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Via Electronic Submission (www.regulations.gov)

June 25, 2013

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS–1599–P
7500 Security Blvd.
Baltimore, MD 21244-8013

Dear Ms. Tavenner:

Re: FY 2014 Inpatient Prospective Payment System Proposed Rule, File Code CMS–1599–P.

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 "*Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation*," 78 *Fed. Reg.* 27486 (May 10, 2013). The AAMC 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 128,000 faculty members, 82,000 medical students, and 110,000 resident physicians who collectively deliver over one-fifth of all clinical care in the nation.

The proposed rule includes sections that would implement Section 3133 of the Patient Protection and Affordable Care Act (ACA), which requires changes in the disproportionate share hospital (DSH) payment formula that apply to all hospitals that currently qualify for DSH payments. The AAMC appreciates the effort CMS has put into designing an entirely new payment for uncompensated care and the Agency's willingness to seek input on the design from the provider community. While the AAMC supports several of CMS' proposals, the Association has concerns with respect to certain aspects of the proposed payment methodology and urges CMS to modify the proposals to avoid unintended consequences.

In the proposed rule, CMS also lays out the framework for determining which hospitals are subject to a penalty from the Hospital-Acquired Condition (HAC) Reduction Program, which starts in FY 2015. The HAC Reduction Program is flawed, in that it applies a one percent

penalty to one-quarter of **all hospitals**, regardless of any improvements made by the hospital or the industry. Based on current proposals, teaching hospitals would be disproportionally affected, with over half of teaching hospitals receiving the penalty. CMS has the obligation to ensure the measurement is as fair as possible and does not create a systematic bias for a particular type of hospital. Fully understanding the options has been challenging, because of a lack of readily available data. For example, early AAMC analysis suggests that hospital performance can vary substantially based on whether or not CMS uses chart-abstracted measures versus claims-based measures. Achieving consensus on measure selection and measure scoring is extremely important. The AAMC requests that CMS extend the time period for comments on this proposal and also release data files to facilitate an accurate analysis of measure selection and scoring methodologies.

Our comments focus on the following areas:

- New Adjustment Methodology for Medicare Disproportionate Share Hospital (DSH) Payments
- Labor and Delivery Days as Inpatient Days in the Medicare Utilization Calculation
- Payments for Residents Training in Approved Residency Programs at Critical Access Hospitals (CAHs)
- Hospital Quality-Related Programs
    - Hospital-Acquired Conditions (HAC) Reduction Program
    - Hospital Value-Based Purchasing (VBP) Program
    - Hospital Readmissions Reduction Program
    - Inpatient Quality Reporting (IQR) Program
- Admission and Medical Review Criteria of Hospital Inpatient Services under Medicare Part A
- MS-DRG Documentation and Coding Adjustment
- Revised MS-DRG Weights/Cost Centers
- Add-On Payments for New Services and Technologies
- Outlier Payments

NEW ADJUSTMENT METHODOLOGY FOR MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS

Sec. 3133 of the Affordable Care Act (ACA) requires changes in the DSH payment formula and applies to all hospitals that qualify for disproportionate share hospital (DSH) payments under Sec. 1886(d)(5)(F)(i)(II). Under this section of the ACA, aggregate DSH payments will be

reduced and repurposed. As discussed in more detail below, the AAMC supports some of the new proposals for this payment program and has suggestions for how to improve others. Specifically, the AAMC supports CMS' proposal regarding the 25 percent of DSH payments that will be paid using the current methodology. We also support the proposed approach that will be used to calculate the new uncompensated care (UC) payments but strongly urge CMS to correct the assumptions used to estimate projected FY 2014 payments. The AAMC supports CMS' proposed proxy for a hospital's costs of treating the uninsured until a better source of data is identified and validated. The Association also urges CMS not to finalize the proposal to pay the UC payment as a periodic interim payment without ensuring that Medicare Advantage (MA) plans include the UC payments in their rates for inpatient services.

CMS Should Finalize Proposals Regarding the 25 Percent of DSH Payments That Will Be Distributed Using the Current Methodology

The statute requires changes that will result in current DSH payments being separated into two types of payment: so-called "empirically justified" DSH payments and a new "uncompensated care payment." DSH-eligible hospitals will receive twenty-five percent (25 percent) of the amount they would have received in DSH payments using the current DSH payment methodology. CMS proposes to pay this 25 percent DSH payments simply by revising claims payment methodologies to adjust interim claim payments to equal 25 percent of what otherwise would have been paid. Final eligibility for Medicare DSH payments and the final amount of these payments for eligible hospitals will be determined at the time of cost report settlement. The AAMC supports CMS' proposals regarding the 25 percent of DSH payments distributed using the current methodology.

CMS' Proposed Methodology to Calculate Factors 1 and 2 of the UC Payments Is Acceptable If Estimates Are Updated

CMS' proposals also implement the statutory requirement that seventy-five percent (75 percent) of current DSH payments be reduced and applied toward a new "uncompensated care payment." CMS proposes to make this payment to hospitals that are currently eligible for DSH payments using three (3) factors. Factor 1 is 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 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, expressed as a percent. 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 payment each eligible hospital will receive.

To calculate the UC payment for DSH-eligible hospitals using the factors, CMS proposes to use estimates of current DSH payments. In the proposed rule, the sources of data CMS uses to estimate Medicare DSH payments are based on the CMS Office of the Actuary's February 2013 estimate, which in turn is based on the December 2012 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2013 IPPS/LTCH PPS final rule IPPS impact file. In the final rule, this estimate will be based on CMS Office of the Actuary's July 2013 estimate. The data will be based on the March 2013 update of the Medicare Hospital Cost Report data and the proposed rule's IPPS impact file.

For purposes of the proposed rule, CMS' estimate for DSH payments for FY 2014 is $12.338 billion (Factor 1). CMS provides the assumptions behind this projection, one of which is there will be a 2.0 percent documentation and coding cut in FY 2014. However the Agency proposes a 0.8 percent documentation and coding cut, rather than a 2.0 percent documentation and coding cut. The AAMC strongly urges CMS to correct this assumption to reflect the proposed -0.8 percent documentation and coding adjustment and update the estimate accordingly. The AAMC also encourages CMS to take into account the impact of Medicaid expansion on the FY 2014 DSH payment projection and to make any necessary adjustments, particularly because there is no opportunity for reconciliation or judicial review.

Finally, the Association asks CMS to reconsider the Agency's assumptions used to determine how the amount overall DSH payments will be reduced to reflect the number of individuals newly insured under the ACA (Factor 2). CMS uses the Congressional Budget Office's assumption of a two percent reduction in the number of uninsured Americans for FY 2014. The AAMC is concerned that this overestimates the number of individuals who will be insured through the Exchanges and how quickly they will be able to enroll.

The AAMC Supports CMS' Proposed Methodology for Calculating the Costs of Treating the Uninsured until a Better Source of Data Is Introduced

To estimate the uncompensated care amounts necessary to make the UC payment, the ACA allows the Secretary to establish a proxy for the costs to PPS hospitals of treating the uninsured. CMS proposes to use Medicaid inpatient days plus Medicare SSI inpatient days as a proxy for measuring the amount of uncompensated care a hospital provides. CMS proposes that the data necessary for this proxy be taken from the hospitals' most recently available cost report. For FY

2014, the hospital's FY 2010 or FY 2011 cost report would be used, including FY 2011 SSI ratios to the extent they are available; otherwise CMS would use the FY 2010 ratios. CMS would calculate each DSH-eligible hospital's Medicaid days plus Medicare SSI days and determine that hospital's percentage of total DSH-eligible hospital Medicaid and Medicare SSI days. To determine the hospital's individual UC payment, this percentage would be multiplied by the pool of the 75 percent of former DSH payments (Factor 1) reduced by Factor 2.

The AAMC supports CMS' proposed proxy for the costs of treating the uninsured until a better source of data is identified and validated. The Association encourages CMS to find an alternative source of data before states begin expanding their Medicaid programs under the ACA, because continuing to use the proposed proxy could lead to future problems. For example, the Medicaid days factor of the proposed proxy could be affected by Medicaid expansion in a way that would excessively penalize institutions in states that choose not to expand their Medicaid programs. The AAMC urges CMS to continue working to develop methodologies that will avert such a redistributive effect.

The Association also agrees with CMS that data from cost report Worksheet S-10, which collects hospital and uncompensated care and indigent care data, is not currently appropriate for use. First and foremost, we are concerned about the use of an overall cost-to-charge ratio that excludes graduate medical education (GME) costs. Before the S-10 can be used as a data source for the costs of treating the uninsured, hospitals need more explicit instructions and guidance regarding how to report on this form. Additionally, CMS must find ways to clarify what can be reported as charity care, because the term can vary significantly among providers and states. CMS should also accept the charity care write-offs that are included in hospitals' audited financial statements as the amount reported on the S-10. Additionally, the instructions for grant and bad debt reporting are vague and would need to be more specific. The AAMC would welcome the opportunity to work with CMS to develop a Worksheet S-10 that is more accurate and can be better used to collect the data on hospitals' costs associated with treating the uninsured. The Association will send a separate letter with further detail regarding our concerns and proposals related to the S-10.

CMS' UC Payment Methodology Must be Modified to Ensure that Medicare Advantage (MA) Plans Include UC Payments in Their Rates for Inpatient Services

CMS proposes to make UC payments through periodic interim payments rather than per discharge. The AAMC is very concerned that Medicare Advantage (MA) plans will underpay hospitals, if CMS' proposed UC payment methodology is implemented as proposed. The

Association urges CMS to modify this proposal to ensure that both "empirically justified" DSH payments and UC payments are accounted for in the Medicare rates and in the CMS Medicare Inpatient PPS PRICER (PRICER) components on which MA plan payments are based. Otherwise, MA payments in FY 2014 may be based on a 75 percent cut in hospital Medicare DSH payments, resulting in inappropriately low MA payments to hospitals. MA plans and hospitals should not be expected to renegotiate their contracts to correct this problem, as doing so would be extremely difficult and burdensome and would risk disrupting beneficiaries' MA provider networks. The AAMC urges CMS to revise the proposed policy to avoid the unintended consequences of overpayments to MA plans and substantial underpayments to hospitals that treat MA patients.

While the AAMC recognizes that finalizing the UC payment methodology as proposed could be administratively convenient for CMS, an estimated $3 billion[1] in payment will be at risk if this proposal is finalized because MA negotiated rates are commonly tied to the PRICER. The effect on existing MA plan contracts and hospital payments is untenable. If CMS finalizes the periodic interim payment as proposed, MA plans will be overpaid by an estimated $3.02 – 3.68 billion and hospitals will be underpaid by an estimated $2.68 billion – $3.27 billion.[2]

To avoid these unintended consequences, CMS could make the UC payments as per discharge payments through the PRICER. For example, CMS could calculate a per discharge uncompensated care add-on rate and pay that through the PRICER. CMS could then do a small reconciliation of the number of discharges at cost settlement.

CMS previously changed the PRICER on multiple occasions to efficiently administer payments, and the AAMC strongly encourages the Agency to do so again to allow for accurate payments under Medicare Part C when the proposed changes to the Medicare DSH payment methodology are implemented. The AAMC supports the American Hospital Association's (AHA) proposal that CMS add a value to the PRICER for additional DSH. For further information, the AAMC refers you to the AHA's FY 2014 IPPS proposed rule comment letter.

