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VIA HAND DELIVERY

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Attention: **CMS-1390-P**

Dear Mr. Weems:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "*Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems [IPPS] and Fiscal Year 2009 Rates.*" 73 Fed. Reg. 23528 (April 30, 2008). 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 IPPS. The Association also represents all 129 accredited U.S. allopathic medical schools; 94 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: capital indirect medical education (IME) payments; the physician self-referral – physician "stand in the shoes" and entity "stand in the shoes" provisions; the disclosure of financial relationship report; the Emergency Medical Treatment and Active Labor Act (EMTALA); quality reporting; hospital readmissions; post acute care transfers; coding improvement; charge compression; the wage index and the outlier threshold.

CAPITAL IME PAYMENTS

In the federal fiscal year (FFY) 2008 final rule with comment period, CMS announced that the Agency plans to eliminate the capital IME adjustment beginning in FFY 2009. According to the rule, the IME adjustment would be reduced by 50 percent in FFY 2009 and eliminated altogether in FFY 2010 and beyond. In response to the Agency's request in the final rule, the AAMC submitted comments on this interim policy on November 20, 2007 urging CMS to rescind its decision. In this proposed rule, the Agency reiterates its

intention to implement this policy starting in FFY 2009, but said it would again accept comments. The Agency plans to respond to both the comments submitted in November and those submitted in response to this proposed rule when it releases the final rule in August.

We would like to take this opportunity to again urge CMS to rescind its decision to reduce and then eliminate the capital IME adjustment. The elimination of the capital IME adjustment would result in an annual aggregate payment cut to teaching hospitals of approximately \$354 million. A payment cut of this magnitude is not warranted and could diminish these hospitals' abilities to continue their core missions of clinical care, education and research.

CMS relies on teaching hospitals' capital margins as a basis for making its decision. According to CMS's analyses, "large urban" teaching hospitals had an aggregate capital margin in 2005 of 11.9 percent, compared to 3.7 percent for all hospitals (73 Fed. Reg. at 23678-679). Yet CMS does not provide the impact on capital margins if IME payments were eliminated. An analysis of 2006 hospital cost reports by Vaida Consulting shows that eliminating capital IME payments would result in an aggregate negative capital margin of -3.5 percent for major teaching hospitals.¹

A decision to cut Medicare capital IME payments also should not be viewed solely from a Medicare lens. Because major teaching hospitals' total margins often hover near zero, payment cuts from any source affect the fiscal condition of these institutions, which influences all aspects of their operations—operations that include providing education for a spectrum of health care professionals; providing an environment where clinical research can flourish; and offering highly specialized services to the community such as burn care, trauma care, and transplant services. Major teaching hospitals are also looked to as front-line responders in the event of biological, chemical, or nuclear attack and depend upon sufficient financial resources to fulfill that role.

CMS has not provided any analyses of the effect that the cuts may have on critical services provided to Medicare beneficiaries and others in the community, or their potential effect on medical education and research. Moreover, CMS has amplified the potential negative impact of the capital IME cuts by planning to implement them on the heels of the FFY 2008 elimination of the 3 percent adjustment to capital payments for large urban hospitals, which affected many teaching hospitals.

PHYSICIAN SELF-REFERRAL – PHYSICIAN “STAND IN THE SHOES”

The AAMC appreciates the work that CMS has put into devising a physician “stand in the shoes” (SITS) concept that does not endanger the mission support payments that are so vital to academic institutions. The Association is particularly grateful that CMS recognized the difficulties that an earlier proposal would have caused academic medical

¹ This margin reflects the elimination of the large urban add-on which occurred in FFY 2008.

centers, and some other entities, and imposed a moratorium to allow more time to study the policy and devise a solution that addresses concerns that were raised. The Association supports the notion that whatever requirements are imposed should be easy to understand, simple to apply, and targeted to arrangements where program abuse is most likely.

Adopt the Most Straightforward Approach

The AAMC believes that the most straightforward way to address arrangements that may be susceptible to program abuse is to apply the physician SITS provisions *only* to owners of a physician organization who have a right to profit distributions of that physician organization. This is a refinement of the proposal found on p. 23687, and will allow for a clear cut analysis of arrangements while appropriately targeting those where the risk of program abuse is greatest.

CMS asked commenters to consider whether the “stand in the shoes” provision should apply to a physician organization that has no physician owners. In general, the answer should be no. However, there are some states that in which physicians operate under the corporate practice of medicine, so physician ownership would be required. That underscores the importance of adopting the approach suggested above since it will accommodate some entities that have physician owners, not by choice but by statutory requirement.

Alternatively, Make the Moratorium Permanent

Alternatively, CMS could make the current moratorium permanent, so that “stand in the shoes” would not apply:

- With respect to an Academic Medical Center (AMC) as described in §411.355(e)(2), to compensation arrangements between a faculty practice plan and another component of the same AMC; and
- With respect to an integrated section 501(c)(3) health care system, to compensation arrangements between an affiliated designated health service (DHS) entity and an affiliated physician practice in the same integrated section 501(c)(3) health care system.

However, with respect to integrated delivery organizations, the AAMC believes that it is preferable not to draw distinctions based on tax status. Additionally, this approach would require a careful definition of an “integrated section 501(c)(3) health care system.” Such definition would need to be published in proposed form so that there would be an opportunity for comments.

An Exception-Based Approach Is *Not* The Preferable Way to Address Physician SITS

CMS also has proposed an approach whereby SITS would not apply to arrangements that

fit into the *bona fide* employment, personal services, or fair market value compensation exceptions. Additionally, CMS suggested:

Revising §411.354(c)(3) to delete the reference to applying the exception in §411.355, and thereby providing that the “stand in the shoes” provisions do not apply where the prohibition on referrals is not applicable because all of the requirements of any of the exceptions in §411.355 are satisfied.

Section §411.355 includes the in-office ancillary exception. Based on discussions between the AAMC and CMS staff, it is unclear whether it is the intent of CMS that the in-office ancillary exception would *not* trigger “stand in the shoes.” Given this uncertainty, combined with a goal of adopting a simplified approach, the AAMC believes it would be preferable for CMS to adopt one of the approaches described above rather than an exception-based approach.

“Stand in the Shoes” and the Academic Medical Center (AMC) Exception

The AAMC also notes that CMS proposed that “a physician would not stand in the shoes of his or her physician organization (for example, a faculty practice plan) when his or her referral for DHS is protected under the exception in §411.355(e) for services provided by an AMC”. The Association appreciates CMS’s recognition that “stand in the shoes” should not apply if all of the requirements of the AMC exception are met. This is consistent with the terms of the moratorium in that it recognizes that the importance of the AMC exception to those entities that are able to meet its rigorous requirements. It should be noted that if CMS applies SITS to the AMC exception, then the exception would, in essence, become worthless. It was created to protect the mission support payments that commonly flow among the various entities that comprise the academic medical center. Were the AMC exception not considered to be sufficient protection against SITS, then virtually all mission support payments would be in danger of violating the self-referral rules. Consequently, the AAMC supports this clarification.

The Complexities of Teaching: Physician Volunteers and Other Issues

Within the SITS proposal, CMS recognizes the complexities of the Medicare requirements that hospitals must follow to receive direct graduate medical education (DGME) reimbursement by proposing that when compensation is paid for the purpose of meeting the requirements of 42 C.F.R. §412, the arrangement will be analyzed by applying the rules regarding indirect compensation arrangements. The AAMC supports this proposal.

There are additional complexities that must be addressed if CMS does not adopt the ownership approach, or make the moratorium permanent; namely, volunteer physicians. An important aspect of the medical profession is teaching—a physician learns from other physicians and frequently, in turn, embraces the notion of participating in teaching medical students and residents him or herself. In teaching institutions it is common for

community physicians to participate in undergraduate and graduate medical education as volunteer faculty. These physicians are not paid as employees for the time they spend in clinical teaching. However, as is typical for any faculty member, these volunteers often are given some benefits such as an e-mail account and library access, parking, professional liability coverage for the clinical teaching activities, reimbursement for travel to volunteer, or continuing medical education opportunities. In some instances, volunteers might receive certain benefits from one component of an organization while providing teaching activities for another component. Providing these items and services benefits the academic medical center, enhances the quality of teaching, and improves access to patient care. For example, the e-mail account is a way to make communication with all faculty uniform and easy. Library access allows the volunteer to keep abreast of developments in his or her field, thus enhancing the quality of teaching and patient care.

Although it may be possible to characterize these items and services as remuneration, the AAMC requests that to avoid disrupting the volunteer system on which teaching hospitals rely, CMS address this common situation either by crafting an exception that allows for limited remuneration for physician volunteers, or by revising the definition of remuneration so that these limited benefits do not fall under the requirements of the statute.

