



VIA ELECTRONIC SUBMISSION

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June 18, 2010

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Attention: CMS-1498-P and CMS 1498-P2

Dear Ms. Tavenner:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) proposed rule entitled "*Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2011 Rates,*" 75 Fed. Reg. 23852 (May 4, 2010), and the supplemental proposed rule entitled "*Medicare Program; Supplemental Proposed Changes to the Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Supplemental Proposed Fiscal Year 2011 Rates,*" 75 Fed. Reg. 30918 (June 2, 2010). The Association's Council of Teaching Hospitals and Health Systems (COTH) comprises nearly 300 general acute nonfederal major teaching hospitals and health systems that receive Medicare payments under the inpatient prospective payment system (IPPS). The Association also represents all 133 accredited U.S. 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:

- Medicare-severity diagnosis-related group (MS-DRG) documentation and coding adjustment;
- identifying "approved medical residency programs";
- electronic submission of affiliation agreements;
- outlier payment threshold;
- MS-DRG reclassification for acute renal failure;
- Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program;
- hospital acquired conditions;
- new standard cost centers for CT and MRI; and
- ICD-9-CM code freeze.

MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

Summary

The proposed rule would impose a 2.9 percent reduction in the IPPS standardized rate in FY 2011 to recoup half of the 5.8 percent payment the Agency asserts has been overpaid to hospitals as a result of documentation and coding requirements under the MS-DRG system that are different than the previous DRG coding requirements.¹ The AAMC is deeply concerned about such a reduction, particularly in light of the fact that the aggregate Medicare overall margin for major teaching hospitals has declined dramatically in recent years according to the Medicare Payment Advisory Commission (MedPAC) and was -1.5 percent in 2008. More importantly, however, we are troubled about the data analysis upon which the payment reduction is based. Along with the American Hospital Association (AHA) and the Federation of American Hospitals (FAH), the AAMC conducted numerous analyses which show dramatically different results. Based on these analyses, we believe the aggregate recoupment for documentation and coding effects is 0.9 percent, not 5.8 percent, and therefore the FY 2011 reduction should be 0.45 percent rather than 2.9 percent.

Background

Hospitals receive predetermined (prospective) specific rates for each Medicare discharge. To determine the payment, each discharge is assigned to a specific diagnosis-related group (DRG). Each DRG has a relative weight that increases as the case complexity increases. The per case payment equals the product of the DRG relative weight and the standardized amount, adjusted by the hospital's wage index and increased by any relevant payment adjustments (such as disproportionate share hospital (DSH) or indirect medical education (IME) payments). A hospital's case-mix index (CMI) reflects the average of the DRG weights for each case treated.

In FY 2008, to better recognize severity of illness in Medicare hospital payment rates, CMS began a transition from 538 "CMS DRGs" to 746 "Medicare Severity DRGs" (MS-DRGs). For FY 2008, Medicare per case payments were based on a blend comprising 50 percent of the CMS DRG relative weight and 50 percent of the MS-DRG relative weight. In FY 2009, the payments were based on 100 percent of the MS-DRG weights.

Under MS-DRGs, cases generally are assigned to one of three severity levels: cases with no complications or comorbidities (CCs); cases with a CC; or cases with a major CC (MCC). In general, an MS-DRG assignment for a case is based on diagnosis and procedure codes that the

¹ According to CMS, the total recoupment requires a 5.8 percent reduction to the standardized amount. CMS anticipates that the other 2.9 percent reduction would be applied in FY 2012. However, as a practical matter, hospital payments would not be further decreased from the FY 2011 level. Because the intent is to recoup overpayments, rather than to impose a permanent reduction, the 2.9 percent reduction in FY 2011 would be reinstated in FY 2012 but then reduced by 2.9 percent (the other half of the 5.8 percent total recoupment requirement).

hospital includes on the Medicare claim submitted to CMS. Because MS-DRGs better reflect patient severity, there is an increased number of diagnosis and procedure codes that contribute to determining to which MS-DRG a case is assigned.

The MS-DRG relative weights for FY 2008 were calibrated with the intention that the change from CMS DRGs to MS-DRGs be budget neutral, with Medicare payments only increasing if there is an actual increase in the severity of patients treated (“real” case-mix change). To the extent that hospitals treat patients of the same severity before and after implementation of MS-DRGs, but document and code their Medicare claims more accurately such that more cases are assigned to higher-weighted DRGs, CMS believes the Agency must recoup these payments. In anticipation of coding improvements, Congress authorized CMS to apply a prospective documentation and coding adjustment of -0.6 percent in FY 2008 and -0.9 percent in FY 2009 and also gave the Agency authority to adjust future payments to the extent that these reductions were more or less than the amounts necessary to account for documentation and coding changes.

Proposed Rule

To identify and quantify the impact of potential documentation and coding adjustments for FY 2008, CMS used a methodology in which the Agency applied the 2007 DRG GROUPER and the 2008 MS-DRG GROUPER to 2008 claims. This methodology resulted in a 2.5 percent increase in CMI between 2007 and 2008. CMS repeated this analysis with 2009 claims (using the FY 2009 GROUPER) and found an additional 2.9 percent increase that the Agency attributed to documentation and coding.

