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Via Electronic Submission (www.regulations.gov)

June 16, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS–1632–P
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Mr. Slavitt:

Re: FY 2016 Inpatient Prospective Payment System Proposed Rule, File Code CMS–1632–P

Dear Acting Administrator Slavitt:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS' or the Agency's) proposed rule entitled, *Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program; Proposed Rule*, 80 *Fed. Reg.* 24324 (April 30, 2015).

The AAMC's Council of Teaching Hospitals and Health Systems (COTH) comprises nearly 300 general acute nonfederal major teaching hospitals and health systems that receive Medicare payments under the IPPS. The Association also represents all 141 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 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians. Below is an overview of the AAMC's comments.

Medicare Disproportionate Share Hospital (DSH) Payments (pages 3-7)

The AAMC's members have missions to care for the sickest and most complex patients regardless of their ability to pay for hospital services. Accordingly, the recent Affordable Care Act (ACA)-mandated reductions to Medicare Disproportionate Share Hospital (DSH) payments have a disproportionate and negative impact on our member institutions. The FY 2016 rule proposals would decrease uncompensated care (UC) payments by $1.28 billion. This is an unsustainable cut for the hospitals serving the many remaining uninsured patients even after the implementation of the ACA, particularly given that many states have chosen not to expand Medicaid coverage. The AAMC has concerns about the projections and estimates that CMS uses as a basis for drastic reductions to the UC payment pool. The AAMC strongly urges CMS to make these projections

and estimates transparent and verifiable and to take into consideration various factors affecting the insured population that have arisen since the passage of the ACA. CMS should use all of its available authority to reduce the magnitude of these cuts and implement them in a way that is more gradual and sustainable for hospitals serving the remaining uninsured. CMS also should mitigate the effects of the proposed reductions in uncompensated care payments, because they disproportionately affect teaching hospitals and safety net hospitals that routinely provide medically necessary services to all comers in keeping with their missions.

Medicare Payments for Short Inpatient Hospital Stays (pages 7-17)

Additionally, the AAMC strongly urges CMS to withdraw during the CY 2016 Outpatient Prospective Payment System (OPPS) rulemaking cycle the Two Midnight rule for stays lasting fewer than two midnights. The substantial challenges and fundamental flaws associated with this policy have been highlighted by both the Medicare Payment Advisory Commission's (MedPAC's) analysis and recommendations, and the provider community's repeated requests for relief from its onerous effects. The Two Midnight rule does not effectively address the issues surrounding short stays, misplaced Recovery Audit Contractor (RAC) incentives, and longer observation stays. At the same time, the rule is also a disincentive to efficient care, a source of administrative burden, and disconnects the physician's complex medical judgment to admit a patient for medically necessary inpatient services from the determination of whether the patient's inpatient stay may be appropriately reimbursed as an inpatient stay.

As a result, this policy and the physician order and certification requirements finalized with it have caused substantial provider and beneficiary confusion, inadequate payment for medically necessary services, and countless operational challenges. For these reasons, it is imperative that CMS promptly return to the Agency's previous policy of deferring to clinical judgment supported by the medical record for stays lasting fewer than two midnights. CMS should withdraw the Two Midnight rule as it applies to short inpatient hospital stays or respond to stakeholder requests for a viable alternative short stay policy that ensures clinically necessary short inpatient stays are characterized as inpatient for the purposes of reimbursement and beneficiary liability.

Hospital Quality-Related Programs (pages 17-34)

- Inpatient Quality Reporting (IQR) Program, pages 21-26
- Hospital Readmissions Reduction Program (HRRP), pages 26-28
- Hospital Acquired Conditions (HAC) Reduction Program, pages 29-31
- Value Based Purchasing (VBP) Program, pages 31-34

The Association also continues to have serious concerns regarding the disproportionate effect of the three performance programs on teaching hospitals. The AAMC encourages CMS to recognize and account for the fact that this disproportionate impact may be due to insufficient risk adjustment, the size of the institution, or other measurement issues. CMS should address the

underlying issues that impact this measurement disparity, most notably by implementing socio-economic status (SES) adjustments.

In addition, CMS should not finalize changes to expand the pneumonia readmissions and mortality measures; nor should the Agency finalize its proposal to require electronic reporting of quality measures. The pneumonia measure has the potential to harm hospitals who care for a higher proportion of complex patients. The measure has to receive endorsement from the National Quality Forum (NQF) to ensure scientific validity and that the risk adjustment is sufficient. The electronic measures have feasibility and validity concerns, and the AAMC does not believe hospitals and vendors are ready for mandatory electronic reporting.

The Bundled Payments for Care Improvement Initiative (BPCI) (pages 34-50)

The AAMC supports the voluntary expansion of the BPCI initiative. If this expansion is implemented through rulemaking, CMS should use a payment model that includes the index hospitalization and post-acute care to incentivize coordination between providers across the care continuum. CMS also should utilize benchmark price and rebasing methodologies that ensure the long-term sustainability of the program by enabling participating providers to continue to pursue efficiencies and realize savings across multiple performance periods. In addition, the AAMC supports the continued exclusion of IME and DSH payments from the target amount.

Other comments will focus on the following areas:

- MS-DRG Documentation and Coding Adjustment (pages 50-51)
- Outlier Payments (pages 51-52)
- Eliminating the Simplified Cost Allocation Methodology (pages 52-53)
- Use of Non-Standard Cost Center Codes (page 53)

MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS

The Projections and Estimates CMS Relies on to Determine the Uncompensated Care Payment Pool and the Amount by Which It Should be Reduced Must be Accurate and Verifiable to Prevent Unreasonable Cuts

CMS proposes the same general methodology as in prior years to determine the pool available for UC payments and how this pool will be reduced and redistributed based on each hospital's relative share of uncompensated care. Factor 1 is equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments. Factor 2 reduces that 75 percent to reflect changes in the percentage of individuals under age 65 who are insured because of ACA implementation (*i.e.*, a ratio of the percentage of people who are insured in the most recent period following ACA implementation to the percentage of the population who were insured in a base year prior to ACA implementation). Factor 3, expressed as a percentage, represents a hospital's uncompensated care

amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in that fiscal year. In short, the product of Factors 1 and 2 determines the total pool available for UC payments. This product multiplied by Factor 3 determines the amount of UC payments each eligible hospital will receive.

The Association is concerned about the accuracy and transparency of the projections used to determine both Factors 1 and 2. Given that the projections that directly affect DSH and UC payments change from proposed to final rule, and from year to year, it is imperative for providers to understand how these projections and estimates are calculated. Finally, the AAMC encourages CMS to make clarifications regarding the data used to calculate Factor 3.

Factor 1

In the FY 2016 IPPS proposed rule, CMS explains that to calculate Factor 1, the Agency used the most recently available projections of Medicare DSH payments for the applicable fiscal year, as calculated by CMS' Office of the Actuary (OACT). The AAMC and the hospital community have repeatedly asked for more information to clarify how the projection for Factor 1 is determined, but stakeholders have yet to receive sufficient information to understand or replicate the methodology behind the relevant projections and estimates. As a result, a critical source of funding for hospitals with missions to take all comers and serve the sickest, most complex low-income patients is being reduced drastically based on estimates and projections that are not transparent or verifiable.

The Association urges CMS to clarify how the OACT makes these projections, so that providers can verify these calculations and comment on any necessary corrections during the rulemaking process. This transparency is particularly critical given that the statute precludes judicial review, and the estimates will not be revised or updated after CMS publishes the final Medicare DSH payments for FY 2016.

The "other" column in CMS' proposed rule supplemental file is meant to show the increase in various factors that contribute to the Medicare DSH estimates. These factors include the difference between total inpatient hospital discharges and the IPPS discharges, various adjustments to the payment rates that have that have been included over the years but are not reflected in the other columns, and a factor for the Medicaid expansion due to the ACA. The lack of transparency regarding the "other" factors is particularly troubling. In the FY 2015 final rule, CMS' "other" estimate for FY 2014 was 1.0355 (a 3.55 percent increase compared to FY 2013). Yet, in the FY 2016 proposed rule supplemental file, the "other" estimate for FY 2014 was 0.9993 (a 0.07 percent decrease compared to FY 2013). This alteration alone resulted in a more than $400 million decrease in the projected DSH payment pool with no explanation for the change in the projection. The AAMC urges CMS to explain the variability in this and other factors that directly impact the DSH pool to allow providers to understand and verify these projections. It is critical that hospitals have some ability to plan for the rate at which Medicare DSH cuts will be implemented.

Factor 2

CMS proposes to use the Congressional Budget Office's (CBO) January 2015 estimates of the effects of the Affordable Care Act on health insurance coverage to calculate the percent of individuals without insurance for purposes of calculating Factor 2. While the methodology used to calculate Factor 2 using these estimates remains unchanged from previous years, the AAMC remains concerned about how these CBO estimates are calculated. There are many unknowns and substantial variability in how the CBO reaches the newly-insured estimates. The Association believes it is critical to understand how these estimates are determined, given that they result in drastic reductions to the UC payment pool.

The intent of the ACA to universally expand coverage was undermined when the Supreme Court's opinion in *National Federation of Independent Business v. Sebelius*, 567 U.S. ___ (2012), 132 S.Ct 2566, made Medicaid expansion optional for the states. As a result, DSH cuts are not adequately counterbalanced by the coverage expansions Congress intended when passing the ACA. Additionally, it is impossible to determine whether the CBO takes into account a number of factors that ultimately affect the insured population and whether they are, in fact, covered for hospital services. As an example, it is unclear whether these estimates take into account the percentage of individuals who will disenroll from coverage because they are unable to pay their premiums (which has accounted for a 13 percent drop in the number enrolled in 2015).[1] Additionally, many insured individuals are not fully covered or cannot pay for the hospital services they receive because of high deductibles and coinsurance rates, which remain prevalent even after coverage expansion.

Given the impact of drastic cuts on hospitals that care for the most vulnerable patients, the AAMC urges CMS to use its authority to implement Medicare DSH cuts as incrementally as possible. The AAMC encourages the Agency to adopt a more gradual and comprehensible approach than the severe reductions that are currently occurring. A good model for phasing in reductions can be found in the more reasonable implementation of the American Taxpayer Relief Act (ATRA) of 2012 documentation and coding recoupment.

Finally, the Supreme Court's impending decision in *David King, et. al. v. Sylvia Burwell, Secretary of Health and Human Services, et al.*, Docket nos. 14-114, may also have a dramatic impact on the number of individuals insured through ACA coverage options. In the event the Court rules against the Administration and many individuals suddenly are without insurance, the Association strongly urges CMS to issue an interim final rule updating Factors 1 and 2 to take into account the ramifications of this decision.

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[1] *See* Pear R. 13% Left health care rolls, U.S. finds. *New York Times.* June 2, 2015; http://www.nytimes.com/2015/06/03/us/13-left-health-care-rolls-us-finds.html?smprod=nytcore-iphone&smid=nytcore-iphone-share&_r=1. Accessed June 15, 2015.

Factor 3

To calculate Factor 3, CMS proposes to continue to employ the utilization of insured low-income patients (defined as inpatient days of Medicaid patients plus inpatient days of Medicare Supplemental Security Income (SSI) patients). CMS states in the proposed rule that the Agency received feedback from the hospital community that providers were facing difficulties submitting accurate data for Medicaid days within the five-month period following the close of the hospital's cost report as required by the Provider Reimbursement Manual. According to CMS, these difficulties were caused by a number of different factors, including challenges receiving eligibility data from state Medicaid agencies.

To address this data deficiency, CMS proposes to compute Factor 3 for FY 2016 using the more recent full year 2012 or 2011 hospital cost report data from the March 2015 update to the HCRIS database. CMS also proposes that if the more recent of the two cost reporting periods does not reflect data for a twelve-month period, CMS would use data from the earlier of two periods so long as that earlier period reflects data for a period of twelve months. The AAMC asks CMS to clarify whether "full year" means full federal fiscal year (FFY), full calendar year, or full hospital cost reporting year. It is important to know if the twelve-month 2012 cost report would have to fall within the FFY, or if CMS is saying that the Agency will use the full year cost report from previous years if there are no full year cost reports during the period, because as an example, a hospital only has an eight-month cost report due to a change of ownership. The AAMC urges CMS to clarify that the Agency intends this to mean full hospital cost reporting year. Otherwise, this proposal creates challenges and confusion for hospitals with July 1 cost report start dates. The example below illustrates this concern:

> The FY 2012 cost report of a hospital with a July 1- June 30 cost reporting period would reflect the cost reporting period that runs from July 1, 2012 – June 30, 2013, but the latter part of that twelve month period (from October 1, 2012 – June 30, 2013) is in FFY 2013. Therefore, if CMS considers this hospital's FY 2012 cost report to be incomplete based on the Agency's interpretation of "full year," the hospital's FY 2011 cost report would have to be used.

It is particularly important to clarify the definition of "full year" because CMS also states in the proposed rule that if the Agency proposes and finalizes using the proxy of insured low-income days to compute Factor 3 in future years, the Agency would continue this policy by using data from the subsequent year. (*E.g.*, for FY 2017, CMS would use the more recent of twelve-month 2013 or 2012 cost reports in the most recent HCRIS database extract available at the time of rulemaking).

CMS also proposes that to calculate Factor 3, CMS would use the FY 2013 SSI ratios. Accordingly, hospitals' per discharge UC payments and total UC payments for FY 2016 would be determined using the FY 2013 SSI ratios. However, the Agency has indicated that the FY 2013

SSI ratios will be used to settle FY 2013 cost reports and FY 2015 SSI ratios will ultimately be used to settle FY 2015 cost reports. Does this mean the SSI ratio used to settle a hospital's cost report will be the SSI ratio that has the cost reporting year beginning in that federal fiscal year? Again, the AAMC encourages CMS to make distinctions between federal fiscal years and cost report years. The following example highlights the source of confusion:

> If the FFY 2015 SSI ratios were to come out around May 2017 (given that the FFY 2013 SSI ratios came out in May 2015), would CMS use FFY 2014 SSI ratios (which would come out around May 2016) to settle FY 2015 cost reports for hospitals that have a cost report that runs July 2015- June 2016 or would CMS use FFY 2015 SSI ratios?

