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Via Electronic Submission (<u>www.regulations.gov</u>)

June 25, 2012

Ms. Marilyn Tavenner Acting Administrator Centers for Medicare & Medicaid Services ATTN: CMS-1588-P 7500 Security Blvd. Baltimore, MD 21244-8013

Dear Ms. Tavenner:

Re: FY 2013 Inpatient Prospective Payment System Proposed Rule, File Code CMS-1588-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 Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes...," 77 Fed. Reg. 27870 (May 11, 2012). The Association's Council of Teaching Hospitals and Health Systems (COTH) comprises nearly 300 general acute nonfederal major teaching hospitals and health systems that receive Medicare payments under the inpatient prospective payment system (IPPS). The Association also represents all 137 accredited U.S. medical schools; 90 professional and academic societies; 90,000 full-time clinical faculty; and the nation's medical students and residents.

Our comments focus on the following areas:

- Including Labor and Delivery Beds for the Indirect Medical Education (IME) and Disproportionate Share Hospital (DSH) Calculations;
- Proposed Change in New Program Growth for New Teaching Hospitals from 3 Years to 5 Years;
- 5-Year Requirements Associated with Section 5503 Residency Positions;
- Proposals Relating to Resident Cap Positions from Closed Hospitals under Section 5506;

- The Medicare-Severity Diagnosis-Related Group (MS-DRG) Documentation and Coding Adjustment;
- The Inpatient Quality Reporting Program;
- Hospital Value-Based Purchasing;
- The Hospital Acquired Condition Program;
- The Hospital Readmissions Reduction Program;
- Outlier Payments;
- Add-on Payments for New Services and Technologies;
- Proposal Regarding Timely Filing Requirements for Claims Relating to Services to Medicare Advantage Enrollees; and
- Hospital Services Furnished Under Arrangements

INCLUDING LABOR AND DELIVERY BEDS IN THE IME CALCULATION AND FOR THE MEDICARE DSH PAYMENT ADJUSTMENT

A hospital's count of its labor and delivery (L&D) bed days is relevant to determining both the intern and resident to bed (IRB) ratio used to calculate its indirect medical education (IME) payment and the level of disproportionate share hospital (DSH) payments it may receive. Prior to FY 2010, CMS specifically excluded L&D beds from the *bed day* determinations relating to IME and DSH payments *and* excluded them from the *patient day* count used to calculate the disproportionate patient percentage (DPP).¹ In FY 2010, CMS changed the Agency's policy to include L&D *patient days* in the calculation of the DPP, so long as the patient was ultimately admitted as an inpatient (e.g., a patient remains excluded in cases of false labor). In the FY 2010 rule, CMS cited as the Agency's rationale that these days were "generally payable under the IPPS," which CMS interpreted as providing an IPPS level of care. In FY 2010, CMS expressly did *not*, however, change the Agency's policy with respect to counting L&D *bed days* for IME and DSH purposes. These L&D bed days have been and currently remain excluded from a hospital's bed count.

CMS now proposes to begin including L&D bed days for purposes of the IME and DSH bed counts. If implemented, CMS would revise the current regulations at 42 C.F.R. § 412.105(b)(4) to remove "ancillary labor/delivery" services from the list of currently excluded beds.

The AAMC strongly urges CMS not to implement this proposal. While the concept of "aligning" patient day and bed day policies has some initial optical appeal, including L&D bed

¹ The L&D patient days and beds at issue are only those beds and days used for patients who did not occupy a routine bed at some point prior to occupying an L&D bed.

days for IME and DSH purposes is inconsistent with longstanding CMS policy regarding services that typically are not covered by the Medicare program. More specifically, CMS' proposal is in direct conflict with the Agency's policy on healthy newborn nursery beds, which are included in the *patient day* count but are excluded from the *bed day* count. In the August 1, 2003, *Federal Register*, CMS explained the Agency's rationale for treating healthy newborn beds differently in each context:

The costs, days, and beds associated with a healthy newborn nursery are excluded from inpatient calculations for Medicare purposes. Meanwhile, for the purpose of computing the Medicaid patient share computation of the DSH patient percentages, these days are included both as Medicaid patient days and as total patient days. Newborn nursery costs, days, and beds are treated this way because the costs are not directly included in calculating Medicare hospital inpatient care costs because Medicare does not generally cover services for infants. However, Medicaid does offer extensive coverage to infants, and nursery costs would be directly included in calculating Medicaid hospital inpatient care costs. Therefore, these costs, days, and beds are excluded for Medicare purposes, but included for determining the Medicaid DSH percentage. (This policy was previously communicated through a memorandum to CMS Regional Offices on February 27, 1997.)

68 Fed. Reg. 45346, 45417 (Aug. 1, 2003) (emphasis added).

Just as with healthy newborn nursery beds, L&D beds are used frequently for services to Medicaid patients (given that state Medicaid programs offer "extensive coverage" to large numbers of child-bearing women) but are not generally used for services provided to Medicare patients (given that the vast majority of Medicare recipients are not of child-bearing age). For the same reasons, then, CMS should continue to exclude L&D bed days from the denominator of the IRB ratio and for DSH bed-counting purposes, while also continuing to include L&D patient days for purposes of calculating the DPP. Keeping the Agency's current policy maintains consistency between labor and delivery and healthy newborn nursery services that are similarlysituated for coverage purposes.

In changing the Agency's policy in FY 2010 to count L&D patient days in the calculation of the DPP, CMS stated in the *Federal Register* that the policy "would not affect existing policies

related to the allocation of costs for Medicare cost reporting purposes or for determining the number of available beds under § 412.105(b)(4) or § 412.106(a)(1)(i). In other words, our hospital instructions in the PRM-I for those purposes remain unchanged and unaffected by the proposed policy." CMS presumably had a logical rationale for continuing to treat these patient days and bed days differently in FY 2010, and the AAMC urges CMS to continue the distinction rather than inappropriately "aligning" the two definitions.

The current policy of excluding L&D beds from the facility bed count is also consistent with CMS' longstanding definition of beds in the hospital cost report. The definition in CMS' instructions for cost report 2552-10, Worksheet S-3, Part I, Column 2, states that:

Beds in labor room, birthing room, postanesthesia, postoperative recovery rooms, outpatient areas, emergency rooms, ancillary departments, nurses' and other staff residencies, and other such areas which are regularly maintained and utilized for only a portion of the stay of patients (primarily for special procedures or not for inpatient lodging) are not termed a bed for these purposes.

Clearly, L&D beds that are not also used for recovery and post-partum care are used "for only a portion of the stay" of any patient. To remain consistent with this definition, CMS should continue to exclude these beds from the bed count.

Additionally, CMS' proposed rule does not appear to take into consideration that there are still two types of L&D beds – those where a mother delivers *and* recovers after having a baby, and more traditional L&D beds only used for delivery. Some hospitals with traditional L&D beds have adopted the reasonable policy of setting aside a recovery room in the hospital's obstetrical unit for the mother and baby once the mother is committed to deliver, even though she may still be in a traditional L&D room. CMS does not address what steps would be taken in this instance to avoid counting two beds for the same time period.

Finally, the AAMC is concerned with the accuracy of CMS' impact calculation of this proposed change on teaching hospitals. CMS estimates that the impact of this proposed change would be to reduce IME payments by \$170 million in the aggregate. In attempting to calculate this impact, the AAMC was not, however, able to replicate the same level of impact on teaching hospitals and requests that if CMS adopts this proposal in the final rule, the Agency explain the impact calculations.

PROPOSED CHANGE IN NEW PROGRAM GROWTH FOR NEW TEACHING HOSPITALS FROM 3 YEARS TO 5 YEARS

The Medicare program limits payments to a teaching hospital to the number of resident full time equivalents (FTEs) the hospital reported during its most recent cost reporting period ending on or before December 31, 1996. Hospitals that were not training residents at that time are, however, permitted to establish FTE caps for direct graduate medical education (DGME) and IME payments by meeting certain requirements. Under the current rules, a new teaching hospital may grow its programs over a period of 3 years for the purpose of establishing FTE resident caps.

CMS acknowledged in the proposed rule that the provider community has found 3 years to be an insufficient amount of time for hospitals to build new residency programs and establish FTE caps that accurately reflect the number of FTE residents the hospital will actually train when its programs are fully grown. CMS explained that the Agency understands that accreditation timelines and prerequisites, combined with hospitals' desire to gain experience in one program before starting another, make the 3-year cap-building window particularly challenging. CMS proposes to extend this window to a 5-year period for new teaching hospitals that begin training residents in new programs for the first time on or after October 1, 2012.

The AAMC applauds CMS for this proposal and strongly encourages the Agency to finalize the proposal to increase the cap-building window to 5 years. The AAMC believes CMS has accurately characterized the challenges hospitals have faced under the 3-year window and appreciates CMS' willingness to extend the cap-building window by two years. This additional time will permit new teaching hospitals to meet accreditation timelines and grow programs responsibly in ways that begin to address the nation's looming physician shortage. The AAMC also encourages CMS to revisit this issue in several years to ensure that a 5-year cap-building window proves to be an adequate amount of time.