According to CMS, since the claims are the same, any change in the CMI must be due to changes in documentation and coding, not patient severity. Yet, under this thinking, because the claims are the same, CMS similarly cannot attribute the increase to documentation and coding changes, because the claims and the corresponding codes did not change between the two years. We believe that neither patient severity nor documentation and coding can be measured using only one year of claims. Rather, analyses must be done over a period of years. Moreover, when examining CMIs over time, it is important to not just compare case-mix change each year, because DRG weights, cases and the GROUPER changes, but to recognize that some components, such as DRG weights, must be held constant.

Based on the analyses conducted by the AHA, FAH, and the AAMC, we believe there is an alternative approach to calculating the effect of documentation and coding changes. The methodology is discussed in detail in the AHA comments, but the results demonstrate a consistent historical trend in case-mix growth. Using this information, we calculated a “predicted” CMI growth rate from FY 2007 to FY 2009, which reflects the growth in CMI if it had continued its historical trend and hospitals maintained consistent documentation and coding practices—this growth rate was 2.8 percent. Because the actual CMI growth over this period was 5.1 percent, we acknowledge that there was a documentation and coding increase of 2.3

Ms. Marilyn Tavenner
June 18, 2010
Page 4

percent (5.1 percent minus 2.8 percent) for FY 2009. We conducted a similar analysis for FY 2008 and found that the documentation and coding increase for that year was 0.7 percent.

However, to determine the level of recoupment that is necessary for the documentation and coding changes, we must account for the legislated reductions that have already occurred. In FY 2008, CMS implemented a 0.6 percent reduction, so the amount remaining to be recouped is 0.1 percent (0.7 percent minus 0.6 percent). For FY 2009, CMS implemented an additional 0.9 percent cut (for a total of 1.5 percent), which means that a 0.8 percent reduction is necessary to recoup remaining overpayments (2.3 percent minus 1.5 percent). Combining the results for FYs 2008 and 2009 means that CMS needs to implement a 0.9 percent cut to recoup overpayments for both years. Implementing half of this reduction, as CMS proposes, results in a reduction of 0.45 percent for FY 2011. We direct the Agency to the AHA's comments for a more in-depth discussion of this issue, as well as detailed data graphs.

We conducted additional analyses with other databases to further examine the trend in case-mix growth, and in each analysis we saw a historical trend of increases. These included analysis of the Medicare CMI using data from the Medical Expenditure Panel Survey, as well as the Healthcare Cost and Utilization Project database. Importantly, however, we also examined the use of intensive care units by Medicare patients, because to the extent this use increases, it would be a strong indication that patient severity has increased. Our analysis discovered that intensive care usage increased steadily between FYs 2000 and 2009. We also found that the average number of days spent in the intensive care unit per Medicare discharge increased over this time period. Additional information about these analyses is contained in the AHA's comments.

We urge CMS to reconsider its proposed recoupment reduction in light of our research findings. We would be happy to discuss with CMS staff any of the data analyses we conducted.

GME AND IME ISSUES IN THE PROPOSED RULE

Identifying "Approved Medical Residency Programs"

Teaching hospitals receive direct graduate medical education (DGME) and indirect graduate medical education (IME) payments for residents in "approved medical residency training programs" up to a hospital-specific resident limit (the hospital's "cap"). Hospitals do not receive DGME and IME payments for physicians who are not part of approved medical residency programs; rather, these physicians, if appropriately licensed and able to meet all applicable Medicare requirements, bill for their services under Medicare Part B.

CMS proposes to clarify the term "approved medical residency program" and to revise the regulatory definitions of "resident" and "primary care resident" (at 42 C.F.R. § 413.75(b)). The regulatory definition of "approved medical residency program" (which CMS does not propose to change), is a program that meets *one* of the following criteria: (1) is approved by the Accreditation Council for Graduate Medical Education (ACGME), the American Osteopathic

Association (AOA), the American Dental Association (ADA), or the American Podiatric Medical Association (APMA); (2) “may count towards certification of the participant in a specialty or subspecialty” listed in the American Medical Association’s (AMA’s) Directory of Graduate Medical Education Programs or the American Board of Medical Specialties’ (ABMS’s) Annual Report and Reference Handbook; (3) is approved by the ACGME as a fellowship program in geriatric medicine; or (4) is a program that would be accredited but for requirements relating to induced abortions.

The regulations currently define a “resident” as “an intern, resident, or fellow who participates in an approved medical residency program including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board” and a “primary care resident” as “a resident who is enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine or osteopathic general practice.” In the proposed rule, CMS states that under these definitions, hospitals have expressed confusion regarding whom to include in a hospital’s DGME and IME FTE count.

