCPCS codes when they are available, whether or not Medicare makes separate payment for the items and services, so that the Agency can better estimate the cost of all drugs and biologicals and ensure equitable payment rates. However, until all hospitals correctly report all items and services with HCPCS codes, the overhead costs associated with uncoded packaged drugs and biologicals may be significantly underestimated and the amount redistributed is likely insufficient.

Given the likelihood of underestimating aggregate costs of drugs and biologicals due to the inclusion of 340B hospital data, as well as the likelihood of underestimating the portion of overhead costs to be redistributed from uncoded packaged drugs and biologicals to separately

payable drugs and biologicals, we urge CMS to reimburse separately payable drugs and biologicals at a rate no less than ASP plus six percent.

While ASP plus six percent may not represent the full costs of these drugs, we believe it is an acceptable rate, at least for now. Given that neither the Government Accountability Office (GAO) nor CMS has conducted surveys of hospital acquisition costs since 2004, this action is consistent with the default rate set forth in the Medicare statute. We also believe that this rate will stop the unwarranted payment reductions for these items, is comparable with the rate payment for these drugs in physicians' offices, and is appropriate given the surrounding context, which must take into account payments for other items, as well as the system as a whole.

PROPOSED ADJUSTMENT FOR CANCER HOSPITALS

Section 3138 of the ACA instructed the Secretary to conduct a study to determine if, under the OPSS, outpatient costs incurred by cancer hospitals exceed the costs incurred by other hospitals, and if they do, the Secretary shall provide an appropriate adjustment to reflect these higher costs. The ACA also required that this adjustment be budget neutral and be 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 OPSS 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 OPSS. This led the Agency to conclude that cancer hospitals are more costly than other hospitals paid under the OPSS 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, however, CMS did not finalize the Agency's proposed adjustments in the CY 2011 final rule.

In the CY 2012 OPSS proposed rule, CMS again proposes to make a hospital-specific payment adjustment for cancer hospitals. The proposed payment adjustment would be determined as the percentage of additional payment needed to raise each cancer hospital's PCR to the weighted average PCR for all other hospitals paid under the OPSS in the CY 2012 dataset. Specifically, this would be accomplished by adjusting each cancer hospital's OPSS payment by the percentage difference between its individual PCR (without transitional outpatient payments (TOPs)³) and the weighted average PCR of other hospitals paid under the OPSS.

This proposal would result in an aggregate increase in OPSS payments to all 11 cancer hospitals of 39.3 percent. At the same time, all other hospitals would experience a decrease of 0.6 percent in payments as a result of the budget neutrality requirement.

³ TOPs are non-budget neutral payments cancer hospitals currently receive to ensure they are not reimbursed at a lower rate under the OPSS than they would have received before implementation of the OPSS.

The AAMC supports a hospital-specific payment adjustment for cancer hospitals to reflect their higher costs. CMS' analysis of cancer hospitals' PCRs compared to those of other hospitals shows that, not including TOPs, on average, payments to the 11 cancer hospitals are approximately 65 percent of reasonable costs, while payments for other hospitals are approximately 90 percent of reasonable cost. When TOPs are included in the calculation of the PCR, cancer hospitals, as a group, receive payments that are 83 percent of reasonable cost. Because this payment rate is below the 90 percent received by other hospitals, a payment adjustment for cancer hospitals is justified.

The AAMC remains concerned, however, that CMS' proposed methodology does not satisfy Congressional intent to provide equitable payments in a budget neutral manner. According to the ACA, "the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs." Because there is an inverse relationship between increases in APC payments and the amount cancer hospitals receive in TOPs, CMS' proposed methodology for determining the adjustment based on a cancer hospital's PCR without TOPs effectively replaces TOPs with the proposed adjustment, lowering federal outlays at the expense of all other hospitals. Additionally, the AAMC remains concerned about the proposed methodology's impact on beneficiaries. Because TOPs are not subject to copayments, any increases in the APC payments and decreases in TOPs will inevitably result in copayment increases for Medicare beneficiaries. The larger the increases in the APC payments, the greater the copayments.