The AAMC acknowledges that CMS would be required to perform a small reconciliation for the volume of discharges associated with the UC payment, because CMS could not project exact Medicare utilization. Therefore, the Agency's UC payment to a hospital would need to be

[1] The Moran Company's analysis suggests that the total MA DSH amount affected (75% DSH) could be as high as $3.02 – 3.68 billion estimated based on different data sources.
[2] The MA FY 2014 rate already includes 100% of the amount that would have been paid in DSH payments, while hospital's uncompensated care payments are reduced pursuant to ACA changes (Factor 2).

reconciled to the actual number of discharges when the cost report is submitted. CMS already makes these small reconciliations for other factors and already proposes to conduct reconciliations for empirically justified payments. There is no reason CMS could not reconcile the amount of a hospital's actual UC payments to the prospectively determined UC payments.

Even if CMS finalizes the proposal to make fee-for-service UC payments through periodic interim payments, CMS should treat MA UC payments differently. CMS already makes adjustments for MA default rates because they do not include IME and DGME payments. CMS could ensure that MA plans include UC payments in their rates for inpatient services by converting the UC payments into a per discharge amount and adding that to the default rate paid by MA plans to hospitals when they do not have a contract. Many MA contracted rates are also based on this default rate. CMS could add another variable to the PRICER by making a modification similar to the changes made for the GME carve out. The AAMC strongly urges CMS to ensure that UC payments are reported through the PRICER for MA claims.

UC Payments Should Be Accounted for in Determining Whether Sole Community Hospitals (SCHs) Are Paid the Higher of the Federal PPS Amount or the Hospital-Specific Amount and in Determining Whether SCHs Are Included in the DSH Eligible Pool

CMS proposes that UC payments not be included in determining whether SCHs are paid the higher of the federal PPS amount or their hospital specific amount. The AAMC opposes this proposal, because CMS' projections will show most sole community hospitals (SCHs) receiving the hospital-specific amount even if this is not ultimately the case. Whether all SCHs or only those that are projected to be eligible by CMS are included in the uncompensated care pool will affect the total UC payment available for distribution. UC payments should be accounted for in determining whether SCHs are paid the higher of the federal PPS amount or the hospital-specific amount and in determining whether SCHs are included in the DSH eligible pool. Accordingly, CMS either should convert UC payments to per discharge payments to ensure these payments are taken into account in these contexts or find another way to address these concerns.

CMS' Proposals Regarding Reconciliation of Empirically Justified DSH Payments and UC Payments Should be Finalized, but Hospitals Should Have an Opportunity to Validate the Estimates and Data Used to Determine the UC Payments

The AAMC supports CMS' proposals related to the reconciliation of payments based on 25 percent of current DSH and the factors used to calculate the UC payment. At the same time, the AAMC urges CMS to establish a timeframe to allow hospitals to self-validate the estimates and

data used to determine the UC payment, because there will be no administrative or judicial review of these payments. For example, CMS could allow hospitals a period between August 1, 2013, and September 1, 2013 (30 days), to self-validate data provided by CMS in the final rule. Alternatively, CMS could provide each individual hospital its data on July 1, 2013, and hospitals would have until September 1, 2013, to validate this data. A timeframe for hospitals to review and correct their Medicaid eligible days could be used to ensure that the data CMS uses to calculate UC payments are accurate.

Validation checks are particularly necessary, because CMS will have to pull the Medicaid days from data sources that have not been used for these purposes before. For example, CMS proposes to obtain data on Medicaid days from Worksheet S-3, Part 1 of the 2552-96 version of the cost report and from Worksheet S-2, Part 1 of the 2552-10 version of the cost report. Because these fields have not previously been used for payment, some hospitals have not been reporting their Medicaid days on these worksheets. It is particularly important to correct these errors, because each institution's UC payments will be dependent on all other DSH eligible hospitals' UC payments.

CMS Should Not Finalize the Proposal to Count MA Patient Days in the Medicare Fraction of the DSH Patient Percentage

The AAMC strongly opposes CMS' proposal to count patient days associated with patients enrolled in Medicare Advantage plans in the Medicare fraction of the disproportionate patient percentage (DPP) calculation. The Agency previously attempted to adopt a policy to include Medicare patient days in the Medicare fraction of the DSH calculation, but in *Allina Health Services, et. al., v. Sebelius*, the Federal District Court for the District of Columbia invalidated CMS' final policy. CMS seeks comment on a proposal to readopt this policy while the government's appeal of the case is still pending. **The AAMC urges CMS not to finalize this proposal because the statute and the Agency's own regulations make it clear Medicare Advantage enrollees are not "entitled" to benefits under Part A.**

Section 1851(a)(1) of the Social Security Act states that persons eligible for Medicare Advantage are "entitled to elect to receive benefits" either "through the original [M]edicare fee-for-service program under [P]arts A and B, or through enrollment in a [Medicare Advantage] plan under [Part C]." The SSA also states that "entitlement of an individual to hospital insurance benefits for a month [under Part A] shall consist of entitlement to have payment made under, and subject to the limitations in, [P]art A."[1] Once MA plan enrollees elect to receive benefits through

[1] Social Security Act § 226(c)(1).

enrollment under Part C, they are no longer entitled to have payment made under Part A, and therefore, they are no longer "entitled" to benefits under Part A. Accordingly, the AAMC strongly opposes CMS' proposal and urges the Agency to continue to exclude Medicare Advantage patient days from the Medicare fraction of the DSH calculation.

LABOR AND DELIVERY DAYS AS INPATIENT DAYS IN THE MEDICARE UTILIZATION CALCULATION

CMS Should Not Include Labor and Delivery Days as Inpatient Days in the Medicare Utilization Calculation

In the FY 2013 IPPS final rule, CMS finalized the Agency's proposal to include labor and delivery (L&D) bed days as available bed days for indirect medical education (IME) payment adjustment purposes. CMS now proposes to include L&D days as inpatient days in the Medicare utilization calculation used to determine Direct Graduate Medical Education (DGME) payments. Considering L&D patient days for purposes of allocating direct GME payments is inconsistent with longstanding CMS policy regarding services that typically are not covered by the Medicare program. The AAMC strongly urges CMS not to implement this proposal for reasons explained in the Association's FY 2013 IPPS proposed rule comment letter. The AAMC continues to oppose the justification for recent policy changes regarding L&D beds and days, particularly absent any direction from Congress. The Association continues to believe that CMS should exclude labor and delivery costs, days, and beds for both DGME and IME payment purposes, because the Medicare program does not generally cover services for labor and delivery.

CMS specifically proposes that patient days associated with maternity patients admitted as inpatients who receive ancillary labor and delivery services when the inpatient routine census is taken would be included in the Medicare utilization calculation. This policy would apply regardless of whether the patient actually occupied a routine bed prior to occupying an ancillary L&D bed and regardless of whether the patient occupied a maternity suite (*i.e.*, where labor, delivery, recovery, and postpartum care all occur in the same room).

For cost reporting periods beginning on or after October 1, 2013, CMS would include Medicare L&D inpatient days in the numerator and all L&D inpatient days in the denominator of the Medicare utilization ratio. CMS acknowledges that this change likely will reduce DGME payments, because the denominator of the patient load ratio (total hospital inpatient days) will increase faster than the numerator (Medicare patient days). This proposal could also impact other Medicare policies where the number of patient days or a ratio of Medicare inpatient days to total inpatient days is used to determine eligibility for payment, such as eligibility for sole community hospital status.

The AAMC opposes CMS' proposal to deviate from longstanding policy in a manner that will reduce DGME payments, particularly when DGME payments already cover only a fraction of the direct costs of training medical residents. Out of $15.4 billion in total DGME costs, Medicare DGME payments account for $3.2 billion (approximately 21 percent), and the other $12.2 billion (approximately 79 percent) in DGME costs are absorbed by teaching hospitals.[3] As the ACA's marketplace reforms are implemented and our country faces looming physician shortages, it is critical to protect graduate medical education and the health care professional pipeline to ensure that expanded coverage does not outpace access. Further, this proposal could have the unintended consequence of incentivizing hospitals to eliminate labor and delivery beds, potentially jeopardizing access for Medicaid recipients and others. For these reasons, the AAMC urges CMS not to include L&D days as inpatient days in the Medicare utilization calculation.

PAYMENTS FOR RESIDENTS TRAINING IN APPROVED RESIDENCY PROGRAMS AT CRITICAL ACCESS HOSPITALS (CAH)

CMS Should Continue to Include the Time Residents Train in Approved Residency Programs at CAHs for Graduate Medical Education Payment Purposes

The AAMC strongly urges CMS not to finalize the Agency's proposal that PPS teaching hospitals that incur the costs of stipends and benefits for residents will no longer be permitted to count the time residents spend training in rotations to critical access hospitals (CAHs) for DGME and IME purposes under Affordable Care Act (ACA) Section 5504 (Sec. 5504). CMS' proposal is inconsistent with longstanding GME payment policy, contradicts CMS' language in the implementing regulations, and is contrary to the legislative history and policy goals of the ACA, because it would have the adverse effect of discouraging training outside the hospital that plays a critical role in combating physician shortages in rural and underserved areas.

CMS' Proposal Is Inconsistent with Longstanding GME Payment Policy

IME payments are patient care payments designed to compensate teaching hospitals for serving a unique and critical role as sole providers of highly specialized tertiary care unavailable elsewhere, such as burn care, trauma, and transplant services. A teaching hospital's rotating residents to a CAH should not change the IME payment to that teaching hospital, because teaching hospitals will continue to provide these specialized services, even if they rotate some of their residents out of the hospital to a CAH.

[3] The Medicare Cost Reports, HCRIS 9/30/2012.

In the DGME context, if the PPS hospital incurs the costs of the stipends and fringe benefits of residents during the time they rotate to the CAH, the PPS hospital should receive DGME payments for those resident FTEs. If the CAH incurs these training costs, it already has an option to be paid directly at 101 percent of its reasonable costs. CAHs support the option for the PPS hospital to incur the costs and receive DGME and IME payments, because they want to ensure that teaching hospitals continue to rotate residents to CAHs. Reimbursing hospitals for resident rotations to CAHs incentivizes training in rural and underserved areas, which has a substantial positive effect on recruitment and retention in these areas.

CMS' Proposal Is Contrary to Existing Statutory and Regulatory Language

CMS' stated reasons for this proposal are not consistent with the Agency's existing regulations or with the legislative intent behind the ACA. In justifying this proposal, CMS assigns new meaning to Sec. 5504's use of the term "non-provider," a term the Agency has previously used interchangeably with the term "non-hospital" setting. CMS explains that CAHs are included in the definition of the term "provider of services" under section 1861(u) of the Social Security Act (SSA). As a result, CMS reasons that a CAH may not be treated as a "non-provider" and, therefore, a hospital may not claim the time FTE residents train at a CAH for purposes of IME or DGME payments, even if the substantive requirements of Sec. 5504 are satisfied. CMS' sudden decision to make new distinctions between the terms "non-hospital" and "non-provider" and to use a different set of definitions to determine whether facilities fall under Sec. 5504 is contrary to preamble language in the regulations CMS issued to implement Sec. 5504 and to Congress' intent based on the legislative history behind this provision of the ACA.