CMS proposes to revise the definitions of “resident” and “primary care resident” for cost reporting periods beginning on or after October 1, 2010, to change the phrases “who participates in” and “who is enrolled in” to “who is formally accepted, enrolled, and participating in” an approved medical residency program. CMS states that the agency will focus on two factors in determining whether an individual is a resident whose time may be counted for DGME and IME payments: (1) whether the individual “actually needs the training in order to meet board certification requirements in that specialty; and” (emphasis in original) whether the individual “is formally participating in an organized, standardized, structured course of study.” In short, our understanding of the intent of the proposed rule is that training that is not done under the auspices of a national accrediting body and for which there is no existing board certification examination may not be counted for DGME or IME purposes.

The AAMC has two concerns regarding CMS’s proposals. First, CMS’s intent is not clear with respect to the continued use of Line 70 of Worksheet B-1 of the Medicare hospital cost report, which currently allows hospitals to enter the costs of interns and residents not in approved teaching programs. In the proposed rule CMS only describes residents whose time may be claimed for DGME and IME payments and physicians who may bill the Medicare program. The Agency does not appear to contemplate the third category of residents, however, whose time may not be claimed and who also may not bill for their services (for example, residents in unapproved programs or residents with limited medical licenses). The AAMC requests that CMS verify that the Agency did not intend to eliminate the use of Line 70 of Worksheet B-1.

Second, our members have expressed concern regarding certain physician training programs, specifically transplant fellowship programs, that are accredited by a body other than those listed at 42 C.F.R. § 413.75(b) and that do not lead to certification by a “medical specialty board” but that legitimately should be considered to meet the definition of a “resident.” Transplant

fellowship programs are approved by the American Society of Transplant Surgeons (ASTS), a nationally-recognized body, and fellows enrolled in these programs participate in a formal match process through match programs including the National Resident Matching Program (NRMP). The training for these transplant fellows also takes place in “Medicare-Approved Transplant Programs” approved by CMS to receive payment under the Medicare program. Given that transplant fellows “formally participate in an organized, standardized, structured course of study,” and that these programs take place under the auspices of a national accrediting body, the AAMC encourages CMS to consider transplant fellows to be residents in an “approved medical residency program.”

Electronic Submission of Affiliation Agreements

Under current regulations, existing teaching hospitals that meet specified criteria may enter into Medicare GME affiliation agreements, under which they may combine their respective resident caps and redistribute them according to their agreement. The sum of the new caps under the affiliation agreement may not, however, exceed the aggregate combined cap.

CMS proposes to increase flexibility in the method by which hospitals submit their Medicare GME affiliation agreements to CMS. Current regulations require each hospital in a GME affiliated group to submit its Medicare GME affiliation agreement to its intermediary or Medicare Administrative Contractor (MAC) and the CMS Central Office no later than July 1 of the residency program year during which the agreement would be in effect. Until now, CMS has only accepted signed hard copies of the Medicare GME affiliation agreements that have been received through the mail. Facsimile (FAX) and electronic submissions have not been permitted.

CMS’s proposal permits a hospital to submit affiliation agreements to the CMS Central Office electronically. The agency is proposing an electronic submission process that would consist of either an e-mail mailbox or a Web site where hospitals could submit their affiliation agreements. Agreements would be required to be received by the electronic system by 11:59 p.m. on July 1 of each academic year, and agreements would have to be submitted as a scanned or PDF version of the signed and dated hard copy agreement.

The AAMC appreciates CMS’s attention to this issue and supports this proposal as a logical and more administratively simple method of submitting affiliation agreements. The AAMC also recommends that CMS provide hospitals with an electronic receipt for each electronically submitted agreement, so that hospitals may have documentation that they completed the submission requirements.

THE OUTLIER PAYMENT THRESHOLD

Under the Medicare IPPS, if the costs of a particular Medicare case exceed the relevant MS-DRG operating and capital payment (including any DSH, IME, or new technology add-on

payments) plus an outlier threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case's costs above the threshold calculation.

The outlier fixed-loss cost threshold is set at a level that is intended to result in outlier payments that are between 5 and 6 percent of total IPPS payments. Outlier payments are budget neutral. Each year the Agency finances the outlier payment pool by reducing the inpatient standardized amount by 5.1 percent and estimating a cost threshold that should result in outlier payments that equal 5.1 percent.

The supplemental proposed rule would increase 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 \$24,165, up from \$23,140 in FY 2010.

While we appreciate CMS's continued efforts to improve the methodology for estimating the outlier threshold, we note that in the FY 2010 IPPS proposed rule, the Agency overestimated outlier payments for FY 2010. After using more recent data from the FY 2009 Medicare Provider Analysis and Review (MedPAR) file, in the FY 2011 proposed rule, CMS estimates that the outlier payments for FY 2010 were actually 4.9 percent of total payments, approximately 0.2 percentage points lower than the 5.1 percent target.

To assess the outlier payment proposal, the AAMC engaged Vaida Health Data Consultants (Vaida) to review the methodology and provide its view on how the methodology could be improved. We urge CMS to accept our recommendations to more accurately estimate outlier payments.

The AAMC appreciates that CMS responded to our comments on the FY 2010 IPPS proposed rule and decided to exclude managed care and organ acquisition charges for organ transplant patients. This change helps improve the accuracy of the data and CMS's determination of the outlier threshold. However, similar problems with the data remain. Vaida's analysis of the CMS FY 2011 Impact File² uncovered two additional types of claims and charges that are excluded from payment under the IPPS and should not have been included by CMS in the Agency's estimation of outlier payments.