Finally, the AAMC encourages CMS to continue its work to modify Worksheet (WS) S-10 of the hospital cost report and to develop guidance to ensure that the data is reported consistently and accurately so that this data could be used to determine each hospital's relative share of uncompensated care for purposes of distributing UC payments. The AAMC encourages CMS to continue to engage the provider community and to review the AAMC FY 2015 IPPS comments regarding necessary modifications to the WS S-10.[2]

MEDICARE PAYMENT FOR SHORT INPATIENT HOSPITAL STAYS

CMS Should Withdraw the Flawed Two Midnight Rule Requirement that Reimburses Medically Necessary Short Stays as Outpatient Stays

The AAMC appreciates CMS' acknowledgment of stakeholder concerns regarding Medicare policies related to short inpatient hospital stays. The Association strongly urges CMS to address these concerns by withdrawing the Two Midnight rule for stays shorter than two midnights during the CY 2016 OPPS rulemaking cycle. This withdrawal is critical to reduce beneficiary confusion, rectify inappropriate shifts from Part A to Part B payment, and maintain longstanding deference to medical judgment regarding inpatient admissions.

The hospital community and MedPAC are aligned in believing there are fundamental flaws with the Two Midnight policy, because it does not effectively address the issues surrounding short stays, overly aggressive RAC review, and longer observation stays. Defining inpatient care on the basis of length of stay without regard to clinical judgment about the inpatient admission is inconsistent with medical practice, results in provider and beneficiary confusion, and is disruptive to the payment system. The AAMC maintains that the complex and difficult clinical decision to admit a patient to the hospital does not lend itself to a time-based, bright-line rule regarding which stays

[2] *See*, Kirch D. Inpatient Prospective Payment System Proposed Rule comment letter June 30; https://www.aamc.org/download/384230/data/aamccommentsontheippsproposedrulefy2015.pdf. Accessed June 15, 2015.

are appropriately categorized as inpatient for reimbursement purposes. Short hospital stays should be reimbursed as inpatient stays under Part A, regardless of the length of stay, as long as the physician believes that admitting the patient best serves that patient's medical needs.

MedPAC reached similar conclusions regarding the Two Midnight rule. The Commission recommended withdrawal of this policy, concluding it does not effectively address the problems surrounding short inpatient stays, longer observation stays, and the RAC review process, and instead creates new challenges for providers and beneficiaries.

While shorter inpatient stays could be considered more profitable, the AAMC's analysis of MedPAC data show that 13 percent of all discharges are one-day inpatient stays, but 17 percent of inpatient stays are eight or more days. On average, hospitals lose 28 cents for every dollar spent caring for Medicare patients. MedPAC data also show that the distribution of inpatient discharges does not vary significantly based on length of stay, which suggests that clinical judgment about the appropriate length of the stay for the patient, rather than reimbursement considerations, guides admission and discharge decisions.

For these reasons, the AAMC urges CMS to withdraw the Two Midnight rule as it applies to short inpatient stays through the upcoming CY 2016 OPPS rulemaking cycle. The AAMC believes it is critical that any policy CMS proposes to replace the Two Midnight rule for short inpatient stays must:

- Remain consistent with the priority to maintain longstanding deference to clinical judgment regarding inpatient admissions; and
- Reduce beneficiary confusion, inadequate payment, and operational challenges faced by providers resulting from the Two Midnight rule.

The Association's fundamental policy priority is that clinical judgment should determine whether to admit a patient as an inpatient, and accordingly inpatient stays should be appropriately reimbursed under Part A, regardless of length. The most reasonable and equitable policy solution remains to withdraw the short stay portion of the Two Midnight Rule, return to the longstanding deference to medical judgment regarding the inpatient admission that is well-documented in the medical record, and implement comprehensive RAC reforms that are outlined below.

At the same time, if the opportunity for relief from the most challenging and problematic effects of the Two Midnight rule is contingent upon proposing an alternative short stay payment methodology, the AAMC's priority is that any alternative short stay payment methodology that CMS proposes would: 1) replace the Two Midnight rule as it applies to stays less than two midnights, and 2) ensure that short inpatient stays are appropriately characterized as inpatient stays for reimbursement and beneficiary liability purposes. These principles must be upheld to effectively remedy the most confusing and onerous challenges associated with the Two Midnight rule.

To this end, AAMC has evaluated a series of alternative short stay methodologies and shared data analysis and policy considerations with CMS in previous correspondence. While none of these short stay payment methodologies is preferable to a return to clinical judgment, the AAMC remains open to ongoing, constructive dialogue with the Agency regarding these or other possible alternatives.[3]

CMS Should Extend the Partial Enforcement Delay until the Later of December 31, 2016 or Implementation of an Alternative to the Two Midnight Rule

CMS' prohibition on RACs' conducting post-payment patient status reviews for claims that would be subject to the Two Midnight rule expires September 30, 2015. The AAMC strongly urges extension of this moratorium. The Two Midnight rule has been extremely challenging to operationalize. Given the critical need to replace this policy, and the ongoing legislative and regulatory debate about the best way to do so, the enforcement delay must be extended until a new policy is put in place and providers have an adequate opportunity to implement and operationalize it.

In the proposed rule, CMS indicates that the Agency may address short stay payment policy options related to the Two Midnight rule in the CY 2016 OPPS rule later this year. CMS should extend the moratorium to accommodate this continued delay of a proposal to replace the Two Midnight rule for short inpatient hospital stays. Hospitals and health systems would need at least a year to adjust to changes, which could go into effect no sooner than January 1, 2016, making December 31, 2016 an appropriate extension timeframe.

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,[4] 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 in 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).

Given that this negative adjustment was based on an OACT assumption of a net increase in inpatient cases, the adjustment would not be justified if this projected increase in inpatient cases

[3] Kirch D. Inpatient Prospective Payment System Proposed Rule comment letter June 30; https://www.aamc.org/download/384230/data/aamccommentsontheippsproposedrulefy2015.pdf. Accessed June 15, 2015.

[4] 2013 IPPS Final Rule, 77 *Fed. Reg.* 53258, 50746 (Aug. 31, 2012).

was unsubstantiated. CMS has never shared the assumptions and analysis that led the Agency to expect a decline in inpatient volume associated with the Two Midnight rule. The AAMC continues to believe that CMS' assumptions are inaccurate. The AAMC and peer hospital associations' data analysis[5] shows that there was a net decline (-4 percent) in inpatient encounters and an 11 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 Encounters[6]

Length of Stay	FY 2013	FY 2014	Percent Change
Less than Two Midnights	1,179,469	1,053,668	-11%
Greater than Two Midnights	8,361,749	8,103,355	-3%
All Cases	9,541,218	9,157,023	-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 Medicare Provider Analysis and Review (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 be in FY 2014 without the Two Midnight rule (using FY 2013 IPPS proposed rule numbers).[7] Next, these projected numbers were compared to actual FY 2014 IPPS proposed 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 and in the attached analysis.[8] 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.

[5] *See* Appendix A
[6] *Id.* Source: FY 2013 and FY 2014 MedPAR (December updates).
[7] 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).
[8] *See* Appendix A.

Difference between Actual and Expected Inpatient Cases Using 2009- 2013 CAGR[9]

Length of Stay	Actual FY 2013 Case Counts	Actual FY 2014 Case Counts (with 2 Midnight Rule in Effect)	2009-2013 CAGR	Projected FY 2014 Case Counts Without Two Midnight Rule (Using 2009-2013 CAGR)	Difference between Actual and Projected FY 2014 Case Counts
Less than Two Midnights	1,179,467	1,053,668	-4.2%	1,130,279	-76,611
Greater than Two Midnights	8,361,749	8,103,355	-1.7%	8,222,870	-119,515
All Cases	9,541,218	9,157,023	-2.0%	9,353,149	-196,126

The nearly 200,000 stay decrease in inpatient volume that would not have occurred absent the Two Midnight rule shows 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 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 even 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 information 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 (included in the Attached Appendix A). 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.

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

CMS Should Remove the Subregulatory Countersignature Requirement for Resident Orders for Inpatient Admission

The AAMC continues to have significant concerns related to CMS' subregulatory guidance implementing the physician order requirements finalized in conjunction with the Two Midnight rule. Language in this subregulatory guidance has resulted in substantial operational challenges and has created unnecessary burden for hospitals that must continue the longstanding practice of allowing residents to furnish inpatient orders, an essential part of their education. Related workflow challenges and unintended consequences are as disruptive as surgeons having to scrub out to meet the requirement to countersign the order before discharge. Given that the countersignature requirement impedes care delivery, to the detriment of patients and providers alike, additional training is not the answer. Instead, it is imperative to modify unprecedented and unnecessary subregulatory guidance language and remove the countersignature requirement for resident orders.

There is no precedent in regulation for requiring that resident inpatient admission orders be countersigned by an attending physician. The Conditions of Participation (CoPs) do not include a countersignature requirement. The only reference to a countersignature is in Interpretive Guidelines associated with 42 CFR § 482.24(c)(1), which requires that entries in the medical record made by residents or non-physicians be countersigned by a supervisory or attending medical staff members when specifically required by state law or hospital policy.[10] Therefore, there is no valid basis for national subregulatory guidance requiring an attending countersignature on inpatient orders furnished by residents and this language should be retracted or modified.

The current requirement poses substantial challenges for hospitals. It has necessitated alterations in longstanding practice, obstructed workflow to the detriment of patient care, and created requirements that are inconsistent with the functionalities of electronic medical records.

To remedy the counterproductive effects of this subregulatory guidance, the AAMC strongly urges CMS to make the following changes:

[10] *See*, 42 CFR § 482.24 Condition of participation: Medical record services. Interpretive Guidelines: When State law and/or hospital policy requires that entries in the medical record made by residents or non-physicians be countersigned by supervisory or attending medical staff members, then the medical staff rules and regulations must address counter-signature requirements and processes.

I) Remove the unnecessary and burdensome requirement to obtain an attending's countersignature on resident orders for inpatient admission

Residents at teaching hospitals are rarely granted their own admitting privileges, as they are not considered to be part of the medical staff. Instead, hospitals' by-laws allow these residents to write orders on behalf of the attending physicians who supervise them. The AAMC encourages CMS to modify paragraph B.2.a of the *Hospital Inpatient Order and Certification* guidance document to allow these individuals to act as proxy for the ordering practitioners without the difficult, confusing, and unnecessary step of countersigning the order. Not only does the requirement disrupt many well-established processes, but it also is impossible to implement in many electronic health records (EHRs) that have no way to add a countersignature. The following modified language would resolve this confusion:

> 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.***

These proposed modifications would be consistent with the relevant CoPs. After CMS finalized the Two Midnight rule and physician order and certification requirements, the updated regulations require that all inpatient admissions must be pursuant to an order by a physician or other qualified practitioner in accordance with 42 CFR §412.3 and §§482.24(c), 482.12(c), and 485.638(a)(4)(iii).[11] None of the referenced CoPs require an attending's countersignature on orders furnished by residents, nor do they necessitate maintaining some of the more problematic language in the subregulatory guidance language.

§ 482.24 Condition of Participation: Medical Record Services.

Section (c) of this CoP, requires that the medical record "must contain information to justify admission and continued hospitalization, support diagnosis, and describe the patient's progress and response to medications and services." It also allows orders to be authenticated by "the ordering practitioner **or by another practitioner**" as long as that practitioner is "acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff

[11] § 485.638(a)(4)(iii) CoP related to clinical records for CAHs) and § 482.22 (c) CoP providing a standard of for medical staff bylaws) do not include language that would preclude hospital bylaws from granting residents privileges to write inpatient admission orders on the behalf of an attending without a countersignature.

bylaws, rules, and regulations."[12] This CoP does not prohibit a resident who is licensed to practice medicine in accordance with state law and granted privileges to furnish orders on behalf of an attending by hospital policies and medical staff bylaws to authenticate an admission order.

§ 482.12(c): Condition of Participation: Governing Body.

This CoP requires that "[p]atients are admitted to the hospital only on the recommendation of a licensed practitioner **permitted by the State to admit patients to a hospital**."[13]

It is worth noting that generally state laws permit physicians to practice medicine and that it is hospital by-laws that determine whether a physician can admit patients to that particular hospital. A resident licensed by the state to practice medicine would be unable to be licensed by the state to admit inpatients (as currently required by CMS' subregulatory guidance language),[14] because admitting patients is not generally covered by state licensure laws. Further, according to the CoP, a resident would not need to be specifically licensed to admit inpatients as long as state law and hospital bylaws and policies **permit** practitioners licensed to practice medicine to admit inpatients. Notably, there is no mention of any countersignature requirement in this CoP.

II) Correct subregulatory guidance language to accurately reflect CoP requirements

States grant licenses to practice medicine, rather than licenses to admit inpatients to hospitals. Therefore, CMS should change the *Hospital Inpatient Order and Certification* guidance language requiring that "[t]he order must be furnished by a physician or other practitioner ("ordering practitioner") who is (a) licensed by the state to admit inpatients to hospitals" [15] to "(a) ***licensed by the state to practice medicine***. ***Licensed by the state includes a limited license or certificate granted by the state to a medical resident in an approved medical residency program***."