The AAMC is concerned, however, with the proposed effective date of this policy change. Rather than applying only to hospitals that begin training residents for the first time on or after October 1, 2012, the AAMC urges CMS to apply the new policy to all hospitals that are currently in their cap-building period as of October 1, 2012. These hospitals are facing the exact challenges CMS describes and would certainly benefit from an additional two years in their capbuilding window, and the new policy could easily be applied to them without any additional administrative burden on the part of CMS.

With respect to new programs, one additional issue that remains problematic is how CMS defines a "new program" for purposes of determining whether a hospital may establish DGME and IME residency caps during a cap-building window. In the FY 2010 IPPS final rule, CMS

clarified the Agency's definition of a "new program" by setting forth a list of "supporting factors" including (but not limited to) whether there are "new program directors and/or new teaching staff, and/or whether there are only new residents training in the program(s) at the different site." 74 *Fed. Reg.* 24080, 24192 (May 22, 2009).

The AAMC expressed extreme concern with this proposal in our June 30, 2009, comment letter, noting that the "supporting factors' offer a hospital no reassurance that a program established today will qualify as 'new' when CMS evaluates the program's status several years from now." The AAMC also noted concerns with CMS' suggestion that a new program should not hire a program director or faculty member from an existing program, lest that program jeopardize its "new" status. As the AAMC stated in 2009, program directors and faculty members who have become experts in their fields should be encouraged – not discouraged – to participate in the formation of new residency programs, and they must have the freedom to teach and practice where they determine their skills will be best employed.

Unfortunately, experience has shown that the fears AAMC expressed in 2009 have indeed come to pass. Hospitals hoping to start brand new programs have discovered that because of CMS' ambiguous criteria, they are unable to obtain a clean opinion either from CMS or from legal counsel that their program will in fact be considered "new." This lack of certainty poses extreme financial risks to a hospital and clear disincentives to taking on a teaching mission. Additionally, hospitals worry they will not be considered "new" if they hire a program director with significant experience to meet the Accreditation Council for Graduate Medical Education (ACGME) requirements for hiring an experienced program director, and that individual happens already to live and practice in their community.

The AAMC strongly urges CMS to revisit the Agency's discussion of this issue and adopt a bright-line rule that will allow hospitals to have certainty about whether they will be considered to have started a "new program." We believe CMS' concerns about duplicating residency positions can be addressed by adopting a clear requirement that the majority of all *residents* be new (and not come from other residency training programs) for the duration of the cap-building period. For example, CMS could require all PGY 1 residents to be new, and 90 percent of all residents in later PGY years to be new.² This type of requirement would alleviate CMS' concerns while permitting new teaching hospitals to accept a minimal number of resident transfers - transfers that happen for legitimate, personal reasons.

 $^{^{2}}$ CMS established precedent for a 90 percent threshold in the Section 5506 Closed Hospital program, when the Agency defined an "entire program" as 90 percent of the residents in that program for purposes of Ranking Criterion #1.

In an era when hospitals should be encouraged to begin training residents in an effort to address an impending physician shortage, hospitals should be given rules that afford them clarity and certainty that they will indeed be deemed "new" and able to build DGME and IME residency caps. Without such clarity, hospitals will remain hesitant to begin new programs and will not be able to avail themselves of the 5-year cap-building window CMS proposes.

Finally, on a technical note, the AAMC believes that the proposed regulatory language at 42 C.F.R. § 413.79(e)(1)(i) regarding how DGME and IME caps are calculated for hospitals whose residents rotate to more than one hospital during the cap-building window should refer to "portions of a program year (or years)" rather than to "an entire program year (or years)" to be consistent with the apportionment proposal CMS describes in the rule's preamble.

5-YEAR REQUIREMENTS ASSOCIATED WITH SECTION 5503 RESIDENCY POSITIONS

Section 5503 of the Affordable Care Act (ACA) required CMS to take 65 percent of the DGME and IME residency slots that went unused by a hospital during a 3-year period and redistribute them according to certain criteria. Hospitals that were awarded slots under this provision were notified of their award in August, 2011, and the slots were effective on July 1, 2011.

The ACA requires that awardees of Section 5503 resident slots meet certain requirements, namely that for 5 years, the hospital (1) may not reduce its pre-redistribution number of primary care residents below the average number of primary care residents training in the hospital during the 3 most recent cost reporting periods ending before March 23, 2010, and (2) must use at least 75 percent of the additional slots for primary care or general surgery. CMS discussed these requirements in detail in the Calendar Year (CY) 2011 Outpatient Prospective Payment System (OPPS) final rule. 75 *Fed. Reg.* 71800, 72133 – 72240 (Nov. 24, 2010).

In an effort to prevent hospitals from "attempt[ing] to circumvent the primary care average or the 75-percent threshold requirement, or both," CMS now proposes to add additional requirements for awardees regarding the use of these positions. First, CMS proposes that hospital awardees must fill at least *half* of their 5503 slots in the first, second, or third cost reporting period of the 5-year period from July 1, 2011, through June 30, 2016. Second, CMS proposes that hospital awardees must fill *all* of the slots they received in their final cost reporting period of the 5-year period. Failure to meet either of these requirements would cause the hospital to lose *all* of its 5503 slots.

The AAMC has several serious concerns with these proposals and, in general, believes that CMS' proposals are unworkable for many Section 5503 slot awardees. Given the late timing of

CMS' announcement of these new requirements (i.e., a final rule would be published mid-way through the second year of the 5-year evaluation period), the fact that hospitals starting new programs often phase in those new programs over a period of years, and the lengthy accreditation and site visit processes new programs must go through, the timeframes CMS proposes will simply be impossible for many awardees to meet. The AAMC's concerns are also magnified by the proposed risk to the hospital for failing to meet the new criteria – i.e., the loss of *all* of a hospital's awarded slots.

The AAMC urges CMS to reconsider the Agency's proposals that a hospital be required to use half of its awarded slots in one of the first three years and all of its awarded slots in the fifth year. Specifically, the AAMC asks that CMS (1) not implement *any* check at the three-year mark (or at any intermediary point), (2) require only that hospitals prove that they *began* their new program(s) (or began to expand existing programs) before the end of the five year period and that they received accreditation for the full number of slots they were awarded, (3) apply any penalty for failure to meet the requirements on a prorated basis, and (4) permit hospitals to define the start of their 5-year evaluation period as *either* July 1, 2011, or July 1, 2012.

An example illustrates that even a hospital that applied for Section 5503 slots with a genuine intent to use them and that *continues* to have such intent may have serious difficulties meeting the proposed requirements.

Example: Hospital A, with a June 30 fiscal year end (FYE), applied for Section 5503 slots to build a new general surgery program (a 5-year program). The hospital was awarded 10 DGME and 10 IME FTE slots,³ because it sufficiently demonstrated to CMS "that it has made a commitment to start a new program." *See* Section 5503 Evaluation form. At the time CMS announced the hospital's award, the hospital still had to complete several requirements before the slots could be put into use, including filing an ACGME Program Information Form (PIF), going through an ACGME PIF review, completing an ACGME Residency Review Committee (RRC) site visit, entering the program into the Electronic Resident Application Service® (ERAS), recruiting residents, and entering slots into the National Resident Matching Program (NRMP).

³ Note that for purposes of simplicity, this example does not take into consideration the important distinction between a hospital's FTE count and the number of individual residents training in a program.

Timeline:

Year 1 (July 1, 2011 – June 30, 2012)

August, 2011 – Hospital receives notification of slot award.

September 2011 – Hospital files its PIF with the ACGME.

January 2012 – ACGME conducts PIF review.

March 2012 – ACGME RRC conducts site visit.

May 2012 – ACGME approves the new program. (Note that this example timeframe is optimistic; processing applications, conducting site visits, and issuing notices of approval is a process that often takes the ACGME twelve months or longer, given each RRC's site-visit schedule.)

<u>Year 1 Conclusion</u>: Hospital A was unable to use its awarded slots in Year 1, because the program had not yet received approval by the time the academic year had begun. Regardless, the academic year had *already* begun by the time CMS awarded the hospital its Section 5503 slots.

Year 2 (July 1, 2012 – June 30, 2013)

July 2012 – Academic year begins; hospital cannot use the awarded slots, as it was unable to recruit residents and enter the NRMP by the January 2012 match deadline.

Summer 2012 – Hospital enters program into ERAS for the first time, so that residents will know about the existence of the new program and can apply for positions.

Fall/Winter 2012 – Hospital recruits residents and conducts interviews.

January 2013 – Hospital submits 2 postgraduate year (PGY) 1 slots (i.e., one-fifth of the 10 general surgery slots it was awarded) into the match, so that it can begin to phase in its new program, one year at a time.

March 2013– Residents match into program at hospital and plan to begin training July 1, 2013.

<u>Year 2 Conclusion</u>: Hospital A will be unable to use its awarded slots in Year 2, because it did not receive program accreditation in time for the program to enter the match.

