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Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1390-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physicians Ownership in Hospitals and Physicians Self-Referral Rules, Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians; 73 Fed. Reg. 23,528 (April 30, 2008).

Dear Acting Administrator Weems:

The American Medical Association (AMA) appreciates the opportunity to provide our comments regarding Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physicians Ownership in Hospitals and Physicians Self-Referral Rules, Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians; 73 Fed. Reg. 23,528 (April 30, 2008).

The AMA has strong concerns about several key provisions in the hospital inpatient prospective payment systems (HIPPS) proposed rule, as discussed below, and we urge the Centers for Medicare and Medicaid Services (CMS) to take these comments into consideration and work with the physician community to achieve consensus on these issues as CMS moves to finalize the proposed rule.

HOSPITAL ACQUIRED CONDITIONS

Under the Deficit Reduction Act of 2005 (DRA), beginning October 1, 2008, CMS can no longer assign an inpatient hospital discharge to a higher diagnosis-related group (DRG) if a certain hospital acquired condition (HAC), pre-selected by CMS, was not present on admission (POA). Under the proposed rule and based on statutory authority, CMS is seeking to expand this list of HACs. (Medicare will continue to assign a discharge to a higher paying DRG if the selected condition was POA.) CMS is requesting comment on proposed HACs that are: (a) high cost, high volume, or both; (b) assigned to a higher paying DRG when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence-based guidelines.

The AMA has strong overarching concerns about implementation of the HAC proposal, as well as concerns about inclusion of specific HACs on the list of HACs for which Medicare will not assign a higher DRG if the HAC was not POA (hereinafter referred to as the “HAC List”).

While provisions included in the proposed rule are well-intentioned, they present confusion and many unintended consequences for both the individual beneficiary and Medicare program as a whole. These include, but are not limited to, provisions that presume that medical conditions and complications are “reasonably preventable” when there is strong, broad disagreement with CMS throughout the medical community that these conditions are reasonably preventable.

Most of the conditions selected by CMS do not fulfill the statutory requirement that they be reasonably preventable through application of evidenced-based guidelines. To be reasonably preventable, there should be solid evidence, published in peer-reviewed literature, that by following certain guidelines, the occurrence of an event can be reduced to zero, or near zero, among a typically broad and diverse patient population, including high-risk patients. We believe, however, that for many of the proposed conditions on the HAC List, that occurrence rates cannot be reduced to or near zero even when all appropriate care is given. Some patients, particularly high-risk individuals, may still develop the conditions on the list.

CMS also requires these conditions to be documented if present on admission, yet often some of these conditions may lay dormant and are not even discernible on admission. Further, CMS refers to these conditions as “never events.” This is extremely confusing, especially to the general public, because it implies that the occurrence of the proposed HACs are always a mistake that should not have happened, when in fact, the condition may not have been avoidable, even while following evidence-based guidelines. Moreover, as discussed below, there may be instances when providing an appropriate standard of care for a patient may knowingly lead to a condition on the HAC List, such as delirium, but the occurrence of such condition is necessary as part of an appropriate standard of care.

Also inherent in the proposed conditions on the HAC List are problems such as: patient

de-selection (especially for high-risk patients); increased utilization of tests and screenings that may or may not improve the overall value of health care services provided under Medicare, but certainly will increase Medicare spending; and delayed care due to the requirement to determine and document conditions that are present on admission, with possible increased risk for patients due to the delay in needed care.

We also wish to raise the critical issue of risk adjustment. CMS must make it a priority to develop adequate risk adjustment models to the proposed HACs, including contracting and consulting with experts, physicians and the Agency for Healthcare Research and Quality (AHRQ), to conduct studies to identify the best risk adjustment techniques. The AMA recognizes that it is no easy task to accurately measure and risk-adjust medical complications and the degree of their preventability. However, it is this complexity that demands a more careful approach by CMS in how and why conditions are added to the HAC List. The agency must advance the science of quality improvement and measurement behind its “not paid for preventable complications” programs to realize true improvements in patient outcomes. *Provnovost, P., Goeschel, C, and Wachter, R. (2008). The Wisdom and Justice of Not Paying for “Preventable Complications,” Journal of the American Medical Association. 299, (18), 2197-2199.*

Risk adjustment must occur first at the patient level to reflect different levels of risk with regard to each patient. After this first level of risk adjustment is achieved, there must also be further risk adjustment to account for the differences in patient populations among hospitals.

Without using a well-developed risk adjustment methodology, patients at higher risk for infection post-elective surgery, for example, may be denied care. Further, hospitals that admit a higher proportion of sicker patients, who are more at risk for some of the conditions, will unfairly bear a larger financial penalty.