Additionally, residents at teaching hospitals are rarely granted their own admitting privileges, because they are not considered to be part of the medical staff. Instead, hospitals' by-laws allow these residents to write orders on behalf of the attending physicians who supervise them. Therefore, CMS should change the *Hospital Inpatient Order and Certification* guidance language requiring that "[t]he order must be furnished by a physician or other practitioner ("ordering practitioner") who is…(b) granted privileges by the hospital to admit inpatients to that specific facility" to "(b) ***granted privileges by the hospital to write inpatient admission orders***."

[12] 42 CFR § 482.24(c)(2).
[13] 42 §482.12(c)(2).
[14] "[t]he order must be furnished by a physician or other practitioner ("ordering practitioner") who is (a) licensed by the state to admit inpatients to hospitals"
[15] *Id*.

CMS Should Acknowledge and Correct the Underpayment of Observation Stays

When evaluating the reimbursement of short inpatient hospital stays and the payment differential between inpatient and observation stays, it is only equitable to consider the payment accuracy of observation stays. Using MedPAC data, the AAMC was able to estimate the payment-to-cost ratio for one-day stays, if they were paid at outpatient rates. The data in the following table[16] show that outpatient rates barely cover 60 percent of the costs associated with these DRGs. To the extent that the Two Midnight rule is based on the premise that these inpatient stays and observation stays represent similar care, the low outpatient payment-to-cost ratio raises serious questions about the adequacy of pricing for outpatient observation services.

Payment-to-Cost Ratio for One Day Stays Versus Payment-to-Cost Ratio at Outpatient Rate

DRG	Description	Average Medicare Inpatient Payment	Payment to Cost ratio for one-day stays	Average Cost of one-day stays	Outpatient Observation Payment	Payment to cost ratio if paid at outpatient rate
313	Chest Pain	$3,716	1.32	$ 2,815	1,655	0.59
310	Cardiac Arrhythmia & conductive disorders	3,677	1.41	$ 2,608	1,420	0.54
392	Esophagitis, gastroenteritis & miscellaneous digestive disorders	4,953	1.82	$ 2,721	1,526	0.56
312	Syncope & collapse	4,972	1.79	$ 2,778	1,689	0.61
287	Circulatory disorders except AMI, with cardiac catheterization without MCC	7,064	1.4	$ 5,046	3,998	0.79
641	Disorders of nutrition, metabolism, fluid/electrolytes without MCC	4,467	1.84	$ 2,428	1,341	0.55

The underpayment of observation stays is a neglected consideration in the discourse around the differential between reimbursement for observations stays and inpatients stays. Instead of changing policy to reduce payment for short inpatient stays (which are currently counterbalanced by underpaid longer inpatient stays), CMS should reevaluate and take into account the accuracy and sufficiency of observation stay payments.

[16] The table provides estimates of the payment to cost ratio if short stays were paid as outpatient observation stays using MedPAC data.

CMS Should Implement Meaningful RAC Reform to Reduce Administrative Burden and Decrease the Appeals Backlog

Overly aggressive RAC denials are a major source of the problems surrounding short inpatient stays and longer observation stays. Additionally, the fact that 68 percent of RAC denials are overturned on appeal[17] does not suggest that medical judgment or misplaced payment incentives are to blame for the unmanageable appeals backlog. Rather, it suggests that RACs often broadly deny these claims irrespective of the medical necessity of the inpatient admission. These problems will remain unresolved without meaningful RAC reforms such as those described here:

- **Expedite Implementation of CMS-Proposed Policy Changes**. In December 2014, CMS announced welcome changes to policies governing RACs, but these changes have not yet been incorporated into most RAC contracts. Proposed improvements include limited look-back periods, requirements that RACs maintain low overturn rates, time limits to complete complex reviews and notify providers of findings, and revised additional document request (ADR) limits. The AAMC urges CMS to incorporate these improvements into RAC contracts as soon as possible.

- **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.

[17] *See*, Sheehy, A. M., Locke, C., Engel, J. Z., et al, Recovery audit contractor audits and appeals at three academic medical centers. *J. Hosp. Med*. 2015; 10: 212–219. "These data also show continued aggressive RAC audit activity despite an increasing overturn rate in favor of the hospitals in discussion or on appeal each year (from 36.0% in 2010 to 68.0% in 2013)."

- **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.

HOSPITAL QUALITY PROGRAMS

Starting in FY 2016, the nation's IPPS hospitals will have at least 5.75 percent of their base DRG payments at risk through three programs:

- **Hospital Value-Based Purchasing (VBP) Program**, a pay-for-performance program that rewards or penalizes hospitals up to 1.75 percent based on performance for a variety of measures;

- **Hospital Readmissions Reduction Program (HRRP)**, a program that penalizes hospitals up to 3 percent for excess readmissions for selected conditions; and

- **Hospital-Acquired Condition Reduction Program (HAC or HACRP)**, a program that assesses hospitals with a 1 percent penalty for relatively poor performance on certain patient safety measures.

In addition, hospitals publicly report measures through the Inpatient Quality Reporting (IQR) program. Because so much of the payments are at stake, CMS has the obligation to ensure that measurement and comparisons are as accurate as possible.

CMS proposes numerous changes to these programs in these IPPS rule; however, the AAMC is disappointed that CMS is not addressing some key overarching issues with these programs, which are creating disparities with respect to the type of hospital being penalized. The following are the AAMC's top concerns with the existing hospital quality reporting and performance programs and policies.

CMS Needs to Address Systematic Biases in Performance Programs

While all types and sizes of hospitals are, in theory, equally at risk for the three programs, the reality is that, certain hospital categories are being penalized much more than others. Based on an analysis (Figure 1) by KNG Health, large hospitals, major teaching hospitals, and hospitals with a higher DSH proportion (indicating higher levels of care for more vulnerable patients) are more likely to be penalized in each of the three programs compared to other hospitals. At least a portion of this discrepancy is due to measurement issues, which are described below.

The current scoring methodology under these three programs is biased against large hospitals compared to small hospitals. As evidenced by Figure 1 in the chart below, the methodology CMS employs leads to 28 percent of the smallest hospitals (bed size under 65) avoiding penalties in all three performance programs, raising serious credibility questions regarding how these penalties are calculated. This is in stark contrast to the only 7 percent of the largest hospitals (bed size over 257) and 5 percent of major teaching institutions which received no penalties for any of the three programs. This wide discrepancy in penalties lacks face validity and should be reviewed by CMS.

Figure 1: FY 2015 Hospital Penalties by Size and Type

Hospital Characteristics	Received No Penalties Across Programs	Received Penalties in All Three Programs
Bed Count		
• Quartile 1 (less than 65 beds)	**28%**	**2%**
• Quartile 2 (between 65 and 136 beds)	**10%**	**8%**
• Quartile 3 (between 137 and 256 beds)	**6%**	**10%**
• Quartile 4 (257 or more beds)	**7%**	**18%**
Teaching Status		
• Major Teaching (Resident to Bed Ratio >= 0 .25)	**5%**	**25%**
• Minor Teaching (0<Resident to Bed Ratio < 0 .25)	**8%**	**12%**
• Non-Teaching (Resident to Bed Ratio = 0)	**15%**	**7%**
DSH Percent		
• High (31.2% or more)	**10%**	**14%**
• Medium (between 20.5% and 31.2%)	**7%**	**9%**
• Low (less than 20.5%)	**21%**	**5%**

*VBP Penalty = if hospital receives less than the withhold amount.
Source: KNG Analysis of Hospital Compare Files, accessed May 6, 2015

The AAMC believes that such systematic differences in penalties cannot be attributed to quality alone, but rather to ***measurement limitations*** that are affecting performance scores. CMS is aware of many of the current measure limitations, including:

- **Adjustments for small sample size differentially affects hospitals.** To add stability and reliability, some measures use a statistical technique that weights small sample sizes with the national average. The result is that it is more difficult to notice true variation for smaller hospitals as compared to larger ones."[18]

- **Lack of sociodemographic (SDS) adjustment for outcome measures.** Outcome measures, particularly readmission measures, are associated with socioeconomic status (SES) or demographic factors (combined, these two categories are referred to as sociodemographic status or SDS). Hospitals that disproportionately care for vulnerable patient populations, who are at higher risk of readmissions, are disadvantaged when these factors are not considered in either the adjustment or the payment scoring methodology.[19]

- **Other limitations in risk adjustment.** Claims measures have limited clinical information, and other data sources are either expensive to collect or may have missing data. Models that do not have all the relevant patient comorbidities or complexities will not have a sufficient risk adjustment.

The cumulative effect of these limitations is that CMS compares "apples to oranges" when the Agency should be comparing "apples to apples." Differences in comparison groups are then compounded when similar or related measures are used in multiple programs.

In addition to developing more robust measures sets, the AAMC asks CMS to perform a thorough reevaluation of the three programs and consider ways to mitigate any unintended biases and make the comparisons more equitable to alleviate disparities in penalties. Two possibilities to help achieve this goal include:

- **Implementation of an SDS adjustment for HRRP and other outcome measures.** The AAMC recognizes that the NQF is currently conducting an SDS trial period. However, in the interim, the AAMC requests that the Agency implement an SDS adjustment via stratification.

[18] *See*, Silber JH, Rosenbaum PR, Brachet TJ, et al. The Hospital Compare mortality model and the volume-outcome relationship. *Health Serv Res.* Oct 2010;45(5 Pt 1):1148-1167.
[19] *See*, Hu J, Gonsahn MD, Nerenz DR. Socioeconomic status and readmissions: evidence from an urban teaching hospital. *Health Aff (Millwood).* May 2014;33(5):778-785.

- **Create peer cohorts or use matching algorithms to create better benchmarks**
  CMS could develop peer cohorts of hospitals of similar size or case mix. Alternatively, CMS could employ advanced matching algorithms to ensure that performance measurement is compared to similar organizations.

CMS Should Address Measure Applications Partnership (MAP) "Conditions" When Proposing New Measures

Numerous times in this proposed rule, CMS proposes to add measures to the performance and reporting programs citing that the MAP had reviewed and recommended the measures. The AAMC supports the MAP process and was therefore disappointed that CMS would include these measures without addressing the conditions the MAP attached to each recommendation. For example, CMS proposed the expanded pneumonia readmissions measure for the HRRP, when the measure had not been reviewed by the NQF nor considered for an SDS adjustment, as recommended by the MAP. It is incorrect to claim the MAP supports these measures if CMS ignores the accompanying conditions.

Request for Enhanced Data for Quality Improvement

Ideally, collection and reporting of quality data provides an opportunity for hospitals to gather important information that leads to improvement through care redesign. Hospitals need timelier, more comprehensive, and more coordinated data support from CMS, particularly for the claims measures, to better understand their performance on Medicare quality measures and how performance affects payments. Currently there are gaps that limit the ability of hospitals to understand their performance. Only clear and timely data will allow hospitals to use this information for care improvement purposes and to model payment impacts in a way that allows hospitals to truly understand new value-based financial incentives.

For FY 2016, there will be 21 finalized measures in the VBP program, five in HRRP, and five in HACRP, with several measures changing each year. The constantly changing dynamic in measures, the different reporting time periods, and the different conversion methodologies used to score the measures in different performance programs make it challenging for hospitals to understand how their measures translate into payment adjustments. In addition, many times the performance periods for the different programs do not align with each other, or with the data available on the Hospital Compare website.

To make the quality improvement data more relevant, the AAMC recommends that CMS provide frequent and comprehensive data sets, especially for claims measures. Ideally, the data sets would be released quarterly and would have sufficient information for hospitals to be able to track their performance for VBP, HRRP, and HACRP.

Summary of Key AAMC Recommendations on Changes to Quality Programs in the IPPS Proposed Rule

- **Do not finalize expansion of the pneumonia readmissions and mortality measures for HRRP and IQR Programs.** The proposed expansion of this measure is not a revision, but a wholesale expansion which could have unintended consequences. This type of significant change must go through the NQF-endorsement process.

- **Do not finalize the requirement for mandatory e-reporting of measures for IQR.** Hospitals, vendors, and CMS are not prepared to fully implement e-reporting at this time. Even leaders in EHR implementation face challenges in mapping medical record data to quality reporting formats, and these vendor-level issues are largely beyond hospitals' control.

- **Incorporate the new CDC standard population and site expansion to VBP and HACRP in FY 2019.** Incorporating these changes into both performance programs at the same time will reduce confusion and will give providers an opportunity to understand and improve performance.

- **Continue to test ways to improve risk adjustment.** EHR and other clinical data conceptually have the potential to improve risk adjustment for outcome measures, but this data must be thoroughly tested.

INPATIENT QUALITY REPORTING (IQR) PROGRAM

Starting in the FY 2018 payment year, CMS proposes several refinements to the IQR program:

- Remove nine chart abstracted measures (although six will be retained as electronic measures)
- Add eight new measures for the FY 2018 payment year:
    - Five episode-based measures,
    - Two excess days in acute care measures, and
    - One measure assessing use of a patient culture survey.
- Requirement for FY 2018 electronic reporting of certain clinical measures will start the last two quarters of CY 2016

In addition, CMS is seeking feedback on the potential use of EHR clinical data for risk adjusting outcome measures. For the complete list of CMS proposed measures and the AAMC recommendations for each, please see Appendix B attached to this letter.

CMS Should Not Mandate Electronic Reporting of Measures

The AAMC strongly opposes an electronic reporting mandate at this time and urges CMS **not** to finalize this proposal. While the AAMC appreciates CMS' desire to transition towards greater electronic reporting of clinical data and to increase alignment between the EHR Incentive and IQR programs, a requirement that forces this type of reporting for two quarters starting in CY 2016 is premature. The AAMC has numerous reasons to be concerned about the feasibility and validity of electronically-submitted measures. As noted in our comments for the EHR Incentive Program Stage 3 Proposed Rule,[20] the Association believes that hospitals and vendors are not sufficiently prepared to fully implement this change within the next year.