Year 3 (July 1, 2013 – June 30, 2014)

July 2013 – Academic year begins, and 2 PGY 1 residents who matched into the new general surgery program begin training.

January 2014 – Hospital submits two PGY 1 slots into the match, so that in the second year of the program, the current PGY 1 residents will become PGY 2 residents, and two new PGY 1 residents will begin training in July 2014.

March 2014– Residents match into program at hospital and plan to begin training July 1, 2014.

<u>Year 3 Conclusion</u>: Hospital A would be able to begin its new general surgery program by Year 3, but it would only have used 2 of its 10 awarded slots – not the 5 slots CMS proposes to require.

Year 4 (July 1, 2014 – June 30, 2015)

July 2014 – Academic year begins, and 4 residents are training in the new general surgery program.

January 2015 - Hospital submits two PGY 1 slots into the match, so that in the third year of the program, the current PGY 1 residents will become PGY 2 residents, current PGY 2 residents will become PGY 3 residents, and two new PGY 1 residents will begin training in July 2015.

March 2015– Residents match into program at hospital and plan to begin training July 1, 2015.

<u>Year 4 Conclusion</u>: In Year 4, Hospital A will be able to use 4 of its 10 awarded slots.

Year 5 (July 1, 2015 – June 30, 2016)

July 2015 – Academic year begins, and 6 residents are training in the new general surgery program.

January 2016 – Hospital submits two PGY 1 slots into the match, so that in the fourth year of the program, two new PGY 1 residents will begin training in July 2016.

March 2016– Residents match into program at hospital and plan to begin training July 1, 2016.

<u>Year 5 Conclusion</u>: In Year 5, Hospital A will only be able to use 6 of its 10 awarded slots, not all 10, as CMS' proposal would require.

Overall Conclusion: Even though Hospital A made an institutional commitment to begin a new general surgery program, was appropriately awarded Section 5503 slots, proceeded in an expeditious manner to meet all accreditation and match requirements to begin its program as quickly as possible, and fully intends to use all of its slots for the intended purposes (general surgery), it still will not be able to meet *either* of CMS' proposed requirements, even assuming no attrition from the program, and would lose *all* of its awarded Section 5503 slots.

In addition to the issues illustrated through this example, CMS' language is ambiguous with respect to the requirement to use all slots in the fifth year. The Agency's preamble discussion states that hospitals would be required to "fill all of the slots they received *in* their final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016 " (emphasis added), while the proposed regulations at 42 C.F.R. § 413.79(n)(2)(ii) state that the hospital "must fill all of the slots it received *by* its final cost reporting period beginning during the timeframe of July 1, 2016" (emphasis added). Regardless of the final policy CMS adopts, the Agency should not measure a hospital's compliance with a rate of usage of 5503 slots based on a single year. Under CMS' proposal, a hospital that used all of its awarded slots in its fourth cost reporting period but failed to use all of the slots during the fifth cost reporting period for reasons completely beyond its control (e.g., a resident left the program to care for a sick family member) would fail to meet the Agency's requirements.

From a practical perspective, CMS also has not set a baseline for how the agency would measure compliance with the requirement that "all" awarded slots be filled in the fifth year of the evaluation period. The Agency has not indicated whether the baseline will be a single year FTE count or an average of years.

The AAMC is sensitive to CMS' concerns regarding hospitals' use of the Section 5503 slots. However, given the late announcement of the Agency's proposed additional requirements and for the logistical reasons described above, the AAMC urges CMS *not* to adopt any intermediate

checkpoint on the use of a certain number of slots and not require that all slots be used in or by the fifth year. If CMS would like to verify that hospitals are using their Section 5503 slot awards for the original intended purposes, the Agency can still accomplish this goal by requiring hospitals to prove that they *began* their new program(s) (or began to expand an existing program) before the end of the five year period and that they received accreditation for the full number of slots they were awarded. A hospital that has gone through the immense effort required to start a new program is extremely unlikely to abandon it both for financial and reputational reasons.

Regardless of the policy CMS ultimately adopts, the AAMC encourages CMS to permit hospitals to select a start date of *either* July 1, 2011, or July 1, 2012, for the 5-year evaluation period. The statute refers to a 5-year period "beginning on the date of such increase," and in the November 24, 2010, final rule with comment period, CMS defined the 5-year period as beginning July 1, 2011, and ending June 30, 2016. Because the award announcement was not made until several months into the 2011-2012 academic year, however, it was not possible for many hospitals to put awarded slots into effect on July 1, 2011, for that academic year. The AAMC appreciates the administrative complexities of having different "dates of increase" for different hospitals. The Association believes, however, that offering only two options would not create an undue administrative burden and would be the most equitable way of defining the beginning of the 5-year evaluation period both for hospitals that were able to use awarded slots immediately and those that were not.

Finally, with respect to applying a penalty for failure to meet any of the requirements associated with Section 5503, the AAMC urges CMS to remove only a proportionate amount of the hospital's FTE award, rather than the entire award amount. It is entirely inequitable for a hospital that used all but 0.01 FTEs, for example, to lose its entire award, particularly given inevitable program attrition that is entirely out of the hands of the hospital. In Section 5503, the ACA gives the Secretary the discretion to "determine whether a hospital has met the requirements under this clause during such 5-year period *in such manner* and at such time as the Secretary determines appropriate, including at the end of such 5-year period." CMS should use this discretion to implement the penalty provisions of this program in a less draconian manner.

PROPOSALS RELATING TO RESIDENT CAP POSITIONS FROM CLOSED HOSPITALS UNDER SECTION 5506

Under Section 5506 of the ACA, the DGME and IME residency slots from any hospital that closed or closes on or after March 23, 2008, must be redistributed on a permanent basis to other

hospitals. In January 2012, CMS announced the first group of slots awarded from hospitals that closed between March 23, 2008, and August 3, 2010. CMS now proposes to make several changes to the closed hospital redistribution program.

CMS proposes to shorten the time a provider may have to submit an application to receive slots under this program from 4 months to 60 days. The AAMC believes a 60 day application period is reasonable and supports the Agency's efforts to expedite the process of awarding Section 5506 slots.

CMS also proposes to modify the effective dates of slots awarded under Section 5506. The proposed changes in effective dates relate to whether a slot should become effective retroactively, based on the graduation date of a particular resident. CMS believes that because hospitals applying for slots under Ranking Criteria #4 through #8 are applying to establish or expand a program or to seek cap relief, they should be awarded slots on a *prospective* basis only. CMS explains this proposal, stating that "the purpose of section 5506 is for hospitals to receive slots from the closed facility to facilitate the continuity of the closed hospital's programs and to promote stability in the number of physicians in a community."

The AAMC acknowledges the complexity associated with the subject of slot effective dates under the Section 5506 program and appreciates CMS' efforts to attempt to streamline the process for granting awarded slots. To simplify the effective date policy even further and in an equitable manner, the Association proposes an alternative approach based on a straightforward concept: that the effective date for Section 5506 DGME and IME positions be the date when the slots are needed by the awardee hospital. Assigning effective dates based on this principle would avoid confusion and some of the problems hospitals encountered under CMS' current system for assigning effective dates.

A policy based on the hospital's need for the slot should function in the following three ways:

• For hospitals that take in displaced residents from a closed hospital (i.e., apply for slots under RC #1 or #3): permanent Section 5506 slots should go into effect when the displaced residents graduate. Hospitals should be permitted to retain their temporary cap slots (slots that are exempt from the 3-year rolling average and the IRB ratio cap) until each slot expires, at which time the permanent slots would go into effect. CMS' current policy of replacing temporary slots with permanent slots after only one fiscal year has proved logistically and financially problematic for many Section 5506 slot awardees. These hospitals incur costs in real time for training displaced residents will be exempt from the

rolling average rules *and* knowing it is uncertain whether they will receive any permanent Section 5506 slots.

- For hospitals that begin new programs (i.e., apply for slots under RC #4, #5, or #6): Section 5506 slots should become effective on the date the hospital's new program begins. For administrative simplicity, the effective date should be the same for all awarded positions (i.e., all slots become effective the date the new program begins). For a hospital that starts and is awarded slots for a new program that happens to begin in the time period between the date it submits an application to CMS and the date CMS announces the slot award, the effective date should be retroactive to the date the hospital actually started the new program. (This issue is relevant particularly given the large time lags between Section 5506 slot application deadlines and award announcements.)
- For hospitals that received slots from the closed hospital under an affiliation agreement and continued to train residents under the terms of the agreement and for hospitals that are over their caps (i.e., apply for slots under RC #2, #7, or #8): Section 5506 slots should be effective the date the hospital closed. Following the principle that the effective date should be the date the awardee hospital actually needs the slots, these are instances in which the slots are in fact needed at the time of the hospital's closure.

The AAMC encourages CMS to following an effective date "as-needed" principle in adopting the Agency's final rules on the Section 5506 residency position redistribution program. Doing so will greatly simplify the effective date assignment process, address concerns of hospitals training displaced residents, and allow applicants to better understand (and predict) what their effective dates would be.