In its analysis of the 2009 MedPAR file, Vaida noted that the data CMS used includes approximately 74,319 Medicare managed care claims that are not being identified as managed care claims in the HMO Paid Indicator field because of apparent incomplete coding of this field in the MedPAR file. However, since the amount reimbursed for these claims is exactly equal to the amount of the IME payment, it is likely these are claims for managed care patients submitted by teaching hospitals. According to Vaida's analysis, including these claims results in overestimating FY 2011 outlier payments by \$61 million.

²The file shows the estimated level of FY 2011 outlier payments by hospital (as percentages). In its analysis, Vaida also used the MedPAR 2009 and the March 2010 update of the Provider Specific File (PSF).

Similarly, the erroneous inclusion of charges for blood clotting drugs, which are also not paid under the IPPS, leads to an overestimation of outlier payments for FY 2011. Blood clotting drug charges cannot be identified in the MedPAR file, as they are bundled together with other pharmacy charges. However, due to a code contained in MedPAR, which indicates whether the patient received blood clotting drugs, Vaida was able to estimate the impact of inappropriately including these charges in the outlier calculations. For example, of the 1,005 patients who received blood clotting drugs in FY 2009 and are estimated to qualify for outlier payments in FY 2011, 314 did not qualify for outlier payments in FY 2009. Given that in FY 2009, CMS's determination of outlier payments excluded the charges for blood clotting drugs for these patients, it appears that these patients' charges should not qualify for outlier payments in FY 2011. Otherwise, including the pharmacy charges for these 314 patients would overestimate the outlier payments by \$24 million.³

The combined effect of using IME managed care claims and pharmacy charges for patients receiving blood clotting drugs whose discharges were not eligible for outlier payments in FY 2009, results in overestimating the FY 2011 outlier payments by approximately \$85 million. This in turn, lowers the outlier pool by approximately 0.05 percent.

The AAMC also makes two recommendations regarding the current outlier methodology that we believe CMS should adopt. The first is to recognize that hospitals have different fiscal year ends and to project their cost-to-charge ratios (CCRs) over different periods of time (some less and some more than one year), based on variations in hospitals' fiscal year ends. Currently, CMS uses an overly simplified methodology of projecting the CCRs for all hospitals for a period of one year. Such a change would also utilize hospitals' most current CCR as it becomes available. The second recommendation is to use a recent historical industry-wide average rate of change of CCRs as the projection factor rather than utilizing the relationship between actual costs and the hospital market basket and assuming that the rate of change is constant over time.

The net result of accepting these two recommendations and making the data changes due to the managed care claims and blood clotting charges would result in an outlier threshold for FY 2011 of \$23,280.

We also understand that CMS models FY 2009 payments rather than using actual FY 2009 payments from MedPAR. We believe this may account for the discrepancy between CMS's estimate of total outlier payments in FY 2009 (5.3 percent) and that of Vaida's (4.9 percent). We recommend that CMS calculate its estimate of the FY 2009 outlier payments based on actual, rather than modeled, FY 2009 payments.

³ Given that blood clotting drug charges were included for the 691 patients who qualified for outlier patients in FY 2009 and will again qualify in FY 2011, it is likely that there are other patients whose charges should be removed from the outlier payment determination.

MS-DRG RECLASSIFICATION OF ACUTE RENAL FAILURE

The AAMC opposes CMS's proposal to reclassify diagnosis code 584.9 (Acute renal failure, unspecified) from an MCC to a CC. This change will have a substantial impact on hospital payments, and CMS should not make such a dramatic change to case-mix calculations without a compensating adjustment to rates.

Acute renal failure is a complex disorder that occurs in a variety of settings with clinical manifestations ranging from a minimal elevation in serum creatinine to anuric renal failure. Emerging evidence suggests that even minor changes in serum creatinine are associated with increased inpatient mortality. Changing the status of code 584.9 from an MCC to a CC would unfairly penalize hospitals that are treating the more severe anuric patients who require more intensive resources.

While clinicians may not have a standardized convention for documenting acute renal insufficiency versus acute renal failure, several groups have recognized these limitations and have worked to correct these deficiencies. These efforts have included consensus conferences and publications from the Acute Dialysis Quality Initiative Group, the American Society of Nephrology Acute Renal Failure Advisory Group, the International Society of Nephrology, and the National Kidney Foundation. CMS should continue to study the data on this diagnosis' impact on resource use until there is a more specific clinical definition of the stages of acute renal failure and there are corresponding diagnosis codes to recognize those differences (as has been done for chronic kidney disease).

