Michael D. Maves, MD, MBA, Executive Vice President, CEO

December 29, 2008

Ms. Karen Jackson
Centers for Medicare and Medicaid Services
Mailstop C5–15–02
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Listening Session on Hospital-Acquired Conditions on Inpatient Settings and Hospital Outpatient Healthcare-Associated Conditions in Outpatient Settings; December 18, 2008

Dear Ms. Jackson:

The American Medical Association (AMA) appreciates the opportunity to provide our views to the Centers for Medicare and Medicaid Services (CMS) regarding hospital-acquired and healthcare-associated conditions (HACs). Under the Deficit Reduction Act of 2005 (DRA), as of October 1, 2008, CMS can no longer assign an inpatient hospital discharge to a higher diagnosis-related group (DRG) if a certain medical condition (HAC), pre-selected by CMS, was not present on admission (POA). The DRA directs that HACs: (a) must be high-cost, high-volume, or both; (b) must be 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.

CMS acknowledged in the final physician fee schedule rule for calendar year 2009 that it received many public comments raising concerns about the HAC policy, as well as about extending this policy to outpatient settings, including physicians' offices. We are disappointed that CMS merely acknowledged these concerns in the final rule, and failed to take them into serious consideration. It is critical that CMS address these concerns, particularly because private payers are adopting this non-payment policy, thereby further compounding the complications raised by this ill-conceived policy. In an Office of Inspector General (OIG) of the Department of Health and Human Services report, *Adverse Events in Hospitals: Overview of Key Issues* (OEI-06-07-00470), the OIG found that HAC nonpayment policies are increasingly popular among payers, and that these policies have drawbacks and may "limit access to care, increase hospital costs, and reduce hospital revenues."

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The AMA strongly opposes non-payment for HACs in the inpatient or in any payment setting that are not reasonably preventable through the application of evidence-based guidelines, developed by appropriate medical specialty organizations based on non-biased, well-designed, prospective, randomized studies. Because the current inpatient HACs do not meet that criteria, we have grave concerns about this policy and about extending it to other payment settings, including physician practices.

Conditions Covered by the Inpatient HAC Policy Are Not "Reasonably Preventable"

CMS has selected conditions for coverage by the inpatient HAC policy that do not fulfill the statutory requirement that they must be "reasonably preventable through application of evidenced-based guidelines." **In developing the HAC policy, CMS confuses events that should never happen in a hospital, like surgery on the wrong patient, with often unavoidable conditions, like surgical site infections.** To be reasonably preventable, there should be solid evidence, published in peer-reviewed literature, that by following certain evidence-based 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. There is strong, unequivocal disagreement with CMS throughout the medical community, however, that many inpatient HACs are reasonably preventable. Some patients, particularly high-risk individuals, may still develop the conditions on the HAC list. The AMA continues to work aggressively to improve quality and efficiency for patients, but simply not paying for complications or conditions that, while extremely regrettable, are not entirely preventable, is not effective or good for patients or the Medicare program.

CMS' decision to apply the HAC policy to medical conditions that often are not "reasonably preventable" can create an ethical no-win situation for hospital, physicians and other health care professionals involved in patient care. For example, prescribing antibiotics prior to surgery may reduce a patient's risk of experiencing a surgical site infection. Yet, there is harm in over-prescribing antibiotics, which can lead to antibiotic resistance infections, like Methicillin-resistant Staphylococcus aureus (MRSA). **A more effective approach to balancing risk and improving patient safety is to encourage compliance with evidence-based guidelines.**

Finally, the HAC policy arbitrarily exposed hospitals, physicians, and other health care professionals to increased risk of liability suits. This arbitrary risk is even more egregious since the HAC policy applies to conditions that often are not "reasonably preventable."