Major teaching hospitals are leaders in EHR implementation, yet the AAMC continues to hear of numerous problems implementing e-measures. Among the challenges, hospitals are frustrated by the staff and resource burden required to map the necessary data elements from the EHR to the appropriate Quality Reporting Data Architecture (QRDA) format, some vendors are not properly equipped to collect and transmit such data through the CMS portal, and hospitals can face additional fees to extract the EHR data from the system. Additionally, mandatory eCQM reporting depends on hospitals using the correct version of specifications, which is generally in the control of the EHR vendors, not the hospitals. The AAMC does not believe this issue is unique to teaching hospitals and asks CMS to publish the number of providers that have successfully transmitted e-measures over the past year.

In addition to the feasibility concerns, AAMC member institutions have reported that data generated from e-measures does not match that of similar chart-abstracted data. Part of this problem is that electronic measures often are unable to capture clinical nuances, which are necessary for determining the exclusionary criteria. The quality and accuracy of this data is a top concern and these issues must be resolved before transitioning to mandatory e-reporting.

The AAMC urges CMS to continue a voluntary electronic reporting option. In the meantime, CMS should reach out to EHR vendors, hospital quality staff, and other affected stakeholders to identify underlying structural problems and barriers to successful reporting of these measures.

Specific Quality Measure Recommendations

Because IQR measures are publicly reported on the Hospital Compare website and are eligible for the VBP program, the AAMC believes these measures should meet a certain standard. In particular, the AAMC considers whether measures proposed for this program have been reviewed by the NQF and follow the recommendations (including any conditions) issued by the MAP. A full list of the CMS proposed measures and AAMC recommendations is included in Appendix B.

[20] *See*, Orlowski J. Meaningful Use Stage 3 Proposed Rule comment letter May 29; https://www.aamc.org/download/433352/data/aamccommentsonmeaningfulusestage3.pdf. Accessed June 15, 2015

CMS Should Not Finalize Expansion of the Pneumonia Readmissions and Mortality Measures

As described in the HRRP section below, the AAMC strongly disagrees with CMS' proposal to expand the populations of the pneumonia and mortality measures to include patients with a principal diagnosis of aspiration pneumonia and patients with a principal diagnosis of sepsis or respiratory failure and a secondary diagnosis of pneumonia. CMS proposed this modification in an attempt to make the measure more comprehensive for pneumonia and to account for potential discrepancies in how the measures are coded. However this "refined" measure has the potential to introduce a more severe complication: it makes hospitals that care for the most complex patients look worse by not appropriately adjusting for the differences in patient population. In fact, one of the journal articles cited by CMS justifying this change noted that "Because our adjustment method, like that of CMS, did not account for acuity of illness beyond existing comorbid conditions, it may unfairly penalize hospitals whose patients present with more severe illness."[21]

CMS has made a major modification to the denominator and some modifications to the risk adjustment. However, such significant changes mean that this measure can no longer be considered NQF-endorsed. The AAMC agrees with CMS that it is important to have measures that are comparable across hospitals. That being said, the Association remains unconvinced that these new measures will adequately make performance comparable, as major teaching hospitals disproportionately care for these more complex patients. This measure should go through NQF for a formal review with experts in the field and should not be finalized at this time.

The AAMC Supports Measures Proposed for Removal in FY 2018

CMS proposes to remove nine chart-abstracted measures from the IQR Program starting in FY 2018, while retaining six of these measures for use as EHR measures. The measures proposed for removal are as follows:

Measures Proposed to be Removed from the IQR Program:

- STK-01: VTE Prophylaxis
- IMM-1: Pneumococcal Immunization (Previously Suspended)
- SCIP-Inf-4: Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (Previously Suspended)

[21] *See*, Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: a cross-sectional analysis. *Ann Intern Med.* Mar 18 2014;160(6):380-388.

Measures Proposed to be Removed as Required Measures in the IQR Program, But Retained as EHR Measures:

- STK-06: Discharged on Statin Medication
- STK-08: Stroke Education
- VTE-1: VTE Prophylaxis
- VTE-2: ICU VTE Prophylaxis
- VTE-3: VTE Patients with Anticoagulation Overlap Therapy
- AMI-7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival

Five of the measures are topped-out (STK-06, STK-08, VTE-1, VTE-2, and VTE-3); two of the measures have had data collection suspended due to concerns with the clinical guidelines and specifications (IMM-1 and SCIP-Inf-4); and one measure is infrequently reported by hospitals. The AAMC supports the removal of measures that are topped-out or do not meet appropriate clinical guidelines or specifications.

AAMC Does Not Support the Addition of New Episode-Based Measures for Public Reporting without NQF Review Starting FY 2018

CMS proposes to add four 30-day extended episode of care measures, along with an extended THA/TKA episode of care measure which includes all payments for the initial 30 episode days, along with all payments for certain care settings and services for the remaining 60 days.

Episode-Based Payment Measures:

- Kidney/Urinary Tract Infection (UTI) clinical episode based payment
- Spine fusion/refusion episode based payment
- Cellulitis clinical episode based payment
- Gastrointestinal hemorrhage clinical episode based payment
- Total Hip Arthroplasty (THA)/Total Knee Arthroplasty (TKA) payment per episode of care

The first four clinical episode-based measures assess all payments (Parts A and B) for these conditions/services and use logic similar to the Medicare Spending Per Beneficiary (MSPB) measure, such as utilizing a 3-days prior to 30-days post-discharge methodology. The Total Hip Arthroplasty (THA)/Total Knee Arthroplasty (TKA) measure assesses hospital payments associated with a 90-day episode-of-care triggered by an admission. The measure includes all payments (Parts A and B) for the initial 30 episode days, along with all payments for certain care settings and services for the remaining 60 days.

The Hospital MAP Workgroup reviewed this measure in December 2014, where it was supported for the IQR program, on the condition that it first be reviewed by the NQF. This condition has not yet been met. NQF stakeholders must have the chance to appropriately evaluate this measure to

ensure that it is scientifically valid, reliable, and feasible, and determine whether it is appropriate for review in the NQF SDS trial period. Until such a discussion occurs, relevant stakeholders do not have the necessary information to make a critical assessment as to whether a measure is appropriate for public reporting or performance programs.

In addition, CMS is testing other bundling programs in the Bundled Payments for Care Improvement (BPCI) initiative and will need to test new bundle logic as required by the Medicare Access and CHIP Reauthorization Act (MACRA). Rather than adding new measures into IQR, CMS should step back and review the Agency's multiple bundling initiatives holistically and make sure these measures are aligned.

Despite these concerns, the AAMC recognizes that providers may benefit from seeing this claims data. While the measures are being reviewed by NQF, providers may want to analyze the information to understand the drivers of high cost payment episodes and possibly identify appropriate interventions that can lead to improved processes of care. While the AAMC does not believe that these measures are appropriate for public reporting at this time, CMS could continue to test these measures by reporting the information confidentially to each institution through a hospital specific report. Confidential reporting will allow providers time to better understand this data while the merits of the measure are discussed by the relevant NQF committee.

Excess Days in Acute Care Measures Should be Reviewed by NQF Prior to Public Reporting

Excess Days in Acute Care Payment Measures

- Excess days in acute care after hospitalization for Acute Myocardial Infarction (AMI)
- Excess days in acute care after hospitalization for heart failure (HF)

The excess days measures assess all-cause acute care utilization for post-discharge AMI and HF patients and include readmissions, observation stays, and ED visits. These measures are a new way to monitor resource use following a patient discharge. The measures are a ratio of a patient's actual acute care utilization compared to expected utilization based on the patient's degree of illness. These measures have not been risk-adjusted for SDS factors.

The AAMC believes these measures should be NQF endorsed before being proposed for the IQR program. The AAMC has concerns as to whether documenting the excess days provides a clear signal of quality. In particular, patients with higher complexity or with difficult personal circumstances may require more days in an acute setting. Until this measure is reviewed by the NQF, excess days does not represent an actionable or meaningful measure for the provider.

Patient Safety Culture Surveys More Valuable than Documenting about the Survey

This proposed structural measure assesses whether a hospital administers a patient safety culture survey to its staff but does not designate a specific survey for use. Rather, CMS requests that hospitals provide a five-question response about the survey via a web-based tool.

The AAMC believes that patient safety culture surveys are valuable to identify gaps in patient safety, raise staff awareness of critical issues, and provide a way to examine trends in patient safety culture over time at an institution. While the AAMC does not oppose reporting this information, the Association does not believe documenting the patient safety survey will add much value.

Use of EHR-Derived Core Clinical Data for Risk Adjustment

In the proposed rule, CMS requested stakeholder feedback on the potential use of EHR-derived core clinical data elements for such purposes as enhancing the risk-adjustment of outcome measures and helping to link the patient's episode with administrative data. CMS has identified 21 core elements routinely collected and extracted from EHRs, including age, gender, temperature, respiratory rate, hemoglobin levels, and platelet counts, which could be used for these purposes. Hospitals would be responsible for sending the extracted data to the Agency, and CMS would perform the measure calculations. CMS envisions using these EHR-derived elements in conjunction with other sources of data (such as administrative claims).

The AAMC has long advocated for improved risk adjustment algorithms and believes integrating EHR data may be a positive step. However, the Association believes more work is needed to ensure the accuracy and completeness of the data. At a minimum, the AAMC recommends that newly developed hybrid measures go through NQF review and thorough testing before being incorporated into pay-for-reporting and pay-for-performance programs. In addition, CMS should test the feasibility of using non-clinical EHR-derived elements, such as education, location, and other factors, to develop appropriate SDS adjustments.

HOSPITAL READMISSIONS REDUCTION PROGRAM

CMS Should Not Finalize the Proposed Expanded Pneumonia Measure

Starting in FY 2017, CMS proposes to adopt a "refinement" of the 30-day pneumonia readmissions measure that would include a **substantially** larger patient population than the pneumonia measure used in the Hospital Readmissions Reduction Program (HRRP). This measure currently includes hospitalized patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial. CMS proposes to expand the measure denominator to include patients with a principal discharge diagnosis of aspiration pneumonia or patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. CMS is proposing this modification in an attempt to make the measure more

comprehensive for pneumonia and to account for potential discrepancies in how the measures are coded. The Agency also acknowledges the expansion would increase the current denominator by **65 percent** and would include more complex patients.

The AAMC strongly opposes adoption of the proposed pneumonia readmissions measure for numerous reasons:

- The ACA statutory language **requires** that readmissions measures be "endorsed by the entity with a contract under section 1890(a)," which is the NQF. The AAMC strongly believes that such a significant expansion of the pneumonia readmissions measure is not a "refinement" but rather more closely resembles a whole new measure. CMS should obtain NQF endorsement before proposing this measure for the HRRP program.

- The MAP recommended this measure contingent on two conditions:
    - NQF endorsement, and
    - Consideration for SDS adjustment.

  Neither of these conditions has occurred prior to this proposal.

- The proposed expanded patient populations can reasonably be expected to have different readmission rates. CMS should conduct a scientific review by outside experts as to the validity of such an expansion.

The Association has serious concerns that the new additions to the current pneumonia readmissions measure are clinically more complex than the current population. For example, aspiration pneumonia often includes stroke patients who can be at higher risk for re-aspiration because they cannot control their swallowing function, leaving them at higher risk for pneumonia readmission. This is the type of discussion clinical experts should be debating through the NQF process. Finalizing this measure without a scientific review of the consequences of adding these two new populations is likely to have unintended consequences and harm academic medical centers disproportionately. Rothberg *et al* acknowledge these concerns when they state that without appropriate risk adjustment, this methodology could "unfairly penalize hospitals whose patients present with more severe illness."[22]

CMS' own estimates have predicted that these additional diagnosis codes would add approximately 634,000 people on top of the current measured pneumonia population of 976,000 patients, a 65 percent increase. However, the distribution of patients will not fall evenly across all hospital types. AAMC review of these claims files showed a wide disparity in the types of

[22] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: a cross-sectional analysis. *Ann Intern Med.* Mar 18 2014;160(6):380-388.

institutions that treat patients with the described conditions. As evidenced by the chart below, adding aspiration pneumonia to the current measure denominator would result in a 26.4 percent increase in the patient cohort for major teaching hospitals, compared to a 20.6 percent increase for non-teaching hospitals. Similarly, adding a principal diagnosis of sepsis translates into a 48.6 percent increase in the measure's patient cohort for major teaching hospitals, compared to a 33.3 percent increase for non-teaching institutions. CMS may be worried about variable coding, but major teaching hospitals often treat the most complex patients. Without additional analysis, this new measure could penalize them for caring for a difficult patient population.

Figure 2: Percent Increase in Claims for each of the Pneumonia Diagnosis Codes by Teaching Status

	Aspiration	**Sepsis**	**Respiratory**
Major Teaching	26.4%	48.6%	11.0%
Minor Teaching	24.4%	37.3%	10.1%
Non-Teaching	20.6%	33.3%	8.4%

Source: DataGen Analysis of 2013 Standard Analytic File

CMS Should Adjust Readmissions Measures for SDS Factors

The AAMC remains extremely concerned that CMS has continued the Agency's policy of not adjusting the readmissions measures to account for SDS factors. The AAMC appreciates that the NQF has started a trial period to review whether there are conceptual and empirical relationships between certain accountability measures and SDS factors. However, this trial period is not slated to end until early 2017. In the meantime, CMS continues to use quality measures in the HRRP that are influenced by community-level factors without an appropriate adjustment. Until the NQF trial period concludes and a formal recommendation is released, the AAMC urges CMS to make adjustments, in a transparent fashion, to account for safety net hospitals that disproportionately treat low-income and more vulnerable patient populations.