Currently, if an inpatient PPS teaching hospital incurs the costs of salaries and benefits for the time residents rotate to a CAH and complies with section 42 CFR § 413.78 requirements for training at "non-hospital" settings, the hospital may count the time the residents train at the CAH for DGME and IME purposes. Under existing policy, CAHs may be paid directly for 101 percent of their reasonable training costs, or, alternatively, teaching hospitals may be paid for those costs if the nonprovider site requirements are met. CMS explains that the Agency has treated a CAH as a nonhospital setting, because the definition of hospital in section 1861(e) of the Social Security Act indicates that a CAH is not a hospital.[4]

CMS' new reliance on the Sec. 1861(u) definition of "provider of services" and the "non-provider" versus "non-hospital" distinction is misplaced. There is no basis to conclude from the legislative history of the ACA and the longstanding use of the terms "hospital" and "provider"

[4] Social Security Act Sec. 1861(e) [42 U.S.C. 1395x] ("the term 'hospital' does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1))").

that Congress intended to use the term "non-provider" in Section 5504 in a manner that would exclude CAHs from this provision. Instead, the purpose of this provision was to modify regulations for counting resident time in clinical settings outside the PPS teaching hospital. Sec. 5504 clarifies that a teaching hospital will meet the requirements to incur "all, or substantially all, of the costs for the training program" outside the hospital, if the teaching hospital incurs the costs of "the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting," as long as the patient care requirements are met.

Section 1886(h)(4)(E) of the Social Security Act (42 U.S.C. 1395ww(h)(4)(E)) was amended to include section (ii), which states "effective for cost reporting periods beginning on or after July 1, 2010, all the time so spent by a resident shall be counted towards the determination of full-time equivalency, *without regard to the setting* in which the activities are performed, if a hospital incurs the costs of the stipends and fringe benefits of the resident during the time the resident spends in that setting." Therefore, contrary to CMS' rationale in the FY 2014 IPPS proposed rule, the amendments to the SSA did not focus on whether the time spent outside the hospital is spent in a "non-hospital" or "non-provider" setting. The substantive change intended by Sec. 5504 was to make it less administratively burdensome for teaching hospitals to send residents outside the hospital to train without regard to setting. To the extent the term "non-provider" setting was used in Sec. 5504, it was used interchangeably with "non-hospital" setting, consistent with CMS' prior usage.

The regulations implementing Sec. 5504 were included in the CY 2010 OPPS Final Rule. In the preamble to this regulation, CMS stated, "Section 5504(a) of the Affordable Care Act made changes to section 1886(h)(4)(E) of the Act *to reduce the costs that hospitals must incur* for residents training in nonprovider sites in order to count the FTE residents for purposes of Medicare direct GME payments."[5] In this final rule, CMS also responded to a commenter's' request to "clarify the definition of a nonprovider site."[6] Another commenter requested that "CMS clarify the definitions of nonprovider and hospital based settings to state that hospital-based settings can include a variety of ambulatory experiences."[7] CMS responded that "a 'nonprovider site' is a setting that does not qualify as a provider-based facility or organization in accordance with the criteria in the regulations at 42 CFR 413.66."[8] CMS mentioned nothing about the definition of the term "provider of services" under section 1861(u) of the SSA. If CMS believed there was a legitimate distinction between the terms "non-provider" and "non-hospital" setting and that the distinction was the result of Sec. 5504, the Agency would have defined these

[5] CY 2010 OPPS Final Rule, 75 *Fed. Reg.* 71799 (Nov. 24, 2010) (emphasis added).
[6] *Id*. at 72135.
[7] *Id.*
[8] *Id.*

terms separately and clarified the distinction in the CY 2010 OPPS final rule implementing Sec. 5504.

The distinction CMS' preamble language focuses on when determining whether time training outside the teaching hospital can be counted is whether the facility where the resident is training is primarily engaged in patient care. Section 413.78(g) of the implementing regulations explicitly state that "the time residents spend in non-provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count, if the resident spends his or her time in *patient care activities* defined at § 413.75(b); or in certain nonpatient care activities, but the training must take place "in a nonprovider setting that is *primarily engaged in furnishing patient care activities,* as defined at § 413.75(b)."[9]

According to 42 CFR 413.75(b), patient care activities "means the care and treatment of particular patients, including services for which a physician or other practitioner may bill, and orientation activities as defined in this section."[10] CAHs clearly are settings where the primary purpose is patient care and, therefore, they should not be excluded from Sec. 5504.[11] Accordingly, teaching hospitals should be permitted to count time residents spend training at CAHs, if the residents are participating in patient care activities, and the hospital incurs the costs of stipends and fringe benefits of the residents.

CMS' Proposal May Reduce Access to Training in Rural and Underserved Areas Contrary to the Legislative Intent of the ACA

Finally, the legislative history of Sec. 5504 of the ACA suggests that Congress did not intend for CMS to create a new distinction between "non-hospital" setting and "non-provider" setting Rather, the Congressional record shows that in passing the ACA, lawmakers intended to encourage teaching hospitals to send residents to rural and underserved areas, where it has often been difficult to recruit and retain physicians. An important part of Congress' rationale for promoting training in the outpatient setting was to ensure the availability of residency programs in areas that are often in the most need of additional physicians and an improved workforce pipeline.

The legislative history indicates that the Sec. 5504 policy changes were meant to "promote training in outpatient settings and to ensure the availability of residency programs in rural and underserved areas," and the policy would do this by providing "increased flexibility in the laws

[9] 42 CFR § 413.78(g) (emphasis added).
[10] 42 CFR 413.75(b).
[11] *Id.*

and regulations governing graduate medical education funding in the Medicare program."[12] The purpose was to have "all resident training time count toward Medicare direct graduate medical education payment "without regard to where the activities are performed," as long as the hospital incurs the cost of stipends and fringe benefits for that time.[13] Further, the legislative history suggests that it was Congress' intention that "all the time spent by a resident in patient care activities in a *nonhospital setting* would be counted toward Medicare indirect medical education payment if the hospital continues or in the case of a jointly operating residency program, the entities continue to incur the costs of stipends and fringe benefits of the resident during the time spent in that setting."[14]

For all of these reasons, the AAMC urges CMS to retain the current policy, which clearly reflects Congressional intent and is consistent with the way CMS has interpreted the statute in the past.

HOSPITAL QUALITY-RELATED PROGRAMS

Starting FY 2015, Medicare will include the following inpatient programs that assess hospitals on either reporting of or performance on certain quality measures:

- Inpatient Quality Reporting (IQR) – pay-for-reporting program
- Hospital Value-Based Purchasing (VBP) – pay-for-performance program
- Hospital Readmissions Reduction Program (Readmissions) – penalty for excess readmissions
- Hospital-Acquired Conditions (HAC) Reductions Program – penalty for poor performance on HAC measures

As these programs all relate to the quality of care provided at hospitals, they must be reviewed both holistically as well as within the parameters of the individual program. A holistic review of all programs allows stakeholders to have a thoughtful discussion about when measures should be brought into specific programs and how to avoid unintended consequences (such as rewarding or penalizing hospitals twice for the same event). The AAMC strongly believes that all quality measures first should be publicly reported in the IQR program for a minimum of one year before being considered for the performance programs. Publicly reporting measures in the IQR program provides transparency, allows stakeholders to gain experience submitting the measures and allows time to identify errors, unintended consequences or other concerns with measure methodology. The VBP statutory language requires all measures in the program to first be

[12] The Senate Finance Committee's "Chairman's Mark of the America's Health Future Act of 2009."
[13] *Id*.
[14] *Id*. (emphasis added).

publicly reported in the IQR program for the reasons outlined above. The AAMC strongly encourages CMS to apply this standard of requiring measures to be publicly reported in the IQR program for a minimum of one year prior to being reported in the Readmissions Reduction or HAC Reduction Programs.

The AAMC also believes that measures in performance or penalty programs should be complimentary, not overlapping. This policy ensures that hospitals are not affected twice by the same (or similar) measure. CMS has appropriately removed readmission measures from VBP because there is a separate readmissions program. The AAMC urges CMS to follow the same policy and ensure that similar measures are not in the HAC Reductions Program and VBP.

One concern related to reviewing the FY 2015 quality programs is that measure adoption cycles do not align for two of the four programs (HAC and Readmissions) were proposed in this year's rule. Measures and methodology for the FY 2015 IQR and VBP were finalized in last year's proposed rule. This mismatched comment cycle creates some inconsistencies:

- Overlapping measures: some of the measures proposed for the FY 2015 HAC Reduction Program already were finalized for the FY 2015 VBP program.

- Misaligned timelines: the COPD readmission measure is proposed for the FY 2015 Readmission Reduction Program, a payment program, but is not proposed for IQR, the reporting program, until one year later in FY 2016.

The AAMC appreciates that CMS establishes the framework for these performance programs a few years in advance as it allows hospitals and providers time to prepare the appropriate infrastructure before the performance period begins; however, CMS needs to offer the flexibility for stakeholders to comment on all the programs in total and should make any necessary adjustments if new proposals conflict with previously finalized programs.

HOSPITAL-ACQUIRED CONDITIONS (HAC) REDUCTION PROGRAM

Summary and Recommendations

Section 3008 of the ACA requires CMS to implement a Hospital-Acquired Condition (HAC) Reduction Program starting in FY 2015. The statute requires that hospitals that fall within the worst quartile of performance will receive an automatic one percent reduction in their payments. In the IPPS proposed rule, CMS outlines a framework to calculate a total HAC score that will determine which hospitals will be subject to this penalty.

The AAMC recognizes the burden HACs place on patients and their families and is committed to reducing the rates of these events among teaching hospitals. The Association is a leader in supporting members' efforts to implement central line bundle protocols and surgical checklist requirements, which is leading to improved outcomes in hospital-acquired conditions. Through the AAMC's Best Practices for Better Care (BPBC) initiative, participating institutions are implementing protocols for using central lines, including using chlorhexidine for skin disinfection; avoiding femoral insertion site; removing catheters when no longer indicated; practicing strict hand hygiene; and, using the most effective safety materials while inserting a central line. Participating sites are documenting compliance and tracking performance, and medical students and resident physicians are being trained on these protocols and are integrating them into local improvement efforts. Member institutions that participate in BPBC also are creating institutional policies mandating the use of surgical checklists in all operating rooms for all procedures and are reporting and tracking compliance and outcomes through periodic chart reviews and other mechanisms.

The AAMC has major concerns with the structure of the HAC Reduction Program. The program automatically penalizes hospitals, even if there is a reduction in infections within the institution or across the nation. Because this penalty is designed by statute to affect one quarter of all hospitals, it is essential that CMS ensure the measurement is as fair as possible and does not create a systematic bias that disadvantages a particular type of hospital. CMS' proposal does not do this, as **teaching hospitals would be disproportionately affected** in two ways. First, CMS estimates that 56 percent of teaching hospitals- more than twice the national average- would be affected by the penalty. In addition, the amount of the reduction for teaching hospitals will be proportionately higher if the penalty applies to add-on payments as well as base operating DRG amounts. The AAMC estimates that applying the penalty to the entire discharge payment (including the add-on payments) would increase the penalty by 63 percent for major teaching hospitals, compared to 20 percent for all other hospitals. The AAMC is very concerned that these results can be attributed primarily to the proposed methodology and the size of our facilities rather than to true differences in the quality of care.