In the proposed rule, CMS also requests feedback on the Agency's program for temporary cap adjustments under 42 C.F.R. § 413.79(h), namely whether the program is still "necessary and appropriate" and whether the exemption from the rolling average for displaced residents should be eliminated. The AAMC strongly urges CMS to maintain the temporary cap adjustment program as it currently exists, including the ability for hospitals to exempt displaced residents from the rolling average.

The AAMC appreciates the program CMS developed to encourage teaching hospitals to help residents who are displaced from a closed hospital to complete their residency training. The need for the type of incentive CMS created through this program is still necessary today, even with the existence of the Section 5506 closed hospital slot redistribution program. CMS acknowledges in the proposed rule that a hospital that takes in displaced residents and applies for Section 5506 slots has *no* guarantee that it will be awarded permanent slots under the Section

5506 program. Given this lack of certainty, the mere *possibility* of being awarded Section 5506 slots is simply not enough of an incentive for the hospital to take on displaced residents. Without the temporary cap adjustment program, it would be much more difficult for displaced residents to find residency placements and would likely lead to unfortunate gaps in these residents' training.

If hospitals in the same geographic area are uncertain whether they will or will not be awarded Section 5506 slots, hospitals in geographic areas different from that of the closed hospital can be certain they will *not* be eligible for these residency positions. For a variety of practical and personal reasons, displaced residents are not always able to (and some may not desire to) continue their residency training in the same geographic location as the closed hospital. If, for example, a displaced resident is training in a specialty program that simply does not exist at any other hospital in the same geographic area as the closed hospital, the resident will be forced to move to a different geographic location to continue residency training. The hospital in another state that agrees to take in that resident will not be eligible for Section 5506 slots and should continue to have the opportunity to be compensated in real time (i.e., without the application of the 3-year rolling average and the IRB ratio cap) for that resident.

To continue to encourage hospitals to take on displaced residents, to allow the hospitals to be paid in the present year for doing so, and to eliminate any uncertainty about how hospitals will be paid, CMS should maintain the Agency's temporary cap adjustment program as it currently exists.

THE MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

In 2008, to better recognize severity of illness in Medicare hospital payment rates, CMS began a transition from CMS diagnosis-related groups (CMS-DRGs) to Medicare-severity DRGs (MS-DRGs). The MS-DRG relative weights for FY 2008 were calibrated with the intention that the change from CMS-DRGs to MS-DRGs be budget neutral, with Medicare payments only increasing if there is an actual increase in patient severity ("real" case-mix change). To the extent hospitals treat patients of the same severity before and after implementation of MS-DRGs, but document and code their Medicare claims more accurately such that more cases are assigned to higher-weighted DRGs, CMS believes the Agency must recoup these payments.

The proposed rule would impose a 1.9 percent reduction in the IPPS standardized rate for FY 2013 to remove increases from FY 2008 and 2009 the Agency asserts are not associated with

true increases in patient severity (referred to as "real" case mix growth). CMS also proposes to make an additional cut of 0.8 percent to remove increased FY 2010 payments from the system. The AAMC remains very troubled about the methodology CMS uses to arrive at the Agency's estimated impact of documentation and coding requirements. CMS' methodology indicated that the entirety of the case mix increases in 2008 and 2009 was a result of hospital documentation and coding and not increases in patient severity. For the past several years the AAMC, along with the American Hospital Association (AHA) and Federation of American Hospitals (FAH), conducted analyses showing that the reduction due to documentation and coding should be much smaller. These analyses were discussed in detail in the AAMC's comment letters on the FY 2011 and FY 2012 inpatient proposed rules. (See AAMC letter to Ms. Marilyn Tavenner, June 18, 2010; AAMC letter to Dr. Donald Berwick, June 20, 2011.) This year, we performed additional analyses to respond to issues CMS raised in the IPPS FY 2013 proposed rule, and our results continue to indicate that a smaller documentation and coding adjustment is warranted. We are also extremely concerned about the possibility that changes in documentation and coding may have decreased the case mix index (CMI) under the CMS-DRGs and urge CMS to study this issue. (We refer CMS to the AHA's comments for a full discussion of these analyses.)

We believe CMS should examine medical records data to distinguish documentation and coding changes from real case mix change and reduce the documentation and coding offset accordingly. If CMS refuses to use medical records, we urge the Agency to use a methodology that reflects historical trends in case mix index changes. As detailed in the AHA letter, the methodologies employed by the hospital associations indicate a documentation and coding effect that is substantially lower than CMS' results.

HOSPITAL READMISSIONS REDUCTION PROGRAM

The ACA requires CMS to implement a readmission payment reduction program that will reduce Medicare payments to those hospitals with higher than expected readmission rates beginning in FY 2013. In the initial year, the payment reduction will be based on the readmission rates for acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PN). While the readmission calculation will be based on these three conditions, the percent payment reduction will be applied to every DRG payment with a cap of one percent in the first year.

Reducing readmissions is a major priority for all hospitals, and the AAMC agrees that preventable readmissions should be minimized to the degree possible. However, fully understanding what causes readmissions is a complex issue. Numerous factors can potentially affect readmissions including provider-based factors, such as the quality of care, and patient-

based and community-based characteristics. These include factors related to SES, such as having a home or support network for the patient post-discharge, and community factors such as the availability and admitting practices of post-acute services in the geographic area. It is also not yet clear what is truly preventable and whether certain readmissions should even be prevented. Not all readmissions can be considered an indicator of poor quality care. A recent study in *The New England Journal of Medicine* entitled "30-day Readmissions - Truth and Consequences"⁴ showed a direct correlation between higher readmission rates and lower mortality for HF, PN, and AMI. As an example, the authors note that hospitals with low mortality rates for patients with HF also have higher readmission rates. This is likely due to the fact that these hospitals are successful at keeping the patient alive, thereby resulting in more readmissions. In addition, the article notes that interventions to improve care coordination and access to follow-up treatments actually end up increasing the number of readmissions. Improved access to care and satisfaction with the services offered, which result in more readmissions, should not be seen as a policy failure.

The AAMC is very concerned about the unintended consequences that may result from implementing a readmission program that fails to adjust for SES factors. There have been several recent studies that show a direct correlation between higher readmission rates and SES factors. A study in *The Journal of the American Medical Association* reviewed readmissions for Medicare patients stratified by race and site of care. "Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care"⁵ concluded that black Medicare patients at minority serving hospitals had substantially higher readmission rates for AMI, PN, and HF compared to white patients at non-minority serving institutions.

The lack of adjustment for SES factors creates an unlevel playing field and is based on characteristics beyond the control of the hospital. Our current analysis shows that a large portion of teaching hospitals will, in fact, have the maximum reduction applied to their DRG payments in the first year of the readmission program. These reductions will be compounded in future years as the number of conditions included in the program is expanded. Furthermore, many teaching hospitals are currently in the early stages of establishing new and innovative programs to reduce unnecessary readmissions. These penalties may place additional strain on such programs before they are given a chance to succeed. **Therefore, CMS should move forward**

⁵ Jha, Ashish et al. *Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care*. Journal of the American Medical Association. Retrieved from:

http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2011.123. 16 Feb. 2011.

⁴ Jha, Ashish and Karen Joynt Karen. *Thirty-Day Readmissions – Truth and Consequences*. <u>The New England</u> Journal of Medicine. Retrieved from: <u>http://www.nejm.org/doi/pdf/10.1056/NEJMp1201598</u>. 25 June, 2012

cautiously, to ensure those institutions, primarily teaching hospitals, that treat medically complex and disadvantaged patients, are not unfairly penalized and that no perverse financial incentives are created to avoid treating high risk patients.

Data Analysis

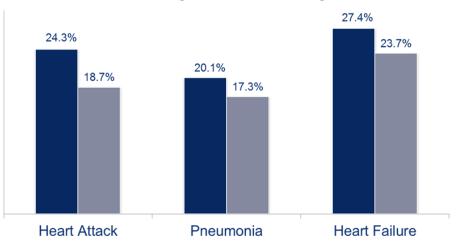
KNG Health Consulting (KNG) conducted a descriptive analysis of current readmission patterns for hospitals, and an evaluation of whether these patterns vary for vulnerable populations and the potential impact on the hospitals treating these patients.

KNG studied readmissions from 2009 in AMI, HF and PN and found that a number of variables that affect readmission rates are not accounted for in the current readmission measures. Several of these variables are statistically significant, even after a risk-adjustment methodology is applied. One of the most notable is patients who are dually eligible for both Medicare and Medicaid. Dual-eligibility was selected as a variable for this analysis, because it is a readily available data element and can serve as a proxy for SES. As Figure 1 shows, dual eligibles are more likely than non-duals to be readmitted. This difference would not be of consequence, if all hospitals treated the same percentage of dual-eligible beneficiaries. However, as seen in Figure 2, a small percentage of hospitals treat the largest percentage of dual-eligibles for PN. This type of distribution curve occurred for all conditions studied.