REPORTING HOSPITAL QUALITY DATA FOR ANNUAL PAYMENT UPDATE (RHQDAPU)

The Medicare Modernization Act created a Quality Reporting Program that requires hospitals to submit data on a set of quality performance measures to receive their full payment update and imposes a penalty for those hospitals that do not participate. The Deficit Reduction Act of 2005 (DRA) increased the number of required measures for submission as well as increased the penalty for not reporting to a reduction in the annual payment update of 2 percentage points. The DRA also gave the Secretary the authority to continue to increase the number of measures reported that reflected consensus among affected parties as well as retire and/or replace those measures that are no longer relevant or scientifically current.

Historically, the IPPS proposed and final rules have included the list of measures required by RHQDAPU one fiscal year at a time. In the FY 2011 IPPS proposed rule, however, CMS has provided a list of proposed measures for three fiscal years, through FY 2014. The AAMC has long advocated for additional time to prepare for any expansion in measure requirements. We commend CMS for outlining a three-year plan for measure expansion and trying to provide some level of predictability for hospitals. However, because the three-year plan is not fully informed

Ms. Marilyn Tavenner
June 18, 2010
Page 10

by the activities required by the Patient Protection and Affordable Care Act (PPACA), we believe the plan should not be finalized at this time.

Measures selected for payment reporting programs must be aligned with a national set of priorities for quality improvement and public reporting efforts. These priorities exist in the work of the National Priorities Partnership (NPP) convened by the National Quality Forum (NQF). As required by the PPACA, the Secretary of HHS will be working with the NPP to further develop and refine these priorities as part of the overall strategic plan for quality improvement as well as to propose measures for input by stakeholders to be used in reporting programs in the very near future.

A long-term plan or vision for public reporting in Hospital Compare should be developed once the national priorities have been finalized. The plan should create a core set of measures for public reporting that truly improve clinical care.

FY 2011

CMS proposes to reduce the number of measures required for the FY 2011 payment determination from 46 to 45 by retiring the Agency for Healthcare Research and Quality (AHRQ) composite, mortality for selected procedures. The measure did not receive NQF endorsement or Hospital Quality Alliance (HQA) approval and was not recommended for comparative reporting purposes. Therefore, the AAMC supports CMS's proposal to retire the measure.

FY 2012

All-patient volume data: For the FY 2012 payment determination, CMS proposes that hospitals be required to submit MS-DRG volume data on 55 MS-DRGs that relate to the conditions currently reported on Hospital Compare. The data would be used to supplement what is already on the Medicare.gov website that displays volume data on 70 MS-DRGs for the Medicare population only. The AAMC does not support this proposal. While we understand CMS may have a desire to report all-patient volume data rather than strictly Medicare data, this is not a quality measure unto itself and should not be required as part of a quality pay for reporting program. Additionally, requiring hospitals to submit all-patient volume data creates an added burden with no clear link to quality improvement.

Hospital Acquired Conditions (HACs): CMS proposes to require eight HACs to be included in the FY 2012 payment determination. The proposed rule states a rate would be calculated for the HACs based on three years of Medicare fee for service (FFS) claims data. The claims would include those that are coded with the selected HAC and have a present on admission (POA) code of "N" (not present on admission) or "U" (medical record documentation is insufficient).

Ms. Marilyn Tavenner
June 18, 2010
Page 11

The AAMC does not support the inclusion of HACs into the pay-for-reporting program at this time. The current HAC payment program relies on POA coding to identify those conditions acquired during the hospital stay. POA reporting is still in its infancy, and while our members are working to improve their coding practices, it is still a work in progress. Until POA coding has matured, it would be inappropriate to publicly report information based on the claims data.

However, if the HAC rates are finalized, we strongly encourage CMS to report risk-adjusted rates. Teaching hospitals traditionally treat patients with a higher severity level than non-teaching hospitals, and the teaching hospital patient population is often more prone to the infections/conditions included in the HAC condition list. If CMS moves to reporting data on a population level, there is no reason why the rates could not be risk-adjusted. However, given that there are various ways to do risk adjustment, we believe any methodology being considered should be shared with the public prior to being implemented.

The proposed rule gives very little information on how the HAC rates would be calculated; therefore, it is difficult to comment on the specifics of the measure calculation. This information needs to be communicated to the public prior to implementation.

In addition, the HAC calculation should not include those cases with a POA code "U", as these cases often represent transfer patients. The documentation provided on transfer patients is often incomplete and leaves the receiving hospital at a disadvantage in being able to code appropriately for POA. The receiving hospital's performance should not be penalized based on the lack of documentation from the originating facility.

Last, if HAC rates are publicly reported, the AAMC strongly encourages CMS to engage in appropriate consumer testing to ensure the information being reported is interpreted appropriately. As we have seen from recent consumer testing, there is significant confusion in determining what this performance data really means when there is a low occurrence rate.

AHRQ Patient Safety Indicators: CMS proposes the inclusion of two AHRQ Patient Safety Indicators (PSIs) for the FY 2012 payment determination. The PSIs would be calculated on Medicare claims over a three-year period prior to FY 2011.

The AAMC continues to have concerns regarding the use of the AHRQ measures. The measures are calculated utilizing claims data that have significant limitations, because they were designed for billing purposes. Current Medicare claims are unable to capture all diagnosis codes submitted on a patient claim and therefore are far less accurate in identifying a patient's severity level compared to clinical data abstracted from the medical record. In addition, these measures were developed for internal quality improvement and not for public reporting.