Do Not Craft an Exception for Mission Support Payments

CMS also posited the idea of crafting an exception that would be limited to “mission support” and possibly other specific types of payments or compensation arrangements. The AAMC urges CMS not to pursue this notion. Developing an accurate and comprehensive definition of what constitutes “mission support” will be extremely challenging and may well result in complexities that will defeat the purpose of developing a system that “simplifies the analysis.”

A Delay in the Effective Date and an Extension of the Moratorium May Be Necessary

Finally, depending on the option that CMS selects for addressing physician SITS, it may be necessary for some organizations to make significant changes in some of their arrangements. To avoid disruptions, the AAMC requests that CMS consider making the implementation date for the physician SITS later than the implementation date for the remainder of the IPPS rule. At a minimum, CMS should allow 12 months from the date of the publication of the final rule for implementation. The moratorium should remain in effect until the effective date.

ENTITY “STAND IN THE SHOES”

The AAMC anticipates that few academic medical centers will be affected by the entity “stand in the shoes” provision. However, while the physician SITS provision is relatively clear cut, the Association notes that the entity SITS concept, as described in the *Federal*

Register, requires a difficult analysis, and at times the results are counterintuitive. Once the physician SITS provisions are finalized, the AAMC urges CMS to consider whether there is a need for an entity SITS. The Association urges that additional time be devoted to study the issue before the Agency proceeds. At a later date, CMS can re-propose this portion of the regulation, again bearing in mind the goals of a straightforward analysis and targeting prohibitions at arrangements that are most likely to be abused.

GAINSHARING

The AAMC is pleased that CMS “recognize[s] the value to the Medicare program and its beneficiaries where the alignment of hospital and physician incentives results in improvements in quality of care.” As Medicare and other payers revise their payment systems to take into account quality issues, and as providers seek ways to reduce costs without limiting access or reducing quality, these arrangements become even more important. The AAMC supports the creation of an exception for gainsharing arrangements and looks forward to the opportunity to work with CMS on this important effort.

DISCLOSURE OF FINANCIAL RELATIONSHIPS REPORT

CMS has been working on the Disclosure of Financial Relationship Report (DFRR) for over a year. In response to the AAMC and others, the Agency has increased the estimated time for completing the DFRR from the original 4 hours to the current 31 hours. This certainly is a significant change, but does not alter the fact that the DFRR is burdensome and not likely to produce information of sufficient utility to justify the cost both to the responding hospitals and to the government in reviewing the responses. Notably, CMS’s burden estimate has gone up significantly, yet the scope of the ICR remains the same.

The Agency estimates that a hospital can prepare a response to the DFRR survey in 31 hours. That is not realistic. Assuming only 31 hours of “administrative” time to gather and assemble the data in the manner required by the DFRR, significantly underestimates the burden of responding. While the Agency may envision hospitals using a simple data processing query to gather the requested information, even in the environment of faculty physicians, such a request would be extremely time consuming and burdensome.

CMS’s estimate is an average taken from estimates received from an equal number of small, medium, and large hospitals. This methodology may significantly understate the burden to large hospitals. Further, CMS relies on the notion that completion of the DFRR is a task that can be delegated to administrative staff since it involves “retrieving the information and printing it from electronic files or copy[ing] it from hard drives.” It remains unclear how administrative staff will be able to complete such instructions as the following for Worksheet 7:

For those compensation arrangements listed in Columns A through D, include not just those that you believe fit within an exception in 42 C.F.R. §411.357, but those that are implicated by the referenced exception.

Given the likely burden for large hospitals to complete the DFRR, and CMS's failure to provide a convincing argument for requiring that 500 hospitals complete it, the AAMC requests that CMS withdraw this proposal. CMS should craft a revised proposal that targets hospitals and arrangements that are most likely to violate the Physician Self-Referral requirements.

EMTALA

CMS proposes several changes related to hospital emergency services under the Emergency Medical Treatment and Active Labor Act (EMTALA; 42 C.F.R. §489.24). The AAMC's comments are limited to proposals to expand EMTALA into the inpatient setting. Specifically, CMS has proposed "to clarify that section 1867(g) of the Act continues to apply so as to protect even an individual who has been admitted as an inpatient to the admitting hospital who has not been stable since becoming an inpatient." (73 Fed. Reg. at 23670). Under this view, a receiving hospital that has the capacity and specialized capability to treat this unstable patient would have an EMTALA obligation to accept the transfer from the admitting hospital. The AAMC strenuously objects to this proposal for the reasons stated below, and urges CMS to withdraw it.

CMS finds support for this proposal by citing the specialized care requirements found in section 1867(g) of the Social Security Act. In the preamble to the proposed regulation, CMS describes section 1867 as setting forth requirements "for individuals who come to the hospital and request examination or treatment for a medical condition." (73 Fed. Reg. at 23668). However, the actual language of the Act addresses "an individual who comes to *the emergency department*." (emphasis added). Applying the requirements to an individual who comes to a "hospital" is overly broad and goes well beyond the statute. Since the requirement for the application of section 1867 is unambiguously that an individual must come to the "emergency department," the plain reading of the non-discrimination provisions found in 1867(g) is that they apply only when an individual comes to an "emergency department." CMS's more expansive reading that this section applies when an individual comes to "the hospital" is inconsistent with the statutory language and does not provide support for the notion that EMTALA obligations are intended to apply to inpatients.

CMS also looks to the recommendation of the EMTALA Technical Advisory Group (TAG) to support the notion that the application of the law's requirements should be expanded to inpatients. This fails to acknowledge that the TAG was highly divided about this recommendation. Two letters from TAG members, each dated September 18, 2007, were submitted to the TAG. In one, two physicians wrote that:

We two physician members of the TAG who voted for the recommendation feel that its implementation should be carefully considered as having the potential for abuse (i.e. patient dumping). (Appendix 3 to Report Number Seven of the TAG, September 17-18, 2007)

A second letter, signed by eight members of the TAG, noted that:

All of the practicing surgical specialty physician representatives as well as all of the hospital representatives of the TAG are in opposition to this recommendation.

With due consideration to our colleagues on the TAG we respectfully wish to formally record our dissent. (Appendix 4 to Report Number Seven of the TAG, September 17-18, 2007)

CMS acknowledges the concern about the effect that this proposal may have by stating that it “may raise concerns among the provider community that such a clarification in policy could hypothetically result in an increase in the number of transfers.” (73 Fed. Reg. at 23670). Among all hospitals, teaching hospitals are most likely to have specialized capabilities, such as trauma centers and burn units, and thus they already are susceptible to a large share of “patient dumping.” Expanding EMTALA to the inpatient setting will exacerbate this problem for the very institutions that already are the safety net providers in many communities. No one wants patients who need care to be denied services, but suggesting that a “clarification” of EMTALA should be the solution to this problem will only create more stress on a frequently overburdened system.

All hospitals that have emergency departments should be capable of evaluating patients that come to those departments. Prior to admitting these patients, and as part of the decision about the proper course of care for those patients who need to be stabilized, hospitals should be required to evaluate the patient’s need for specialized care in light of the hospital’s capability to provide that care. If that specialized capability does not exist, then it is incumbent upon that hospital to transfer, rather than to admit, the patient. CMS should recognize that the admission of an unstable patient by the original hospital is *prima facie* evidence that the hospital has the capability to treat that patient. Once the patient is admitted, the EMTALA obligation for the original admitting hospital is ended; no new EMTALA obligation should be created for a potential receiving hospital.

CMS also asks for public comments on:

whether the EMTALA obligation imposed on hospitals with specialized capabilities to accept appropriate transfers should apply to a hospital with specialized capabilities in the case of an individual who had a period of stability during his or her stay at the admitting hospital and is in need of

specialized care available at the hospital with specialized capabilities. (73 Fed. Reg. at 23670).

Just as the AAMC believes that EMTALA should not be expanded to unstable inpatients, we believe that it should not be expanded to cover inpatients who have a period of stability and then become unstable, for the reasons discussed above. To do otherwise would open the door to the possibility of such extensive patient dumping that the financial stability of hospitals with specialized capabilities could be severely threatened.

Imposition of this policy could lead to a situation where a patient is admitted for pneumonia, for example, and then becomes unstable because of a totally unrelated condition that the admitting hospital does not have the capacity to treat. To suggest that there is an EMTALA obligation for a hospital with specialized capabilities to accept this transfer is to put forth a policy that far exceeds the reach of law. Further, it would encourage hospitals to dump patients when an unexpectedly difficult case suddenly appears. While no one would argue that in this—and every—instance patients should receive appropriate care, EMTALA is not the vehicle through which this can, or should, be mandated. CMS should work with the provider community and, if necessary, Congress, to find an appropriate way to ensure that all individuals receive the care that they need, and that payment is made to the providers of that care.