In addition, certain high-risk patient populations should almost always be excluded from the HAC policy. Trauma patients and patients near the end of life receiving palliative care are examples of high-risk patient populations that should not be included in this payment policy for most of the proposed conditions.

Finally, the AMA is concerned that the proposed HAC payment policy will increase costs to the health care system overall because agreement among experts about diagnoses associated with some of the proposed HACs is poor or unknown. *Ibid, 2197.* Ensuring that an HAC is POA, especially with regard to high-risk patients, will require additional expensive screening tests (as well as assess the patient’s risk and history of medical complications) to ensure proper documentation on admission. This increased screening activity may decrease the amount of preventable harm and marginal costs associated with HACs, but these benefits must be weighed against the additional costs of increasing screening activities on all patients entering an inpatient hospital setting. There is a fine line between limiting harm and promoting quality health care that improves the value of services delivered under Medicare. To achieve “value,” a desired quality outcome for patients must be produced at a reasonable cost to the system. Testing and screening all patients to determine whether certain

conditions are POA exponentially increases health care costs to Medicare, patients and the health care system overall, while the quality of health care services delivered is only slightly increased. In implementing the “HAC POA” requirement, CMS must consider the significant compliance costs to Medicare, beneficiaries and the health care system overall.

As discussed in more detail below, we strongly urge CMS to consider our comments and work closely with the physician community to better understand the serious ethical, practical, and financial implications surrounding how CMS moves forward in finalizing this proposed rule.

Overall Considerations for Alternative Approaches to the HAC List

CMS has requested public comment on alternative models for approaching payment adjustments with regard to HACs on the HAC List. While CMS recognizes that it may need statutory authority to implement some of these alternatives, the AMA offers CMS a number of considerations for approaching payment adjustments for preventable HACs.

“All or Nothing” Approach to HACs is Not Appropriate or Cost-Effective, Does Not Achieve Overall Quality Goals and Will Create Disincentives for Needed Care

The AMA does not believe that an “all or nothing” approach to the proposed HACs is appropriate or cost-effective, and it will not achieve the overall goal of improving quality.

CMS refers to the proposed HACs in the rule as “never events,” *i.e.*, conditions that should never occur in a hospital. This concept, with regard to many of the proposed HACs, is a misnomer. The assumption that evidence-based guidelines can “prevent” all occurrences of both current and proposed HACs is fundamentally flawed. Determining whether a diagnosis is actually POA is not always possible. Moreover, often, as discussed above, hospitals take all appropriate measures to prevent an HAC, yet, in some patients the HAC may nevertheless occur and the root cause is beyond the control of the hospital, physician or other medical provider involved in the care of a patient. Hospitals (nor physicians) should not be penalized in these instances under an “all or nothing” approach to HACs.

Under an “all or nothing” approach hospitals may have an incentive not to treat high-risk patients that are likely to develop an HAC even though evidence-based guidelines are followed. Thus, an all or nothing approach creates incentives for hospitals to select low-risk patients, leaving high-risk patients with little or no access to appropriate care, which could ultimately lead to more costly complications for these patients.

A more effective approach would be to encourage compliance with evidence-based guidelines. To this end, CMS should consider an approach that denies payment for an HAC that is not POA only if evidence-based guidelines were not followed. Under this approach, hospitals would be required to implement certain evidence-based measures

appropriate for reasonable prevention of an HAC, and if a hospital meets all of these measures, Medicare would still pay in the event that an HAC occurs.

Alternatively, CMS could consider a payment structure based on the development of a pre-established “baseline” that would measure the amount of times that each HAC (on the HAC List) is likely to occur in an individual hospital when there is compliance with all appropriate evidence-based guidelines. Payment adjustments would be made if the inpatient hospital’s HACs exceed this baseline.

Reliable, Valid Risk Adjustment Techniques Must Be Used in any HAC Payment Policy

Some medical conditions put patients at higher risk of an HAC than other medical conditions. For example, if a condition compromises a patient’s immune system that patient will be at higher risk to acquire an infection in the hospital. Yet, the “all or nothing” standard established by CMS for HACs does not take into account that certain HACs may be reasonably preventable in some patients, but not in others. **As discussed at length above, CMS must consider adequate risk adjustment techniques to address this critical factor.** Appropriate risk adjustment is necessary to secure meaningful comparability, particularly when data on outcomes are reported and when the information is used to make coverage and payment policies.

Application of Nonpayment for HACs to Other Settings

Although CMS would need new statutory authority to expand the approach of Medicare not paying for preventable health care-associated conditions to Medicare payment settings other than HIPPS, the agency has requested public comment about the prospect of applying this approach to other settings, including physician practices.