AAMC Supports Inclusion of Extraordinary Circumstance Exception Policy

CMS has proposed the inclusion of an extraordinary circumstance exception policy for the HRRP starting in FY 2016, a policy that currently in place for the VBP Program. The AAMC supports the inclusion of an exceptional circumstance policy for all performance programs but urges CMS to consider a range of extenuating circumstances that could adversely affect a hospital's ability to submit data in a timely fashion. The AAMC also requests that CMS allow for an appeals process governing extraordinary circumstance decisions.

HOSPITAL-ACQUIRED CONDITIONS (HAC) REDUCTION PROGRAM

CMS Should Mitigate the Disproportionate Penalties in the HACRP

As CMS transitions into the second year of the HACRP, the AAMC remains extremely concerned that this program continues to overwhelmingly and disproportionately impact the nation's major teaching hospitals. By CMS' own estimate, approximately 42 percent of major teaching institutions will be penalized by the program in FY 2016, which is twice the national average and far higher than any other type or group of IPPS hospital, as identified by CMS. Unlike VBP and HRRP, the HACRP also includes penalties for add-on policy payments, such as IME, DSH, and UC, which disproportionately affect teaching hospitals. Hospitals are being identified as poor performers due to limitations in the scoring methodology, data collection, risk adjustment, and the size of teaching facilities, rather than to true differences in the quality of care.

CMS has highlighted potential deficiencies in the quality measures used in this program, noting that MedPAC and other stakeholders have raised concerns that the claims-based measures used are not "as reliable or actionable" as the CDC NHSN measures. Additionally, hospitals that have instituted a rigorous program to identify (and treat) infections are placed at a disadvantage when they are compared to those with less comprehensive quality programs. Because this program is mandated to penalize 25 percent of all hospitals, CMS has an obligation to ensure that the measures used are as fair and accurate as possible and do not create a systematic bias that disadvantages any particular type of hospital.

AAMC Supports the Narrative Rule, but Urges HACRP Scoring Technical Expert Panel (TEP) to Address Other Program Deficiencies

In December of 2014, CMS convened a TEP to reevaluate the HACRP's scoring methodology. The TEP issued one modest recommendation, included in the FY 2016 proposed rule, which would treat Domain 2 measures independently for purposes of determining a Domain 2 score. The AAMC supports this proposal and agrees that all eligible hospitals should be required to submit all relevant Domain 2 measures or face penalties under the program.

However, the AAMC does not believe that the TEP went far enough to address the underlying scoring concerns and methodological issues raised by stakeholders. The Association urges CMS and the TEP to review and discuss the options highlighted below. For a complete list of AAMC recommendations, please refer to the AAMC comment letter on the TEP's proposal[23]:

- **Use of Hospital Peer Cohorts to Determine Overall Performance.** The AAMC recommends that CMS explore measure performance within specific hospital peer cohorts so that hospitals with similar characteristics and risk profiles are compared to each other.

[23] *See*, Orlowski, J. HACRP TEP Report comment letter Dec 18; https://www.aamc.org/download/420312/data/aamccommentsonthecmshactep.pdf. Accessed June 15, 2015

The use of peer cohorts may help mitigate limitations in comparing hospitals with different types of service mix and patient complexity.

- **Comprehensive Review of PSI-90 Composite Measure.** The AAMC recommends that CMS examine potential scoring issues associated with the AHRQ PSI-90 measure. Under HACRP requirements, a hospital must have at least 3 possible occurrences in order to be assessed under this measure. There should be a review as to whether there is a significant variation between hospitals with small sample sizes compared to those with large sample sizes.

AAMC Supports the Increase in Weight for the Clinically-Validated Measures in Domain 2

In the FY 2014 IPPS Proposed Rule, CMS finalized using two measure domains for the HACRP, each utilizing a separate data source. Domain 1 consisted of the AHRQ PSI-90 composite measure and was weighted at 35 percent, and Domain 2 consisted of the CDC NHSN measures of CLABSI and CAUTI was weighted at 65 percent. In FY 2015, CMS added surgical site infections (SSI) to Domain 2 and increased the weight of this domain to 75 percent; Domain 1 was decreased to 25 percent of the total weight.

In the FY 2016 IPPS Proposed Rule, CMS proposes to further increase the weight of the CDC NHSN measures in Domain 2 to 85 percent, while decreasing the Domain 1 weight to 15 percent starting in FY 2017. CMS cites two justifications for this change:

- Two new measures (already finalized) – MRSA Bacteremia and *c. difficile* – will be added to Domain 2 starting in FY 2017. The weights for each domain should reflect the number of measures in each.

- MedPAC and other stakeholders (including the AAMC) recommended that Domain 2 be weighted higher because the CDC-NHSN chart-abstracted measures are more reliable and actionable than the PSI-90 measure.

The AAMC strongly supports increasing the weight of Domain 2 to 85 percent. The CDC NHSN has a rigorous methodology for collecting information on safety events which is more reliable than using claims data. If there is a discrepancy in performance, then the measures based on clinical data should take precedence.

AAMC Recommends CMS Implement CDC Changes in FY 2019 to Align with VBP Program

Starting January 1, 2015, the CDC has expanded data collection for two NHSN infection measures, CLABSI and CAUTI. In addition to being collected in the Intensive Care Unit (ICU), CLABSI and CAUTI data are now being collected in pediatric and adult medical wards, surgical wards, and

medical/surgical wards. The CDC is also updating its standard population (previously referred to as the "national baseline") data, which is used to compute the standardized infection ratios (SIRs) for all of the NHSN infection measures. The standard population data had previously varied by measure; now the CDC will use data collected in CY 2015 to compute the standard population for all NHSN measures. CMS anticipates that the new standard population data will affect the HAC Reduction Program starting in FY 2018, when the performance period for the CDC NHSN measures will be CYs 2015 and 2016.

To maintain consistency with the VBP Program, the AAMC recommends that CMS delay using the updated standard population and expanded CAUTI and CLABSI data for payment purposes until FY 2019. Standardizing CDC data collection for these two programs will lead to less confusion on which data is reported and when, and will allow providers additional time to review, understand, and explain the changes in performance that may occur due to a new baseline before the changes affect payment.

AAMC Supports Inclusion of Extraordinary Circumstance Exception Policy

CMS has proposed the inclusion of an extraordinary circumstance exception policy for the HACRP starting FY 2016, which is currently in place for the VBP Program. The AAMC supports the inclusion of an exceptional circumstance policy for all performance programs, but urges CMS to consider a range of extenuating circumstances that could adversely affect a hospital's ability to submit data in a timely fashion. The AAMC also requests that CMS allow for an appeals process governing extraordinary circumstance decisions.

HOSPITAL VALUE-BASED PURCHASING PROGRAM

Starting in FY 2018, CMS proposes to adopt one new measure, and remove two process of care measures from the VBP Program. Due to the proposed removal of these two measures and the transfer of another process measure to the Safety Domain, CMS proposes to eliminate the Clinical Care – Process Subdomain starting FY 2018, while maintaining the Clinical Care – Outcomes Domain (now referred to as the Clinical Care Domain). The Safety Domain would increase from 20 to 25 percent and the Clinical Care Domain would decrease to 25 percent. The other domains would remain unchanged so that the weights for each would be 25 percent. Starting in FY 2021, CMS proposes to add COPD Mortality to the VBP Program. For the complete list of CMS proposed measures and the AAMC recommendations for each, please see Appendix B attached to this letter.

AAMC Supports Removal of Clinical Care - Process Subdomain, But Urges CMS to Incorporate Good Process Measures into the VBP Program

The AAMC appreciates CMS' priority in including outcomes and safety measures in the VBP Program. While the AAMC supports the removal of IMM-2 (Influenza Immunization) and AMI-

7a (Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival) from VBP, the Association believes that good process measures continue to have value and a place in VBP. Process measures can be used to identify gaps that may not be immediately apparent from outcome measures, because not every poor process automatically results in a bad outcome. Additionally, measuring processes gives hospitals the data they need to improve performance. Therefore, while the AAMC supports the proposal to remove process measures as a domain, the *AAMC does not believe process measures should be removed permanently from VBP*. CMS should continue to look for and evaluate process measures and insert them as appropriate into the existing domains.

CMS Should Reconsider Scoring Methodology for Certain Outcome Measures in Light of Removal of Process Measures

At the outset of the VBP Program, CMS focused on process of care and HCAHPs measures for which every hospital in theory had the opportunity to achieve maximum achievement points. As CMS transitions away from process measures, the Agency should acknowledge that maximum achievement points are not possible for all outcome measures and should review how these measures are scored in the future. For example, MSPB is a *relative* measure, and by design, half of all hospitals do not have any opportunity to obtain achievement points. CMS may want to consider other options, such as scoring statistical outliers differently compared to those clustered around the mean, or lowering the achievement threshold so that hospitals have greater potential to attain achievement points.

Individual Measure Recommendations

Measures Proposed to Be Removed in FY 2018

Starting in FY 2018, CMS proposes to remove two process of care measures from the VBP Program:

- IMM-2: Influenza Immunization,
- AMI-7a: Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival

CMS has identified IMM-2 as topped out, meaning that "performance on this measure is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made." Regarding AMI-7a, CMS has said that the measure "is not widely reported by hospitals," and that most AMI patients receive PCI instead of fibrinolytic therapy, making the measure inapplicable. To reduce measure burden, CMS proposes to remove these two measures from the VBP Program. The AAMC supports CMS' proposal to remove these measures.

Measures Proposed to Be Added in FY 2018

Starting FY 2018, CMS proposes to add one measure as part of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient survey:

- 3-Item Care Transition (CTM-3)

The CTM-3 measure, which adds three questions to the HCAHPS survey, is NQF endorsed, and recommended by the MAP. The AAMC supports the inclusion of this measure to the HCAHPS survey in the VBP Program.

The AAMC has concerns about how consistency points are calculated for the HCAHPS. Consistency scores may reward good performance but may also reward poor performance (*i.e.* rewarding institutions who are consistently bad). CMS may want to consider using a threshold (such as the 25th percentile) rather using a consistency score.

Measures Transferred between Domains in FY 2018

CMS proposes to transfer PC-01 - Elective Delivery from the Clinical Care - Process Domain to the Safety Domain in FY 2018. The AAMC agrees that this measure is appropriately classified as a safety measure and supports its inclusion in the Safety Domain.

Measures Proposed to Be Added in FY 2021

Starting in FY 2021, CMS proposes to add one additional measure to the VBP Program:

- Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD)

The AAMC supports the inclusion of the COPD mortality measure in the VBP program; however, the Association strongly urges CMS to include adequate risk-adjustment modifications to the measure that address both SDS and clinical factors. In addition, the current measure does not adequately address end-of-life or palliative care, which can inappropriately affect those hospitals with large palliative care programs.

AAMC Supports CMS' Proposal to Incorporate Updated CDC Data in the VBP Program Starting in FY 2019

As discussed in the HACRP portion of the AAMC's letter, the CDC expanded data collection for two NHSN infection measures, CLABSI and CAUTI, starting January 1, 2015. In addition to the ICU, CLABSI and CAUTI data is now being collected in pediatric and adult medical wards, surgical wards, and medical/surgical wards. CDC is also updating its standard population (previously referred to as the "national baseline") data, which is used to compute the standardized

infection ratios (SIRs) for all of the NHSN infection measures. The standard population data had previously varied by measure; now the CDC will use data collected in CY 2015 to compute the standard population for all NHSN measures.

To ensure that hospitals are being assessed on comparable baseline and performance periods, CMS proposes to use FY 2019 as the first payment year with the newly-revised measures. FY 2019 would include a baseline period of CY 2015 and a performance period of CY 2017. The AAMC supports CMS' proposal to use FY 2019 as the first year for the newly revised measures. As discussed above, the AAMC asks that CMS also use FY 2019 as the first payment year of the revised CDC NHSN measures in the HACRP program.

BUNDLED PAYMENTS FOR CARE IMPROVEMENT

AAMC is committed to improving quality and cost of care by breaking down the existing silos of care, aligning providers' incentives, and improving patient outcomes and satisfaction. As a facilitator convener under the Bundled Payments for Care Improvement (BPCI) initiative, the AAMC has a vested interest in the initiative and the voluntary expansion of bundled payment. The AAMC provides the following comments based on the experience of our 30 teaching hospital participants.

Potential Payment Model Expansion

The AAMC supports the voluntary expansion of the BPCI program and appreciates that CMS is beginning the process of seeking adequate stakeholder input. To the extent that CMS chooses to expand the program beyond the July 1, 2015 participants, the AAMC supports CMS' proceeding through the rulemaking process and certifying the model using the established process. The AAMC believes CMS should provide for the seamless transition of existing BPCI participants into the program, by allowing them to remain in the program and simply updating their applications until a national program is established. The AAMC also anticipates that there will be ongoing operational issues that need a routine process for resolution if and when the initiative converts to a permanent national program. Thus, the Association believes that CMS should commit to annual rulemaking as soon as the Agency determines that a model is sufficient to scale.

As the AAMC has previously noted, CMS and its contractors could benefit from a formal advisory group to focus on all aspects of program expansion design, pricing, and quality, as well as minimizing the burden on participants. The AAMC recommends that CMS establish a formal multi-stakeholder technical expert panel (TEP) as it considers making bundled payment a permanent national program.

Breadth and Scope of an Expansion

AAMC Does Not Support Mandatory Expansion of BPCI

CMS Does Not Have the Statutory Authority to Mandate Participation in BPCI

Section 1115A(c) of the Social Security Act, as added by section 3021 of the Affordable Care Act (ACA), permits the Secretary to use rulemaking to expand the duration and scope (potentially including implementation on a nationwide basis) of a model, such as the BPCI initiative, that is being tested under section 1115A (b) of the Act if the following findings are made, taking into account the evaluation of the model(s) required under section 1115A(b)(4):

1) the Secretary determines that the expansion is expected to either reduce Medicare spending without reducing the quality of care or improve the quality of patient care without increasing spending;
2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net Medicare program spending; and
3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits.