The HAC Policy Is Not Appropriate Or Cost-Effective, Does Not Achieve Overall Quality Goals, And Creates Disincentives for Needed Care

The AMA believes that the current HAC policy is not appropriate or cost-effective, does not achieve overall quality goals, and creates disincentives for needed care. The assumption that evidence-based guidelines can "prevent" all occurrences of HACs is fundamentally flawed, and determining whether a diagnosis meets the POA requirement is not always possible. Moreover, often hospitals take all appropriate measures to prevent a 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, as occurs under the current approach to HACs. This creates incentives for hospitals to avoid treating high-risk patients that are likely to develop a HAC even though evidence-based guidelines are followed, leaving high-risk patients with little or no access to appropriate care, which could ultimately lead to more costly complications for these patients.

As discussed above, a more effective approach would be to encourage compliance with evidence-based guidelines. Thus, CMS should adopt an approach that denies payment for a 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 a HAC occurs.

The HAC Policy Will Increase Medicare Program Spending

The HAC policy requires hospitals to ensure that certain medical conditions are not POA. **To determine whether a condition exists when the patient enters the hospital will increase Medicare spending on tests and screenings with questionable benefit to patients. This could also delay needed care, with possible increased risk for patients due to the delay.**

Ensuring that a HAC is POA, especially with regard to high-risk patients, will require additional expensive screening tests (as well as assessing a 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.

CMS should immediately assess amounts that are saved through application of the HAC policy and compare those amounts with implementation costs for hospitals, including the costs of increased tests to determinate whether a condition is POA.

Reliable, Valid Risk Adjustment Techniques Must Be Used In A HAC Payment Policy

Some medical conditions put patients at higher risk of a 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 current HAC policy does not take

into account that certain HACs may be reasonably preventable in some patients, but not in others. **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.

Without using a well-developed risk adjustment methodology, patients at higher risk for post-surgical infection, 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.

<u>POA Documentation Is Confusing and Onerous</u>

The POA documentation process is causing significant confusion. It is unclear who is responsible for conducting the POA screening. Further, the responsible medical personnel may not have the expertise to correctly document a particular problem. This confusion is causing unnecessary friction between hospitals and physicians, as well as raising concern for false billing (which carries significant penalties) due to potential unintended incorrect coding. It may also cause hospitals to be unnecessarily penalized for undocumented HACs that otherwise could have been properly documented.

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 a 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 a 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.**

Finally, we are concerned that the POA indicator process will require extensive administrative resources to appropriately document whether a 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.**

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.**

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 a 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.

Application of Nonpayment for HACs to Other Settings

CMS does not have the statutory authority to extend the inpatient HAC policy to other settings, including physician office practices. Under the Deficit Reduction Act of 2005, Congress specifically provided CMS with the authority to begin applying the HAC policy to the hospital inpatient setting. If CMS were to extend this policy to other settings, it would likewise need similar statutory authority granted by Congress.

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.

CMS should conduct an analysis of the current inpatient HAC policy, in consultation with technical experts, physician organizations, hospitals and other impacted providers, before expanding the HAC policy any further. Such analysis must also occur before considering extending this approach to other settings.

It is unacceptable that CMS is considering expansion of the inpatient HAC policy when the agency has not yet conducted any analysis of it. It defies 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.

Further, expanding the inpatient HAC policy to other settings would be extremely problematic, especially in physician offices, because the payment approach is completely different from the hospital setting. For example, in the inpatient setting, Medicare denies the portion of payment associated with care complications when the complications are associated with a condition on the HAC list. Yet, there is no clear way to determine some portion of a physician's payment that would be denied due to presumed mismanagement of a reasonably preventable condition. 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 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. **Since many factors outside of a physicians' control could cause a patient to acquire various conditions while under a physician's care, CMS should instead encourage compliance with evidence-based guidelines rather than extending the HAC policy.**

The AMA appreciates the opportunity to provide our views and concerns on this critical matter. We urge CMS to immediately resolve these concerns before moving forward to expand this ill-conceived HAC policy.

Sincerely,

Michael D. Maves, MD, MBA