QUALITY REPORTING PROGRAM

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) created a Quality Reporting Program that required hospitals to submit data on ten hospital performance measures in order to receive their full payment update. If hospitals did not report their performance data, their annual payment update was reduced by 0.4 percentage points in FFYs 2005 and 2006. The Deficit Reduction Act of 2005 (DRA) increased the penalty for hospitals not reporting their performance data to minus 2.0 percentage points in FFYs 2007 and beyond and increased the number of measures to be reported. The DRA also gave the Secretary the authority to continue to increase the number of measures reported that reflected consensus amongst affected parties as well as retire and/or replace those measures that were no longer relevant or scientifically current.

In the current IPPS proposed rule, CMS is proposing the addition of 43 quality measures to further expand the quality reporting program. In order for hospitals to be eligible for their full payment update they would need to submit data for the 43 proposed measures in addition to the 30 current measures already being reported, for a total of 72 performance measures.

The proposed measures include:

- One surgical care measure
- Four nursing sensitive measures
- Three readmission measures

- Six venous thromboembolism (VTE) measures
- Five stroke measures
- Nine patient safety and quality indicators from the Agency for Healthcare Research and Quality (AHRQ)
- Fifteen cardiac surgery measures from the Society of Thoracic Surgeons (STS) registry

We appreciate the need to expand the quality reporting program and as members of the Hospital Quality Alliance (HQA) have been active in making recommendations of approved measures for hospital reporting. However, to propose the addition of 43 new measures in one reporting year shows a lack of focus on the value of this many additional measures, inadequate analysis of impact of this dramatically expanded obligation on providers, and—ultimately—the impact of reporting these measures on the added value or lack thereof of the care provided to Medicare patients.

As a member of the HQA we were dismayed to see that in the proposed rule CMS did not follow the legislated approach set forth in the DRA, which states that measures need to reflect a consensus amongst the affected stakeholders before they are implemented. Historically, CMS has worked with the HQA in the review and selection of measures. However the proposal for this fiscal year is categorically different than what was approved and recommended by the HQA. We believe strongly that all measures included in the quality reporting program must be approved and recommended by the HQA and endorsed by the National Quality Forum (NQF).

Furthermore, the success of the reporting program to date is because the hospital community has had a level of predictability regarding measure selection, by knowing a year in advance what measures to plan and prepare for, as well as by monitoring the activities of the HQA and having a sense as to what measures are being considered for the public reporting program. With the proposed measures, hospitals have not had adequate time to prepare since the proposed measures are so different from what they expected with respect to the types of condition areas and the sheer number of additional measures. There has never been such a significant number of measures proposed for a single reporting year. The claim that some of the measures proposed are claims-based is not meritorious. Implementing data collection mechanisms as well as changing care processes takes significant time and resources.

While we appreciate CMS's stated interest in trying to minimize the burden on hospitals for submitting data for public reporting, the addition of 43 measures irrespective of the data source does not equate to minimizing burden. In addition to the resources necessary for abstracting the necessary information in the cases of chart-based measures and preparing cases for those measures that rely on registry data, there also is an investment in resources to implement processes and system changes. It is not apparent from the list of 43 measures that hospitals would be putting resources in areas that would be most relevant and beneficial for consumers, patients and providers. Unfortunately, there is no easy fix for the burden issue and as long as we continue to add measures to the reporting

program, and do not have electronic medical record systems that are able to easily and consistently generate the data necessary for the quality measures, quality reporting will always require a significant level of time, money and resources.

Proposed Measures for FFY 2010

Based on our comments below we believe CMS should only implement the NQF-endorsed and HQA-approved measures for FFY 2010.

- Surgical Care (perioperative beta blocker usage) – This measure is NQF-endorsed and was previously approved by the HQA. In an effort to build out the surgical care improvement project (SCIP) measures we are supportive of this measure being included in the quality reporting program.
- Nursing Sensitive Measures – The nursing sensitive measures have previously been endorsed by the NQF. However, the measures had not been properly field tested for reliability/validity and feasibility (such as collecting human resources data as well as audit and validation of observational studies). The measures are currently being tested through the Joint Commission which is not scheduled to conclude testing until December 2008. As a result of the testing, the Joint Commission will determine whether the measure specifications need modification and, if so, if they need to be returned to the NQF for re-evaluation. The early feedback on the testing thus far suggests that significant changes will be made to the measure specifications. We believe the work of the Joint Commission to appropriately test the measures should continue and, once that work is completed, the measures should be re-evaluated by NQF and then be considered for future reporting. We, therefore, believe the nursing sensitive measures are not ready for implementation in FFY 2010.

We would also like to point out that there is duplication in the nursing sensitive measure set and the AHRQ set. The Failure to Rescue measure is listed in both sets and has been renamed as “death among surgical patients with treatable serious complications.”

- Readmission Rates – While we are supportive of readmission measures, the HQA has not approved any of these measures and NQF has only endorsed the Heart Failure measure. Therefore we do not support these measures for inclusion in the FFY 2010 reporting program.

The HQA has approved a measure of condition-specific readmission rates paired with condition-specific average length of stay (ALOS). CMS should incorporate what has been approved by the HQA.

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Kerry Weems, Acting Administrator

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- Venous Thromboembolism (VTE) – These measures were endorsed by the NQF and approved by the HQA. We recommend their inclusion in the quality reporting program for FFY 2010.
- Stroke – Stroke is a priority area for the HQA and we are supportive of including stroke measures on Hospital Compare in the future. However, the call for stroke measures had not occurred prior to the HQA review of measures. As a result, the HQA focused on those measures that had been NQF endorsed and were suitable for implementation in FFY 2010. At this point the stroke measures are still not NQF-endorsed; therefore we recommend that stroke measures be considered for future reporting.
- AHRQ Patient Safety Indicators and Quality Indicators – The HQA has adopted three of the nine AHRQ measures proposed by CMS, including postoperative wound dehiscence, accidental puncture or laceration and abdominal aortic aneurysm mortality rate. We believe these measures are appropriate for public reporting, although significant infrastructure challenges still exist to collect and transmit administrative data on patients of all payers.

The other AHRQ measures may have value to hospitals for quality improvement purposes, but in their current format some lack the sensitivity and specificity required for use as a comparative, publicly-reported measure. Because they are derived from administrative data, they are less sensitive than measures derived from clinical chart abstraction at identifying relevant patients and excluding other patients. Some of the AHRQ indicators have very high false positive rates, meaning that they indicated potential problems, but further investigation showed the care was adequate and the indicator was wrong. To be considered for HQA adoption, and therefore be ready for implementation in the pay-for-reporting program, these measures need extensive field-testing and respecification.

- Cardiac Surgery Measures (via STS registry) – Hospital Compare is currently displaying measures in four condition areas. Two of those four conditions are cardiac-related, with a significant number of measures within each of those conditions. While the cardiac conditions are a priority area for the HQA, there also are several other priority areas where there are no measures represented on Hospital Compare. We would question the added value to patients of so many additional measures in the area of cardiac care, an area that is already well represented, before trying to build out other conditions areas that may have more value.

Currently, approximately 20 percent of hospitals with cardiac surgery programs are not participating in the STS registry. In order to participate, hospitals need to pay a significant fee. We do not think it is appropriate for a federal program to be implementing measures from a program that would benefit financially from this endorsement. We believe this is a conflict of interest and can be construed as

serving the financial interests of a third party. This is further compounded by the use of the proposed measure “Participation in systematic database for cardiac surgery.”

For those hospitals that do not participate in the STS registry, they would need to have an alternative mechanism to submit their data, which would be the CMS Abstraction and Reporting Tool (CART). CART, however, has been under-resourced to date. For example, critical access hospitals are still unable to submit hospital outpatient data through CART.

We appreciate the interest in using data collected from outside registries and STS in this particular case, however we have significant concerns about how the measures derived from a clinical registry can be integrated into the existing national reporting structure. The use of registry data has not yet been tested and there are significant concerns about ensuring the consistency with the current process for chart abstracted measures. For example, the issue of validation is unclear. Would STS be responsible for validating the data and if so, how would CMS audit the data and ensure they were meeting the same validation criteria as the other data coming into the data warehouse? The specifications and data definitions for the measures in the registry would need to be consistent with those measures currently being collected via chart abstraction. There has been no information as to what the requirements would be in order to extract the information from the STS registry which may cause an issue with the current infrastructure.

Additionally, we are also uncertain regarding the process for hospital to ensure their data are released from the appropriate entities to CMS. Would hospitals need to fill out another form or contact STS separately to make sure their data are released in addition to the other forms they need to complete for the reporting program?

And finally, there is an issue of burden. While we are pleased that CMS is looking at alternative options to minimize the burden on hospitals, the use of the STS registry measures is still burdensome from a cost and resource perspective. Not all of the hospitals that have cardiac surgery programs are participating in the STS registry and, therefore, there would be a new significant financial requirement to be eligible for their full payment update. And, for those hospitals that are participating, not all of them are currently reporting all eligible cases. This highlights two potential problems that hospitals would need to overcome to submit all relevant cases.