CMS should consider the following principles when implementing the HAC Reduction Program. First, measures should be designed to identify and fairly compare HACs across all types of hospitals. We also believe that all measures must be tested, reliable, endorsed by the National Quality Forum (NQF), and approved by the Measure Applications Partnership (MAP) and that the HAC measures should be clinically-validated when possible. Ideally, the measures should represent events that should not occur if proper care is provided. Unfortunately, many of the currently available measures fall short of these principles. For example, CMS proposes to use the Centers for Disease Control (CDC) National Health Safety Network (NHSN) and Agency for

Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSI) for the HAC Reductions Program. The CDC NHSN measures are clinically-validated, yet not all hospitals report this information. Patient Safety Indicators (PSIs) on the other hand, were not designed for comparing across hospitals. The measures' results are derived from claims data, are subject to coding biases, and tend to have results that skew towards hospitals with more admissions and surgical cases, because these events are so rare.

Given the importance of this program, the AAMC recommends that CMS:

1. Not finalize the current proposal.
    - Continue the HAC measure and scoring discussion with providers by extending the time period to submit comments on this program.
    - Release supporting data files to stakeholders to allow them to make more informed comments.
2. Apply the HAC penalty only to the base operating DRG payments. Add-on payments, such as IME and DSH, should be excluded as is the case with VBP and the Readmissions Reduction Programs.
3. Remove measures that are finalized in the HAC Reduction Program from the VBP program.
4. Weight clinically-validated measures (Domain 2) more than claims based measures (Domain 1).

Recommendation 1: Do Not Finalize the Current Proposal and Extend Time Period for Comments to Allow Additional Data Analysis

The HAC Reduction Program, by statute, will penalize one-quarter of all hospitals. CMS must therefore ensure that the program's methodology has no unintended consequences. The Agency proposed a set of measures and a framework for scoring those measures but did not release the necessary files that would allow stakeholders to evaluate the scoring methodology in detail. While some measure projections can be calculated using data from Hospital Compare, many measures have to be estimated using other data sources. The AAMC, with other hospital associations, contracted with KNG Health to model the impact of the proposal as well as to understand alternatives. While the AAMC has some preliminary data to estimate the impact and provide feedback to CMS, the Association is still in the process of analyzing different measures and scoring options to ensure that there are no unintended consequences. We have serious concerns that certain claims-based measures may unfairly target large hospitals, such as teaching hospitals.

Small changes in the methodology can affect which hospitals are subject to the penalty. The limitations in these measures have a very real impact for major teaching hospitals, as CMS estimates that 56 percent of teaching hospitals will face the 1 percent penalty in FY 2015. The AAMC wants to ensure that such penalties are related to true differences in quality and are not associated with underlying measure characteristics or biases.

Stakeholders are struggling to understand the impact of including claims-based PSI measures. Many of the individual measures are not reported on Hospital Compare and the suggested composite measure overlaps with clinically-validated measures in the CDC NHSN. If claims-based measures need to be included in the HAC program, CMS should have further discussion about what the right measures are and how they should be weighted compared to clinically-validated measures. In addition to the AAMC, other stakeholders are considering the feasibility of adjusting the measures to get the most appropriate claims-based measure, or assembling new composites.

Another methodology question concerns the number of hospitals receiving a valid Domain 2 score. The CMS impact table on page 27805 of the *Federal Register*, states that 696 hospitals are in the top quartile for Domain 2. Using that number, approximately 2,784 (696*4) hospitals have a Domain 2 score. Yet the table on page 27809 indicates that only 1,927 hospitals have complete data for Domain 2. The AAMC asked CMS to reconcile the difference in these numbers, but we have not yet received a response. Knowing the number of hospitals with a Domain 2 score is an important element to understanding the HAC proposed methodology.

In a program with such high stakes penalties, CMS should accept as many informed comments as possible. Therefore, we request that CMS not finalize this program as proposed and should extend the discussion period. CMS should also release supporting data files so that stakeholders have the ability to make more informed comments. Because the program does not affect payments until FY 2015, the AAMC believes that CMS has the flexibility to extend the proposed rule's deadline for this program to ensure that there is a thoughtful dialogue.

Recommendation 2: Apply the HAC Penalty Only to the Base Operating DRG Payments

The statutory provision in Section 1886(p) of the Social Security Act, also known as the HAC payment provision, references the 1 percent payment reduction as "the amount of payment under this section," which admittedly could be interpreted as including all add-on payments such as IME and DSH. While the FY 2013 IPPS Proposed Rule does not address how the HAC payments will be applied, the AAMC believes the penalty should be tied to the base-operating MS-DRG just as it is for the other performance-based programs, VBP and Readmissions Reductions. Restricting the penalty to the base operating DRG will ensure consistency across

the programs and reduce confusion. Including IME/DSH payments in the penalty program would disproportionately affect teaching hospitals and safety net hospitals that provide important complex services to vulnerable patient populations. Our preliminary estimates show including the add-on payments would increase the penalty by 63 percent for major teaching hospitals, compared to 20 percent for all other hospitals. The AAMC strongly urges CMS to apply the HAC penalty only to the operating base DRG amount.

Recommendation 3: Remove Measures That Are Finalized in the HAC Reduction Program from the VBP Program

The AAMC firmly believes that hospitals should not be penalized twice for the same measures in two different performance programs. In the 2013 IPPS final rule, CMS finalized the AHRQ PSI-90 composite measure and the Central Line Associated Blood Stream Infection (CLABSI) measure to be included as part of the outcomes domain for the FY 2015 VBP program. In this year's proposed rule, CMS proposed the Catheter-Associated Urinary Tract Infection (CAUTI) measure for both the HAC Reduction Program and the VBP Program. The AAMC urges CMS to remove the AHRQ Composite measure and the CLABSI and CAUTI measures from VBP if these measures (or a subset of these measures) are finalized in the HAC Reduction Program.

Recommendation 4: Weight Clinically-Validated Measures (Domain 2) More than Claims Based Measures (Domain 1)

For the FY 2015 HAC Reduction Program, CMS proposes to use measures in two domains. Domain 1 is a set of six AHRQ patient safety indicators (PSIs). CMS is also seeking feedback on using an alternative measure for Domain 1, which would be the AHRQ PSI-90 composite score, a summation of eight individual PSI measures. The second domain consists of two measures from the CDC NHSN. Each measure would be weighted equally within each domain and each domain would also be weighted equally. The AAMC does not believe that both domains should be weighted equally. Rather, the AAMC believes that the validated data in Domain 2 should be weighed more than the Domain 1 score.

Proposed Measures

Domain 1: AHRQ PSIs

For several years, the AAMC has noted its concerns with the use of the AHRQ PSIs in the hospital quality programs. These measures are calculated using administrative claims data that have significant limitations since they were designed for billing purposes and are less accurate in identifying a patient's severity level compared to clinical data abstracted from the medical record. The measures lack a robust risk-adjustment methodology and were originally developed

for internal quality improvement and not for public reporting and payment purposes. In fact, several individual PSI measures were removed from the IQR program starting in FY 2015, the year the HAC Reduction Program starts. Finally, the AAMC is concerned that the PSI measures tend to penalize hospitals with larger case volumes, as compared to those with smaller case volumes.

The AAMC has serious concerns with the PSI measures and has not previously supported them for payment purposes; however, the Association also recognizes that the HAC Reduction Program needs to measure all hospitals. The only other alternative, measures from the CDC NHSN, do not apply to all hospitals. Therefore, the AAMC reluctantly understands that CMS needs to include some claims-based measures for the HAC Reduction Program on a temporary basis. Until the claims-based measures are removed, the AAMC believes that greater weight should be placed on the CDC NHSN measures for hospitals that report this data. We also recommend that CMS transition away from claims-based measures once clinically-validated measures are available for all hospitals.

We urge CMS to revise the PSI measures so that they are more appropriate for comparisons across hospitals and do not disproportionately discriminate against hospitals with large surgical caseloads. Possible revisions could include developing a new composite measure which would remove the overlap in measures with the CDC NHSN data or revising the denominator of the measures. The AAMC would be happy to work with CMS and other stakeholders to develop a more appropriate claims-based measure.

Domain 2: CLABSI and CAUTI

CMS proposes to include two CDC NHSN measures in the HAC program starting in FY 2015: Central Line Associated Blood Stream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI). The AAMC supports the inclusion of these two measures, given that they are vetted, well-tested, publicly reported, and clinically-validated. These measures are also NQF endorsed and MAP approved. The AAMC believes that because these measures are clinically-validated, they are a better alternative to claims-based measures.

Surgical Site Infections (SSI)

Starting in FY 2016, CMS proposes to expand Domain 2, to include a measure of surgical site infections (SSI), which would be stratified by surgery site: SSI following colon surgery and SSI following abdominal hysterectomy. This measure is endorsed by the NQF and approved by the MAP. While the rates of SSI have declined, there is still significant variability in reporting and number of infections across surgical procedure types. Therefore, the AAMC believes this

measure is more suited to the VBP program where a hospital can receive credit for improving its individual score. In addition, as noted earlier, the AAMC does not support measures in both the HAC and VBP; therefore the AAMC does not support this measure for the HAC program.

Methicillin-resistant Staphylococcus aureus (MRSA)/Clostridium difficile (C. difficile)

CMS proposes to continue expanding the CDC NHSN measures to include Methicillin-resistant Staphylococcus aureus (MRSA) and *Clostridium difficile* (*C. difficile*) in FY 2017. The AAMC believes it is important to measure MRSA and *C. difficile* rates, but it is premature to include these measures in either the HAC or VBP program. These measures should be given time to be evaluated in the IQR program first. The MAP also recognizes that these measures may not be ready for use in a performance program. At this point, the MAP did not fully "support" these measures for VBP and HAC, instead opting to "support direction" of the measure. They indicated that the measures were not yet ready for implementation in VBP and HAC. The AAMC does not support these measures for HAC or VBP at this time.

Proposed Scoring and Weighting

CMS proposes a scoring mechanism where hospitals are rated from 0 to 10 on each measure, where 10 represents worst performance. Hospitals that are not in the worst quartile for a measure would receive zero points. Hospitals in the worse quartile would receive a score from 1 to 10 based on where their rate falls within the quartile. This score is calculated by taking values in the worst quartile and dividing them into deciles. If a hospital's performance score falls in the lowest decile (which is the best performance in the quartile), then a hospital would receive 1 point. A hospital with a score in the top decile receives 10 points. For measure PSI-5 (Foreign Object Left in Body), the scoring is slightly different. Hospitals have a zero score if there are no occurrences and score 10 points if the hospital had any occurrences in the reporting period. Hospitals need to have at least three complete measures to have a Domain 1 score. Hospitals also need at least one measure in Domain 2 to have a Domain 2 score.[15] For hospitals that have Domain 1 and Domain 2 scores, each domain is weighted equally.