Figure 1

Readmission Rates are Higher for Dual <u>Eligibles</u> (2009)

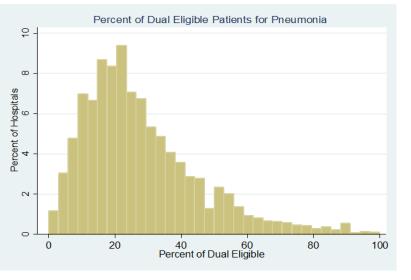
30-Day Readmission Rates for Dual and Non-dual Eligible Beneficiaries





Source: KNG Analysis of 2009 100% Medicare inpatient file and FY2011 Hospital IPPS final rule impact file.

Figure 2



Distribution of Hospitals by Percent of Duals: Pneumonia

Source: KNG Health Analysis of 2009 100% Medicare inpatient claims data and 2009 100% denominator file. Note: Sample includes hospitals with 25 or more admissions for the condition during a hypothetical 3-year period (i.e. 3 times the number of admissions in 2009).

Alternative Approaches for Adjustment

The National Quality Forum (NQF) recently convened a steering committee to review the hospital-wide readmission (HWR) measure submitted by CMS. The committee, which consisted of clinical experts, statisticians and others, had a robust discussion concerning the appropriate adjustment of SES factors in the measure methodology. There was widespread agreement that SES factors affect readmissions, and the measure developer found a similar correlation using Medicaid data. A recommendation of the committee, which aligns with the NQF measure criteria, is that the HWR measure should be stratified by SES. For alignment purposes, a stratification recommendation for the HWR measure should be applied to the condition specific measures.

Therefore, in support of the AAMC concerns and the NQF recommendation, KNG Health developed a stratification approach that would not require a material change to the measures. The stratification model, a patient-level approach, is based on dual-eligible status. As stated previously, dual-eligibility was selected, because it was a readily available data element and a

good proxy for SES. The "blended" model estimates a separate model for both duals and nonduals. In other words, a hospitals' excess readmission ratio is calculated first based only on the dual population. Second, the excess readmission ratio is calculated for the non-dual population. The two results are weighted by the percent of dual eligible populations, added together, and multiplied by the national unadjusted readmission rate for an individual hospital's readmission rate. This adjustment allows each hospital's rate to be based on its percentage of dual-eligible patients and creates a level playing field when comparing hospitals that treat different patient populations. This is one example of how a stratification methodology could be applied to this program. Measuring separately by dual status does not give any hospital a "pass," because hospitals will have to perform better than expected for their relative patient populations. This adjustment does allow people to 1) understand the differences in readmission rates between the two populations and 2) work towards reducing the differences without impacting access, or penalizing providers for serving these vulnerable populations.

Based on our analysis, the AAMC believes the stratification approach by dual-eligibles is the most appropriate way to incorporate SES factors in the readmission program. However, in the proposed rule, CMS published a chart showing the distribution of hospitals readmission adjustment factor by DSH patient percentage (DPP) by decile. The chart shows the impact of the readmission program by cohorts of DSH hospitals. While CMS did not state its intention for publishing this chart, the AAMC interpreted the chart as another way to stratify hospitals utilizing DSH percentages. The AAMC performed a similar analysis, but was not able to replicate CMS' results. Without having additional data to confirm how CMS calculated its results, the AAMC believes the data in the proposed rule is incorrect. In our modified chart (Table 1), we display CMS' DPP analysis from the proposed rule next to the AAMC's own analysis of DPP. In addition, we included KNG's stratification of hospital patients with dualeligible status in the table. As you can see, the revised chart re-iterates our previous narrative, regarding dual-eligibles, that high DSH hospitals will have a disproportionate impact compared to low DSH hospitals. Further, the high DSH hospitals also have the higher percentage of dualeligibles. And as Figure 3 demonstrates, there is a demarcation line between the sixth and seventh deciles showing a significant increase in the number of high DSH hospitals that will have the maximum payment reduction. Because of this marked difference between deciles, should CMS consider an adjustment or stratification approach based on hospital level DSH patient percentages rather than dual-eligibles, we believe it is appropriate to include an adjustment for hospitals in the top four deciles only. Due to the complexities in calculating DSH, the AAMC believes that applying an adjustment to all hospitals may result in unintended consequences for low DSH hospitals. One way to implement a DSH adjustment that compares like hospitals is to compare an individual hospital's excess readmission ratio to the average

excess readmission ratio for the hospitals in the decile (or even quintile), rather than to the national rate.

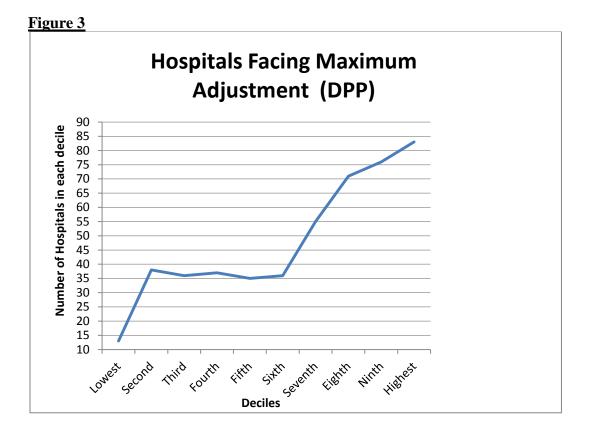
Table 1: CWS Readinessions Froxy Aujustinent by DFF and Duai-Eligible Status						
	Number of Hospitals:		Number of Hospitals:		Number of Hospitals: KNG	
	CMS DPP Analysis		AAMC DPP Analysis*		Analysis of Proportion of	
					Hospital Patients with Dual-	
					Eligible Status**	
Decile	-1 Percent	No	-1 Percent	No	-1 Percent	No Readmission
	Floor	readmission	Floor	Readmission	Floor	Adjustment
	Adjustment	Adjustment	Adjustment	Adjustment	Adjustment	Ĵ
Lowest	38	145	13	218	24	138
Second	57	118	39	127	26	141
Third	44	127	36	128	24	134
Fourth	48	121	37	119	28	122
Fifth	42	115	33	105	29	106
Sixth	43	125	38	111	32	110
Seventh	44	108	56	102	66	80
Eighth	43	114	67	83	72	72
Ninth	58	102	78	80	92	65
Highest	61	96	83	74	87	82
Total	478	1,171	480	1,147	480	1050

Table 1: CMS Readmissions Proxy Adjustment by DPP and Dual-Eligible Status

*Source: AAMC Analysis of IPPS Proposed Rule Impact File, FY 2012 and Hospital Readmissions Reduction Program Supplemental Data File, IPPS Proposed Rule, FY 2012

Note: Deciles based on DSH Patient Percentage from IPPS Final Rule FY 2012

**Source: KNG Analysis of 2009 CMS Denominator File



In summary, the AAMC firmly believes that SES needs to be accounted for in the readmission program for the measurement to be fair. We strongly recommend using a patient-level adjustment, such as the dual-eligible stratification methodology discussed above. A hospital-level adjustment based on DSH, while not ideal, is better than no adjustment. Because the number of hospitals that will receive the maximum penalty in the first year jumps sharply between the sixth and seventh deciles, we suggest that any hospital-level adjustment based on DSH be applied to the top four deciles. We would be happy to discuss these methodologies further with CMS.

Unrelated Readmissions

The ACA requires that the measures of readmissions must "have exclusions for readmissions that are unrelated to the prior discharge (such as planned readmissions or transfer to another applicable hospital)" (Section 3025). CMS states that the Agency intends to use the NQF-endorsed 30-day all cause readmission measures for AMI, HF, and PN. CMS proposes no changes to the NQF measure specifications, asserting that the measures meet all of the criteria for inclusion in the payment reduction program.

The AAMC believes the current readmission measures do not meet the legislative criteria for exclusions of unrelated readmissions. The Association believes the intent of the law was to focus only on those readmissions related to the index admission and that hospitals should not be financially penalized for those readmissions that are unrelated and that they have limited ability to control. The AMI measure is the only measure that includes exclusions for a small number of procedures that could be deemed planned readmissions. However, there are no exclusions for the HF and PN measures. In addition, we believe the current exclusions for the heart attack measure do not account for all planned readmissions. That being said, this does not address the broader issue of unrelated readmissions within the three condition categories. While the panel responses were not consistent across the condition categories, the responses clearly showed that there are numerous readmissions that would be viewed as unrelated by a consensus of clinical opinion and should be excluded. **The AAMC suggests that CMS to convene a clinical expert panel to identify those readmissions that are unrelated and/or planned and exclude those readmissions from the payment program.**

Excluded Readmissions

As the AAMC has previously stated, there are several conditions/disease categories that can result in multiple hospitalizations due to the type of illness. Notably, transplant, end stage renal disease (ESRD), cancer, burn, and trauma patients, as well as patients suffering from psychosis or substance abuse, are often hospitalized multiple times within a short timeframe. Under CMS' proposal, these hospitalizations would be counted as readmissions, even though they are not related to the index admission. Hospitals should not be penalized financially for treating patients with these conditions. Therefore, all readmissions associated with a diagnosis or treatment code for transplants, ESRD, cancer, burn, trauma, or a primary or secondary diagnosis of psychosis or substance abuse should be excluded from the payment program.