Post-operative Respiratory Failure: While this is an important safety measure, it does not account for the varying degree of risk associated with the included surgeries. Therefore, CMS should consider risk-adjusting by type of surgery or stratifying the results by surgery type. In

addition, the risk adjustment methodology is somewhat limited and is unable to assess appropriately the clinical risk of the patients being measured.

Post-operative DVT/PE: This measure had a high rate of false positives during an initial round of validation testing. The measure is currently in a second round of validation testing as a result of several coding changes. The testing has not been completed and therefore has a time-limited endorsement from the NQF. As a result, the AAMC does not support inclusion of this measure in the RHQDAPU program at this time.

FY 2013

CMS proposes to add AMI Statin at discharge to the list of required measures for the FY 2013 payment determination. This measure is similar to the statin measure for stroke patients and is supported by a strong evidence base. The measure has been endorsed by the NQF and approved by the HQA. Therefore, the AAMC supports CMS's proposal to include this measure in the RHQDAPU program.

CMS also proposes the requirement of additional measures for the FY 2013 payment determination to be submitted by alternative data collection mechanisms. Hospitals would be required to collect and submit data on two health care associated infection measures, surgical site infections (SSI) and central line related blood stream infections (CIRS) to the Center for Disease Control (CDC) National Healthcare Safety Network (NHSN).

National Healthcare Safety Network: The AAMC supports the reporting of the two infection measures; however, we have concerns with the proposed data collection mechanism and timeline. The NHSN is an important epidemiologic and public health tool that was created for surveillance and monitoring. One of its purposes is to "collect data from a sample of healthcare facilities in the United States to permit valid estimation of the magnitude of adverse events amongst patients and healthcare personnel." As a testament to its value, many of our members submit data to the NHSN and have been doing so over a long period of time.

However, as a result of our members' participation the following concerns have been raised:

Burden: While many of our members submit to NHSN, there is agreement that the system is very onerous and resource-intensive. Due to the cumbersome nature of the system, hospitals often require additional staff resources to submit the necessary data. This concern has been expressed regularly, but major modifications or a streamlining of the process have yet to occur. While we understand the CDC is working with TheraDoc to allow for electronic transmission through an electronic health record (EHR), this technology is not fully in place and is only available for one measure.

Lack of consistent definitions: While the CDC has standardized definitions for the data collected through its system, this is not the case for all organizations requiring data submission to NHSN. Currently, several states require infection reporting through NHSN, yet the definitions are not standardized and require modifying the data collection more than once to meet the disparate definitions. The CDC and states need to come together to ensure all measure definitions are aligned and allow hospitals to collect and submit data once without modification.

Validation: Since the NHSN was designed as a surveillance system and not a reporting system, there is no process in place to validate the data being submitted similar to what occurs in the RHQDAPU program. Before any measure is included in public reporting, an adequate validation mechanism must be in place.

Uptake: The CDC website states that 2,100 hospitals are reporting into the NHSN. If the requirement for reporting infection data to NHSN is finalized, the CDC will have to double the number of hospitals participating within a very short period of time. It is hard to imagine that within that timeline all “new” hospitals would be registered, trained and proficient in reporting. Initially, we expect a wide variation in reporting from those hospitals that are proficient and those hospitals submitting data for the first time. This could potentially disadvantage those hospitals that have been reporting for some time, as the new hospitals may under-report until they become more familiarized with the data collection system.

Given the above concerns, the AAMC strongly encourages CMS to delay the public reporting of the infection data. This would provide the CDC time to streamline the reporting process and develop an appropriate validation process and would allow all hospitals to get the appropriate training and become proficient in collecting and submitting the required data.

In addition to the above measures, hospitals would be required to choose one of four topic areas – ICD complications, stroke, nursing sensitive care, and cardiac surgery – and report the identified measures to a “CMS qualified registry.” The number of measures required is based on the registry topic area selected. Hospitals would direct the registry to calculate the measure results and release the results and other required information to CMS for the RHQDAPU program.

Registry reporting: Exploring the feasibility of utilizing registries for public reporting has been a focus of numerous organizations. A recent study conducted through the Quality Alliance Steering Committee (QASC) showed that registries can play a great role in quality improvement; however, many registries are not structured for public reporting at this point. There is a lack of standardization across registries in key areas, including: validation, risk-adjustment, standardized measure specifications, transparency and data submission processes.

While some registries are more sophisticated and are better positioned for public reporting, such as the STS registry, in order for a registry to be considered as a data collection mechanism utilized in public reporting, it should meet the following criteria:

Validation: Any approved registry must have a robust validation system that should be certified by CMS. The validation system must test not only the data submitted but must also have a system in place to identify missing data to ensure that all relevant data are submitted. The validation system must be standardized across all mechanisms to ensure that data collected meet the same requirements irrespective of the data collection mechanism.

Transparency: All hospitals should have access to the measure specifications and definitions so they can replicate the measure calculations. This would avoid the “black box” effect.