One of the AAMC's concerns with CMS' proposed methodology is that the probability of being penalized increases with the hospital's bed size. As you can see from Table 1 below, there is a strong correlation between bed size and the likelihood that a hospital will be penalized under the HAC program.

[15] Hospitals that are eligible to report Domain 2 measures and do not report an ICU waiver will automatically receive 10 points.

Table 1: Percent of Hospitals Penalized by Bed Size Using CMS' Proposed Scoring Methods

Hospital Bed Size	Percentage of Hospitals Penalized
Under 50	7.2%
50-99	15.5%
100-199	26.8%
200-299	37.3%
300-399	39.9%
400-499	47.6%
500 or more	51.7%

Source: 78 Fed. Reg. at 27807.

CMS' impact analysis confirms that this correlation with size appears to hold true for the claims-based PSI measures. For both the original and alternative Domain 1 measures, the proportion of hospitals in the worse performing quartile increases with bed size. The correlation does not appear to hold true for the measures in Domain 2, where poor performance are not strictly tied to hospital bed size.

Table 2: Percent of Hospitals in Worst Quartile for Domains 1 & 2 by Bed Size

Hospital Bed Size	Domain 1 (6 PSIs)	Domain 1 Alternative (PSI Composite)	Domain 2 (CDC NHSN Measures)
Under 50	9.1%	11.1%	2.6%
50-99	21.1%	23.5%	8.0%
100-199	21.5%	15.3%	40.7%
200-299	23.6%	27.1%	36.4%
300-399	34.2%	34.2%	33.1%
400-499	46.0%	50.0%	34.3%
500 or more	51.7%	49.8%	5.2%

Source: 78 Fed. Reg. at 27803, 27805.

As noted above, the AAMC believes that the CDC NHSN measures are better, because they are clinically-validated, sufficiently risk-adjusted, and are NQF endorsed and MAP approved. However, we also understand that not all hospitals will have a Domain 2 score. The AAMC conducted a preliminary analysis that suggests poor performance in the two domains is not correlated. A hospital that does poorly in Domain 1 may not necessary perform poorly on Domain 2, and vice versa. In fact, less than 10 percent of the hospitals fall into the worst performance quartile for measure scores in both Domain 1 and Domain 2. See Table 3 below.

Table 3: Distribution of Performance for Hospitals that Have Measures in Domains 1 and 2

	Worst Performance Quartile for Domain 2	Not in Worst Performance Quartile for Domain 2	Total # of Hospitals
Worst Performance Quartile for Domain 1	192 (9.7%)	573 (29.0%)	765 (38.7%)
Not in Worst Performance Quartile for Domain 1	308 (15.6%)	902 (45.7%)	1210 (61.3%)
Total # of Hospitals	500 (25.3%)	1475 (74.7%))	1975 (100%)

Source: AAMC analysis based on KNG Estimates. Quartiles were assigned based on all hospitals that had a complete score. For Domain 1, 868 hospitals were identified in the worst quartile. For Domain 2, 500 hospitals were classified in the worst quartile.

When there is a discrepancy in the performance across the two domains, the AAMC does not believe that both domains should have equal weight. The Domain 2 measures are clinically-validated, whereas Domain 1 measures are not. In addition, Domain 1 performance appears to be correlated to size. **Therefore, AAMC strongly believes the clinically validated measures in Domain 2 should have substantially more weight.**

HOSPITAL VALUE-BASED PURCHASING

VBP Quality Measure Recommendations

FY 2016 Measures

CMS proposes to adopt three new measures and remove three measures from the VBP program starting in FY 2016. In addition, CMS also proposes to re-adopt the CLABSI measure for FY 2016 that was previously adopted in FY 2015 because CMS is still waiting for NQF to review the measure's reliability adjustment.

Measures for Removal

The three measures recommended for removal are: primary PCI received within 90 minutes of arrival; blood cultures performed in ED prior to initial antibiotic; and heart failure discharge instructions. All three measures are proposed for removal because they are no longer NQF endorsed, are topped-out, or evidence shows that that the measures are not leading to improved outcomes. The AAMC supports the removal of these three measures.

Proposed Measures

Influenza Immunization (IMM-2)

CMS proposes to include one chart-abstracted prevention measure starting in the clinical process of care domain: Influenza Immunization. This global immunization measure addresses inpatients age 6 months and older who were screened for influenza immunization status and vaccinated prior to discharge. The measure is NQF endorsed and MAP approved. **The AAMC supports the inclusion of this measure into the VBP program.**

Surgical Site Infection (SSI)

CMS proposes to include two additional hospital-acquired infection measures for inclusion in the VBP program starting in FY 2016 that would be collected via the National Healthcare Safety Network (NHSN). The first proposed NHSN measure is for surgical site infections. When the measure was finalized for the IQR program, it was stratified by surgery site: SSI following colon surgery and SSI following abdominal hysterectomy. For VBP, CMS proposes to keep SSI as a single measure and will score it as an equally weighted average of the measure's strata by applicable cases per stratum. This measure is endorsed by the NQF and approved by the MAP. CMS proposes this measure in the HAC Reduction Program as well as VBP; however, the AAMC does not support having measures in both programs. **The AAMC supports adding this measure to the VBP program, but not to the HAC Reductions Program.**

Catheter Associated Urinary Tract Infection (CAUTI) and Central Line Associated Blood Stream Infection (CLABSI)

The second proposed NHSN measure is CAUTI, which assesses the rates of catheter-associated urinary tract infections. CMS also proposes to re-adopt the CLABSI measure that was finalized for FY 2015, but was not subject to immediate re-adoption. Both measures have been proposed for inclusion in the HAC Reduction Program.

The AAMC believes that measuring rates of CAUTI and CLABSI is a critical aspect of managing hospital-acquired infections; however, we strongly believe that CAUTI and CLABSI should not be reported in both the HAC Reduction Program and VBP, because hospitals may be unfairly penalized twice on the same measures. **The AAMC supports these measures for the HAC Reduction Program. If these measures are eventually finalized for the HAC Reduction Program, they should be removed from VBP starting in FY 2015.**

Expansion of the CLABSI and CAUTI Measures Beyond the ICU

For CY 2014, CMS proposes to expand the CAUTI and CLABSI measure data collection beyond the ICU setting. The AAMC has reservations about such an expansion, and are also concerned about how this change would affect the VBP program. Any time a measure in VBP is modified, CMS should explain how the Agency plans to score improvement points when data in the baseline period may not match data in the performance period. While the AAMC is not recommending CAUTI and CLABSI for VBP, we believe that this principle will apply to other measures in this program.

Future Measures

Efficiency Measure Related to Rebilling Part B Claims

In the proposed rule, CMS introduces the idea of developing a future efficiency measure for inclusion in the VBP program that would assess hospitals on the rate or dollar amount for rebilling Medicare Part B inpatient services subsequent to a denial of Part A inpatient claim. The AAMC does not believe that rebilling Part B services is in any way connected to hospital efficiency. CMS should not develop a measure around this principle.

Methicillin-resistant Staphylococcus aureus (*MRSA)/ Clostridium difficile* (*C. difficile)*

CMS seeks feedback on the Agency's intent to propos*e* MRSA and *C. difficile* in the VBP program starting in FY 2017 VBP. These measures should be evaluated in IQR first. The MAP also recognizes that these measures may not yet be ready for payment. MAP did not fully "support" these measures for VBP and HAC, but only "support[ed] direction." They indicated that the measures were not yet ready for implementation in VBP and HAC. The AAMC believes it is important to measure MRSA and *C. difficile* rates, but it is premature to include these measures in either the HAC or VBP program.

CMS Should Increase the Weight for the Clinical Process of Care Domain and Reduce the Weights for the Patient Experience Domain and the Efficiency Domain

The following table summarizes the finalized domain weights for FY 2014, FY 2015, and the proposed weights for FY 2016. Over this three year period, the process of care measures will decrease in weighting from 45 percent to 10 percent, while weights for outcomes and efficiency measures will increase.

VBP Domain Weights, FYs 2014-2016

Domain	FY 2014 (Final)	FY 2015 (Final)	FY 2016 (Proposed)
Process of Care	45%	20%	10%
Patient Experience	30%	30%	25%
Outcomes	25%	30%	40%
Efficiency	n/a	20%	25%

Process of Care Domain

The AAMC appreciates that CMS wants to transition the VBP program to place greater priority on outcome measures. However, as we have commented previously, we are very concerned that the distribution of measures in the VBP program does not align with each domain's weighting. There are 10 measures proposed for the process of care domain, seven measures proposed for the outcome domain, one measure (with 8 dimensions) in the patient experience domain, and one measure in the efficiency domain. **The clinical process of care measures are still valuable. Therefore their domain weight should receive greater emphasis under the FY 2016 domain weighting scheme, and the experience and efficiency domains should receive less weight.**

Patient Experience Domain

Although the patient experience domain is proposed to decrease from 30 percent to 25 percent the AAMC believes the weight for this domain still remains too high. The Association has commented previously that the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey analysis conducted by the Cleveland Clinic, an AAMC member, indicates that this tool can produce inequitable results for subsets of hospitals, particularly those that treat severely ill or disadvantaged patient populations. Until there is more research to better understand how patient severity and socioeconomic status affects HCAHPS scores, we believe that the weighting for this domain should be reduced further. This lower weighting would recognize the importance of patient experience without unduly penalizing hospitals solely because of their patient population.

The AAMC has additional concerns regarding the increasing length of the HCAHPS survey and the overlap with current and new proposals to measure patient experience in other care settings. There are patient-experience of care surveys for physicians, hospitals, nursing homes, and home health agencies. In addition, CMS has also proposed to add the emergency department (ED), outpatient departments, ambulatory surgical centers, and hospice care as patient care settings to receive such a survey. Those who receive overlapping care in these settings could receive multiple surveys, leading to confusion for the patient as to which clinicians or facilities are being assessed. This is especially true if a separate ED survey is implemented, as there are ED specific questions on the current HCAHPS survey. Compounding this problem is the fact that surveys

are not distributed until days or even weeks after patients have received care. The confusion may have an impact on the ratings, which is a significant concern for providers when these tools are being used in pay-for-performance programs. The AAMC requests that CMS take steps to prioritize the development of these survey tools to a limited subset of provider settings until the issue of overlapping of care is resolved.

Lastly, in the FY 2013 IPPS rule, CMS finalized additional questions in the "About You" section of the HCAHPS, asking patients if he or she was admitted to the hospital through the emergency room and would also be asked to provide an assessment of his or her overall mental or emotional health. The proposed rule also does not address how these questions would be incorporated into the patient-mix adjustment. The AAMC requests additional clarification on how the patient mix adjustment would be modified based on these questions.

Efficiency Domain

The AAMC is concerned that increasing the proposed weighting of the efficiency domain, which still contains only one measure, Medicare Spending Per Beneficiary (MSPB), puts an unacceptable amount of a hospital's performance at risk for factors that may be difficult for a hospital to control. This risk is compounded by the way the measure is translated into points for VBP.

In VBP, hospitals are rewarded achievement points for having a score greater than the threshold (median performance for all hospitals.) Hospitals also get points for improving their own score relative to their historical performance period. The final VBP score for a measure is the greater of the achievement or improvement points.