The AMA would have strong concerns about adopting this approach for physician practices. CMS has not yet conducted any analysis of: (i) the impact of the current HAC List with regard to the concerns raised above, *i.e.*, impact on the quality of care delivered to patients, especially in proportion to the additional costs to the Medicare program required to comply with the HAC requirements; (ii) the need for appropriate risk adjustment techniques; and (iii) the reasonable number of expected incidences in which these conditions will occur in individual hospitals, especially with regard to high-risk patients, when evidence-based guidelines are followed.

We, therefore, urge CMS to conduct an analysis of the current HAC policy, in consultation with technical experts, physician organizations, hospitals and other impacted providers, before moving forward to expand the proposed HAC List. Such analysis must also occur before considering extending this approach to other settings. It would defy any logical rationale to extend an approach to other settings when it is not clear that the approach achieves its quality improvement goals and, in fact, may cost significantly more money in proportion to overall program benefits and delay or deny access to needed care for patients.

Expanding the non-payment strategy for preventable health conditions acquired beyond the hospital setting would be extremely problematic, especially in physician offices because the payment approach is completely different from the hospital setting. For example, the appropriate level of an evaluation and management service is based on the conditions managed at a given encounter and the time and intensity of the work associated with those conditions. Because the presence and severity of additional conditions that are present during the visit will vary greatly among patients, identifying and valuing the work attributable to a preventable condition managed by the physician at a visit would be very difficult. In addition, the lack of adequate risk adjusters is an even greater problem in physician practices than in hospitals because some physicians specialize in treating the riskiest patients and do not have the ability to make up for losses on these patients through care of patients with below-average risks. Further, patient compliance outside of the physician office setting would be extremely difficult to assess and monitor, which also could seriously hamper any risk adjustment techniques. Many factors outside of a physicians' control could cause a patient to acquire various conditions while under a physician's care. It is critical that CMS, in considering expanding the HAC payment approach beyond the HIPPS setting, ensure that any such approach does not create disincentives to treat high-risk patients, who most need care and for whom early intervention avoids more costly conditions over the long-term.

We are pleased that CMS recognizes in the proposed rule that the implications of applying the HIPPS HAC payment policy approach "would be different for each setting, as each payment setting is different and the reasonable preventability through the application of evidence-based guidelines would vary for candidate conditions over the different settings." **In considering any similar approach for physician practices, we urge CMS to focus its efforts on encouraging compliance with evidence-based guidelines and addressing areas where there are gaps in quality of care, as well as fostering strategies to improve early diagnosis and disease management.**

Proposed Conditions That Are Not Appropriate for the HAC List

CMS is proposing a number of new conditions for the HAC List and has requested public comment on whether these HACs meet the three criteria set forth above, *i.e.*, (i) high cost, high volume, or both; (b) assigned to a higher paying DRG when present as a secondary diagnosis; and (c) reasonably preventable through the application of evidence-based guidelines.

The AMA has strong concerns that many of these HACs are not appropriate for the HAC List because they do not meet the "reasonably preventable" criterion. Accordingly, we urge CMS to withdraw the HACs discussed below from the proposed HAC List.

Surgical Site Infections Following Specific Elective Procedures

The AMA does not believe that surgical site infections (SSIs) following certain specific elective surgeries are appropriate for the HAC list. First, SSIs are not events that can be uniformly prevented and do not meet CMS' "could reasonably have been prevented through the application of evidence-based guidelines" criterion. SSIs can occur even when evidence-based guidelines are followed and it is not possible to always predict whether someone will get an infection. Prospective studies evaluating deep wound infections, for example, following prophylactic antibiotics demonstrate rates of 1% or more, even when best practices are followed. (Tang, W. M. et al. Efficacy of a single dose of cefazolin as a prophylactic antibiotic in primary arthroplasty. *J Arthroplasty* 18, 714-718 (2003)). Further, a recent study involving total knee arthroplasty patients receiving pre-operative antibiotics before incision with those receiving antibiotics before deflation of the thigh tourniquet showed no difference in infection rates of between 1.9% and 3.4% at 3 months and 2.6% and 3.6% at 12 months. (*Clin Infect Dis.* 2008;46:1009-1014.)

These findings highlight the need for following evidence-based guidelines, and not denying payment for occurrences that research suggests will occur despite best efforts. Hospitals, physicians and other providers should not be penalized for an infection when evidence-based guidelines are followed.

Accordingly, since SSIs in many cases do not meet the "reasonably preventable" criterion, CMS should not include them on the HAC List.

Staphylococcus aureus Septicemia

Staphylococcus aureus Septicemia (*S. aureus*) also is inappropriate for the HAC List since it does not meet the "could reasonably have been prevented through the application of evidence-based guidelines" statutory criterion.