Standardized measure specifications: All measure definitions should be standardized to ensure consistency across all measures being reporting in the RHQDAPU program.

We also are concerned with the ability of some hospitals to participate that are not already submitting data to one of the certified registries. There should be an alternative approach for data submission that does not mandate participation in a registry with an associated fee.

Finally, the CMS proposal requires hospitals to choose one of four registry-based topic areas for public reporting. Allowing a hospital to choose which registry topic area it wishes to report has the potential to result in inconsistent reporting on Hospital Compare and an inability to make comparisons across all hospitals. The AAMC sees and supports instances where it would be appropriate for hospitals to report on particular measure sets most relevant to the care they provide, which may not be applicable to all hospitals. However, there is a concern that a hospital could choose not to report on a measure set that is very relevant to the care it provides and therefore result in reporting inconsistencies. Last, we seek clarification on how the possible inclusion of measures derived from registries that only account for a subset of hospitals could be utilized in a value based purchasing program.

FY 2014

CMS proposes to require hospitals to report on two emergency department (ED) throughput measures and two global immunization measures for pneumonia and influenza.

ED Throughput: The AAMC supports the ED throughput measures as they are NQF endorsed and HQA approved. However, we have concerns given that these measures can adversely affect large safety net providers because of their structures and patient populations served. In addition, these measures look at median times, which is not the most appropriate measure of efficiency given their variability. If these measures are finalized, we recommend CMS stratify the results by type of hospital to achieve a more appropriate comparison among institutions.

Global immunization: The proposed rule lists two global immunization measures and indicates they were endorsed by the NQF through an Immunization project in 2008. After reviewing the Immunization report, the measures in that project were specified for nursing home patients only. Therefore, there are no specified and endorsed measures for the inpatient facility. Until these measures are specified for the inpatient facility and are reviewed by the NQF and HQA, the AAMC does not support their inclusion in the RHQDAPU program.

Measure Retirement

CMS proposes a set of criteria to be used to determine whether a measure should be retired. In addition, CMS provides a list of 11 measures that have been suggested for retirement at a future date.

The NQF Board recently adopted a new maintenance and endorsement process that will begin later this summer. Under this new process, NQF anticipates that it will begin to address specific criteria for measure “retirement” or “non-endorsement.” The hope is that this new process, over time, will allow for greater harmonization among measures, weed out the measures that are no longer “best in class,” and consistently define a set of metrics for the definition of “topped out.” In addition, the process will address the unintended consequences of measures previously endorsed and determine if those consequences warrant a de-endorsement of a measure. For these and other reasons, the HQA has expressed the sentiment that the cycle of quality measurement from endorsement to “retirement” should, with some exceptions, fall under the purview of the NQF. Approximately half of the measures currently in the RHQDAPU program are up for measure maintenance in 2010 and 2011. The AAMC supports NQF review of all measures proposed for retirement by CMS, and encourages CMS to consider the criteria and outcome of the consensus-based recommendations and any additional recommendations from provider stakeholders before taking final action in removing measures from the RHQDAPU program or from data collection.

The AAMC also supports the retirement of measures due to changes in science or updates to the evidence base supporting a measure. We also believe in reducing the number of measures being reported to a core set that truly improve care. However, this process needs to be thought out carefully before any changes are made. First, CMS needs to work with the NQF and other stakeholders to determine the actual definition of “retirement.” The clarification of that definition will inform the development of any criteria for retirement of measures included in the RHAQDAPU program.

Validation

CMS has proposed to implement the validation process that was finalized in the FY 2010 rule for the FY 2012 payment determination. The process would randomly select 800 hospitals for validation and would require a review of 12 cases per quarter for three quarters. Each hospital

Ms. Marilyn Tavenner
June 18, 2010
Page 16

would need to attain a score of at least 75 percent in order to pass validation. The AAMC believes that the proposed validation system minimizes the burden for many hospitals and implements a more rigorous process for validation compared to what is currently in place. We support CMS's proposal to implement the new validation process for FY 2012.

Data Submission Requirements

Currently, the data collection periods for measures required in the pay-for-reporting program cover different calendar quarters. The AAMC supports CMS's proposal to align the data collection periods for all measures required in the pay-for-reporting program by FY 2013. This alignment provides the ability to look at performance for a given fiscal year across all measures. In addition, the alignment will increase efficiencies at hospitals no longer needing to maintain separate collection and reporting periods.

HOSPITAL ACQUIRED CONDITIONS (HACs)

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

For FY 2012, CMS proposes not to make any additions or deletions to the current list of HACs nor make any changes to the POA reporting or payment. Instead, CMS will continue to evaluate the impact and reliability of the payment policy. The AAMC is pleased CMS has not expanded the list of selected conditions and appreciates the public release of the initial POA analysis.

However, the AAMC encourages CMS to modify the POA payment policy. Under the current policy, CMS does not make a higher payment if one of the selected HACs is coded on the claim with a POA of "N" (not present on admission) or "U" (medical record documentation is insufficient). We believe claims with a POA code of "U" should be paid. CMS stated that non-payment for "U" cases would improve medical record documentation; however, many of the "U" cases often represent transfer cases where complete documentation is not always available or is incomplete. The receiving institution should not be penalized for the lack of documentation received from the originating facility and therefore should receive payment for "U" cases.