The proposed rule states that the decision of whether or not to expand will be made by the Secretary in coordination with CMS and the Office of the Chief Actuary based on whether the evaluation findings meet the criteria for expansion.

Among the issues identified for public input, CMS raises the following question: "would the model best be expanded with voluntary participation or be most effective if participation were required within the chosen models, episodes, and regions." While the AAMC supports BPCI and has several members that are BPCI participants, The Association opposes any expansion, including nationwide, under which participation would be compulsory. As we discuss below CMS, does not have statutory authority to require participation.

The Centers for Medicare and Medicaid Innovation (CMMI) provision in the Affordable Care Act (ACA) includes a testing phase – subsection (b), "TESTING OF MODELS (PHASE I)" – and an expansion phase – subsection (c), "EXPANSION OF MODELS (PHASE II)." The statute clearly states that the Secretary's authority to waive requirements of titles XI and XVIII of the Act applies only to the subsection (b) testing phase. Specifically, the statute states:

"(d) Implementation.—

(1) Waiver authority.—The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and1903(m)(2)(A)(iii) as may be necessary solely for

> *purposes of carrying out this section with respect to testing models described in* subsection (b)."

The provision establishing the innovation center originated in the House Energy and Commerce Committee was included in the House-passed bill, and was retained by the Senate with no change to the waiver language. The House Report on the Affordable Health Choices Act of 2009, H.R. 3200, states: "The Secretary would have the authority to waive Medicare statutory requirements and certain Medicaid rules governing provider payments and state plans, but only for purposes of testing of models under this section." (House Report 111-299 - America's Affordable Health Choices Act of 2009, Part 1, Committee on Energy and Commerce, October 14, 2009, p. 661 in reference to Sec. 1910, Establishment of Center for Medicare and Medicaid Payment Innovation (CMPI) within CMS).

The provisions of title XVIII of the Act stipulate which services are covered by Medicare, the entities that can provide them, and the scope and amount of payment, among many other detailed requirements. Medicare fee-for-service beneficiaries enjoy freedom of choice of providers and the statutory provisions govern payment for the providers delivering the services. Bundled payment programs, on the other hand, can require beneficiaries to receive services from providers participating in the bundled payment program. Bundled payment arrangements require waivers from various statutory provisions in order to limit coverage and payment of services to what is provided by entities participating in the bundled payment program and to the amount established for payment by the bundled payment arrangements. In a bundled payment program established through proper rulemaking, providers and suppliers could choose voluntarily to participate in the program and beneficiaries could make an informed choice to receive services from a bundled payment system entity or another entity. We note that a mandate on all hospitals to participate in a BPCI model also would require waiver of certain provisions of title XI of the Act, especially with respect to prohibitions on inducements.

The AAMC opposes a mandatory bundling program and firmly believes that the Medicare statute does not give CMS authority to compel providers, suppliers and beneficiaries to participate in a bundled payment program. Nothing in the language of the statute or the legislative history of the ACA supports the conclusion that Congress intended to delegate this type of policymaking authority to CMS. CMS may not rely on waiver authority under a demonstration program to mandate fundamental changes on beneficiaries and on all the relevant Medicare participating providers outside the demonstration.

The AAMC believes that Medicare's assurance of access to care and freedom of choice for all Medicare beneficiaries, regardless of their severity of illness, can best be supported by implementing an expanded bundled payment program on a voluntary basis.

CMS Should Pursue the Voluntary Expansion of BPCI

Academic medical centers facilitate the care of patients using multidisciplinary teams, collaborating with multiple local providers and remote sites of care. Of the four models currently being tested by CMS, the AAMC believes that Model 2 presents the greatest opportunity for care redesign and aligned provider goals across the care continuum. Under an expanded program, CMS should pursue a single model that mirrors Model 2's inclusion of both the index hospital admission and post-acute care (PAC). This model should include two overarching payment options: 1) a prospectively set and paid target amount; and 2) retrospective reconciliation.

CMS Should Not Expand BPCI Models 1, 3, 4

AAMC's observations regarding each of the four current BPCI models is provided below:

Model 1 may have been helpful in the early days of reform to assist hospital and physician relationships in areas that were strained, but the uptake of this model is low. It also has a limited duration of 30 days post discharge. Bundling of any given segment of care alone will not achieve the transformations that patients, providers, and the government are seeking. Model 1 should not be expanded nationally.

Model 4 had many theoretical advantages including prospective payment. Yet it also has had limited uptake. Given the experience of two prominent AMCs in Model 4, we recommend the elimination of Model 4 in its current form. In most states and regions, we believe neither providers nor CMS are ready for national implementation of a prospectively paid bundle. However, in the future, when CMS can administer such a model without excessive administrative hurdles and payment issues, a prospectively paid bundle should be an option for groups of providers who can manage a single payment.

The Model 3 post-acute care-only bundle is not optimal for patients. The right care results when all providers caring for the patient are aligned in their commitment to cost and quality. The incorporation of acute inpatient, outpatient and community care, and post-acute care into a single payment bundle provides the best opportunity for health system innovation. In an expanded model, providers would have strong incentives to work together to provide quality, cost-effective services across the acute and post-acute spectrum of care and to actively manage transitions between sites of service.

While a separate bundle would offer post-acute providers new incentives to improve coordination within the bundle, this model leaves out other key providers. For example, a patient plan of care initiated for the post-acute bundle that is separate from the discharging hospital's planning and readmission reduction efforts could result in duplication of effort among providers, confusion for beneficiaries and their families, and is unlikely to achieve the most efficient use of Medicare's resources.

CMS Should Base Any Expansions on BPCI Model 2

The AAMC has seen considerable care redesign occur at the hospital, physician, PAC, and community levels during 90-day episodes under Model 2. Our teaching hospitals are creating new partnerships, electronic and personal communication methods, strategies to manage transitions of care, and ways of reducing total costs for Medicare. Hospitals have adopted the targeted use of care managers to help track and manage a patient's post-discharge care in an effort to improve the patient experience and reduce readmissions. Providers developed care process maps to identify opportunities for enhanced efficiencies and improved care regimens. For example, one hospital examined its post-operative protocol for total hip replacement patients and found that the increased adoption of certain drugs improved patient mobility and pain management resulting in a decreased length of stay. In other instances, hospitals have developed strong relationships with home health providers. These providers meet on a regular basis to review readmitted patients and identify root causes and opportunities for future improvement. Model 2's design creates incentives that foster such collaborations and improvements. Under an expanded program, CMS should pursue a single model that mirrors Model 2's inclusion of both the index hospital admission and post-acute care.

The AAMC believes that Model 2's inclusion of the index hospital admission and up to 90 days post-discharge renders it superior to other models, such as Model 3, that only include the post-acute period. In addition to creating stronger incentives for collaboration among providers across the care continuum, Model 2 complements and builds upon other Medicare programs, such as the inpatient Value-based Purchasing (VBP) program, the physician Value-based Payment Modifier (VM), and the Hospital Readmission Reduction Program. These programs score hospitals' ability to efficiently manage care across 30 days post-discharge and reduce readmissions. A combined payment bundle encourages more fruitful results from these requirements by aligning post-discharge care coordination activities of hospitals with those of post-acute providers, and providing the tools needed to ensure that care is delivered efficiently throughout an episode of care.

It is time to integrate the multiple innovative models of care piloted over the past several years. Rather than integration of care, the complexity of models and their rules, the multiple levels of incentives and penalties, and the array of durations of care episodes now increase the risk of fragmentation. In a combined model, communities can make decisions regarding which entity is best positioned to assume the ultimate risk, eliminating the confusing precedence rules that now exist. If CMS expands the BPCI program nationally, a model that mandates or greatly incentivizes the hospital-PAC continuum will result in the most fundamental improvement in underlying care delivery.

CMS Should Expand the Voluntary BPCI Program Nationally

We do not believe that an expansion of the program should be confined to certain regions. The AAMC sees no reason to limit the availability of the model nationally.

CMS Should Allow Participants to Select the Clinical Episodes for Which They Take Risk

Under a voluntary national expansion of BPCI, we recommend that CMS continue to allow participants to select one or more of the existing 48 conditions for which to accept risk. Early observations and financial results suggest that a subset of the 48 episodes present greater and more easily realized opportunity and that others present serious unanticipated risk. Therefore CMS should not limit provider autonomy by precluding certain episodes from bundling and mandating others. Providers should have the opportunity both to capitalize on their institutional strengths and pursue targeted care improvement initiatives for more challenging and less commonly selected conditions.

Should CMS decide to mandate that providers take risk for certain conditions in a voluntary program, it is critical that providers only be expected to do so if their historical case volume meets a minimum threshold. Furthermore, CMS should not mandate participation in ill-defined episodes with low uptake rates under BPCI (such as urinary tract infection (UTI)). These episodes are not yet sufficiently tested for their viability clinically or statistically and are usually broad and unmanageable with the current episode definitions. CMS should develop a threshold volume of episode cases to determine which conditions are ready for expansion.

The AAMC supports the exploration of ambulatory bundles, both for high-volume outpatient procedures that have multiple claims, such as colonoscopy, hernia repair, and knee arthroscopy, as well as for populations with complex multi-morbid conditions where a single primary condition is not an appropriate way to care for their medical needs.

Episode Definitions

CMS Should Maintain the Current Methodology of Defining Episodes by DRG

The AAMC supports the current methodology of identifying episodes using DRGs. DRGs are well-known and well-defined for hospitals, which for many years have used software to determine an admission's DRG from documented and coded clinical data. DRG definitions are sufficiently broad to include relatively large numbers of patients in the episodes, which is critical for financial stability. However, the AAMC believes it may be optimal for some episodes to encompass a period prior to the hospital admission, thus extending the bundle duration and increasing care management opportunities.

While the AAMC supports using DRGs to define episodes, in some instances, patients with different diagnoses that fall under the same DRG have largely divergent care pathways. This fact is especially pronounced in the case of fracture patients vs. non-fracture patients in the major joint replacement of the lower extremity episode (DRGs 469 and 470). This issue grows troublesome when the prevalence of patients with a specific diagnosis changes over time, as the baseline target no longer represents an accurate benchmark. One Model 2 BPCI participant's fracture rate in the

major joint episode increased by approximately 11 percentage points between the baseline period and 2014. This hospital now faces an increased challenge to generate savings despite excellent care, as fracture patients have much higher post-acute and readmissions costs when compared to elective joint replacement patients. Consequently, some BPCI stakeholders have called for the creation of a new major joint replacement (MJR) DRG that would only contain fractures.

Beyond the need for a specific episode definition and exclusions list modification, the fracture case described above illustrates the larger need for an expanded program to institute a formal regular episode definition review and refinement process. This strategy could resemble the commercial insurance clinical policy bulletin process: a public, transparent, evidence-based, regularly reviewed process in which expert clinicians detail the services and procedures considered to be medically necessary, related to the condition, or unproven and excluded from the bundle.

CMS Should Incentivize a 90-day Bundle through a Lower Discount Amount

When considering episode durations, the AAMC believes that a 90-day period enhances the commitment to caring for patients over time. This duration is sufficiently long to allow for the capture of many complications and engage multiple providers in inpatient, outpatient, and post-acute care settings. This duration also moves providers closer to achieving long-term population health management, one of the main aims of risk-based models such as the Medicare accountable care organization (ACO) programs and full capitation models. However, some providers prefer to initially to approach their risk management efforts over a more concentrated timeframe. CMS should allow providers to select their episode duration and retain a lower discount for those willing to take the longer episodes.

CMS Should Maintain the Current BPCI Exclusions Structure and Study the Impact of the Transition to ICD-10

Overall, CMS' system of excluding inpatient readmissions at the DRG level and outpatient services with ICD-9 diagnosis codes is clinically reasonable. However, building an accurate benchmark that predominantly holds providers accountable for manageable patient risks will require refinements. While using ICD-9 codes as the core criterion is fitting, it may be too blunt of an instrument on its own. For instance, a patient may receive a cancer drug during an inpatient admission categorized under a non-cancer DRG that is included under BPCI. Not all appropriate exclusions can be determined from ICD-9 codes. Adding HCPCS and/or CPT code-based exclusions could mitigate this issue.

The implementation of ICD-10 creates many unknowns. The AAMC encourages CMS to closely monitor the impact of this shift on BPCI and encourage feedback regarding necessary program changes as a result of the adoption of ICD-10.

Setting Bundled Payment Amounts

An optimal target price methodology should produce accurate, predictable, and fair target prices. Granted, these principles are often at odds, so the best methodology should seek to achieve the optimal balance amongst these features. The methodology must also provide for the long-term sustainability of the program, such that participating providers may hope to continue to pursue efficiencies and realize savings across multiple performance periods. The AAMC outlines our preferences in the following section. It is important to note that the AAMC also supports the continued exclusion of IME and DSH payments from the alternative payment models.

The AAMC does not support the mandated participation in a prospective model in which targets are prospectively set and paid. Rather, the AAMC advocates that CMS offer participants the option between two overarching bundle payment methods: 1) a prospectively paid bundle; and 2) a retrospectively paid bundle.

CMS Should Implement a Five-Year Performance Period

The AAMC recommends that baseline prices remain fixed for the five-year expansion, subject only to trending, to allow the marketplace to be rewarded for efficient, and high-quality health care delivery.