CMS maintains that evidence-based guidelines suggest *S. aureus* is reasonably preventable. In discussing prevention of *S. aureus*, CMS focuses on the importance of effective and fastidious hand washing by both staff and visitors, using gloves and gowns where appropriate, applying proper decontamination techniques, and exercising contact isolation where clinically indicated.

Although the AMA agrees that hand hygiene may lead to some measure of prevention of *S. aureus*, hand hygiene alone will not reasonably prevent *S. aureus* from occurring. There are other methods for passing this condition from one individual to another. For example, carriers could transfer *S. aureus* via their shoes or even a tie. In addition, there can be asymptomatic carriers of *S. aureus*. **This suggests that hand-washing alone could not reasonably prevent the transfer of this condition. Additional protection could be offered by putting gowns and boots on everyone – including family members – who enters the patient's room but the cost to the health system would be enormous. Total**

isolation of all patients would also reduce the risk, but would also deny patients the company of friends and family who often speed recovery in intangible ways.

In addition, although CMS does not mention it as a factor, *S. aureus* occurrences also can be due to an indwelling catheter, and an important part of *S. aureus* prevention is appropriate catheter care along with keeping catheter use to the minimum duration necessary. Yet, even when caregivers employ all appropriate infection control techniques, *S. aureus* infections can occur, either from the CVC or other causes. **While it is appropriate to promote proper catheter care, inclusion of *S. aureus* on the HAC List is inappropriate as these infections are not completely preventable.**

Clostridium Difficile-Associated Disease

Although some percentage of *Clostridium Difficile* (CDAD) cases may be reasonably preventable, a significant percentage cannot be reasonably prevented.

For example, an oncologist may have to hospitalize an immunosuppressed unstable patient with a neutropenic fever. Some of these patients will develop antibiotic-induced diarrhea which is found to be caused by CDAD, even when evidence-based guidelines are followed to prevent spread of CDAD. To deny payment for an illness caused by medically necessary antibiotics changing the intestinal flora balance to allow overgrowth or pre-existing gut flora, such as CDAD, is not warranted.

We also understand that no standard laboratory test for CDAD is available to detect this condition on admission, and there are high rates of false positive results for the typically-used toxin test since the relevant toxin degrades at room temperature. Further, the difficulty of uniform prevention of CDAD is highlighted by the CDC's "*Guidelines for Environmental Infection Control in Health-Care Facilities*," which state that "[a]t present there are no EPA-registered products with specific claims for inactivating *C. difficile* spores." **Thus, 100 percent prevention of CDAD is not reasonable and it should not be included on the HAC List.**

Ventilator-Associated Pneumonia

Reducing the incidence of Ventilator-Associated Pneumonia (VAP) is possible through a number of interventions outlined in the proposed rule that are already being addressed, in part, through the PQRI program (2008 Measure #75). Many commenters in CMS' December 2007 HAC and POA Listening Session, however, stated that this condition is not always preventable and thus is not a reasonable measure for inclusion in the HAC program. The AMA agrees.

For example, VAP is often a complication in ICU patients who are already seriously immuno-compromised and are not able to be taken off of a ventilator due to various conditions, such as sepsis, severe injury or head trauma. Despite appropriate respiratory care, a patient's upper airway can become colonized with the patient's own flora or hospital-acquired bacteria. **Therefore, VAP is often not reasonably preventable and should not be included on the HAC List.**

Deep Vein Thrombosis/Pulmonary Embolism

It is not reasonable to establish a rigid requirement mandating that *Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)* should never occur. The likelihood of DVT occurring as an HAC substantially depends on the risk-level of the patient. In recognition of the fact that DVT is not always preventable, the National Quality Forum (NQF) has established a “stratified” quality measure based on risk-levels. These risk-levels were developed for a population-based approach to reporting, and not for the individual patient level. Therefore, the inclusion of DVT in the HAC List (which focuses on individual patient measurement) is inappropriate, and does not reflect the complexity of DVT complications reflected in NQF’s developed measure.