For these reasons, the AAMC encourages CMS revise the Agency's proposed methodology for calculating the cancer hospital adjustment to include cancer hospitals' expected TOPs. We believe the Agency has the statutory authority to modify the cancer payment adjustment in this manner. If, however, CMS believes that the current statutory language does not permit the Agency to include TOPs payments in calculating the cancer payment adjustment, the AAMC urges CMS to work with Congress to find a solution that would permit TOPs payments to be included in the calculation.

Finally, the AAMC urges CMS to examine the adequacy of OPSS 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.⁴ If such analyses reveal that differences are due to the unique missions of teaching hospitals, the AAMC believes a teaching adjustment should be included in the OPSS to ensure equitable payments for all classes of hospitals.

SUPERVISION OF OUTPATIENT SERVICES

CMS reimburses hospitals for outpatient diagnostic and therapeutic services only when those services are provided under Medicare rules governing the level of physician supervision. Through a series of policy changes over the past several years, the Agency adopted "direct

⁴ 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.

supervision” as the standard for all outpatient therapeutic services covered and paid by Medicare. Direct supervision requires the supervising physician to be “immediately available” to furnish assistance and direction throughout the performance of a hospital outpatient therapeutic service or procedure.

In the proposed rule, CMS discusses the Agency’s plans to create an independent advisory review process to consider stakeholder requests to assign supervision levels other than direct supervision to specific outpatient hospital therapeutic services. CMS announced the Agency’s intention to designate the Federal Advisory Ambulatory Payment Classification (APC) Panel as the body that would evaluate these supervision assignment requests. The APC Panel would then make recommendations to CMS about whether the service requires general, direct, or personal supervision, and CMS would take the APC Panel’s recommendations into consideration when deciding what level of supervision to assign to the service.

As a threshold matter, the AAMC strongly urges CMS to defer to physicians to determine, on a case-by-case basis, what level of physician supervision is appropriate for each service, rather than adopting direct supervision as a default for all outpatient therapeutic services. Physicians are in the best position to make clinical decisions regarding how the thousands of different outpatient procedures they perform should be supervised. Their professional judgment, rather than an Agency-imposed default, should govern these decisions.

To the extent CMS requires a formal process for setting supervision levels for individual services, however, the AAMC agrees with the Agency’s proposal to engage the APC Panel as the independent body that will review supervision decisions. Because the AAMC believes it is important that providers have a voice in the review process, we believe that the APC Panel’s membership makes it a good candidate for becoming the reviewing entity. If CMS ultimately decides not to defer to the judgment of physicians and hospitals as we urge, the AAMC encourages CMS to finalize the APC proposal and to give considerable weight to the APC Panel’s recommendations in making Agency decisions regarding the assignment of supervision levels.

PARTIAL HOSPITALIZATION SERVICES

The partial hospitalization program (PHP) is an outpatient program for psychiatric services provided to patients in lieu of inpatient care. Because CMS considers a day of care as the unit that defines partial hospitalization services, payment for the PHP APC is determined based on a per diem methodology.

In CY 2009, CMS adopted a two-tiered payment system for PHP services, under which the Agency pays one amount for days with three units of service and a higher amount for days with four or more units of service. In CY 2011, CMS computed median per diem costs for days with three services and days with four or more services separately for Community Mental Health Center (CMHC)-based PHPs and for hospital-based PHPs and decided that differences in cost structures between the two types of treatment sites warranted lower payments to CMHC-based

PHPs than to hospital-based PHPs. CMS then adopted the following four APCs: Level I Partial Hospitalization (3 services) for CMHCs (APC 0172); Level II Partial Hospitalization (4 or more services) for CMHCs (APC 0173); Level I Partial Hospitalization (3 services) for hospital-based PHPs (APC 0175); and Level II Partial Hospital (4 or more services) for hospital-based PHPs. Under this new methodology, CMS calculates payments to CMHC providers based solely on CMHC data and payments to hospital PHPs based solely on hospital data.⁵

Under the proposed rates to hospital-based PHPs for CY 2012, rates for both Level I and Level II services would decline 23 percent. The AAMC is extremely concerned about this proposal to significantly reduce PHP payments – a reduction that could have severe consequences for beneficiary access to these services. To ensure continued beneficiary access for this vulnerable population, the AAMC urges CMS to maintain payment rates for PHPs for CY 2012 at the CY 2011 payment rates.