INPATIENT QUALITY REPORTING PROGRAM

Quality Measures

FY 2015 Measures

Removal of Measures

The AAMC applauds CMS for the proposal to remove eight Hospital Acquired Conditions (HACs), three Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators

(PSIs), and five AHRQ Inpatient Quality Indicators (IQIs) measures from the Inpatient Quality Reporting (IQR) program. The AAMC has long supported the removal of the HAC rates, as they are not risk-adjusted and have not gone through the National Quality Forum (NQF) endorsement process. In addition, this minimizes the double jeopardy concern with these measures being included in both the IQR and HAC payment programs. The AAMC has had similar concerns with the AHRQ measures regarding their lack of a robust risk-adjustment methodology and appropriateness for a performance-based payment program rather than internal quality improvement. The Measure Applications Partnership (MAP) made the recommendation to remove these measures, and we are very pleased to see CMS incorporating the MAP input into the Agency's decision making process.

CMS also proposes to remove the SCIP-VTE 1 measure, as it has a significant overlap with SCIP-VTE 2 and the measure was not recommended for continued endorsement by the NQF. The AAMC supports the removal of the SCIP-VTE 1 measure. **The AAMC supports CMS' proposal to remove all 17 measures from the IQR program. However, we also urge CMS to remove these measures from the IQR program for FYs 2013 and 2014 as well.** If CMS is unable to remove these measures before FY 2015 because it was not proposed in this rule, we would urge the Agency to use the CY 2013 outpatient PPS proposed rule to remove these measures from the FY 2013 and 2014 IQR program. We also ask CMS to remove these measures from the *Hospital Compare* website as soon as possible.

New Measures for FY 2015

Elective Delivery Prior to 39 weeks

CMS proposes to add one new chart abstracted measure for FY 2015, Elective Delivery Prior to 39 Completed Weeks Gestation. The measure will be used along with other initiatives to address and reduce the number of pre-term births. The AAMC supports the inclusion of this measure in the IQR program.

Hip and Knee Readmission and Complication Rates

CMS proposes to include two outcome measures related to hip and knee arthroplasty: 30-day all cause readmission rate and 90-day complication rate. The AAMC supports the inclusion of these measures in the IQR program; however, we reiterate the Association's objection to CMS' not adequately adjusting for socio-economic status (SES) factors and believe the measures should be modified prior to implementation. In addition, the AAMC urges CMS to update this measure by:

• Differentiating between planned and unplanned readmissions;

- Differentiating between related and unrelated readmissions;
- Excluding extreme circumstances (transplant, end-stage renal disease, burn, trauma, psychosis, and substance abuse), and

Hospital-Wide Readmission Rate

CMS is proposing to implement a hospital-wide readmission measure that will report 30-day allcause readmission rates based on a summary score of five specialty care cohorts: medicine, surgery/gynecology, cardiorespiratory, cardiovascular, and neurology.

The AAMC appreciates that CMS and its measure developer made several improvements in the measure methodology since it was released for public comment last summer. Specifically, we are pleased a methodology was developed to determine and exclude a set of planned readmissions. Additionally, we applaud the exclusions for the medical treatment of cancer, transplants and primary psychiatric diagnoses. We have previously commented to CMS that patients who receive routine care through multiple hospitalizations based on the nature of their illness or through natural disease progression should be excluded from the denominator population. We believe the modifications made to this measure should be applied to the condition-specific measures as well, to ensure alignment and consistency.

However, as previously stated the AAMC has strong concerns about the lack of adequate adjustment for social economic status (SES) factors, and the Association believes this measure should not be implemented until appropriate adjustments are made. This is critical to ensuring that the hospitals that treat complex and disadvantaged patients, and the patients themselves, are not unfairly penalized, thereby creating unintended consequences related to access and ability to treat vulnerable patient populations.

Additionally, while we appreciate CMS' methodology for planned readmissions, the Association believes the list of readmissions is incomplete. Our clinical experts state that the list falls short of identifying all readmissions that would be considered planned for the identified clinical cohorts. The AAMC urges CMS and its developer to conduct further analysis to incorporate a more exhaustive list of planned readmissions.

Lastly, the readmission measures that are currently reported on Hospital Compare are conditionspecific. Given the condition-specific focus, they resonate with consumers as well as provide some information for hospitals in trying to identify appropriate interventions to reduce readmission rates. The hospital-wide readmission measure, which is an aggregate score of five sub-models for particular specialty cohorts, provides very little direction for providers. There are too many factors involved to begin to address an overall hospital readmission rate. In addition,

because these are all-cause readmissions, the possibilities could be endless in identifying the causes for hospital-wide readmissions, making it very difficult to determine appropriate interventions. The lack of timeliness of the data compounds the problem, because the data for this measure would be at least 18 months old before it could be used to improve care processes. Not only is the data not current, but hospitals are not given all the data necessary for improving readmissions, such as data for those patients who are readmitted to other hospitals. This information is critical for understanding the readmission patterns and implementing solutions or appropriate interventions.

3-Item Care Transition Tool

In order to address the quality of care transitions, CMS is proposing the 3-Item Care Transition Tool measure. The tool is comprised of three questions related to the discharge process and would be incorporated into the current Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. The AAMC agrees that care transitions are an important area to address and improve, especially because the quality of those transitions can have an impact on readmissions. While the Association appreciates the inclusion of this tool in the current HCAHPS survey, we have some concerns with the wording of the following question in the Care Transition Tool: "During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left the hospital."

The AAMC has concerns that this question may improperly seek to measure the wishes of family members or caregiver against the preference of the patient. Therefore, the "and" in the question should be changed to an "or." While patients may have had their preferences considered, their dissatisfaction with the final decision regarding post-discharge care may impact how they respond to this question.

HCAHPS Additional Questions

CMS proposes to include two additional questions in the "About You" section of the HCAHPS survey. The patient would be asked 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. We appreciate CMS' efforts to improve the patient-mix adjustment by including these two additional questions in the HCAHPS survey. Research performed by our members indicates that various patient populations, including those who have extended lengths of stay, are depressed, or have a high severity of illness, tend to give lower HCAHPS scores. Ensuring an appropriate adjustment factor is in place to account for these patient population

differences across hospitals is critical, as hospitals are now being paid based on these results. That being said, we have some concerns on how the questions may be implemented. We understand the data element previously used to determine ED-originated admissions is no longer being collected, hence the proposal for a patient reported question. However, the accuracy of the responses to the first question can be a major concern as the path for admission can be confusing for the patient and ultimately may lead to inaccurate responses. This is especially true for patients who are transferred to another hospital during the course of their treatment. The AAMC believes there should be some other administrative driven data element that can serve as a proxy for the ED originated admission.

Similarly, the same concern for accuracy can be echoed for patient assessment of mental and 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 before we can provide a final determination about their inclusion.

Measures for FY 2016

Safe Surgical Checklist

The AAMC is very supportive of widespread use of surgical checklists. The AAMC has taken the lead in enlisting more than 100 medical schools, hospitals, and health systems to implement best practices to improve health care at their institutions. This initiative, known as Best Practices for Better Care (BPBC), includes the utilization of a surgical checklist. Under the BPBC initiative, institutions create policies requiring the use of surgical checklists in operating rooms for all procedures, document the use of checklists in patient charts, report compliance rates, and demonstrate that medical students and residents understand the importance of standard processes and improved communication.

While we support the use of safe surgical checklists, we have some concerns with its inclusion in the IQR program. First, this is not an NQF-endorsed quality measure with a specified numerator and denominator. The measure is proposed as a structural measure and would only assess whether a surgical checklist is in place, which could result in a "check the box" process. We urge CMS to focus on <u>how</u> the measure should be implemented, including specifying standardized criteria to be followed instead of whether the checklist is simply in place. We also urge CMS to submit this measure for NQF endorsement.

Future Measures

To be aligned with the current NQF specifications for the central line associated blood stream infection (CLABSI) and catheter associated urinary tract infection (CAUTI) measures, CMS proposes to expand the data collection in the future from intensive care unit (ICU) patients only to include non-ICU patients as well. The AAMC is concerned with this proposal, as the data collection burden for collecting data outside of the ICU will be incredibly burdensome, especially for academic health centers with high numbers of patients on devices compared to other institutions. Because the CLABSI measure has not yet undergone validation testing under the current specifications, the AAMC believes it is premature to include the CLABSI measure with the expanded specifications in IQR and value based purchasing (VBP). This proposal should be revisited at a later date.

Validation process

CMS has proposed two separate validation approaches to the quality measures. The process for validating chart-based clinical process measures would not change, and the process for validating the CLABSI measure would be expanded to include the additional hospital-acquired infections (Surgical Site Infection [SSI] and CAUTI). Previously, hospitals needed to receive a score of 75 percent or better to pass validation. Due to the dual approach, CMS is proposing to modify the language and require a 75 percent pass rate for each measure set individually, not as an overall percentage. In addition, the number of hospitals selected for validation has been reduced from a random sample of 800 to 400, because more than 99 percent of hospitals pass validation. The AAMC supports the proposed validation process.