Proposal for additional measures – We were surprised to see that in the list of proposed measures CMS did not include the two infection measures that have been approved by the HQA. These measures (central line association blood stream infection and surgical site infection rate) have been NQF-endorsed and have enjoyed wide support from the

stakeholder community as well as being valuable to the consumer community and an important tool for hospitals to look at and reduce infections in their institutions. We recommend that CMS include the two infection measures for the quality reporting program.

Future measures – In order to provide direction for the types of measures that should be included on Hospital Compare moving forward, CMS should look to the work of the NQF Priority Partners. The goal of the Priority Partners is to engage all stakeholders in a shared effort to make quality improvements in the most important areas of patient care. The HQA has agreed that the NQF's national goals should provide a foundation for its future work and we believe CMS should do the same.

Retirement of measures – We are in agreement that the Pneumonia Oxygenation Assessment measure should be retired. However, there should be specific criteria developed for the retirement of measures. A multi-stakeholder group should be convened including measure developers, vendors and providers to discuss this issue and develop the appropriate criteria.

Measure maintenance – We appreciate the fact that measure modification is difficult when tied to the regulatory rulemaking process. However, any change to a measure must allow for a public comment period. We need to ensure that the stakeholders are aware of what is being proposed and have an opportunity to comment on the proposed change. A sub-regulatory process with no public comment would provide CMS the ability to make changes to measures without the knowledge or input of the provider community.

Using alternative data sources – There are significant issues with collecting data through alternate data sources that need to be fully resolved before implementation. CMS needs to ensure that data from a third party can be validated. If validation is performed by the third party, CMS needs to be able to audit the data and ensure they subjected to the same level of validation as those measures being collected directly by CMS. Measure specification and definition of data elements would need to be reviewed and modified to ensure they are consistent with what is already in place. Further work also needs to be done to determine the technical requirements in order to receive the third party data. Given that each third party source would have its own requirements, CMS would need to have the technical flexibility in order to accommodate the different requirements across multiple data sources.

Hospital Compare Website – There has been significant conversation within the HQA, including CMS, on how to improve the Hospital Compare Website to be more user-friendly and understandable by consumers. Until recently, the Compare site included 30 condition-specific measures. With the recent addition of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data, as well as the payment and volume information, there is a need to make sure the website does not become overwhelming and even more confusing and cumbersome than what is being displayed currently. With the addition of 43 measures we fear that the Compare site will

be unable to provide an overall benefit for consumers. CMS needs to identify resources to develop and implement a planned revision of the current site based on current and future measure build-out to ensure it achieves its intended goal of being intuitive, easy to navigate and easily understood by consumers.

Infrastructure issues – The current infrastructure used to collect the performance data for public reporting has been routinely characterized as fragile. We have been regularly reminded about the limitations of the current system be it the technological issues or process issues associated with data submission. We continue to be concerned about the ability of the current system to accommodate increases in measures, particularly with the proposal to add 43 measures, which would be a dramatic expansion. The proposed list includes measures from different data sources which would also require a new data submission process that has yet to be tested and integrated into the current infrastructure. As we look forward to the potential of Value Based Purchasing, and tying a hospital's performance to payment, resources need to be identified to develop and support a system to accommodate the growing number of measures being reported in a consistent and reliable manner.

Data submission – We continue to have issue with the fact that hospitals are unable to re-submit their performance data when errors are identified. We recently became aware of a situation in which a hospital identified a problem in their data due to a change in microspecifications for one of the measures. The error was not identified until after the data had been submitted. Since they were unable to resubmit their data, their performance was inaccurately reported. Hospitals should be able to resubmit their data after they identify a problem to ensure that what is publicly reported is accurate and not marred by identified errors that were unable to be changed.

HOSPITAL-ACQUIRED CONDITIONS (HAC)

The DRA required CMS to identify, by October 1, 2007, at least two preventable complications of care that could cause patients to be assigned to a complication or comorbidity (CC) diagnosis-related group (DRG). The conditions also must be either high-cost or high-volume or both, result in the assignment of the case to a DRG that has a higher payment when the CC is present as a secondary diagnosis, and be reasonably preventable through the application of evidence-based guidelines. The DRA mandates that for discharges occurring on or after October 1, 2008, the presence of one or more of these preventable conditions would not lead to the patient being assigned to the higher-paying DRG.

In the FFY 2008 inpatient prospective payment system (PPS) final rule, CMS adopted eight conditions for which it would no longer pay a higher DRG rate beginning in FFY 2009 if the conditions were not present on admission. Those eight conditions were:

- Object left in during surgery;
- Air embolism;

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- Blood incompatibility;
- Pressure ulcers;
- Falls and trauma;
- Catheter-associated urinary tract infections;
- Vascular catheter-associated infections; and
- Surgical site infection – mediastinitis after coronary artery bypass surgery.

This year, CMS proposes to expand the list to include nine additional conditions when the payment policy takes effect on October 1. The nine conditions are:

- Surgical site infections following elective procedures;
- Legionnaires' Disease;
- Glycemic control;
- Iatrogenic pneumothorax;
- Delirium;
- Ventilator-associated pneumonia;
- Deep-vein thrombosis/pulmonary embolism;
- *Staphylococcus aureus* septicemia; and
- *Clostridium difficile*-associated disease.

In addition to providing care across the full array of patient conditions, major teaching hospitals disproportionately treat complex and severely ill patients who often present with multiple co-morbidities and serious, or rare, complications of routine medical conditions. As major referral centers, we are often the recipients of complex and high risk patients who are transferred from non-teaching hospitals. Teaching hospitals also provide unique services not found at other hospitals, including transplantation, trauma and burn care, participation in clinical trials, and other services.

Teaching hospitals embrace their responsibility to ensure that the care provided to all individuals is of the highest quality, reflecting the latest scientific evidence and technological advances. We appreciate CMS' acknowledgement of the high risk patient population we serve and providing a potential refinement to the HAC program by looking at risk adjustment. While we are not recommending risk adjustment at this time, we would be more than happy to coordinate a group of member representatives to meet with you to help identify the best way to accommodate the high risk patient population within the HAC program.

We are supportive of a program that is aimed at reducing harm and avoiding negative outcomes. Hospitals have been very active in implementing quality improvement strategies to reduce infections and eliminate serious reportable adverse events. However, hospitals need additional help in developing, accessing and implementing necessary changes. We believe that CMS and its Federal partners should be doing more to facilitate the development and distribution of guidelines and "checklists" that will help improve outcomes in hospitals. As stated in a recent report from the Government and

Accountability Office (GAO) and congressional testimony, the Department of Health and Human Services (HHS) has lacked the leadership to develop, prioritize and help guide implementation of evidence-based practices in hospitals.

Any type of HAC program needs to select conditions that are supported by evidence-based guidelines, apply to all patients equally, can be diagnosed accurately, and are supported by proper coding procedures. Several conditions that have already been selected, as well as those that are currently being considered, are not always easy to diagnose.² Implementation of conditions that are difficult to diagnose require a large cost expenditure to conduct appropriate testing. In addition, even after the appropriate tests are completed, there still can be a high false positive rate and hospitals are put in the position of treating patients for a condition they may not have. For example, pyelonephritis and urethritis are included in the CMS coding for urinary track infections (UTIs), when, in fact, they may not have the associated UTI. Similarly, coding law requires that, if reported in the physician's progress notes, 100,000 CFU of any single organism in a urine culture be coded as UTI, when, in fact, it may be colonization.

The HAC program is based on the premise that the selected conditions are reasonably preventable. This implies that not all conditions will be avoidable even when the appropriate guidelines are followed. Yet hospitals are still being held financially accountable. More specifically, teaching hospitals are at greater financial risk because they treat large patient populations with increased risk factors and multiple comorbidities, making the likelihood of some of these conditions occurring much greater. Conditions selected for this program should be equally avoidable amongst all patients irrespective of their risk factors or complications.

The proposed rule includes a list of nine additional conditions being recommended for inclusion in the HAC program effective October 1, 2008. Since CMS had already finalized the initial eight conditions for the HAC program in the FFY 2008 IPPS Final Rule we do not believe that additional conditions should be added for FFY 2009. Since this is a new program it should be implemented and then evaluated prior to additional measures being added. In addition, hospitals need the time to be able to adjust their systems and processes to accommodate the initial eight conditions. Any additions to the HAC program should not occur until FFY 2010.