Additionally, because teaching hospitals care for a large population of complex, fragile patients, the AAMC urges CMS to ensure that payments for all PHP services are appropriate for the level of care provided. Beyond the refinements CMS has already made to PHP payments over the past several years, the AAMC encourages CMS to conduct additional analyses to determine whether adding an additional APC (for example, 4 – 5 services, and then 6 or more services) would be appropriate. The Association urges CMS to adopt PHP policies that provide equitable payments to hospitals that treat patients with multiple, concurrent mental health conditions and that do not create unintended consequences for those individuals or the physicians and institutions that treat them.

PROPOSED INPATIENT-ONLY PROCEDURES

For CY 2012, CMS proposes to remove three CPT codes from the “inpatient list”: codes 21346, 35045, and 54650. 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. CMS then submits recommendations to the APC Panel to receive feedback and further suggestions of codes appropriate for removal from the inpatient list.

At its February 28 - March 1, 2011, meeting, the APC Panel recommended removing CPT codes 21346, 35045, and 34650, as well as eight additional codes, from the inpatient list. After further clinical review, CMS chose not to accept the APC Panel’s recommendations to remove the eight additional codes, as the Agency does not “believe that these procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries...due to the clinical intensity of services provided.” 76 *Fed. Reg.* at 42277.

⁵ Prior to CY 2009, CMS calculated the PHP APC payment rate by combining hospital-based and CMHC median per-diem costs derived from both hospital and CMHC claims data. For CYs 2009 and 2010, CMS calculated median costs for the PHP APC payment rate based on hospital-based PHP claims data only.

The AAMC is disappointed that CMS is proposing to remove so few procedures from the inpatient list for CY 2012. We believe that hospitals and providers, not CMS, should decide which setting is most clinically appropriate to perform specific procedures. We are concerned that this policy unfairly affects teaching hospitals, as these institutions often perform less common, small volume procedures that may never reach a point so as to fit the Agency's criteria for removal from the inpatient list. We urge CMS to, at the least, accept the recommendations of the APC Panel, and if the Agency does not, CMS should provide more detailed explanations as to why the recommendations of this knowledgeable panel are being rejected.

WAGE INDEX PROPOSALS

CMS has consistently applied the final hospital inpatient prospective payment system (IPPS) wage index as the wage index for adjusting OPPS standardized amounts for labor market differences. In the proposed rule, however, CMS expressed concern about "significant fluctuations" in the wage index caused by various "manipulation(s) of the rural floor." 76 *Fed. Reg.* at 42212. To address these concerns, CMS seeks comments on several proposals that would set certain OPPS wage index policies independently from IPPS wage index policies.

The AAMC urges CMS not to make any changes to the OPPS wage index at this time. Instead, the Association encourages CMS to wait until the Institute of Medicine (IOM) has completed both of its commissioned reports on the hospital wage index. These reports will be helpful to the Agency in informing changes on geographic and wage-related issues, and CMS should address any OPPS-specific concerns as part of a comprehensive wage index review process.

SUMMARY

Teaching hospitals' outpatient departments are critical to providing needed services to beneficiaries as well as fulfilling the mission 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.

Administrator Donald Berwick

August 30, 2011

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If you have questions concerning comments on the quality reporting or value-based purchasing programs 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 that reads "Karen A. Fisher". The signature is written in a cursive style with a large initial "K".

Karen Fisher, JD

Senior Director and Senior Policy Counsel

cc: Jennifer Faerberg, AAMC

Lori Mihalich-Levin, JD, AAMC