The AMA agrees that DVT/PE incidence can be reduced, but it cannot be completely eliminated through adherence to evidence-based guidelines. For example, unrecognized patient condition, such as Factor V Leiden mutation and Protein C deficiency, play a significant role in DVT/PE development (e.g. Okumus, G. et al. Hereditary thrombophilic risk factors and venous thromboembolism in Istanbul, Turkey: the role in different clinical manifestations of venous thromboembolism. *Clin Appl Thromb Hemost* 14, 168-173 (2008)). Further, some patients, such as bed-ridden cancer patients, are inherently at risk for DVT/PE. They may require surgical procedures and often have pre-existing conditions increasing their risk of bleeding. In these cases, DVT prevention mechanisms can be used when it is clinically safe to do so, yet clots can occur anyway, despite the use of appropriate prevention mechanisms. **Accordingly, DVT and PE should not be added to the HAC List.**

Legionnaires’ Disease

The incubation period for Legionnaires’ is two to ten days (with a median of four days) and is followed by an abrupt onset of high fever, nonproductive cough, chills, and headache. This means that the point of infection could occur after POA reporting during an inpatient stay, but it could have been acquired prior to admission. In this case, it would be impossible to prevent Legionnaires’ from occurring. **Thus, Legionnaires’ is not reasonably preventable in many instances and should not be included on the HAC List.**

Delirium

Delirium can occur in a significant percentage of hospitalized patients, especially ill elderly Medicare patients, and there are many potential causes for delirium, including such conditions as dementia.

There are many causes and clinical realities that lead to delirium, such as sepsis, psychiatric disorders, medications and pre-existing conditions that may not be determinable on admission. While some of these causes can be minimized using appropriate quality measures, delirium is not “reasonably preventable” in many instances. Further, there can be instances when providing an appropriate standard of care for a patient may knowingly lead

to some delirium. For example, treatment of patients with brain metastases or cord compression with high doses of steroids may cause elevated blood sugars and delirium. In these instances, the CMS HAC policy would unfairly force hospitals to forgo payment in order to provide a patient the appropriate standard of care, or, it could provide disincentives to treat these patients altogether.

Delirium is also extremely common as a pre-terminal event, and to expect, especially in these cases, that delirium can be uniformly prevented is medically unjustified. Inclusion of delirium on the HAC List could provide a serious disincentive to provide appropriate care to many very sick patients, including those imminently dying.

Delirium, therefore, should not be included on the HAC List.

Extreme Aberrations in Glycemic Control

The AMA agrees that some episodes of each of the extreme glycemic aberrations set forth in the proposed rule are potentially preventable, particularly those associated with medication or equipment error. In a number of cases, however, there are factors outside the control of the facility and the clinicians caring for the patient that can lead to challenges with glycemic control. These include severe infection, patient non-compliance, stress response from surgery or trauma, exaggerated response to the initiation of insulin therapy and others. Early detection and standardized treatment do reduce ICU and hospital length-of-stay for diabetic ketoacidosis. Yet, these protocols do not guarantee uniform prevention of glycemic aberrations. **Accordingly, inclusion of glycemic control on the HAC List does not meet the “reasonably preventable through evidence-based guidelines” statutory criterion.**

Present on Admission (POA) Indicator Reporting

CMS proposes to require POA indicator information, to identify which conditions were acquired during hospitalization, for the HAC payment provision and for broader public health uses of Medicare data. The AMA urges CMS to consider the concerns enumerated below with respect to the POA indicator reporting process.

POA Documentation

As discussed at length above, ensuring that an HAC is POA, especially with regard to high-risk patients, will require additional expensive screening tests to ensure proper documentation on admission. **CMS must consider the costs of complying with the “HAC POA” requirement for hospitals, the Medicare program and beneficiaries, who incur higher cost-sharing.** The cost of meeting this requirement with respect to the proposed HACs could significantly outweigh the benefit. Subjecting patients, especially high-risk patients to these additional tests, may not be in the interest of delivering the highest quality of care.

We also emphasize that, to meet the “law and regulation” factor of the sustainable growth rate (SGR) formula, CMS is required by law to measure the impact of these additional tests (due to the HAC POA requirement) on Medicare spending on physicians’ services when calculating the SGR. The AMA supports appropriate medical screening related to providing individualized, quality health care services for patients. It is clear, however, that hospitals need to take additional steps to screen for HACs, and if resultant additional Medicare spending on physicians’ services is not factored into the SGR target, physicians will be penalized with additional Medicare payment rate cuts. **Therefore, it is imperative that CMS reflect in the SGR target additional spending on physicians’ services due to the “HAC POA” requirement. Not doing so could have unintended consequences on a beneficiary’s access to physicians’ services.**

The AMA is also concerned that compliance with the POA indicator reporting process may not be feasible in some cases, and CMS should create an exception process for these instances. For example, it may not be feasible to determine if an HAC is POA when a patient is being treated on an emergency basis. In the case of an emergency, the Emergency Medical Treatment & Labor Act (EMTALA) generally requires that a hospital treat and stabilize a patient who comes to the emergency room. It may not be possible to act immediately to stabilize a patient and, at the same time, conduct all appropriate tests to determine if an HAC condition is POA. Additionally, meeting the POA requirement could delay the delivery of appropriate care to patients, whether or not an emergency exists, perhaps putting a patient at further risk. Such delays may be necessary to comply with the HAC POA law and regulations. Otherwise, hospitals risk being denied significant amounts of dollars for medically necessary care. The POA requirement could create legal, financial and ethical conflicts for physicians and hospitals. **CMS must establish an exception process to account for these circumstances.**