For most VBP measures, a hospital knows what achievement threshold is required to attain achievement points, as well as what performance is needed to earn improvement points. However, the MSPB measure is a ratio, where the amount a hospital spends is relative to national spending, and not relative to a hospital's individual performance. (A value less than one means the hospital spending is less than national spending. A score of one is no different from national spending, and a score greater than one is greater than national spending.) Because hospital spending is compared to a national threshold, performance is not relative to one's prior performance. Rather scores are based on how well a hospital improves compared to all other hospitals. This makes earning improvement points particularly challenging.

One of our member hospitals recently shared with the AAMC its May 2013 MSPB Hospital Specific Report. According to the report, the hospital's MSPB score is 0.99, less than the national spending amount and an indication that the hospital is relatively efficient. In this report,

the median MSPB score for all hospitals is 0.98. Because 0.99 is higher than the median, this hospital will not receive any achievement points. Because this hospital also had an MSPB score of 0.99 in its previous reporting period (and the rate did not decrease), they also receive zero improvement points. Effectively this hospital, for which spending is **less than** the national spending amount, would receive zero points for the efficiency domain. Its efficiency score could be the same as the most expensive hospital. If the FY 2016 weights were finalized, this "zero" score for a fairly efficient hospital would affect 25percent percent of its performance score.

It is unclear how hospitals can improve their MSPB scores without displacing other hospitals. CMS has not yet released the updated hospital-specific MSPB files on Hospital Compare, so the AAMC cannot comment further on how many hospitals were able to improve and change their scores. In addition, the MSPB measure is not yet NQF-endorsed. At a recent NQF steering committee meeting, none of the participants voted that this measure had high validity.

The AAMC is extremely concerned that the MSPB measure and the VBP scoring of the measure may generate unexpected consequences. Until these issues are known, CMS should **not** increase the efficiency domain. **In fact, the Agency should reduce the weight of this domain to no more than 5 percent.** There are too many unknowns with the efficiency measures to increase the weight at this time. **We also believe that the VBP scoring for this measure may need to be modified moving forward to more accurately weight a hospital's efficiency performance.**

Domain Alignment with the National Quality Strategy Is Premature

Starting in FY 2017, CMS proposes to reorganize the VBP quality measure domains to align with the National Quality Strategy (NQS) domains. CMS proposes to regroup measures by domain areas that align with the NQS, including: patient and caregiver centered experience of care/care coordination, patient safety, efficiency and cost reduction, and clinical care. As proposed for FY 2017, CMS intends to place the CAUTI, CLABSI, AHRQ Composite, and SSI measures in a patient safety domain and weight it at 15 percent. The mortality measures and the process of care measures would be placed in the clinical care domain. Mortality measures would be weighted 25 percent and clinical care process measures would still be weighted at 10 percent, for a total domain score of 35 percent. The efficiency domain would have one measure (MSPB) and the new consolidated patient experience domain would continue to report only HCAHPS. Those two domains would retain the same weight at 25 percent.

In the previous section, the AAMC outlines its comments on the weighting for VBP domains. In general, we feel the clinical process of care measures should be weighted more and the patient experience and efficiency measures weighted less than what is outlined for FY 2017. The AAMC also supports the alignment of quality reporting programs using the NQS to achieve a

long-term goal. The use of the domains can assist in identifying measure gaps in particular domain areas and highlight areas for measure development. However, the AAMC sees some potential challenges with shifting the VBP domains to the NQS framework for payment purposes.

The biggest challenge is that not all domains may have a sufficient number of measures. Under CMS' proposal, there is only one measure in the Care Coordination/ Person and Caregiver Centered Experience and Efficiency domains. The AAMC believes that measures should not be in both the VBP and HAC Reduction Program, which means the number of measures in the proposed patient safety domain may be limited as well.

The AAMC believes it is premature to realign the measures into different domains for purposes of payment determination at this time. Until there is an adequate number of NQF endorsed and MAP approved measures for each domain, CMS should not transition to a new domain structure for payment purposes.

VBP Disaster Waiver Should Be Finalized with a Minor Modification

In the rule, CMS proposes to implement a VBP disaster waiver to temporary exempt hospitals from the VBP program that face extraordinary circumstances, such as a natural disaster. The waiver will be modeled after the IQR waiver, and CMS has said that a reprieve under the waiver program would be used sparingly. The AAMC supports the implementation of the VBP disaster waiver; however, we ask that CMS extend the requirement to submit the waiver from 30 to 60 days.

Baseline and Performance Periods Should Be Consistent and Reliable

The AAMC recognizes that some measures require longer reporting periods to obtain reliable sample sizes. CMS should reconsider how achievement and improvement scores are calculated when it takes years to show a change in score. VBP is aimed at capturing year over year improvement. When longer baseline and performance periods are used, hospitals are disadvantaged by performance in earlier periods. CMS should consider the feasibility of giving greater weight to more recent data in calculating hospital performance on measures when using multi-year data.

CAUTI, CLABSI, and SSI Measures

CMS did not include the baseline and performance periods for the CAUTI, CLABSI, and SSI measures for the FY 2016 VBP program. The AAMC asks that CMS include this information in an extension of the rulemaking process.

Mortality Measures

For FY 2017, CMS proposes to use an 18-month performance period to report the three 30-day mortality measures in the VBP program. While this is an improvement on the 9 month reporting period that CMS finalized for FY 2016, the length of time is still too short to determine reliability. According to an independent analysis conducted by Mathematica Policy Research, a CMS contractor, less than half of hospitals achieve reliability with 24 months of data. The AAMC supports the proposal to extend the mortality time periods for FYs 2018 and 2019 and believes the longer time period should be adopted sooner.

AHRQ PSI Composite Measure

CMS has proposed unequal baseline and performance periods for the AHRQ composite measure for FY 2016. The baseline for the measure is 8.5 months (October 15, 2010, through June 30, 2011) and the performance period is 20.5 months (October 15, 2012, through June 30, 2014). The AAMC asks CMS to ensure that the baseline and performance periods are equal.

The Transition from ICD-9 to ICD-10 Codes Should Be Considered

The ICD-10-CM/PCS is currently scheduled to begin October 1, 2014. CMS does not address how the hospital performance may change for pay-for-performance programs when ICD-10-CM/PCS codes begin to be used for claims-based measures. The AAMC asks that CMS to release a plan that outlines how the Agency will measure hospitals during this time of transition. It would be inaccurate to compare a hospital's measurement results using ICD-9-CM in the baseline period and ICD-10-CM/PCS in the performance period.

HOSPITAL READMISSIONS REDUCTION PROGRAM

The first penalties for excess readmissions were levied in FY 2013. In the initial year, payment reductions were based on the readmission rates for acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PN). The percent payment reduction is applied to every DRG payment with a cap of one percent in the first year. In our comments last year, the AAMC expressed our concerns with the current Readmissions Reduction Program, including the lack of adjustment for socio-economic status (SES) and the failure to exclude planned and unrelated

readmissions. In this rule, CMS proposes to expand the measures included in the readmissions program and to adjust for planned readmissions. However, CMS does not propose to adjust the methodology for SES factors.

Reducing readmissions is a major priority for all hospitals; however, fully understanding what causes readmissions is a complex issue. The AAMC is leading efforts to understand and reduce preventable readmissions in our member institutions. Through the AAMC/UHC Best Practices for Better Care (BPBC) initiative, teaching hospitals are working to ensure that high risk patients receive proper follow-up care after a hospitalization. BPBC participating sites are implementing best practices, including contacting all high-risk patients within 72 hours of discharge to review their care instructions and confirming that they understand the plan for follow-up care. Teaching hospitals are currently in the early stages of establishing new and innovative programs to reduce unnecessary readmissions. Adding penalties as these programs are being established will place additional strain on hospitals before they are given a chance to succeed.

Readmission Methodology Should Incorporate Socio-Economic Status (SES) Indicators

The AAMC is disappointed that CMS did not propose to adjust or stratify readmission rates by SES factors. The failure to include such an adjustment has led to an unlevel playing field based on characteristics that are beyond the control of the hospital. In our FY 2013 IPPS comments, the AAMC outlined specific proposals for implementing a fair methodology that properly accounts for SES without giving hospitals a "pass" to provide poor quality care. Hospitals will still have to perform better than expected compared to other hospitals with their relative patient populations to avoid penalties.[16] We continue to strongly recommend that CMS adopt a patient-level or hospital-level adjustment, stratifying by either dual-eligible status or by DSH patient percentage, to ensure that institutions that treat medically complex and disadvantaged patients are not unfairly penalized by the Readmissions Reduction Program.

The Medicare Payment Advisory Commission (MedPAC), in its 2013 June Report to Congress, echoed our concerns that higher readmissions are positively correlated with low-income populations. In the report, MedPAC suggests measuring readmission rates among hospital peer groups, which are defined by the hospital's share of beneficiaries on supplemental security income (SSI). While this alternative was not a formal recommendation, it does illustrate the need for an adjustment. The AAMC asks that CMS consider the alternative discussed by MedPAC as one way to account for SES factors.

[16] https://www.aamc.org/download/295512/data/aamccommentletteronfy2013ippsproposedrule.pdf.

Planned Readmissions Should Be Excluded

Starting in FY 2014, CMS proposes the inclusion of a planned readmissions algorithm to identify, and therefore not count, certain planned readmissions that follow an index admission. The algorithm was developed based on a hospital wide cohort of patients using AHRQ's Clinical Classification Software and will apply to AMI, PN, and HF. These updated measures have been endorsed by the NQF. For FY 2015, CMS proposes that the algorithm will use a revised list of planned procedures for the Total Hip Arthroplasty and Total Knee Arthroplasty readmission measures. The AAMC supports the inclusion of this algorithm for the readmission program.

CMS also proposes a change in the methodology that would not count readmissions that occurred after a planned readmission within the 30-day period following the index admission. The AAMC supports this change as well.

The AAMC also asks CMS to refine the measures to exclude certain unrelated admissions that typically represent extreme circumstances and often are beyond the control of a hospital. These include transplants, ESRD, burns, trauma, and psychosis or substance use.

New Readmission Measures Should Be Reported in the IQR Program First

FY 2015 Measures

The statutory language in the ACA states that CMS shall "to the extent possible" expand the number of readmissions measures to include four conditions (coronary artery bypass (CABG), chronic obstructive pulmonary disease (COPD), percutaneous coronary intervention (PCI), and other vascular conditions) identified by MedPAC in its Report to Congress in June 2007. CMS did not propose readmission measures for PCI and other vascular conditions, noting that creating inpatient readmission measures for these categories may not be feasible, because these procedures occur more often in the hospital outpatient setting. The AAMC agrees with the Agency's assessment. CMS is also contemplating how to incorporate CABG readmission measure in the future.

CMS proposes to include two new readmission measures in FY 2015: 1) COPD and 2) Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA). The AAMC believes that all measures should be reported in the IQR program before being used in a payment program. The THA/TKA measure is scheduled to be reported in IQR for FY 2015 and the COPD readmission measure is proposed not to be in IQR until FY 2016. The AAMC recommends implementing the COPD readmission measure (with caveats, which are listed in the IQR section) in IQR starting in 2015. Because it takes up to 18 months for data processing and reporting, if these measures are reported in the IQR in FY 2015, they should not be considered for the readmission program until

2017. The AAMC also urges CMS to incorporate SES into the risk-adjustment methodology, and to exclude unrelated readmissions for these measures.