CHANGES TO MEDICARE COST REPORT, INCLUDING NEW STANDARD COST CENTERS FOR CT AND MRI

In response to certain comments received on its proposed hospital cost report form notice (Form CMS-2552-10, published in the *Federal Register* on July 2, 2009) requesting that CMS create

cost centers that separate the costs of magnetic resonance imaging (MRI), Computed Tomography (CT) and nuclear medicine services, CMS proposes to adopt new standard cost centers for CT and MRI. CMS acknowledges that the Agency does “not know the impact on CCRs and estimated costs of adopting standard cost centers specific to CT scanning and MRI.” CMS’s rationale for creating standard cost centers for CT scanning and MRI is that it “would improve the estimation for these services, in part by creating incentives for hospitals to more accurately allocate the capital and equipment associated with these services.”

The AAMC recommends that CMS postpone the proposed changes until such time as the Agency can evaluate the impact of the proposal on the CCRs of CT and MRI, which in turn affect payments for these technologies. Our concerns stem from the fact that even hospitals that currently have separate CT and MRI cost centers may not allocate CT and MRI equipment costs to those cost centers on the Medicare report. Thus, separating the CCRs for CT and MRI may result in inappropriately lower CCRs than the current all-radiology CCR. This, in turn, would result in inappropriately low reimbursement rates for these technologies.

In addition, the AAMC would like to take this opportunity to restate a previous request. In our comment letter on the Medicare and Medicaid EHR Incentive Program (see http://aamc.org/members/gir/hit/aamc_commentletter_cms.pdf), we requested that for health information technology incentive payment purposes, CMS use a multi-pronged approach that allows a “hospital” to be defined in ways that acknowledge the varied organizational structures of multi-hospital systems. We would like to reiterate that CMS could use the hospital cost report, with certain modifications, to collect the hospital-specific data that will be necessary to determine a separate EHR incentive payment for each hospital. Specifically, hospitals with multiple sites that are under a single Medicare provider number but are in different core-based statistical areas currently must report separate wage data for each site on the cost report. CMS could create a similar worksheet on which hospitals with multiple sites that are under a single Medicare provider number separately report EHR incentive payment data for each site.

ICD-9-CM CODE FREEZE

Proposed last regular, annual update to both ICD-9-CM and ICD-10 on October 1, 2011

The Association acknowledges the benefits that ultimately will derive from the adoption of ICD-10-CM/PCS. To ease the transition to this new system, the AAMC supports CMS’s recommendation that the last regular, annual update to both ICD-9-CM and ICD-10-CM/PCS be made on October 1, 2011.

An October 1, 2011, coding freeze will allow sufficient time for all affected parties to focus on the complex implementation process. On-going updates to the three classification systems during the transition period would not only prove burdensome to maintain, but would be costly to the federal system as well as the healthcare industry. An October 1, 2011, freeze would reduce administrative costs associated with updating coding systems and training staff for IT

Ms. Marilyn Tavenner
June 18, 2010
Page 18

adoption in preparation for health information technology (HIT) incentive funds. Additionally, staff would not need to be trained with any new ICD-9 code updates during this time and could focus on learning the new ICD-10 code updates. A 2011 freeze also would provide some relief from the concurrent stresses caused by preparing for participation in the health information technology (HIT) incentive program for meaningful use of EHRs and the January 1, 2012 compliance date for new HIPPA transaction standards, Version 5010.

Proposed limited annual code updates to capture new technologies and diseases for both systems on October 1, 2012

We support CMS's recommendation for limited annual code updates on October 1, 2012, as updates for new technologies and diseases do traditionally occur on an annual basis. Limiting updates to only the most urgent circumstances will help facilitate the education process for member IT staffs. However, these limited updates must be decided using the process in place today - by the Coordination and Maintenance Committee, following public comment and a sound rationale for their necessity.

Proposed limited annual code updates to both systems on October 1, 2013

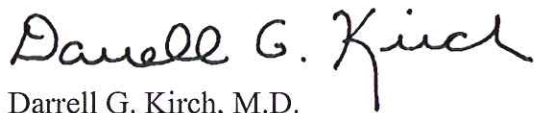
We support CMS's recommendation for limited coding updates on October 1, 2013, but only in extreme circumstances, such as pandemics, that cannot otherwise be reported using existing codes.

Finally, we urge CMS to allow a suitable amount of time to test with health plans and allow time for corrections and modifications based on the results of the testing. If new codes can still be introduced into ICD-10-CM/PCS on the go-live date, it will result in continuous changes and add to the already onerous task of ICD-10-CMS/PCS implementation.

CONCLUSION

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Karen Fisher, J.D., at 202-862-6140 or at kfisher@aamc.org.

Sincerely,



Darrell G. Kirch, M.D.

cc: Joanne Conroy, M.D., AAMC
Karen Fisher, J.D., AAMC