We are also concerned that the POA indicator process will require extensive administrative resources to appropriately document whether an HAC is POA. This requirement may be extremely costly to hospitals and ultimately the Medicare program. **CMS should monitor this process and develop strategies to ensure minimum use of additional administrative resources.**

Finally, it is unclear who would be responsible for conducting the POA screening. The responsible medical personnel may not have the expertise to correctly document a particular problem, and, at the physician level, for example, a cardiologist may not correctly document a gastroenterology problem. Without further guidance, there will be substantial confusion, which will seriously hamper the POA indicator reporting process and cause hospitals to be unnecessarily penalized for undocumented HACs that otherwise could have been properly documented.

Public Reporting of POA Indicator Reporting

We encourage CMS to maintain a database of POA indicator reporting. This information would be very useful for CMS in developing appropriate risk adjustment

techniques, which are critical for purposes of fair performance comparison, payment and accurate public reporting.

The AMA, however, remains very concerned about public reporting, which if not approached thoughtfully, can have unintentional adverse consequences for certain patients. For example, patient de-selection can occur for individuals who may be at higher risk for an HAC due to age, diagnosis, severity of illness, multiple co-morbidities, or cultural characteristics that make them less compliant with protocols that are based on evidence-based guidelines. Further, health literacy may not be adequate to comprehend basic medical information. Programs must be designed so that appropriate information is available to patients to enable them to make educated decisions about their health care needs. If done correctly, public reporting has the potential to help provide such appropriate information to patients. There remain, however, several critical issues that must be resolved before public reporting provisions can be implemented. There needs to be a method for ensuring that any publicly reported information is: (i) correctly attributed to those involved in the care; (ii) appropriately risk-adjusted; and (iii) accurate, user-friendly, relevant and helpful to the consumer/patient. Moreover, hospitals, physicians and other providers involved in the treatment of a patient must have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. Any such comments should also be included with any publicly reported data. This is necessary to give an accurate and complete picture of what is otherwise only a snapshot, and possibly skewed, view of the patient care provided by a hospital, physician or other involved provider.

Adoption of ICD-10 to Identify HACs is Premature

Currently, the International Classification of Diseases, Ninth Revision, Clinical Modification, (ICD-9-CM) is used for diagnosis coding in both the inpatient and outpatient settings, as well as for procedure coding in the inpatient setting pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which called for using standardized transactions and code sets. CMS has requested public comment concerning the adoption of ICD-10-PCS to facilitate more precise identification of HACs.

The AMA recognizes the importance of updating the current coding scheme, ICD-9, with ICD-10. Yet, we have strong concerns about how and when the transition process will be implemented because it is a very complex and costly undertaking. A well-defined and executed transition plan is critical to ensuring the success of a migration of this magnitude, and a drawn-out, costly process can be avoided if an appropriate transition plan to move to ICD-10 is fully developed through a consensus process that involves multiple stakeholders, including physicians.

The transition to the ICD-10 system will increase the number of possible codes ten-fold. Physicians, and other stakeholders, including health plans and payers, clearinghouses, and software vendors, need adequate time to successfully plan the move to a new diagnostic coding system. In addition to incurring significant costs for implementing a new coding system, physician practices will also face additional challenges transforming their practices,

including upgrades or replacements of practice management and billing systems and software, adjustments to current operational protocols, and staff education and training costs. Private and public payers will also have to upgrade or replace their own payment processing and data management systems to accommodate the significant body of data generated by this extensive transition. **Therefore, the AMA recommends pursuing a realistic transition time period to ICD-10 to ensure that the delivery of health care, claims and payment processing, and acquisition of critical health information technologies are not adversely impacted due to this substantial coding migration.**

It is important to keep in mind that physicians are currently struggling to implement existing HIPAA requirements, including the ongoing transition to the National Provider Identifier. In addition, physicians must comply with Medicare and other public and private payer mandates while facing shrinking payer revenues, that have failed to keep pace with increases in medical practice costs, along with steep Medicare payment cuts projected for the coming decade. Unlike other professionals and businesses, physicians are limited in their ability to pass on the costs or practice investments in the form of higher charges for their services. These costs are especially difficult to absorb for small physician practices, which comprise the vast majority of physician practices. The costs that will be incurred due to system upgrades or replacements are more demanding for smaller practices that face greater technological, operational and financial challenges.