Alignment with National Strategy

CMS proposes to utilize the National Quality Strategy (NQS) domains to assist in selecting measures for the IQR program starting in FY 2015. The overarching goal is to provide alignment between the IQR, Value-Based Purchasing, and Meaningful Use programs. The NQS domains address patient and family engagement, patient safety, care coordination, population and public health, efficient use of healthcare resources, and clinical processes and effectiveness.

The AAMC supports the alignment of all 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 illustrate a plan for future measure development. However, the AAMC

believes it is premature to utilize the NQS domains for purposes of making payment determinations.

Incorporating the MAP Process

As required by the Affordable Care Act (ACA), the Measure Application Partnership (MAP) was formed as a multi-stakeholder group that provides input to CMS regarding quality measures used in all CMS quality reporting and payment programs. The process requires CMS to generate a list of measures being considered in the next rulemaking cycle. MAP then makes recommendations on which measures should be included and excluded in the reporting programs and where there may be gaps in measurement.

The AAMC believes that this was a successful first year for the MAP. The AAMC is especially pleased that CMS is working closely with the MAP to incorporate the Partnership's reviewed measures into the proposed rule. However, we also hope that CMS and the MAP will strive to streamline the measure review process in the future. Specifically, the Association requests that the list of measures for MAP review be submitted to the MAP well in advance of the statutory deadline, that the list of measures contains substantial descriptive information, and that all relevant and appropriate information concerning the inclusion of measures into the various payment programs is properly transmitted to the MAP

HOSPITAL VALUE-BASED PURCHASING

Quality Measures

FY 2015 Measures

CMS proposes to retain 12 of the 13 process of care measures for FY 2015 that previously were adopted for FY 2014. CMS also proposes to remove SCIP-VTE-1 from the both IQR and VBP programs in FY 2015, because this measure was not recommended for continued endorsement by the NQF. CMS also proposes to include one new process of care measure, Statin Prescribed at Discharge for Acute Myocardial Infarction, starting in FY 2015. The AAMC supports both measure proposals for the VBP program.

Central Line Associated Bloodstream Infection (CLABSI)

CMS proposes to include the CLABSI measure in the outcome domain starting in FY 2015. As we iterated in our comments in the IQR section of this letter, the AAMC supports the inclusion of CLABSI for the IQR and VBP programs. However, the AAMC has concerns with CMS' proposal to expand the data collection to include non-ICU locations in the future. This could create a data collection challenge and has not been tested. Since the CLABSI measure has not yet undergone validation testing under the current specifications, the AAMC believes it is premature to include it with the expanded specifications in VBP.

Mortality Measures

CMS proposes three 30-day mortality measures- heart failure (HF), pneumonia (PN), and acute myocardial infarction (AMI)- for the VBP program, starting in FY 2015. **The AAMC supports the inclusion of the mortality measures in VBP; however, we strongly urge CMS to include adequate risk-adjustment modifications to the measures that address both SES and clinical factors.** The need for an appropriate risk-adjustment methodology is critical when applying financial incentives to ensure that no hospitals are unduly penalized. In addition, the current measures do not adequately address end-of-life or palliative care, which can inappropriately affect those hospitals with large palliative care programs.

AHRQ Patient Safety Indicators

CMS also proposes to include the AHRQ Patient Safety Indicators (PSI) Composite as a measure in the outcome domain. The AAMC continues to have concerns with the inclusion of this measure in the VBP program. This composite measure was originally developed for use in a hospital's internal quality improvement efforts, not for public reporting. Since CMS is using claims data to calculate this measure, the Agency's ability to validate an actual occurrence is limited. The use of administrative data also limits CMS' ability to accurately capture the severity or risk of included patients due to the capacity to only look at eight diagnosis codes. Therefore, given these concerns with the PSI composite measure, we believe it is premature to link it with financial incentives. We urge CMS not to include this measure in the VBP program at this time.

Medicare Spending Per Beneficiary

The AAMC applauds CMS for the Agency's work in developing specifications and a sophisticated model for calculating the Medicare spending per beneficiary (MSPB) measure,

which quantifies Medicare spending from patient episodes across hospitals. The MSPB measure calculates spending for a hospital episode three days prior to admission and 30 days postdischarge and includes both Medicare Parts A and B services. The measure is calculated on Medicare claims and does not include IME and DSH payments or transfers between acute care hospitals. While the AAMC agrees it is important to track and measure Medicare spending, this measure also highlights how complex it is to define hospital efficiency. We are still in a nascent stage, and there is more to be understood before such a measure can be included in a performance-based payment program.

Domain Weighting

CMS has proposed the following methodology for the FY 2015 VBP program, which would weigh the care domains as follows:

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

For FY 2015, CMS proposes to include 12 measures in the Process of Care domain, five measures in the Outcomes domain, and one measure each for the Patient Experience and Efficiency domains. The AAMC strongly recommends that CMS modify the weighting of the care domains to more appropriately reflect the quality of care provided by hospitals. The AAMC has previously commented on the weighting of both the HCAHPS and the efficiency domains. We continue to believe that the proposed weight of 30 percent for the HCAHPS domain is inappropriately high. As we commented previously, the HCAHPS 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 the relationship between HCAHPS and severely ill and disadvantaged patients, it is imprudent to weight this domain at the 30 percent level. We strongly believe that weighting the HCAHPS domain no greater than 10 percent recognizes the importance of patient satisfaction without unduly penalizing hospitals solely due to their patient population.

The AAMC also previously commented on the efficiency domain, which contains only one new and relatively untested measure for FY 2015, Medicare Spending Per Beneficiary. As stated previously, the AAMC believes it is premature to include such a measure in VBP. If CMS moves forward, the domain should be weighted no more than 5 percent, as 20 percent of the total

performance score should not be based on one untested measure as currently proposed. The AAMC supports the goal of transitioning the VBP program from process of care measures to efficiency and outcomes measures. However, we urge CMS not to rush this process before the care domains contain an appropriate number of NQF approved and tested measures.

Alignment with the National Quality Strategy

Starting in FY 2016, CMS proposes to reorganize the quality measure domains to reflect the recommendations in the National Quality Strategy (NQS) and to further align the VBP program with the Meaningful Use and IQR programs. CMS proposes to group measures by domain areas that align with the NQS, including: patient and family engagement, patient safety, care coordination, population and public health, efficient use of healthcare resources, and clinical processes and effectiveness.

The AAMC supports the alignment of all 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, it is premature to realign the measures into different domains for purposes of payment determination at this time. Under CMS' model, there is only one measure each for the Care Coordination, Efficiency, and Person and Caregiver Centered Experience and Outcomes domains. Additionally, the NQS domains do not allow for differentiation between process and outcome measures, which has been a strong interest by CMS. **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.**

Mortality Measures

For FY 2015, CMS proposes to report three 30-day mortality measures (heart failure, pneumonia, and acute myocardial infarction) for the VBP program using a nine month baseline and performance period. As CMS notes in the proposed rule, Mathematica Policy Research, an Agency vendor, performed an independent analysis entitled *Reporting Period and Reliability of AHRQ, CMS 30-day and HAC Quality Measures-Revised* that questions the reliability of these mortality measures if the reporting period is less than 24 months. With respect to these measures, the analysis concluded that the majority of hospitals "do not achieve reliability with 12

months of data. A little less than half achieve moderate reliability using 24 months of data."⁶ CMS acknowledges the concerns of using unreliable data, but justifies its proposal by stating that "we believe that holding all hospitals accountable using the same time period alleviates these concerns."

The AAMC supports the eventual inclusion of mortality measures in VBP. We acknowledge that CMS is under tight time constraints for implementing VBP, but believe that it is inappropriate to use inaccurate data in the measure calculation. We urge CMS not to sacrifice accuracy simply for additional outcome measures and strongly urge the Agency to include these measures in VBP once it has achieved a reliable sample with an extended baseline and performance period.

Base DRG Definition

The statutory language in the ACA defines the base operating DRG for both the VBP and Readmissions Reduction Program as the payment amount that would otherwise be made under subsection D; with the exclusion of special payments for IME, DSH, outliers, and low volume. CMS is proposing to modify this definition by including technology add-on payments in the base DRG calculation. Therefore, the new definition would be defined as the "wage adjusted DRG operating payment, plus any applicable technology add-on payments." CMS proposes to include the technology payment, because the Agency claims that new technology is a treatment decision, unlike other add-on payments. The AAMC supports the proposed definition.

Distribution of Incentive Payments

Starting with FY 2013 discharges, CMS will fund the VBP incentive pool by reducing the base DRG payment amounts by one percent, gradually increasing this amount to two percent by FY 2017. Starting in January 2013, CMS proposes to process the DRG reduction and incentive payment adjustment simultaneously through the claims processing system. All FY 2013 claims prior to January will be reprocessed. For the FY 2014 payment year, CMS will make the incentive payments to hospitals as part of the claims payment process starting on October 1, 2013. Hospitals will be notified of their reduction/incentive payment 60 days prior to the start of the fiscal year. **The AAMC supports CMS' proposal for the distribution of the incentive payments; however, CMS should recognize that the delay in processing claims will result in additional burden on hospitals.** Contractual numbers and reimbursements will be understated

⁶ http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf

for the claims from October through January, and hospitals will require significant time and manual resources to update local systems once the claims have been re-processed.