We continue to have issue with the way this program is being promoted. In the media and popular press this program is being referred to as the Never Events program. This is an inaccurate representation of this program and if that were truly the case then the only conditions that should be included in this program are the appropriate conditions from the list of serious reportable events endorsed by the NQF. The continued reference to this program as the Never Events program sets up false expectations amongst consumers and patients regarding their healthcare. Certainly, hospitals want to avoid hospital acquired

² Pronovoste, P., Goeschel, C., and Wachter, T. "The Wisdom and Justice of Not Paying for 'Preventable Complications.'" *Journal of the American Medical Association*, Vol 299, No. 18, page 2197-99 (May 14, 2008).

conditions, however no one can say that developing a pressure ulcer, one of the selected conditions, will never happen when we know the evidence says for certain patient conditions it is very likely.

Most of the conditions selected by CMS do not fulfill the statutory requirement that they be reasonably preventable through the application of evidence-based guidelines. To be reasonably preventable, there must be solid evidence, published in peer reviewed literature, that by engaging in a certain set of practices, clinicians can reduce the occurrence of an event to zero or near zero, among a typically broad and diverse patient population. However, there is significant evidence that patient factors (co-morbidities, risk factors, etc.) have a great impact on the ability of hospitals to reduce the likelihood a patient would develop or contract a particular condition.

While the primary goal of this program is to reduce the number of hospital acquired conditions, since it is based on claims data this program becomes more focused on the ability to document and code appropriately than focused on implementing evidence-based guidelines. Similarly, the use of nursing notes should be allowed to minimize burden on providers who are engaging in duplicative documentation in order to increase the likelihood that coders will have the necessary information to be able to code properly for those conditions that are primarily the responsibility of the nursing staff.

Additional Proposed Conditions for FFY 2009

In addition to the concerns stated above, for the specific reasons listed below we do not support the addition of any of the proposed Hospital Acquired Conditions for FFY 2009.

- Surgical Site Infections (SSI) Following Elective Surgeries – The list of three surgeries for SSI is not appropriate for this program. The proposed surgeries are performed either on an outpatient basis or a short term stay. Any type of infection that was to develop from the surgery would most likely be post-discharge. If the patient then needed to seek treatment for the infection it would be considered “present on admission” (POA) if they returned to the hospital where they had their initial surgery. At this point, CMS is unable to link hospital stays except for Medicare data and this condition should, therefore, not be included.
- Legionnaires’ Disease – Most cases of Legionnaires disease are community acquired and not hospital acquired. The rate of incidence in the hospital is quite low. Determining whether Legionnaires’ disease is POA would require screening and additional diagnostic testing for all patients which would be costly and unnecessary. We do not think Legionnaires’ disease should be included in the HAC program.
- Glycemic Control – While there is scientific evidence to suggest that controlling blood glucose levels can prevent infections for surgery patients, tightly controlling blood glucose levels for all patients has not been scientifically

validated. In fact, under certain conditions, blood glucose levels that are too tightly controlled could put the patient in danger of hypoglycemia.

Some diabetics have poorly controlled blood sugar levels that are not a result of any care the hospital did or did not provide. If a diabetic patient with poorly controlled blood glucose levels is admitted to the hospital for immediate, necessary surgery, the hospital may have to take the risk that the patient's blood glucose levels will become even more elevated during the surgery. Balancing the risks and benefits for each treatment for each patient is a fact of providing care. Just as there is "no one-size-fits-all" way to practice medicine for all patients, this condition cannot be applied to all patients under this policy.

- Iatrogenic Pneumothorax – Due to patient factors such as adhesions, scarring and physical irregularities, it is impossible for a trained and highly skilled clinician to eliminate the possibility of a Pneumothorax, even with the best precautions.
- Delirium – There is no clear clinical definition of delirium. It is also difficult to code for delirium cases based on medical record documentation due to the unclear definition. Delirium, as a result of medication, is difficult to predict or prevent since each patient responds differently to medication. In addition, each patient's particular combination of medications can be experienced differently. Delirium not associated with medication is usually related to advanced stages of illness in the elderly and is certainly not a preventable condition.
- Ventilator Associated Pneumonia (VAP) – Certain patients, such as trauma or immunocompromised patients, may be at a high risk for developing ventilator-associated pneumonia. For some patients, their medical conditions make it more difficult or impossible to implement all evidence-based practices. For example, trauma patients with certain injuries might not be able to have the head of the bed elevated as suggested in some guidelines. CMS states in the proposed rule that the scientific evidence suggests that 60 to 80 percent of ventilator-associated pneumonia cases *cannot* be prevented, which again, does not meet the definition of reasonably preventable.

We also are concerned over the lack of standardized clinical definitions or criteria for ventilator-associated pneumonia. The fact that the definition is open to interpretation means that clinicians may diagnose it differently in similar patients. These differences would be reflected in the medical record documentation and might unfairly penalize those organizations that more liberally diagnose ventilator-associated pneumonia.

- Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) – This condition is similar to pressure ulcers in that there may be certain trauma patients who are at risk for developing a clot, but their condition is such that they cannot be moved from one stationary position. Additionally, patients with clotting disorders, or

who are in a hypercoagulated state, may be more likely to develop a blood clot that could not be prevented even with the best of care. Blood clots can be difficult to detect on admission if the typical symptoms of swelling and inflammation are not yet apparent, even though the clot has already formed.

- *Staphylococcus aureus* septicemia – Accurately identifying the presence of *staphylococcus aureus* septicemia on admission will be a challenge. Patients may be admitted to the hospital with a *staphylococcus aureus* infection of a limited location, such as pneumonia, urinary tract infection or skin infection. Subsequent development of *staphylococcus aureus* septicemia may be the result of the localized infection and not a hospital-acquired condition. Additionally, the proliferation of changes in coding guidelines for sepsis in recent years present further challenges to hospital coding personnel to accurately capture present-on-admission status. Finally, there is still some debate among clinicians regarding the prevention guidelines for *staphylococcus aureus* septicemia.

We believe the category of *staphylococcus aureus* septicemia is simply too large and varied to be able to say with confidence that the infections were reasonably preventable. We urge CMS to narrow this category to include only patients for whom it is reasonably clear that the hospital was the source of the infection and that it could have reasonably been prevented.

- *Clostridium difficile*-associated disease (CDAD) – Developing CDAD as a result of antibiotic administration is a problem both in the inpatient and outpatient settings. As patients are appropriately prescribed antibiotics they can be at risk of developing CDAD. So, by appropriately treating an infection that may result in an unintended side effect, a hospital may incur a financial penalty under the HAC program.

Present on Admission (POA) Coding – The implementation of the HAC program necessitated the need for POA coding which is now required in all participating hospitals. It is important to recognize that POA coding can not be quickly or perfectly implemented in many instances within the teaching hospital environment. Because teaching hospitals provide many emergency and standby services such as burn and trauma care, POA coding may be neglected because it sacrifices timely, appropriate, and often lifesaving care. Many patients admitted to our institutions are transferred from other facilities that are unable to provide a higher level of care and documentation from the original provider may be insufficient.

In the proposed rule, CMS states that the Agency will be monitoring the frequency and appropriateness of the POA codes. As a new system is put in place it is appropriate to evaluate its effectiveness. However, CMS goes beyond evaluation and also proposes to use the POA coding as another vehicle to withhold payment for the use of the “U” POA code, which represents that the medical record documentation is insufficient. CMS states that withholding payment for the “U” code would help improve medical record

documentation. We believe that hospitals need time to adjust to the new POA system and no payment should be withheld based on any type of POA coding until sufficient experience has been gained. As a reference point, some states have had POA coding required for a significant period of time and are still having issues with the accuracy and completeness of the coding.

Appeal process – Other federal quality related programs have an appeals process. We encourage CMS to develop a similar process for hospitals to appeal payment determinations that fall within the HAC program.

VALUE-BASED PURCHASING

The DRA mandated that CMS develop a plan to implement value-based purchasing (VBP) for hospitals under the Medicare program, which was submitted to Congress on November 21, 2007.

Implementation of value-based purchasing requires action by Congress. However, the proposed rule announces that CMS intends to test the potential impact of its VBP plan by conducting a simulation of hospitals' performance under the program and assessing the performance scores and the financial impact of the proposal (73 Fed. Reg. at 23661).

According to the proposed rule, the simulation testing is being conducted to better understand the impact of the proposal and further the development of the program. Data will be analyzed at the individual hospital level and by various hospital groupings, including geographic location, size, and "teaching status." CMS seeks comments about how to best utilize the data collected during this testing phase.

We believe that the data obtained during this "testing phase" have the opportunity to be an important learning tool for hospitals. Hospitals should be allowed to see their data as well as data at more aggregate levels, such as state, national and by the various groupings. Sharing this information with the various stakeholder groups will also allow the health care community to understand the potential impact of the VBP plan.

We agree with the American Hospital Association that CMS should bring together a technical advisory panel which would help to help identify elements of the proposed design that put particular hospitals at an advantage or disadvantage and suggest improvements to the plan. We would be happy to participate in such a panel and/or identify appropriate teaching hospital representatives to serve on such a panel.