On April 1, 2008, the AMA, along with multiple medical specialty groups, the BlueCross BlueShield Association, and other key health care stakeholders sent a letter to the Department of Health and Human Services (HHS) recommending the following process and timeline for moving to the ICD-10:

Adoption, Testing, and Verification of Version 5010 of HIPAA Electronic Transactions Standard Prior to Moving to ICD-10

The current HIPAA electronic transactions standard version 4010 is not compatible with ICD-10. Moreover, version 5010 significantly differs from 4010. As the National Committee on Vital and Health Statistics (NCVHS), an advisory body to the HHS on health data, statistics and national health information policy, recommended in their September 26, 2007, letter to HHS Secretary Leavitt, implementation of ICD-10 should not take place simultaneously with the adoption of the version 5010.

Implementation of a Comprehensive Pilot Testing of ICD-10 Prior to National Roll-Out

HHS should pilot test ICD-10 in order to identify potential issues and problems early on, allow time to develop solutions, and gather feedback from pilot participants that will assist in the national transition process.

Incorporation of Adequate Time in the Transition Process and Timeline to Train Coders

A transition from ICD-9 to ICD-10 will require an appropriate supply of coders. Training coders for ICD-10 will require the development of a new curriculum, publication of curriculum materials, and most importantly, adequate workforce training to support the providers and billers under ICD-10; a system with approximately 10 times more codes than are in ICD-9.

Pursuit of an Aggressive Outreach Strategy to Covered Entities and Vendors

An important lesson from the transition to version 4010 and the current transition to the NPI is the essential need to begin educating the covered entities and vendors—especially the smallest practices and software vendors—as early and as often as possible. Given the significant resources, administrative complexities and advance planning that are required to retool or replace systems and processes that depend on ICD-9 logic, the AMA recommends that HHS work collaboratively with all health care industry stakeholders, especially physicians, in order to develop an effective transition plan to use ICD-10.

CMS Should Help Educate Health Professionals About Compliance with HAC Policies

The AMA urges CMS to initiate education programs for hospitals, physicians, non-physician health care professionals, hospital administrative staff, and hospital visitors involved with regard to effective prevention of HACs and compliance with the POA indicator reporting requirements. Effective prevention and documentation of HACs that can be reasonably prevented depend on the education and knowledge of all participants.

AVOIDABLE READMISSIONS

In the proposed rule, CMS requests public comments on considerations and options for applying incentives to reduce avoidable hospital readmissions, especially with regard to issues relating to measurement, accountability, and interventions, as well as on potential approaches to applying financial and non-financial incentives to reduce avoidable readmissions. In applying incentives to reduce avoidable readmissions for public comment, CMS is focusing on three alternative policies: (1) direct adjustment to hospital DRG payments for avoidable readmissions; (2) adjustments to hospital DRG payments through a performance-based payment methodology; and (3) public reporting of readmission rates. CMS recognizes that either type of adjustment to hospital payments for readmissions would likely require new statutory authority for the Medicare program.

The AMA encourages the development of effective approaches to reduce avoidable hospital readmissions, as this is a uniformly-accepted worthy goal. Specifically, CMS should consider the development of tools and mechanisms to permit hospitals, physicians, other health care providers and patients to work together to improve care coordination and disease management. We emphasize, however, that such approaches often require more care in physicians' offices. Although better for patients, these approaches may lower Medicare

health spending overall, while increasing Medicare spending on Medicare Part B services. If this increased spending is not reflected when calculating the SGR spending target, additional Medicare physician payment rate cuts will result. **We urge CMS to ensure that increased Medicare spending on physicians' services due to any statutory or regulatory initiatives directed toward reducing avoidable hospital admissions, through the use of greater physicians' services, be adequately reflected in SGR calculations.**

Further, we urge CMS, in developing approaches to reduce avoidable hospital readmissions, to exercise extreme caution to ensure that any such approach does not create incentives that are adverse to appropriate and cost-effective patient care. We are encouraged that CMS has recognized in the proposed rule many important dynamics that need strong consideration before moving forward with new financial and non-financial incentives to reduce avoidable readmissions.

Specifically, CMS recognizes in the proposed rule the need for: routine, valid, and reliable measurement of hospital-specific rates of readmissions; data risk adjustment to assign accountability (especially when there is shared accountability); and account for patient-specific factors that influence the likelihood of readmission, such as age, disease severity and co-morbidities. CMS also recognizes that the goal of zero readmissions may not be appropriate, as an extremely low rate of readmissions could indicate restricted access to needed medical services, overuse of hospital resources during the initial hospitalization (for example, prolonged length of stay), or excessive intensity of post-acute care services.