Review, Corrections, and Appeals Process

CMS proposes to adopt a 30-day review and correction process for the VBP program, similar to the process that is currently in place for the IQR program. For the IQR program, CMS provides confidential reports to hospitals with measure rate calculations and discharge level information prior to public reporting of this data. Hospitals have 30 days from when the reports are made available on Qualitynet to submit corrections to these reports. A hospital's measure rates and scores would be open to review and correction under the proposed rule. **The AAMC fully supports the inclusion of a review and corrections process for the VBP program. However, the Association asks that CMS allow a minimum of 60 days, instead of 30 days, for hospitals to review the measure rate calculations and total performance feedback reports.**

For performance assessment calculations that continue to be disputed beyond the initial review and corrections period, CMS proposes to implement a process that would allow hospitals to appeal an adverse initial ruling from the Agency. The AAMC is pleased that CMS proposes to incorporate this appeals process to allow hospitals to submit additional concerns. However, CMS does not specify any timeline in the proposed rule for issuing resolutions on disputed calculations, or whether a hospital's information will be publicly posted during the disputed time period. The Association urges CMS to include additional details in the final rule on the appeals process and deadlines for resolving appeals for disputed calculations.

Transition from ICD-9 to ICD-10

The ICD-10-CM/PCS is currently scheduled to begin October 1, 2013. CMS recently issued a proposed regulation that would delay the implementation by one year to October 1, 2014. Even if a delay is finalized, we have concerns with how CMS' measurement of hospital performance may change when ICD-10-CM/PCS codes begin to be used for claims-based measures.

The AAMC asks that CMS compare baseline data to performance data using the same classification system. It would be unfair and impractical to compare a hospital's measurement results using ICD-9-CM in the baseline period and ICD-10-CM/PCS in the performance period. For calculation of the claims-based measures, we urge CMS to either re-run the baseline data using ICD-10-CM/PCS or re-run the performance data using ICD-9-CM.

HOSPITAL-ACQUIRED CONDITION PROGRAM

The Deficit Reduction Act (DRA) required the Secretary to identify at least two conditions that are high cost or high volume or both; result in a DRG that has a higher payment when presented as a secondary diagnosis; and could have been reasonably prevented through the application of evidence-based guidelines. Any claim submitted that includes one of the selected conditions that is not present on admission (POA) and is the only complication condition or major complication condition (CC or MCC) listed, is no longer reimbursed at the rate of the higher-paying DRG.

For FY 2013, CMS proposes to expand the list of hospital acquired conditions (HAC) included in the non-payment program by adding the following two conditions: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Pneumothorax with Venous Catheterization. CMS also proposes to add two diagnosis codes to the existing vascular catheter-associated infection HAC category, which went into effect October 1, 2011 but were not finalized in time for inclusion in FY 2012 rulemaking. These codes are 999.32 (bloodstream infection due to central catheter) and 999.33 (local infection due to central venous catheter).

The AAMC believes the occurrence of the two proposed conditions can and should be reduced. However, the Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures is similar to the SSI HAI measure that has already been adopted for the IQR program. Similarly, the AHRQ PSI composite measure in both the IQR/VBP programs contains Pneumothorax. Therefore inclusion of these conditions in the HAC program would be an unnecessary duplication. Additionally, these measures represent complications of care rather than true never events. Keeping these measures in the IQR/VBP programs also allows for some level of risk-adjustment, unlike the HAC program. **The AAMC does not support the addition of the two proposed conditions to the HAC program, although the Association supports the inclusion of the vascular catheter associated infection codes.**

Section 3008 HAC Payment Reduction Program

The AAMC notes that no information has been released regarding the implementation of the HAC payment reduction program (ACA Section 3008), which is statutorily required to start in FY 2105. The Association requests that CMS begin providing information on the implementation of this program including payment methodology, proposed measures, and performance periods.

OUTLIER PAYMENTS

Under the Medicare IPPS, if the costs of a particular Medicare case exceed the relevant MS-DRG operating and capital payment (including any DSH, IME, or new technology add-on payments) plus an outlier threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case's 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 IPPS 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.

The proposed rule would set the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus \$27,425, a 22.5 percent increase from FY 2012. In the June 11, 2012, correction notice, CMS explained that the Agency had inadvertently applied the incorrect adjustment factors to the operating and capital cost-to-charge ratios when calculating the FY 2013 fixed-loss cost threshold. The correction notes that the updated fixed-loss cost threshold is decreased by approximately \$1,000 and proposes a revised threshold equal to \$26,337.

The AAMC, in conjunction with the American Hospital Association, has worked to simulate CMS' analysis. In doing so, we obtained an estimated fixed-loss amount of \$23,780, which is significantly lower than the fixed-loss threshold of \$27,425, as well as the corrected value of \$26,337 that CMS estimated was needed to achieve a 5.1 percent outlier payment level.

The AAMC is extremely concerned about the ongoing inaccuracy in CMS' estimation of outlier payments. As noted in the proposed rule, "CMS has not met the 5.1 percent for some time." 77 *Fed. Reg.* at 28144. CMS estimates for FY 2011 outlier payments will be approximately 4.7 percent of actual total DRG payments and for FY 2012 outlier payments will be approximately 6.0 percent of actual total DRG payments. While CMS' estimate indicates that FY 2012 payments were higher than the 5.1 percent, in the majority of the past ten fiscal years CMS has made outlier payments in an amount less than the 5.1 percent target. As CMS itself notes, "while these estimates differ—with one being under the target and one above the target—they draw attention to the potential for improving our estimation methodology." *77 Fed. Reg.* at 28144. The AAMC wholeheartedly agrees that there is signification potential for improvement in this area.

Because CMS reduces the standardized amount by 5.1 percent and does not make retroactive adjustments to outlier payments when outlier payments total less than 5.1 percent of total DRG payments, providers consistently have been shortchanged by the Agency's incorrect estimations. Given the ongoing and consistent nature of this problem, the AAMC expresses concern that there is a fundamental flaw in CMS' outlier estimation calculations and encourages the Agency to discover the source of the problem and further refine the outlier payment methodology to improve annual outlier estimates.

ADD-ON PAYMENTS FOR NEW SERVICES AND TECHNOLOGIES

Each year, new technologies can be considered for an add-on payment if the technology meets the established criteria for newness and the DRG prospective payment otherwise applicable to the discharge is deemed inadequate. For FY 2013, CMS proposes that one new technology from FY 2012 will continue to receive the add-on payment: AxiaLIF 2L+ System. CMS proposes new technology payments for four new technologies for FY 2013, though seeks comments on a variety of issues related to each: Glaucarpidase (Trade Brand Voraxaze®),DIFICIDTM (Fidaxomicin) Tablets, Zilver® PTX® Drug Eluting Stent, and Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft. As the AAMC previously stated in comments to the Agency, the Association believes CMS should consider more new technologies each year for add-on payments, so as to best ensure accurate payment for new devices and services.

TIMELY FILING REQUIREMENTS FOR CLAIMS RELATING TO SERVICES TO MEDICARE ADVANTAGE ENROLLEES

Teaching hospitals must submit so-called "shadow bills" to receive DGME and IME payments associated with services provided to patients enrolled in the Medicare Advantage (MA) program. CMS proposes to clarify that all claims filing requirements that apply to Medicare claims, including the time limits, also apply to submission of MA-related claims.

The AAMC encourages CMS to recognize that there are many nuances to shadow billing and that the inherent complexities often cause delays in the processing of these bills. In the final rule, CMS should provide an estimate of the administrative and cost burdens to hospitals that result from the requirement to file a second shadow bill for each Medicare managed care discharge. The Association also urges CMS to acknowledge that this proposal is a new rule rather than simply a "clarification" of existing policy.

HOSPITAL SERVICES FURNISHED UNDER ARRANGEMENTS

In the FY 2012 IPPS final rule, CMS adopted a new policy that routine services (i.e., bed, board, nursing, and other related services) must be furnished by the hospital and may not be furnished "under arrangements" outside of the hospital. In this proposed rule, CMS proposes to delay the implementation date of the new under arrangements policy to October 1, 2013, because the Agency recognizes that hospitals need more time to comply with the policy.

The AAMC appreciates CMS' proposal to delay the effective date of this policy but remains concerned by CMS' ongoing lack of clarity as to the reasons for the Agency's policy change. CMS has not yet offered a policy rationale for the change or explained the types of circumstances that are causing the Agency to be concerned. The AAMC urges CMS to provide additional information as to why this change is needed and not simply impose this level of burden on hospitals without articulating a clear reason for the requirement.

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. For questions regarding the quality provisions please contact Jennifer Faerberg at 202-862-6221 or jfaerberg@aamc.org.

Sincerely,

Danell G. Kinch

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