AVOIDABLE HOSPITAL READMISSIONS

While not proposing any specific changes, the proposed rule encourages comments about the Medicare program providing incentives that would reduce avoidable hospital readmissions. The proposed rule references a study by the Medicare Payment Advisory

Commission (MedPAC) which indicates that nearly 18 percent of beneficiaries who are discharged from the hospital are readmitted within 30 days (73 Fed. Reg. at 23673).

The proposed rule includes three potential approaches for reducing avoidable readmissions: direct payment reduction adjustments for avoidable readmissions, payment adjustments through a performance-based methodology, and public reporting of readmission rates. CMS notes that the first two options would require new statutory authority.

As MedPAC notes, there are significant hospital readmissions of Medicare patients. The key point for quality purposes is reducing “avoidable” readmissions. Reducing these admissions is important for both Medicare patients and the Medicare program. However, determining those admissions that are “avoidable,” and identifying the right strategy to reduce them, is a complex process. Because of the age of this population, hospital readmissions are more common, particularly for the “frail” elderly and complex patients, many of whom are treated at teaching hospitals.

We appreciate that the proposed rule acknowledges there are a number of issues to consider, including the timeframe for which an admission should be considered a “readmission,” the fact that often more than just hospitals are involved in the decision to readmit a patient (most prominently the physician), as well as the causes for that readmission, and the need for adequate risk adjustment so as to not have incentives to avoid appropriate readmissions.

We caution CMS to not move to a payment-reduction answer too quickly, if at all. There may be other incentives that are better to achieve the ultimate goal. As CMS acknowledges, avoidable readmissions involve many factors, including the complexity of our health care system. It is imperative that hospitals and physicians work together to address this problem, with likely assistance from post-acute care providers. The AAMC has issued a policy statement in support of the medical home. This concept, as well as other continuity of care efforts, are better suited to improve readmission rates. We would be happy to work with CMS to think through efforts Medicare could pursue to help health care providers improve care coordination and ultimately reduce hospital readmissions.

POST-ACUTE CARE TRANSFER POLICY

Medicare patients in certain qualifying MS-DRGs who are discharged from an acute care hospital before the mean length of stay, and receive post acute care services, are viewed as “transfers.” Post-acute care services are those services that are provided by rehabilitation hospitals and units, long-term care hospitals and units, cancer hospitals, psychiatric hospitals, children’s hospitals, skilled nursing facilities and home health agencies. The transferring hospital is paid a per diem rate, not to exceed the full MS-DRG payment. The post-acute care setting receives the full payment based on its respective payment system.

Since the FFY 1999 final rule, CMS has been applying the post-acute care transfer policy when a patient receives home health services within three days after the date of discharge. The Agency's rationale for implementing a three-day time frame rather than a shorter time frame (i.e. on the same day as the patient is discharged from the hospital), was to diminish the financial incentive to delay home health care in order to avoid the application of the post-acute care policy.

The proposed rule would extend this time frame so that the post-acute care transfer policy would apply to all cases in which the patient receives home health services within seven days. CMS states that this proposal is based on its analyses of FFY 1999 through FFY 2003 data from home health agencies, which suggest that home health care services are being delayed until just beyond the three-day time frame for patients discharged prior to the mean length of stay. According to CMS these data show that: 1) average Medicare payments per home health care visit are consistently higher for patients discharged prior to the mean length of stay than for patients discharged at or after the mean length of stay and 2) the ratio of average payments per home health visit for these two groups of patients peaks on the fourth day after discharge. CMS asserts that patients released from hospitals before the mean length of stay should indicate that they are less sick than patients released at or after the mean length of stay. Consequently, their data analyses lead the Agency to conclude that hospitals may be releasing patients too soon and substituting home health services for inpatient services and that at least some of the home health services are not being provided until after the third day after discharge.

We are concerned with CMS's analysis that forms the basis for the proposed expansion of the post-acute care transfer policy to seven days for several reasons. First, CMS's analyses are based on data that were gathered before the implementation of major policy changes to the home health PPS. In calendar year 2008, CMS replaced the 10-visit-therapy threshold with a system of multiple thresholds in an attempt to "better align costs and payments and avoid incentives for providers to distort patterns of good care." (72 Fed. Reg. at 49776) We urge CMS to reconsider making major changes to the post-acute care policy affecting hospitals based on data that according to CMS, may not accurately reflect the overall patient care dynamics as well as costs and payments.

Secondly, CMS concludes that hospitals may be releasing patients too soon and substituting home health services for inpatient services because payments per home health visit are consistently higher for patients discharged prior to the mean length of stay than for patients discharged at or after the mean length of stay. However, in reaching this conclusion the Agency fails to take into account that payments per visit are affected by the number of visits for a patient and not just by the total payments. For example a patient who is released from a hospital prior to the mean length of stay may indeed be less sick than a patient who is released at or after the mean length of stay. Consequently, that patient would require fewer home health visits than a patient released at or after the mean length of stay. Since payment per visit is determined by the ratio of total payment

(for a patient) to number of home health visits (for that patient), then fewer visits for a patient who is relatively less sick would result in a higher payment per visit.

Finally, the assertion that home health care is being delayed beyond the three-day window so that hospitals avoid the application of the post-acute care policy is based on the assumption that hospitals have control over home health services delivery. This assumption is incorrect because home health care delivery depends on a variety of factors that are not under the hospital's control. First, it is the physician—either the physician who took care of the patient while the patient was in the hospital or the patient's primary care physician—and not the hospital that typically orders home health care. If the patient's primary care physician orders home health care, then there may be an even longer delay in the delivery of home health care, as it may take some time for the patient to have an appointment with his primary care physician, then another day or two to be able to receive home health care services. Secondly, other factors such as family availability, insurance coverage and access to home health services may also delay the delivery of such services. For example, a patient's family may care for the patient immediately after the discharge from the hospital, but if the needs of the patient are too complex, the patient may seek home health services. Furthermore, patients may be discharged at the end of the week and may not be able to receive home health care until after the weekend.

In light of these factors, the AAMC urges CMS to rescind this proposal, which would only penalize hospitals for providing efficient care.

MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

Under the IPPS, Medicare pays hospitals a per-case payment that varies according to which diagnosis-related group (DRG) the case is assigned and the DRG's payment "weight."³ Each weight is intended to represent the average hospital resources required to treat a case within a DRG compared to the average required per case resources across all DRGs. Thus, cases that require higher levels of resources, on average, will have higher weights than cases that require relatively lower levels of resources.

On October 1, 2007 (FFY 2008), CMS replaced the previous 535 DRGs with 745 Medicare-severity DRGs (MS-DRGs). The MS-DRGs are intended to better recognize patient severity of illness in Medicare payment rates. The new MS-DRGs are being phased in, with the Medicare per case payment in FFY 2008 being determined by "blending" 50 percent of the payment weight based on the DRG weight and 50 percent based on the MS-DRG weight.

Medicare recognizes that overall IPPS payments may rise due to an increase in the severity of patients treated in the current year compared to the previous year ("real" case

³ These payments may then be adjusted for other purposes, such as whether the hospital is located in a high or low wage area, whether it is a teaching hospital, and whether it treats a disproportionate share of low income patients.

mix increase). However, because the new MS-DRG system relies on different coding rules, particularly the coding of complications and comorbidities, CMS is concerned that there may be improved documentation and coding that CMS did not anticipate in developing the MS-DRG weights. Such an increase in hospitals' case mix indices (CMI), and therefore Medicare payments, would contravene CMS's budget neutrality requirement.

Consequently, the FFY 2008 final rule had included prospective documentation and coding adjustments to the Medicare per case standardized amount of -1.2 percent for FFY 2008, -1.8 percent for FFY 2009, and -1.8 percent for FFY 2010. Congress modified these reductions in the TMA, Abstinence Education and QI Programs Extension Act of 2007 (PL 110-09). As a result in FFY 2008, the standardized amount was reduced by -0.6 percent and for FFY 2009 the amount will be reduced by -0.9 percent, yielding a combined effect of -1.5 percent. The law specifies, however, that to the extent these reductions overestimate or underestimate the impact of coding adjustments, CMS will adjust payments in FFYs 2010-2012 to offset the estimated increase/decrease that occurs in FFYs 2008 and 2009 (73 Fed. Reg. at 23541).

Because of the payment ramifications, it is critical that CMS accurately apportion the increase in hospitals' CMIs in FFYs 2008 and 2009 between that which is due to patient severity, for which the associated payment increases are not subject to recoupment, and that which is due to coding improvements, if any. An incorrect determination that payment recoupment is warranted has important, and potentially devastating, financial consequences for major teaching hospitals that already operate with razor-thin operating margins.