Adequate risk adjustment could help to elucidate the avoidability of readmissions by identifying an expected readmission rate for a given patient or patient population. Further, CMS recognizes that potential unintended consequences resulting from a financial incentive to avert readmissions need to be considered. For example, hospitals could begin discharging patients to settings that provide more intensive post-acute care to avoid readmissions, thereby potentially driving up total costs for episodes of care and total Medicare spending. As another example of potential unintended consequences, hospitals could begin to resist medically necessary readmissions from post-acute care providers, creating an access problem.

The AMA is equally concerned about each of the above considerations. Financial or non-financial incentives to reduce avoidable readmissions cannot be implemented on an "all or nothing" basis. Readmissions will occur in a certain percentage of cases in which the hospital has provided all appropriate care, especially with regard to high-risk patients, as is also the case with non-POA HACs. Thus, appropriate risk adjustment techniques are critical.

We are also concerned about measuring shared accountability, which is very difficult to achieve, especially when it involves patient non-compliance outside of the hospital setting. If not done properly, this could lead to economic credentialing of physicians. If a physician treats a certain number of patients at high-risk for readmission, a hospital may not allow the physician to have hospital staff privileges. This could seriously disadvantage access for

these high-risk patients, who ultimately will end up in a hospital emergency room, with complications that may be very costly to the Medicare program.

Accordingly, we encourage CMS to exercise extreme caution in the event that CMS, based on statutory authority, were to move forward with these initiatives, and to ensure that patient access and quality of care are not unintentionally and adversely impacted.

HOSPITAL QUALITY DATA

The AMA remains an active member of the Hospital Quality Alliance (HQA), a public-private collaboration dedicated to improving the quality of care provided by the nation's hospitals by measuring and publicly reporting on that care. The measures adopted by the HQA have enjoyed broad stakeholder support and can be readily implemented into the national reporting infrastructure. It is critical to maintain that stakeholder support. Yet, in establishing new measures for which hospitals would report quality data in fiscal year 2010, CMS has proposed a significant number of measures that have not been adopted by the HQA or endorsed by the NQF.

A key strategy articulated in the CMS Quality Road Map is that the agency will “work through partnerships to achieve specific quality goals.” The members of the HQA continue to want a constructive relationship and open communication among its partners so that together we can effectively advance quality. Adopting hospital quality measures that have not been adopted by the HQA, however, seems incongruous to the public-private partnership and undermines the goals of this partnership. **We urge CMS, in considering adoption of hospital quality measures, to ensure that any new such measures have been adopted by the HQA and endorsed by the NQF, thereby ensuring a rigorous, consensus-based assessment, as well as broad stakeholder support, of the measure.**

FINANCIAL RELATIONSHIPS BETWEEN HOSPITALS AND PHYSICIANS

CMS is soliciting public comments on a mandatory “Disclosure of Financial Relationships Report” (DFRR) to collect information about financial relationships between hospitals and physicians. The proposed rule would also expand an existing hospital condition of participation to require disclosure to patients of hospital ownership interests held by physicians and their relatives. CMS notes that, “this expanded condition of participation will allow patients to make more informed treatment decisions.” The AMA agrees that transparency with regard to hospital and physician ownership issues will allow patients to make more informed decisions regarding their health care. To that end, the AMA strongly urges CMS to further expand the existing hospital conditions of participation to require the disclosure to patients of physician practice ownership interests held by hospitals. We believe this is an important component of any health care transparency initiative as patients have a right to know about hospital ownership of physician practices and hospital tactics that require or strongly encourage referrals be made to a hospital or preclude physician involvement in a competitor facility.

Acting Administrator Kerry N. Weems

June 13, 2008

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Increasingly, hospitals have been buying physician practices in order to counter physician investment in medical facilities and to solidify their patient bases and sources of referrals for specialists and hospital services. The hospitals then require the physicians to exclusively refer patients to their facilities for ancillary services and prohibit the physicians from investing in, or referring patients to, competitor facilities. Hospitals have imposed these restrictions insidiously by implementing so-called "conflict of interest policies," conditioning certain privileges or positions on a promise not to refer to competing facilities, and outright pronouncements from hospital boards or trustees forbidding staff physicians from having relationships with new facilities. These tactics restrict a physician's ability to provide health care based on his or her professional judgment and a patient's needs. We believe that short of restricting this type of behavior, patients should know that their treatment options and quality of care may be compromised by these pernicious tactics.

The AMA appreciates this opportunity to provide our views on these critical issues, and we look forward to working with CMS to achieve consensus on the foregoing matters and develop payment and coverage policies that maintain Medicare beneficiary access and improve their quality of care.

Sincerely,

A handwritten signature in cursive script, reading "Mike Maves", written in black ink on a white background. The signature is positioned to the left of a vertical red line.

Michael D. Maves, MD, MBA