INPATIENT QUALITY REPORTING (IQR) PROGRAM

All Performance Program Measures Should Be Publicly Reported in IQR First

As discussed above, the AAMC strongly believes that all quality measures should first be reported in the IQR program for a minimum of one year before being proposed in any performance program. Publicly reporting measures in the IQR program allows stakeholders to gain experience submitting the measures, and allows time to identify errors, unintended consequences, or other concerns with measure methodology. The VBP statutory language requires all measures in the program to be first publicly reported in the IQR program for the reasons outlined above. We ask CMS to extend this requirement for measures proposed for the Readmissions and HAC Reduction Program as well.

CMS Should Not Adopt a Star Rating System

In the proposed rule, CMS discusses the possibility of moving to a star rating system to evaluate hospitals on Hospital Compare. The AAMC strongly opposes the use of a star rating system, which may make inappropriate distinctions for hospitals whose performance is not statistically different. A star rating system can also exaggerate minor performance differences on measures. The AAMC would be happy to work with CMS to identify other methods to make Hospital Compare more user-friendly and accurate for consumers.

IQR Quality Measure Recommendations

The AAMC supports CMS' proposal to remove eight measures (seven chart abstracted and one structural) that are topped out, do not lead to improved outcomes, or cannot be feasibly implemented. These eight measures are:

IQR Measures Proposed for Removal Starting FY 2016

Topic	Measure
Acute Myocardial Infarction	• Aspirin prescribed at discharge (AMI-2) • Statin prescribed at discharge (AMI-10)
Pneumonia	• Blood culture performed in the emergency department prior to first antibiotic received in hospital (PN-3b)
Heart Failure	• Discharge instructions (HF-1) • ACEI or ARB for LVSD (HF-3)
SCIP	• Surgery patients with perioperative temperature management (SCIP-Inf-4)
Immunization	• Immunization for pneumonia (IMM-1)
Structural Measure	• Participation in a systematic clinical database registry for stroke care

While CMS proposes the removal of these measures starting in FY 2016, we ask that they be removed from IQR and Hospital Compare immediately, barring any concerns with unintended consequences that may result from their removal, particularly for the two measures that are in the VBP program (PN-3b and HF-1).

CMS also proposes minor refinements to four measures in the IQR program. CMS has proposed to incorporate the planned readmissions algorithm into the 30-day readmissions measures finalized in FY 2014 and 2015. These measures include AMI, HF, PN, THA/TKA and the Hospital-wide readmission measures. The AAMC supports the inclusion of the planned readmissions algorithm; however, we also ask CMS to incorporate SES into the risk-adjustment methodology for these measures, as described under the Readmissions Reduction section of our comments.

CMS plans to adopt the revised specifications for SCIP Inf 4: Controlled 6AM Glucose for Cardiac Surgery Patients and revisions to the MSPB measure to include Railroad Retirement Board beneficiaries. The AAMC supports the proposed refinements to these two measures.

Expansion of CAUTI and CLABSI

The Agency also proposes to expand CLABSI and CAUTI data collection to select non-ICU locations starting with discharges on January 1, 2014. The Association has reservations about the ability and burden for all hospitals to comply with this expansion.

FY 2016 Measures

Starting in FY 2016, CMS proposes to add five new claims based measures: Hospital 30-day All-Cause Risk Standardized Readmissions Rate following COPD Hospitalization, Hospital 30-day All-Cause Risk Standardized Mortality Rate following COPD Hospitalization Risk, Hospital 30-day All-Cause Risk Standardized Readmissions Rate following an Admission for Acute Ischemic Stroke, Hospital 30-day All-Cause Risk Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke, and the Risk-Standardized Payment Associated with a 30 Day Episode of Care for AMI.

Stroke Readmissions and Mortality Measures

The AAMC has serious concerns with the stroke readmission and mortality measures. These measures are not NQF endorsed, were not recommended by the MAP, and have not been validated. The measure developer withdrew the measures from NQF consideration to reevaluate their approach to the risk-adjustment methodology. The AAMC does not support these measures for IQR.

COPD Readmissions and Mortality Measures

As stated earlier, CMS proposes to add the 30-Day All Cause COPD Readmissions measure to the Readmissions Reduction Program starting in FY 2015, and to the IQR Program in FY 2016. The AAMC supports efforts to reduce COPD readmissions, and this measure is NQF endorsed and MAP approved. Moreover, we strongly believe that all measures should be reported in the IQR program before being used in a performance program. Therefore, the Association supports inclusion of the readmission measure (with modifications) in the IQR program for FY 2015, and not in the Readmissions Program before FY 2017. We reiterate the Association's objection to CMS' not adequately adjusting for socio-economic status (SES) factors and believe this measure should be modified prior to implementation.

The AAMC supports the inclusion of the COPD mortality measures in the IQR program; however, we strongly urge CMS to include adequate risk-adjustment modifications to the measures that address both SES 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.

AMI Payment Per Episode of Care

Last, CMS proposes to add an AMI episode of care measure to track variation in the cost of care for AMI surrounding an AMI hospitalization. This measure is not NQF-endorsed, nor was it

supported by MAP (MAP did support the direction, but required NQF endorsement). The AAMC is concerned that this measure is another variant of measures used for other Medicare programs. For example, the Bundled Payment for Care Improvement (BPCI) Initiative has logic for measuring costs around an AMI admission. Similarly, CMS is developing an episode grouper for physician measurement. It is unclear how this AMI measure relates to these other measures.

Alignment of IQR and MU Programs

CMS has proposed an initiative to allow hospitals to electronically report 16 measures in the IQR program in CY 2014. These 16 measures include eight stroke measures, six venous thromboembolism measures, one perinatal care measure, plus one of two emergency department measures. Hospitals would electronically report at least one quarter of their CY 2014 quality measure data for these measures, and could choose to use this electronically reported data to fulfill the requirements of the EHR incentive program. While the proposed program is voluntary, CMS intends to make electronic reporting mandatory for select measures in next year's IPPS rule.

The AAMC appreciates that CMS has listened to stakeholders' concerns and comments about electronically reporting EHR measures. The proposed EHR reporting option is voluntary and removes some previous barriers to alignment. The proposal also recognizes that data extracted from an EHR may not be accurate enough for public reporting or pay-for-performance programs.

Unfortunately, the AAMC believes the proposal focuses more on electronic submission and less on the accuracy of the information. An alternative approach is allowing hospitals to receive credit when they either: 1) pull quality data from an EHR and allow a chart abstractor to validate that information in the IQR specifications, or 2) have a chart abstractor use the EHR to pull the required data with the IQR specifications. Ultimately, the AAMC believes that new measures developed specifically for EHR reporting will need to be developed and tested. However, with these options, the focus is on receiving information that is correct and using the EHR as a tool, rather than the reverse.

QUALITY REPORTING PROGRAMS FOR OTHER FACILITIES

PPS Exempt Cancer Center Hospital Quality Reporting (PCHQR) Recommendations

As CMS continues to implement and expand the PCHQR program, the Agency should consider the relative value and associated burden of reporting measures. In particular, CMS should consider the appropriateness of cancer-specific measures, particularly outcome measures. CMS should also consider implementing a sampling protocol, similar to IQR, to minimize burden.

Inpatient Psychiatric Facility Quality Reporting Program (IPFQR) Recommendations

The AAMC does not support two of the proposed measures: 1) Alcohol and Drug Use Status after Discharge; 7 and 30 days, and 2) Follow-up after Hospitalization for Mental Illness; 7 and 30 days. The Alcohol and Drug Use Status 7 and 30 days after Discharge is not NQF endorsed and requires contacting each patient after discharge. Follow-up after Hospitalization for Mental Illness is specified by the steward for either collection through chart abstraction or calculation using claims/administrative data. Hospitals do not have access to claims data or to outpatient services provided outside their institution or system, creating a significant barrier to data collection.

ADMISSION AND MEDICAL REVIEW CRITERIA OF HOSPITAL INPATIENT SERVICES UNDER MEDICARE PART A

CMS makes a number of proposals and clarifications regarding admissions policies and criteria for medical review for hospital inpatient services. These proposals stem from the Agency's concern about the increase in the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours. CMS notes that "the trend towards the provision of extended observation services may be attributable in part to hospitals' concerns about Medicare's payment policy for billing under Part B when a Part A hospital inpatient claim is denied because a Medicare review contractor determines that the inpatient admission was not reasonable and necessary under section 1862(a)(1)(A) of the Act."

As discussed in detail below, the AAMC has concerns regarding CMS' proposed requirements for physician orders for inpatient stays, proposed guidelines for inpatient admissions, and proposed payment adjustment. The AAMC also urges CMS to use the Agency's regulatory authority to count observation days when determining whether the three-day requirement for skilled nursing facility (SNF) coverage is met.

CMS Should Modify Requirements for Physician Orders for Inpatient Stays So Supervised Residents in Approved Training Programs Can Meet the Criteria

CMS proposes revising the Condition of Participation found at 42 CFR §412.3(b) that "the hospital inpatient admission order must be furnished by a physician or other specified practitioner." The AAMC requests that CMS specify that an order by a resident who is in an

approved training program and admits a patient while under the supervision of an attending physician will meet these criteria.

It is a common and regular occurrence at teaching hospitals for residents to admit patients and is done in accordance with state licensure, practice requirements and hospital by-laws. The attending physician is the patient's physician of record, while the resident proceeds with all necessary tests, orders and initial treatment for admission of the patient to the inpatient setting, in consultation with the attending and other physicians. Allowing residents to admit patients under these circumstances would be analogous to CMS' decision to allow residents to sign orders and referrals and would improve the quality of care and speed of needed treatment for patients. As CMS said in the final rule, *Changes in Provider and Supplier Enrollment, Ordering, and Referring, and Documentation Requirements* (77 *Fed. Reg.* 25284):

> . . . if States allow residents who have a provisional license, or are otherwise permitted by State law to practice or order and certify services, we will permit them to enroll in Medicare to order and certify, at the direction of their teaching institution. (p. 25306)

CMS should be clear that allowing residents to admit patients is not an improper delegation by the attending physician. The resident is considered part of the care team and a benefit to patients. Additionally, residency is a necessary and required part of every physician's training.

CMS' Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A Should be Revised

The AAMC appreciates CMS' attempts to address the serious problems for hospitals and beneficiaries caused by contractor denials of one-day inpatient stays. While the Agency puts forth a proposal to address the problem, the proposal does not provide reassurance to either hospitals or beneficiaries that decisions made by physicians about care will not continue to be overturned frequently by Medicare contractors. Also, CMS proposes no change to the policy that observation stays will not count toward the 3-day stay that is required if Medicare is to pay for a beneficiary's care in a skilled nursing facility (SNF).