CMS Should Use Historical Data to Calculate the Baseline Target Price

The AAMC supports the current BPCI Model 2 payment methodology of calculating a provider's target price using the provider's own historical Medicare claims data. The AAMC also supports the use of a national trend factor as it based on a sufficiently large case volume to produce accurate factors. However, this trend factor methodology has limitations. Academic medical centers are often early adopters of changes in care practice or new technology, a fact which, can cause AMCs' payment growth to outpace the national trend. This, in turn, can result in AMCs facing a greater challenge in beating their target price and producing savings. Other stakeholders have similar concerns regarding the impact of the use of new drugs in the Oncology Care Model. The AAMC believes it is important for CMS to ensure the trend factor and payment methodologies do not stifle innovation by inadvertently penalizing providers that adopt changes in care practice and technology that improve care or reduce total cost. The Association is currently working with CMMI to identify ways to resolve this issue and encourages CMS to coordinate with CMMI.

Under the Retrospective Payment Option, CMS Should Allow Participants to Choose Between Prospectively or Retrospectively Set Targets

The AAMC does not support a mandatory prospective payment of a bundled amount in an expanded program as configured in BPCI Model 4. As seen by the poor uptake of Model 4, few providers are ready to assume the role of a third party administrator capable of distributing payments to all providers involved in the care of a patient in a prospectively paid bundle. However,

the AAMC does believe CMS should provide an on-ramp to prospective payment by giving participants the option to operate under a prospectively set target.

The prospectively set target methodology entails applying the current trending methodology to the years directly preceding the performance year, and then employing the Model 4 trending methodology (which incorporates regulatory rate changes for the coming year) to the current performance year. This method preserves the inclusion of productivity adjustments by using the prior year's utilization. For example, for episodes beginning in Q1 2015, CMS should adjust all targets up to Q1 2014 using the current methodology of comparing national average episode costs in 2012 to the costs in Q1 2014, followed by the use of the prospective method currently employed in Model 4 to calculate update factors to adjust from Q1 2014 to Q1 2015.

The current BPCI Model 2 methodology involves a retrospectively set target price. A quarterly trend factor is applied to the benchmark target to account for national regulatory payment updates and utilization changes that occur during the performance period. While this method renders the performance period target price highly accurate, it does not offer providers the level of predictability that a prospectively set target allows. Granted, the reverse is true of prospectively set targets, in that they afford predictability to participants, but they are not as accurate as retrospectively set targets. Furthermore, under a prospectively set target, there is a higher likelihood that subsequent true ups of a performance quarter would tend to worsen over time, as claims continue to come in without the opportunity for the target price to change. Upon reviewing this trade-off, members of AAMC's BPCI convened group were divided in their preferences between retrospectively or prospectively set targets. Generally, the AAMC advocates for the retrospectively set target due to its enhanced accuracy. CMMI should recognize that some providers will favor the prospectively set target due to concerns about cash flow and financial predictability.

Under an expanded model, the AAMC encourages CMS to offer participants the choice between operating under a prospectively-set target or retrospectively-set targets, each of which would be retrospectively reconciled.

CMS Should Adopt a Rebasing that Incentivizes Participation by the Efficient Provider

The AAMC firmly believes that in developing a rebasing methodology, CMS must take great care not to lower target prices progressively at an untenable rate. Rebasing methodologies pose the risk of creating a race to the bottom, that is, lowering targets to such an extent that providers will have no further efficiencies to realize and will struggle to break even. CMS could avoid this race to the bottom through the adoption of one of the following rebasing methodologies:

1) Incorporate the positive net payment reconciliation amount (NPRA) realized during the initial performance period into the target of the subsequent performance period;

2) Set the target price at the higher of the provider-specific or regional average episode payment amount; or
3) Stratify the CMS discount based on the quartile of the provider's average episode cost and quality score relative to other providers. Providers in the highest–cost quartile would be required to give a higher discount percentage, while providers in the lowest-cost quartile would have a discount one percentage point lower than the current percentage.

All CMS decisions about rebasing and trends should be based on transparent impact analyses. CMS should also release specific proposals through additional rulemaking once the data are available. Until that occurs, stakeholders do not have sufficient information on which to base comments. In addition, CMS should create tracks similar to the Medicare Shared Savings Program (MSSP) to ensure that high-cost providers are encouraged to enter and remain in the program. While allowing choices may reduce the overall savings of the program, it will nonetheless reduce overall Medicare spending when compared to a scenario where high-cost providers return to traditional fee-for-service.

Mitigating Risk of High Cost Cases

CMS Should Not Implement Additional Risk Adjustment for BPCI Model 2

Overall, AAMC strongly believes robust risk adjustment is needed to ensure adequate comparisons of hospital performance. However, as currently designed, the BPCI program does not need additional risk adjustment. Under BPCI, hospitals' targets are based on their own historical performance; hospitals are not compared to one another. Risk adjustment is embedded within historical benchmarks. While not perfect, AAMC does not think additional risk adjustment adds enough value to justify the complexity of the implementation within the BPCI program. Should the BPCI baseline target be created using another methodology, then CMS would need to revisit the need for additional risk adjustment.

CMS Should Allow Providers the Option of Selecting their Preferred Risk Track

The AAMC favors the current risk track structure and believes that the current limits are appropriate for most circumstances. In many cases, risk track A provides the greatest opportunity to realize savings while still protecting hospitals from extremely high-cost cases. The lower risk tracks provide additional levels of protection from lower-volume DRGs with the potential for multiple high-cost outliers (like the PCI DRGs). The AAMC supports affording providers the opportunity to select from risk tracks A, B, and C.

Quality Measurement and Payment for Value

CMS Should Collect a Parsimonious Set of Primarily Outcomes-based Measures

CMS should focus on a parsimonious set of primarily outcomes-based measures. In addition, the AAMC supports measures that can be tracked within an EHR, so that this data is available to providers at the point of care. The AAMC suggests that the vast majority of the measures used for performance evaluation be harmonized with existing Medicare quality reporting programs. If the measures are already reported under another program, CMS should leverage that program for BPCI and not require duplicative reporting. However, the AAMC recognizes that there are gaps in measurement, particularly for specialists, post-acute care settings, and patient-reported outcomes, and that some of the existing measures are not constructed for episodes. Thus, CMS should work with NQF and other national entities to establish a roadmap for enhancing the measurement program.

CMS Should Not Tie Savings to Performance at This Time

The AAMC appreciates the importance of balancing quality performance and enhanced efficiency in all new alternative payment models, including BPCI. Reduced costs cannot be realized at the expense of quality outcomes. Unfortunately, a group of measures that correlate to quality of care in an aligned manner for 90-day episodes does not exist. Furthermore, episodes under bundled programs often have low case volumes, a fact that prevents meaningful measurement. As a result, the AAMC does not currently support predicating the receipt of savings on the achievement of certain quality thresholds.

A model for linking quality with savings should be developed and tested among a small group of willing participants before it is scaled. In a permanent or expanded program, CMS could choose a small set of measures to ensure that a minimal level of quality is achieved before the providers and suppliers are able to share in savings with CMS. In the future, CMS could allow quality results to affect payment. For example, CMS could lessen the percent required discount based on meeting benchmarks for achievement or improvement.

Lastly, the AAMC cannot overemphasize the importance of adopting measures through the rulemaking process to allow providers an opportunity for input regarding proposed measures. Measures that are accepted as meaningful and important, through a process that allows for provider buy-in have the most potential to result in significant quality and efficiency improvements.

Participants Should be Allowed to Select Their Gainsharing Metrics

As is the case in the current program, bundlers should be able to choose the quality measures they wish to include as part of their gainsharing programs. Identifying reliable measures is particularly

challenging because of the need to ensure a statistically valid number of cases for each measure at the individual physician or physician practice level over 90-day episodes. CMS should not underestimate the challenges involved in identifying clinically meaningful quality measures, especially at the physician specialty, subspecialty, and individual physician levels. Providers should be given latitude to develop measures that match their goals for patient care. While CMS may wish to know which measures the bundlers are using, bundlers should not have to submit the measure results to CMS. Thus, the metrics used as part of the gainsharing programs should be left to the best judgment of the participants of that contract and results should not be required to be submitted to CMS at this time.

Data Needs

Comprehensive Claims Data Should Continue to be Provided on a Monthly Basis

If the BPCI program is expanded or made permanent, participants will continue to need the monthly claims data currently provided. Such data is essential for success in any bundled payment initiative. All organizations taking financial risk will need access to claims for the services for which they are liable. The AAMC commends CMS for the form in which the Agency has provided data during the demonstration. The format and organization of the BPCI data facilitated its use. In contrast to the MSSP ACO data, the BPCI data was fully adjudicated, episodes were already constructed, and only relatively minor manipulations were necessary to place the data into a usable form. The AAMC strongly emphasizes the need to provide this type of monthly claims data on an ongoing basis in any bundled payment initiative.

However, CMS currently does not provide data related to substance use diagnoses and services in the monthly files. This information is key for bundlers to understand the full risk associated with patients and identify appropriate care management. While the Association understands the sensitivity of such services and CMS' exclusion of them in the files, we believe there are options that would provide bundlers with more information, while not risking beneficiary privacy. Therefore, the AAMC urges CMS to provide the de-identified cost and claim data for these services. If this is not possible, CMS should provide the aggregate payment amount of these services in the monthly claims and claim line feed (CCLF) files.

CMS currently cuts off post-episode data 13 months after the service was provided, although several months of reconciliation true-up remain after this cut off, leaving providers unable to predict financial outcomes. CMS should provide the claims data for as long as the episodes are under review or within their CMS reconciliation period.

The claims data were instrumental in AAMC participants' decisions about whether to enter the program and for which conditions. In a voluntary expansion, the Association urges CMS to provide claims data in advance of a providers deadline for committing fully to the program. CMS

should maintain the concept of Phase I and Phase II in an expanded voluntary program where data is made available to participants prior to assuming risk.

Finally, the AAMC urges CMS to make the full national datasets available to those participants and researchers who wish to replicate CMS calculations. Such users would need to submit applications with detailed study protocols and enter into a data use agreement with CMS. During the demonstration, several errors were made in the calculations. Participants such as the AAMC had to identify the problems through extensive internal reviews and discussions with other conveners and participants. The AAMC urges CMS to make the methodologies for an expanded or permanent BPCI program fully transparent and to make national data available to those who apply.

CMS Should Share Quality Metric Performance Data with Participants

Under the MSSP, participants receive quarterly reports including the results of certain quality metrics and other key utilization indicators. In particular, these reports are helpful for risk adjusted quality metrics such as readmissions. The AAMC urges CMS staff to develop similar reporting structures and learn from the experiences of that program. CMS should make quality metric performance along with other key indicators available to participants.

Program Roles and Relationships

CMS Should Limit the Contractual Relief Offered by Third Parties

One concern the AAMC shares with other conveners is the role of awardee conveners that contract with physician participants in Models 2 and 3, and in so doing assume significant amounts of downside risk and savings. In our experience, Episode Initiators who assume the majority of the risk of the episodes in which they participate are maximally invested in care transformation and the program overall. Providers engaged with risk-bearing awardee conveners who are not engaged in care delivery have little incentive to make demonstrable change in their care, because they do not bear risk. This is counter to the CMMI's stated intent of bundled payment: to bring providers together to fundamentally change the provision of care to increase the value and patient experience of care. To reduce the prevalence of what is essentially a reinsurance model, the AAMC recommends that reinsurance or other contractual relief offered by third parties not exceed 10 percent of the episode cost, and that all Episode Initiators take risk for 90 percent of the episode cost.

CMS Should Uphold the Application of Waivers in the Event that a Potential Episode is Ultimately Dropped

The AAMC believes there is a fatal flaw in the current system regarding the application of payment waivers. Given the BPCI design, a beneficiary may be treated as part of a bundle that is

subsequently rescinded. For example, if a patient has one hip replaced and a few weeks later has the other hip replaced, the first hip bundle is nullified and the second hip bundle is activated. This means that a provider who uses the three-day stay waiver as part of the first hip replacement loses that waiver protection, and the beneficiary is responsible for the copay associated with the skilled nursing facility (SNF) stay. In this case, CMS has been unwilling to allow the bundlers to cover the expense for the beneficiary, or allow this clinically-appropriate SNF stay to be waived. As a result, AAMC members rarely use the waivers.

Another example is when the CMS beneficiary eligibility files lag and it is later discovered that the beneficiary is no longer eligible for BPCI (*e.g.*, the beneficiary has moved to Medicare Advantage or become eligible under the ESRD benefit). The AAMC believes that if the bundler uses a waiver in good faith (enters the patient presumptively into BPCI because the patient fits all criteria), the episode should be paid as part of the BPCI initiative, and the waiver should stand even if for programmatic or CMS data lag reasons a bundle is later nullified.

CMS Should Expand the List of Payment Waivers Provided Under BPCI

The AAMC believes that the payment waivers CMS proposed to apply within the MSSP for those providers who take risk should apply to any expansion of the BPCI program. Similar to MSSP participants, these organizations have both financial incentives and quality measurement thresholds that hold them accountable for the overall cost and outcomes associated with the episode. Thus, there is less risk that the payment waivers will result in increased spending or poorer outcomes. Specifically, the AAMC urges CMS to finalize the following waivers for a bundled payment expansion:

- Hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services;
- The SNF three-day stay rule, which requires Medicare beneficiaries to have a prior inpatient stay of no fewer than three consecutive days to be eligible for Medicare coverage of inpatient SNF care;
- Medicare requirements for payment of telehealth services, such as limitations on the geographic area and provider setting in which these services may be received; and
- The homebound requirement for home health, which requires that a Medicare beneficiary be confined to the home to receive coverage for home health services.