We appreciate CMS's intention to conduct a thorough evaluation of FFYs 2008 and 2009 claims data and the presentation of its preliminary analysis plans. We recognize that the proposed rule discussion likely reflects only the initial thoughts of the Agency, but we are concerned about the paucity of information provided. We urge CMS to pursue this project with the resources and methodological rigor needed to ensure the correct outcome. For example, the proposed rule points out the existence of historical data from the Hospital Payment Monitoring Program (HPMP), which is supported by the Medicare Clinical Data Abstraction Center (CDAC). Because these data include a statistical sample of medical records over several years, we believe it could be an important data source to evaluate case-mix change. Yet, the Agency equivocates on using this data source by stating it "may" use it "if feasible." (73 Fed. Reg. at 23541).

We also believe that it is critical to have the best case-mix measurement possible given the payment recoupment that could ensue. Consequently, we believe that the CDAC data could be used to replicate the well-respected case mix analyses conducted by the Rand Corporation in 1990 and 1991.⁴ While we recognize that these types of analyses require

⁴ Carter, G., J. Newhouse, and D. Relles, *How Much Change in the Case-mix Index Is DRG Creep?*, RAND Report R-3826-HCFA, April 1990, and Carter, G., J. Newhouse and D. Relles, *Has DRG Creep Crept Up? Decomposing the Case-mix Index Change between 1987 and 1988*, RAND Corporation Report R-4098-

significant resources, we believe that the payment implications require this level of investment.

The AAMC has been working with the American Hospital Association and Federation of American Hospitals to think through the various factors that can increase a hospital's "real" case mix. These include:

- shifts in the site of service to hospital outpatient departments or ambulatory surgery centers, which could lead to higher hospital inpatient case mix if the patients shifted to other sites of service have fewer co-morbidities;
- aging of the Medicare population leading to increased co-morbidities;
- increasing severity of illness unrelated to aging of the Medicare population, such as rising rates of co-morbidities associated with higher levels of obesity; and
- changes in medical practice affecting average length of stay and the distribution of length of stay by MS-DRG or the intensity of services by MS-DRG.

While the above factors lead to gradual change over time, more sudden shifts in case mix can occur because of specific policy changes. There are a number of CMS policy changes that have occurred simultaneously with the implementation of the MS-DRGs that likely will accelerate case-mix growth rate. For example:

- The implementation of "present-on-admission" coding is leading hospitals to assess patients for a broader array of conditions. This is likely to result in additional secondary diagnoses being identified, treated and coded, which involves a real increase in resource use and, therefore, real case-mix change.
- The permanent expansion of the Recovery Audit Contractor (RAC) program is encouraging hospitals to even more carefully scrutinize low-acuity patients and shift care to the outpatient setting to avoid short-stay admissions. This change in practice will increase the average acuity of patients that remain in the inpatient setting.
- The implementation of Medicare Part D has resulted in acceleration of beneficiaries moving to Medicare Advantage. Medicare Advantage has been shown to attract the younger and healthier segment of the Medicare population, thereby increasing the average acuity level of the population that remains in fee-for-service Medicare.⁵
- Effective in calendar year 2008, CMS made dramatic changes in the criteria for procedures that can be done in an ambulatory surgery center, thereby adding

HCFA/ProPAC, 1991. These reports built on earlier work in Carter, G. and P. Ginsburg, *The Medicare Case-mix Index Increase: Medical Practice Changes, Aging, and DRG Creep*; RAND, 1985.

⁵ See Landon BE, Zaslavsky AM, Bernard SL, et al.: Comparison of performance of traditional Medicare vs Medicare managed care. *JAMA*, April 14, 2004;291(14):pp 1744-1752; Call KT, Dowd B, Feldman R, et al.: Selection experiences in Medicare HMOs: pre-enrollment expenditures. *Health Care Financing Review*, Summer 1999;20(4):pp 197-209; and Morgan RO, Virniq BA, DeVito CA, et al.: The Medicare-HMO revolving door: the healthy go in and the sick go out. *New England Journal of Medicine*, July 17, 1997;337(3):pp 169-175.

hundreds of additional procedure types. We believe that these changes will accelerate the move of lower-acuity patients to the outpatient setting, again resulting in increased acuity in the inpatient setting. The majority of ambulatory surgery centers involve physician ownership and self referral, creating a strong incentive for shifts in site of service that did not exist when physicians were deciding between the inpatient and outpatient hospital setting.

We believe all of these issues must be considered when analyzing case mix changes. Unless already contemplated, we urge CMS to begin immediately to think through these factors and incorporate them into the Agency's analysis plan.

REFINEMENT OF THE MS-DRG RELATIVE WEIGHT CALCULATION AND "CHARGE COMPRESSION"

In the FFY 2007 final rule, CMS began a three-year transition from using a charge-based methodology for determining the DRG/MS-DRG weights to one that is based on hospital costs; FFY 2009 will reflect 100 percent cost-based weights.

While seemingly a simple concept, developing "cost based" weights is actually a complex undertaking. Calculating the costs for a particular Medicare case cannot be accomplished directly. Rather, these costs must be "estimated" using cost-to-charge ratios (CCRs) that are derived from hospitals' Medicare cost reports. The cost-based methodology that CMS is using relies on national aggregate CCRs for 15 hospital departments.

Moving from a charge- to a cost-based weighting methodology also introduces (or exacerbates) a phenomenon known as "charge compression." This refers to hospitals' practice of applying higher percentage markups to relatively lower cost items and lower percentage markups to higher cost items. To the extent that the costs and charges of both types of items are reflected in the calculation of a particular CCR (i.e. the CCR is an average of both low and high markup items) it can introduce bias in the DRG weights, by either artificially understating or overstating cost estimates for specific DRGs. For example, weights for DRGs that contain high costs items (such as devices and implants) tend to be understated.

In response to the issue of charge compression, CMS proposes to add a cost center to the cost report which would separate the costs and charges for relatively inexpensive medical supplies from more expensive devices, such as pacemakers and other implantable devices. Medical supplies and devices were targeted because most observers and researchers agree that charge compression in this area has the greatest impact on the DRG weight computations. The result would be that the current "medical supplies and equipment" cost-to-charge ratio (CCR) would be split into "Medical Supplies Charged to Patients" and "Implantable Devices Charged to Patients."

CMS proposes that the instructions as to which cost center should be used for a particular device could be based on the criteria used to identify devices that would qualify for payment as a transitional pass-through device category under the outpatient PPS. In essence, the proposal is based on the concept that only implantable devices that remain in the patient at discharge would be included in the implantable device category. CMS acknowledges that its proposal could include relatively inexpensive items, as well as exclude more extensive devices that do not remain in the patient at discharge.

While we appreciate the Agency's efforts to address charge compression, we must first express our concerns about incremental changes to the cost report that expand administrative requirements for teaching hospitals. While seemingly simple and straightforward, adding just one cost center has important implications for large teaching hospitals that average nearly 30,000 discharges per year and must keep track of innumerable devices and supplies. Consequently, we have concerns when the proposed rule uses language such as "we are proposing to begin making cost report changes" and noting the additional cost center proposal is a "first step." (73 Fed. Reg. at 23544).

We believe it is time that the Medicare cost report be reviewed in its entirety with the goal of comprehensive reform. There is much expertise within hospitals that could help facilitate such an effort. The goal of a cost report that is streamlined yet provides the information necessary to support the Medicare payment methodologies is not insurmountable. Rather, we believe it is attainable and necessary. We would be happy to work with CMS to identify individuals in the teaching hospital community who would be willing to assist in such a worthwhile effort.

In terms of adding a specific implantable device cost center, we do not oppose the proposal, but note that our comments should not be viewed as an endorsement to adding additional cost centers in the future. The addition of any new cost center should not be entered into lightly and we expect that CMS, despite the proposed rule rhetoric, will proceed with extreme caution with any additional incremental changes.

We support the comments of the American Hospital Association (AHA) that rather than using the outpatient pass-through criteria, the Medical Supplies and Equipment Cost center could be separated into two costs centers using existing revenue codes and associated definitions that would distinguish implantable devices and medical supplies. Such a solution achieves the results desired without imposing unnecessary administrative burden.

On a related issue, over the past year, we, along with the AHA and Federation of Americas Hospitals have recommended that hospitals prepare their Medicare cost reports so that Medicare charges, total charges, and total costs are aligned with each other, and with the current categories in the MedPAR file. We continue to believe that this is an important effort. Our proposed methodology for splitting supplies and devices is consistent with these past recommendations. We appreciate CMS' efforts to inform the fiscal intermediaries (FIs) and Medicare Administrative Contractors (MACs) to work

with hospitals to accomplish this goal (CMS transmittal #321). However, we are concerned that the transmittal letter failed to address the need by some hospitals to elect a cost-estimation approach to ensure costs and charges for supplies are aligned. We urge CMS to instruct the FIs/MACs not to reverse or undo reporting that relies on estimation approaches to achieve this alignment, provided that hospitals submit adequate documentation of their methodology.