> <u>CMS Should Give Presumptive Weight to Physician Orders and Certification Unless There is Substantial Evidence of a Pattern of Inadequate or Missing Documentation</u>

CMS states that "[n]o presumptive weight shall be assigned to the physician order under §412.3 or the physician's certification . . . in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act." The Agency then describes the documentation that will be reviewed to establish that an inpatient stay was medically necessary. The AAMC

supports the need for the medical record to substantiate physician orders and certification. However, CMS should recognize that for good quality patient care, and because of the robust compliance programs hospitals have implemented to ensure that CMS requirements are followed, documentation in the medical record will be sufficient in the vast majority of cases. Therefore, the AAMC asks that CMS give presumptive weight to physician orders and certification except in cases where there is substantial evidence—such as a pattern of inadequate or missing documentation—that indicates that a review of the medical record is warranted.

CMS' Inpatient Hospital Admission Guidelines Need to Be Revised

CMS proposes that contractors would "presume" that hospital inpatient status is reasonable and necessary for beneficiaries who require more than one Medicare utilization day–*i.e.*, encounters crossing 2 midnights—after admission if in the physician's judgment, the beneficiary's length of stay would exceed a 2-midnight threshold.

CMS requests comments on the proposed method of calculating the 2-midnight requirement that would "start the clock" when the beneficiary is moved from any outpatient area to a bed in the hospital in which the additional hospital services will be provided. At high occupancy hospitals, such a those of the AAMC members, it is not unusual for a patient to have to wait several hours or more for a bed to become available, even after a physician has written an inpatient order. For example, a physician may write an inpatient order in the emergency room at 10 p.m. on a Monday night, the patient may be moved to the inpatient setting at 1 a.m. Tuesday morning, and the patient may be discharged at 7 a.m. on Wednesday morning. Under CMS' proposal, this case would not have qualified for presumptive reasonability, even though the patient required inpatient care across two midnights. Circumstances outside the control of the hospital should not result in the denial of an inpatient admission that is reasonable and necessary. **If the 2 midnight proposal is finalized, the AAMC urges CMS to make the starting point the time at which the physician orders the inpatient stay.**

Although CMS says the Agency is creating a presumption that a stay crossing 2-midnights is appropriate, it is clear CMS expects contractors to review these stays to ensure that the medical record supports "a reasonable expectation of the needed duration of the stay relative to the 2-midnight threshold." Even with this new policy, the reality seems to be that hospitals can expect little change in audit activity. Hospitals will remain at risk for having these stays reviewed and will remain concerned that despite their best efforts, the stay will be denied.

The Agency also makes clear that if the 2 midnight threshold is not crossed, "the services would be generally inappropriate for payment under Medicare Part A" and that "medical review efforts

will focus on those inpatient hospital admissions with lengths of stay crossing only 1 midnight or less." These instructions leave contractors with a very subjective decision about whether these stays were appropriate for inpatient admission.

The Agency also notes that audits are to be expected for hospital admissions greater than 2 midnights and will focus on "undue delays in the provision of care in an attempt to meet the 2-midnight threshold . . ." **The AAMC urges CMS to be clear that Medicare contractors will be directed to audit stays of 1 midnight or less, 2-midnights, or 2-midnight stays that are longer than expected, only if a pattern of abuse is detected. CMS also must change the audit criteria contractors are expected to use, so they are consistent with the policy that is adopted in the final rule.**

Finally, CMS proposes that even if the physician's expectation of a 2-midnight stay is fully supported by appropriate documentation, transfer or death that result in a shorter stay will be deemed exceptions to the 2-midnight rule. The AAMC supports these exceptions.

CMS Should Use the Agency's Regulatory Authority to Count Observation Days When Determining Whether the 3-Day Requirement for SNF Coverage is Met

CMS' proposed policy regarding medical review criteria addresses the issue of denials of certain inpatient stays, but it fails to address a problem that falls particularly hard on beneficiaries—observation stays are not counted for the 3-day stay that is required for Medicare coverage of a beneficiary's skilled nursing care. When a beneficiary does not meet the 3-day requirement, Medicare will not pay for the skilled nursing stay, even if it is medically necessary. When CMS published the proposed rule, *Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006* (70 *Fed. Reg*. 29070), the Agency solicited comments about whether observation days should be counted for the 3-day requirement. At that time, the Agency noted that practice and treatment of observation time may have changed and that "the effect of not counting this observation time under the existing policy ultimately might be to restrict SNF coverage to a narrower segment of the beneficiary population than Congress originally intended" 70 *Fed. Reg*. 29099. CMS chose not to finalize this proposal, saying "we note that we are continuing to review this issue, but are not yet ready to make a final determination at this time." 70 *Fed. Reg*. 45050. Eight years later, this issue continues to plague Medicare beneficiaries—and the providers who care for them—as many continue to be denied coverage for needed stays in SNFs. CMS has demonstrated that the Agency can change current policy through regulation, particularly when the change reflects current health care practice. **The AAMC urges CMS to take this opportunity to revise the regulation and allow observation stays to count toward**

the 3-day requirement. This proposal received adequate comment in 2005 and should now be finalized.

CMS' Proposed Payment Adjustment Based on the 2-Midnight Proposal is Unprecedented and Cannot be Verified

The AAMC strongly opposes CMS's proposal that the 2-midnight policy requires a reduction in the standardized amount by 0.2 percent. This proposed payment adjustment is against all IPPS precedent, and it is questionable whether CMS has the authority to take it. Support for this proposed reduction rests on actuary estimates. However, CMS has not shared the data used for these estimates, and it has not been possible to replicate the finding that this change will result in a $220 million in additional IPPS expenditures. Therefore, the AAMC requests that CMS not finalize this proposed reduction.

THE MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

CMS Should Gradually Implement 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 to the extent that higher payments have resulted from more cases being assigned higher-weighted DRGs since the transition to MS-DRGs without evidence of a change in a hospital's real case mix, the Agency should recoup these higher payments. 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. We urge 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 -0.8 percent recoupment adjustment to begin to recover the $11 billion required by the ATRA. CMS estimates that this proposed adjustment would recover almost $1 billion in FY 2014. While CMS does not propose a prospective adjustment, the proposed rule states that if CMS were to apply an additional prospective adjustment, it would be -0.55 percent.

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 Mr. 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.

REVISED MS-DRG WEIGHTS/COST CENTERS

CMS Should Not Finalize the Proposed CT and MRI Cost-to-Charge Ratios (CCR)

In recent years, CMS has added four cost centers to the cost report to get a better understanding of the costs associated with specific services. In the FY 2009 inpatient PPS final rule, CMS split the medical supplies cost center into two – one for relatively inexpensive medical supplies and another for more expensive devices (such as pacemakers and other implantable devices). In the FY 2011 inpatient PPS final rule, CMS split the general radiology cost center into three – one for general radiology, one for magnetic resonance imaging (MRI) scans and another for computed tomography (CT) scans. The FY 2011 IPPS rule also finalized splitting cardiology into two categories: cardiology and cardiac catheterization.

CMS now proposes to add these four new cost centers to the calculation of MS-DRG relative weights starting in FY 2014. This proposal would increase the number of cost-to-charge ratio (CCR) categories from 15 to 19. The AAMC is particularly concerned about adding the two new radiology CCRs. Although a large number of hospitals are reporting the new cost centers, AAMC members have noted that the capital costs for CT and MRI are not applied consistently. For example, some hospitals do not directly allocate capital expense, but rather allocate by the square foot, which undercounts the relatively high capital costs for CT and MRI machines. Other hospitals have difficulty separating out the CT and MRI costs from the general radiology costs.

These variations in applying costs could distort the relative value of advanced imaging services. CMS estimates if the Agency uses three CCRs (one general radiology, MRI scans, and CT scans), general radiology would have a relative weight of 0.170, but MRI and CT scan CCRs would be reduced to weights of 0.091 and 0.045, respectively. These levels seem exceptionally low and do not pass face validity. The new CCRs could affect outpatient fees as well as physician office fees and could result in a CT of the abdomen or head being reimbursed at a similar level to a routine chest X-ray. This distortion would also underpay MS-DRGs that rely on these services for proper patient care. For example, the six MS-DRGs that would experience the most decreases from this proposal are trauma and concussion.

Inaccuracies in the relative weights result in distortions in the payment system. The AAMC has serious concerns about the validity and accuracy of the CT and MRI CCR, and urges CMS to reconsider adopting them. The Association also asks CMS to consider if there are similar issues with other new cost centers.

ADD-ON PAYMENTS FOR NEW SERVICES AND TECHNOLOGIES

Each year, new technologies may be considered for add-on payments if they meet the established criteria for newness and the DRG prospective payment otherwise applicable to the discharge is deemed inadequate. For FY 2014, CMS proposes that three new technologies from FY 2013 will continue to receive the add-on payment: Voraxaze®, DIFICID™, and Zenith®F. Graft. CMS proposes new technology payments for five new technologies for FY 2013, though the Agency seeks comments on a variety of issues related to each: Kcentra™, Argus®II Retinal Prosthesis System, RNS® System, Zilver®PTX®, and MitraClip® System. The AAMC supports add-on payments for these new technologies to ensure accurate payment.

OUTLIER PAYMENTS

Inpatient PPS, hospitals receive an outlier payment if the costs of a particular Medicare case exceed the relevant MS-DRG operating and capital payment (including any disproportionate share hospital (DSH), indirect medical education (IME), or new technology add-on payments) plus an outlier threshold. This sum is referred to as the outlier "fixed-loss cost threshold." To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's cost to charge ratio (CCR) is applied to the total covered charges for the case to convert the charges to estimated costs. Payments are then made based on a marginal cost factor, which is equal to 80 percent of the case's estimated costs above the threshold calculation.

The outlier fixed-loss cost threshold is set at a level that is intended to result in outlier payments that are between 5 and 6 percent of total operating DRG payments plus outlier payments. Outlier payments are budget neutral. Each year, the Agency finances 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. For FY 2014, CMS continues to set the target for total outlier payments at 5.1 percent of total operating DRG payments.

For a number of years, CMS has received comments from many stakeholders, the AAMC included, regarding the accuracy of the Agency's methodology for calculating the outlier threshold. In the FY 2013 IPPS proposed rule, CMS welcomed comments on ways to enhance the accuracy of the calculation methodology for the outlier fixed-loss cost threshold. 77 *Fed. Reg.* at 28144. The Agency received many comments regarding this policy and is proposing revisions for FY 2014 and subsequent years.

CMS proposes two key changes in the proposed rule. First, for FY 2014, CMS proposes a new methodology to inflate charges using a one-year period of the most recent charge data. CMS

believes this will provide a more stable projection for the average charge per case, because the increased data in the one-year period leaves the measure less subject to fluctuations due to any single case. Second, CMS proposes a simpler methodology for CCR adjustment. CMS proposes to adjust the CCRs from the December 2012 update of the Provider Specific File (PSF) by comparing the percentage change in the national case-weighted operating CCR and capital CCR from the December 2011 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2012 update. The AAMC supports these changes in methodology that aim to increase the accuracy of the outlier threshold. We appreciate CMS' acknowledgement that the methodology needed refining, and, should this policy be finalized, expect that CMS will continue to monitor the outlier threshold to determine if the new methodology has in fact improved accuracy.

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 Lori Mihalich-Levin, J.D., at 202-828-0599 or at lmlevin@aamc.org or Allison Cohen, J.D. at 202-862-6085 or at acohen@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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