In the spirit of increasing flexibility for care options, the AAMC supports the inclusion of the waiver of the Inpatient Rehabilitation Facility (IRF) PPS "60 Percent Rule." The rule requires that at least 60 percent of all of an IRF's patients (Medicare and non-Medicare) have conditions or diagnoses that fall within a list of 13 specific diagnostic categories, either as a primary diagnosis or as a qualifying comorbidity.[24] We believe the 60 percent Rule should be waived given the

[24] *See* Office of the Federal Register. *Medicare, Medicaid, and SCHIP Extension Act*. Washington, DC: Government Printing Office; 2007. 42 C.F.R. §412.23(b).

expected decrease in the volume of patients referred to an IRF. The rule itself is designed to control for inappropriate cases in FFS Medicare being treated at IRFs: BPCI participants have no incentive to over-utilize or inappropriately direct patients to IRFs, but may find good clinical rationale for short-stays at IRFs for some patients, such as allowing beneficiaries to return to their communities more quickly.

Payment and coverage rules restricting the efficient transfer and admission of the beneficiary to a skilled nursing facility on a short-term basis should be waived. BPCI participants should have maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short and long term recovery goals. In addition, payments are reduced for LTCHs that exceed established percentage thresholds for patients admitted from certain referring hospitals during a cost reporting period.[25] Payment adjustments specific to the traditional FFS system such as the "25 Percent Rule" for LTCHs have little relevance to the BPCI or its participants, which do not require the safeguards or control mechanisms the payment rule otherwise provides in traditional FFS. BPCI participants should be able to freely access the LTCH setting for their beneficiaries, for short, mid or long-range stays, regardless of traditional FFS payment policies that may prevent it.

CMS Should Expand the List of Legal Waivers Provided Under BPCI

Patient Incentives

The AAMC also believes that the Beneficiary Inducements Civil Monetary Penalty[26] and the Federal Anti-Kickback Statute should be waived. BPCI participants should be permitted to provide beneficiaries with free or less than fair market value items and services to beneficiaries as part of care received under the BPCI and as part of a treatment goal such as prevention or adherence to a treatment regimen. For example, under such a waiver, a beneficiary being treated under the BPCI could receive an electronic device to access a BPCI organization's electronic platform to conduct activities including scheduling follow-up appointments, uploading their biometric data, receiving medication updates, and submitting questions or concerns. A waiver addressing patient incentives has also been promulgated as part of the Medicare Shared Savings Program.[27] The AAMC supports consideration within MSSP and the Next Generation ACO Model, and the President's FY 2016 proposed budget to waive the primary care copayments. This would encourage beneficiaries within a bundle to seek the appropriate follow-up care that would not only help reduce readmissions but also allow patients to be discharged to a lower level of post-discharge care.

[25] *See* 42 C.F.R. § 412.534; 42 C.F.R. § 412.536; MMSEA § 114(c); 42 C.F.R. § 412.23(e)(6)-(7).
[26] *See* Social Security Act § 1128A(a)(5).
[27] Medicare Program; Final Waivers in Connection with the Shared Savings Program; Interim Final Rule with Comment Period, 76 Fed. Reg. 67992 (Nov. 2, 2011).

Gainsharing

The AAMC supports a waiver to add non-physician practitioners to the list of suppliers with whom a bundler can gainshare. Physician Assistants, Nurse Practitioners and others are key team members in the care transformation that bundlers are undertaking.

Pre-Admission Home Evaluation Services

Home Health Aides (HHAs) are prohibited from performing free pre-operative home safety assessments for patients scheduled to undergo surgery.[28] A waiver of this policy would result in more informed and patient-centered post-acute care plans and a decreased likelihood of falls and readmissions. HHAs are especially adept at working with clinicians to assess the patient's care needs, including his or her ambulatory limits or other functional impairments, and should not be prevented, under the BPCI, from working collaboratively to generate a care plan at the pre-admission stage that helps transition the beneficiary to the lower cost community-based setting.

Transition Planning

Additionally, the AAMC believes the Federal Anti-Kickback Statute should be waived to allow BPCI participants, including, without limitation, home health providers, to assist with discharge planning for beneficiaries and coordinate care transitions. For instance, better transition planning, in particular the assessment of readiness for in-home care services or other lower cost settings, is critical to the success of this population, because patients prefer to recover in their communities. Moreover, BPCI participants, along with discharge planners and patients' families, are best positioned to help identify the most clinically appropriate and cost-effective post-hospital setting for the patient. Current restrictions that prevent active coordination in transition planning obstruct the BPCI's goals of ensuring that patients are discharged to the setting that best suits their needs.

Additional Comments

CMS Should Test Patient Assessment Instruments

CMS considered requiring the BPCI Continuity Assessment Record and Evaluation (B-CARE) tool at hospital discharge and 30 days later as part of the demonstration but indefinitely suspended those plans. Most health systems have tools and procedures to gather, report, collate, and manage patient risk, functional status, and quality measures within an EHR.

Any standard national assessment tool must be tested, allow review of published results, be comprised of a small number of the most predictive measures, and be pulled from EHRs with data

[28] *See* U.S. Dept. Health and Human Services-Office of Inspector General ("HHS-OIG") Advisory Opinion No. 06-01, March 27, 2006; concluding that performing these assessments potentially generates prohibited remuneration under the Anti-Kickback Statute.

available to build on the current clinical care processes. This will ensure perceived utility by providers, reduced beneficiary inconvenience, and maximal accuracy of the information for quality improvement and program evaluation.

THE MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

CMS Should Continue Gradual Implementation of the Documentation and Coding Adjustments Required by the American Taxpayers Relief Act of 2012 (ATRA)

The purpose of the transition from CMS diagnosis-related groups (CMS-DRGs) to Medicare-severity DRGs (MS-DRGs) was to better account for severity of illness in Medicare hospital payment rates. When this process began, the MS-DRG relative weights for FY 2008 were calibrated with the intention that this transition would be budget neutral. The goal was for Medicare payments to increase only if there was an actual increase in patient severity ("real" case-mix change). CMS believes the Agency should recoup any higher payments that result from more cases being assigned higher weights without evidence of a change in a hospital's real case mix. The AAMC continues to strongly oppose the documentation and coding adjustments the Agency has made, because the Association believes that higher-weighted DRGs can in fact result from increases in patient severity. The AAMC urges CMS to examine medical records data to distinguish documentation and coding changes from real case mix change and reduce the documentation and coding offset accordingly. Alternatively, the Agency should use a methodology that reflects historical trends in case mix index changes.

Congress passed the American Taxpayers Relief Act of 2012 (ATRA) to avert the "fiscal cliff." Sec. 631 of ATRA requires the Secretary of the Department of Health and Human Services (HHS) to make a recoupment adjustment or adjustments totaling $11 billion, to recover overstated payments from FY 2010 through FY 2012. The adjustment is required to be completed by FY 2017. The ATRA requires a one-time recovery of prior overpayments, such that once the necessary amount of overpayment is recovered, any adjustment made to reduce rates in one year eventually will be offset by a positive adjustment.

CMS proposes a third year of a -0.8 percent recoupment adjustment to continue recovering the $11 billion required by the ATRA. CMS estimates that the first and second years' adjustments recovered almost $6 billion in FYs 2014 and 2015, and that this year's adjustment would recover approximately $3 billion in FY 2016.

In the FY 2013 final rule, CMS reduced the FY 2013 standardized amounts by 1.9 percentage points. This adjustment was intended to complete the adjustments determined to be necessary to account for coding changes occurring in FY 2008 and FY 2009. In previous IPPS proposed rule comment letters, the AAMC found fault with the methodology used to determine prospective documentation and coding adjustments related to the FY 2008/FY 2009 case mix changes. In the

AAMC's comment letter on the FY 2011 inpatient proposed rule, the Association discussed analysis that we, the American Hospital Association (AHA), and Federation of American Hospitals (FAH) conducted showing that the reduction due to documentation and coding should be much smaller than CMS' methodology indicated, because the documentation and coding effect is substantially lower than CMS' results. (*See* AAMC letter to Ms. Marilyn Tavenner, June 18, 2010.) The following year, we performed additional analyses to respond to issues CMS raised in the FY 2012 IPPS final rule, and our results continued to indicate that a smaller documentation and coding adjustment was warranted. (*See* AAMC Letter to Dr. Donald Berwick, June 20, 2011.) Accordingly, the Association disagrees with Congress' rationale for requiring a recoupment adjustment in the ATRA, based on the reasoning that delaying prospective adjustments from the FY 2008/FY 2009 transition through FY 2013 resulted in IPPS payments in FY 2010, 2011, and 2012 that were overstated.

At the same time, the AAMC understands that CMS has been directed by Congress to make an $11 billion recoupment adjustment over a four year period. Recognizing this, the AAMC appreciates CMS' proposal to phase in this adjustment and strongly encourages CMS to continue to implement this adjustment gradually through FY 2017.

OUTLIER PAYMENTS

CMS Should Explain the Data Used to Calculate the Charge Inflation Factor Used for Outlier Payments

The AAMC encourages CMS to be transparent in the Agency's calculations of the charge inflation factor used to calculate the outlier payment threshold. Under the Medicare IPPS, a hospital will receive an outlier payment if the costs of a particular Medicare case exceed the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments and an outlier threshold. The sum of all these components is also referred to as the fixed-loss cost threshold (FLT). When determining if a case qualifies for outlier payments because the costs of the case exceed the FLT, a hospital's total covered charges are converted to estimated costs using the hospital's cost-to-charge ratio (CCR). For cases that qualify, outlier payments are 80 percent of the case's costs above the FLT.

CMS proposes to continue to set the target for total outlier payments at 5.1 percent of total operating DRG payments (excluding adjustments for value-based purchasing and the readmissions reduction program). Therefore, CMS will again finance the outlier payment pool by reducing the inpatient standardized amount by 5.1 percent and estimating a cost threshold that should result in outlier payments that equal 5.1 percent. Additionally, CMS proposes to continue the policy adopted in the FY 2014 final rule to include the UC payments in determining the outlier threshold and in calculating outlier payments.

The proposed rule would set the outlier threshold at $24,485. CMS attributes the lower FY 2015 threshold to the charge inflation factor's being lower for FY 2016 than for FY 2015. The AAMC appreciates that CMS has begun to use more updated data in calculating the proposed outlier threshold. However, the Association remains concerned that CMS has not provided clear information or data to allow the underlying numbers used in the inflation factor calculation to be able to be replicated or tested for accuracy. This inability to replicate CMS' calculations limits stakeholders' ability to make meaningful comments.

Additionally, while CMS projects that the proposed outlier threshold of $24,485 for FY 2016 will result in outlier payments equal to 5.1 percent of operating DRG payments, the AAMC is concerned about the ongoing inaccuracy in CMS' estimation of outlier payments. CMS' current estimate is that actual outlier payments for FY 2015 were 4.88 percent of actual total MS-DRG payments. Because CMS reduces the standardized amount by 5.1 percent and does not make retroactive adjustments to outlier payments when outlier payments total less than 5.1 percent of the total DRG payments, providers repeatedly have been shortchanged by the Agency's incorrect estimations.

ELIMINATING THE SIMPLIFIED COST ALLOCATION METHODOLOGY

CMS Should Not Finalize the Proposal to Eliminate the Simplified Cost Allocation Methodology

The AAMC believes that CMS substantially underestimated both the number of hospitals using the simplified cost reporting methodology and the burden that eliminating it would create for those hospitals that currently use this methodology. Accordingly, the AAMC urges CMS not to finalize the proposal to eliminate the simplified cost allocation methodology option for cost reporting periods beginning on or after Oct. 1, 2015.

CMS made the simplified methodology available as an option, because stakeholders had expressed concerns that cost-finding methodologies for the allocation of direct and indirect costs were costly. In the FY 2016 IPPS proposed rule, CMS proposes to eliminate the simplified methodology because, according to the Agency, only a small number of hospitals (23) and CAHs (9) use it. Additionally, there is a concern that when the costs of hospitals that use the simplified cost allocation methodology are included in cost determinations, less precise CCRs are generated, resulting in lower payments for hospitals. Furthermore, CMS states that advances in technology have reduced the cost of recordkeeping and should make it easier and more affordable to change to a more precise allocation methodology.

Based on feedback from member institutions, the AAMC believes that CMS' count of the institutions using the simplified methodology is well below the actual number applying this

methodology. The AAMC also opposes elimination of the simplified methodology, because the institutions that use it maintain that it is less time consuming and costly. The burden associated with elimination of the methodology far outweighs any benefit, particularly because this would require manual tracking of certain complicated statistics. In addition there is a lack of consistency and comparability year to year in how these statistics are tracked, and it would be difficult to audit them for accuracy.

USE OF NON-STANDARD COST CENTER CODES

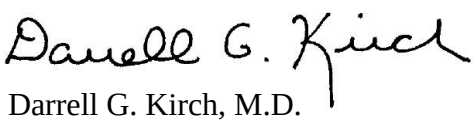
CMS Should Maintain Some Flexibility to Allow Hospitals to Add Non-Standard Cost Center Codes

While there is a need to provide further guidance regarding the use of non-standard cost center codes, hospitals need some flexibility to insert non-standard cost centers as needed due to changes in the delivery of care. CMS should consider additional proposals that would make reporting of non-standard codes more consistent and less confusing, but would still allow some flexibility to add non-standard cost center codes. For example, CMS could publish a list of frequently used non-standard cost centers and, before finalizing a proposal, seek to allow only certain non-standard codes to be used. Additionally, CMS should implement a process for obtaining provider input regarding the implementation of future cost centers.

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 medical center community. If you have questions regarding hospital payment issues please feel free to contact Ivy Baer at 202-828-0499 or at ibaer@aamc.org. For questions regarding the quality provisions please contact Mary Wheatley at 202-862-6297 or at mwheatley@aamc.org.

Sincerely,



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