Finally, we note that CMS stated it welcomed public comments on its decision not to adopt a "hospital-specific relative value" (HSRV) methodology in setting the MS-DRG weights (73 Fed. Reg. at 23543). We reiterate the strong opposition that we have expressed in past comment letters to not implementing the HSRV methodology. The methodology does not recognize legitimate differences in costs across hospitals. Teaching hospitals that have higher costs because of their various missions would be unfairly disadvantaged. The methodology also exacerbates inaccuracies that may arise because of the mix of patients treated at a particular hospital. Consequently, we believe that introduction of the HSRV methodology would not only not improve the current system, but would be deleterious to it. We believe this issue does not merit further consideration by CMS.

WAGE INDEX

CMS is proposing changes to the wage index stemming from recommendations contained in the June 2007 MedPAC Report to the Congress. The report was mandated by the Tax Relief and Health Care Act of 2006 (TRHCA) and includes recommendations for a new wage index. In the TRHCA, Congress requires CMS to review MedPAC's proposals and include proposals to revise the hospital wage index in the FFY 2009 IPPS proposed rule.

Rather than making wholesale changes to the wage index as recommended by MedPAC, the proposed rule includes only two limited proposals that would change the way the Agency finances reclassifications and would tighten the criteria to qualify for reclassifications.

The proposed rule would apply the rural and imputed rural floor budget neutrality adjustments to the wage index at the state rather than the current, national level. The rural floor provision requires CMS to give urban hospitals within a state a wage index that is no less than the applicable rural wage index in that state. Similarly, the imputed rural floor provision established a wage index floor in order to protect hospitals in states that have no rural hospitals and therefore no rural floor. Currently, payments to hospitals to which a rural or imputed rural floor applies are subsidized through the application of a national budget neutrality adjustment, which in effect lowers payments to hospitals nationwide.

Under the proposed rule, the budget neutrality adjustment would be applied at the state level, so that the increase in payments to hospitals that receive the rural or imputed rural floor in a state would be subsidized by a decrease in payments to the hospitals in that

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state only. The AAMC opposes this policy because it will have a negative impact on the hospitals located in states in which the rural and imputed rural floors apply and will not address the inequities and volatility of the current system. As CMS states in the proposed rule, the rural floor provision was adopted in order to address “anomalous occurrences where certain urban areas in a State have unusually depressed wages compared to the State’s rural areas.” To address these inequities, CMS adopted the rural and imputed floor and applied a national budget adjustment. Furthermore, under the current system, the impact on payments to hospitals nationwide resulting from the application of a national budget neutrality adjustment is much smaller than the impact that the application of a statewide budget neutrality adjustment would have on the hospitals located in states in which the rural and imputed rural floor apply. As a result of the proposed policy those hospitals located in states with a rural or imputed rural floor would have to share a heavier burden than hospitals nationwide would share under the current policy. We urge CMS to revoke this proposal to avoid creating more volatility and inequities and continue to search for a wage index system that addresses the multiple problems with the current system.

A similar policy is also being considered for geographic reclassifications. Specifically, the FFY 2009 President’s Budget includes a legislative proposal to apply geographic reclassification budget neutrality at the State rather than the current national level. In the proposed rule CMS states that it supports this legislative initiative. The AAMC opposes this policy on the same grounds as those delineated for the proposed policy for the rural and imputed rural floor.

Although CMS did not propose major changes to the methodology for calculating the wage index based on MedPAC’s recommendations at this time, the Agency notes that it has charged Acumen, LLC to conduct an impact analysis of MedPAC’s methodology and assist in developing proposals to revise the wage index. The Agency also notes that it will include these analyses and any proposals that will result from this study in the final rule or in a subsequent special Federal Register notice.

We welcome CMS’s decision to study the effects of MedPAC’s approach and would like to express our views regarding MedPAC’s recommendations. MedPAC uses wage data from the Bureau of Labor Statistics (BLS) in place of self-reported wage information from hospital cost reports. According to MedPAC, the use of BLS data would also eliminate the need to obtain occupational-mix data through the occupational mix survey. MedPAC would also use Census data to create county-specific relative wage values thereby creating more refined geographic areas. Benefits data would be derived from hospital cost reports submitted to CMS.

We agree with the American Hospital Association (AHA)’s comments that MedPAC’s approach presents a few areas of concern. One of the main concerns with MedPAC’s approach is the data used in calculating the wage index, particularly the BLS data. For example, Part A physicians’ time unrelated to medical education, overtime pay, shift

differentials and jury duty pay are excluded from the BLS data but are included in the current CMS data.

The use of Census data to determine the variation between counties is also problematic. Since the most recent Census data available is the 2000 Census data, estimates of wage differences between counties, based on data that are eight years old, may not accurately reflect current wage differences.

Because the BLS data do not include benefits information, under MedPAC's approach, CMS would need to continue to collect hospital-specific wage data. This would not help ease the collection burden for either CMS or hospitals.

Finally, according to MedPAC, its approach would eliminate the need for an exception process. However, MedPAC also notes that "there are no perfect definitions of labor market areas and the wage and benefit data are also imperfect." The need for reclassifications will continue to exist as long as no system can perfectly address area wage differences.

THE OUTLIER PAYMENT THRESHOLD

Under the Medicare inpatient prospective payment system, if the costs of a particular Medicare case exceed the relevant 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 five and six percent. 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 decrease 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 \$21,025, a decrease of 5.3 percent below the FFY 2008 threshold of \$22,185.

Prior to FFY 2008, the methodology used to calculate the outlier threshold involved the use of charge inflation only. The AAMC along with the AHA and FAHS had urged CMS to change the methodology to incorporate both cost and charge inflation, which we believe makes the threshold calculation more accurate and reliable. Starting in FFY 2008, CMS changed the methodology to include the use of both charge and cost inflation. We appreciate CMS's adoption of the methodology we suggested, but we urge the Agency to continue its effort to improve the methodology for determining the outlier

threshold so that teaching hospitals receive the appropriate level of outlier payments to help offset those cases with extremely high costs.

This year, as in past years, CMS estimates that the outlier pool has been underspent. CMS estimates that the actual outlier payments for FFY 2007 were 4.64 percent of actual total DRG payments, less than the 5.1 percent target. Similarly, for FFY 2008 the Agency estimates that the actual outlier payments will be 4.8 percent of actual total DRG payments, 0.3 percentage points lower than the 5.1 percent they projected in setting the outlier threshold for FFY 2008.

Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in two consecutive years, contrary to the intent of the outlier payment policy. We believe the FFY 2009 cost threshold needs to be further reduced and the methodology for calculating the outlier threshold be reevaluated in order to ensure that the entire 5.1 percent outlier pool is spent.

Along with the AHA, we conducted an analysis that we believe reveals two flaws in the methodology used for calculating the FFY 2009 outlier threshold. First, CMS estimates that it is appropriate to apply a one-year adjustment factor to the CCRs. However, we believe that for many hospitals, CCRs should be projected over periods of time other than one year to more accurately reflect the actual CCRs used in FFY 2009. For example, CMS uses the December 31, 2007 Provider Specific File (PSF) to determine the outlier threshold for FFY 2009. CMS states that CCRs are updated nine months after the end of hospitals' fiscal periods. Since the PSF file contains files of hospitals that have fiscal periods ending in all months of the year, there is a great deal of variation with regard to the projection periods that should be used to determine the CCRs of hospitals with different fiscal periods.

Secondly, CMS estimated the rate of change in CCRs by assuming the relationship between costs and the hospitals market basket stays constant over time. We urge CMS to consider the methodology described by the AHA to estimate the rate of change. Specifically, the suggested rate of change uses a recent historical industry-wide average rate of change as the projection factor, which is how CMS currently projects charge inflation.

Thus, we urge CMS to look into the methodology suggested by the AHA and consider incorporating it in order to more accurately estimate CCRs and ultimately arrive at an outlier threshold that would allow the Agency to more accurately estimate the outlier payments. This would ensure that hospitals with high cost cases receive the appropriate payments.

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CONCLUSION

Thank you for this 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 health care community.

If you have questions regarding the capital IME, cost report proposed changes or hospital readmissions please feel free to contact Karen Fisher at (202) 828-0490 or by email at kfisher@aamc.org. For questions regarding EMTALA, physician and entity “stand in the shoes” provisions and disclosure of financial relationship report please feel free to contact Ivy Baer at 202-828-0499 or ibaer@aamc.org. If you have questions regarding quality-related provisions, please contact Jennifer Faerberg at 202-862-6221 or at jfaerberg@aamc.org. For other questions please contact Diana Mayes at 202-828-0498 or at dmayes@aamc.org.

Sincerely,



Robert Dickler

cc: Karen Fisher
Ivy Baer
Jennifer Faerberg
Diana Mayes