AMA
AMERICAN
MEDICAL
ASSOCIATION

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Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: *Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals;* 75 *Fed. Reg.* 23,852 (May 4, 2010).

Dear Acting Administrator Tavenner:

The American Medical Association (AMA) appreciates the opportunity to provide our comments regarding *Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals*; 75 *Fed. Reg.* 23,852 (May 4, 2010).

<u>The Study of the Hospital-Acquired Condition-Present on Admission Policy is Flawed Because it Does Not Consider Compliance Costs with this Policy</u>

In September 2009, the Centers for Medicare and Medicaid Services (CMS) contracted with Research Triangle Incorporated (RTI) to study the impact of the Hospital-Acquired Condition-Present on Admission (HAC-POA) policy on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. This study is also for the purpose of evaluating additional conditions for future selection. The AMA has significant concerns about the RTI evaluation CMS discusses in the proposed rule. In the proposed rule, CMS discusses results from the RTI evaluation. Since the RTI study is ongoing, and thus what is presented in the proposed rule is incomplete, the AMA will continue to update our comments as additional data and results of the study are further released in the final rule.

The AMA has strong concerns that, although CMS contracted with RTI to conduct a study of the impact of the HAC-PAO policy, CMS did not request that RTI evaluate a key,

critical element of this policy -- the cost of complying with this policy and its impact on patients, the Medicare program, hospitals, and the health care system overall.

As the AMA has previously commented to CMS, we have strong concerns that the HAC-POA policy will increase costs to the health care system overall because ensuring that a HAC is POA, especially with regard to high-risk patients, will require additional expensive screening tests (as well as an assessment of 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 patients in the form of higher copayments, along with significant costs to the Medicare program, hospitals, and the health care system overall, while the quality of health care services delivered is only slightly increased. In implementing the HAC-POA policy, CMS must consider these significant compliance costs, as well as the risk to patients, especially high-risk patients in subjecting them to additional tests that may not be in the interest of delivering the highest quality of care.**

Yet, the RTI study did not evaluate these costs. This is a critical element in determining the impact of the HAC-POA policy. The proposed rule discusses that 3,038 MS-DRGs were changed due to a HAC at a "net savings" of $16.44 million. This data is misleading because it is impossible to determine the "net savings" when there has been no evaluation of the output on compliance costs due to the HAC-POA policy. If there is $16 million in savings, but the compliance costs incurred (by patients, hospitals and the Medicare program) in providing additional tests to determine if a condition is POA significantly exceeds this $16 million, this may not be considered savings, especially if this level of savings does not achieve "value," *i.e.,* a desired quality outcome for patients produced at a reasonable cost to the system. Further, it is likely that compliance costs were significant because CMS reports in the proposed rule that the RTI study evaluated 216,764 discharges that included a HAC-associated secondary diagnosis, and of these 216,764 discharges, 3,038 MS-DRGs were changed due to a HAC. It is likely that hospitals furnished a substantial number of costly and additional tests to determine whether a HAC was POA in each of these 216,764 cases. While some of these additional tests may have reduced harm to patients, others may have put some patients, especially high-risk patients, at further risk, and still others may have produced negligible or no benefit in terms of promoting quality of care. **It is critical, as CMS moves forward in evaluating the HAC-POA policy, that the agency engage RTI to study the impact of the significant compliance costs on patients, the Medicare program, hospitals, and the health care system overall. Otherwise, any evaluation of the HAC-POA policy is misguided and the impact of this policy will continue to be inconclusive and inaccurate. Further, if CMS is also going to use the RTI study to evaluate additional HAC conditions for future selection, RTI must study the costs of complying with this policy.**

CMS Should Use a More Effective Approach to Balancing Risk and Improving Patient Safety by Encouraging Compliance With Evidence-Based Guidelines

The AMA also reiterates our previous comments that we strongly oppose 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 continue to have grave concerns about this policy. 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, co-morbid individuals, may still develop the conditions on the HAC list.

Further, CMS' decision to apply the HAC-POA policy to medical conditions that often are not "reasonably preventable" can create a "catch 22" situation for hospitals, physicians, and other health care professionals involved in patient care. For example, antibiotics used prophylactically to reduce post-operative infections may sometimes unpredictably increase the incidence of other infections, *e.g., Clostridium difficile.* The AMA is also concerned that the HAC-POA policy arbitrarily exposes hospitals, physicians, and other health care professionals to increased risk of liability suits. This arbitrary risk is even more egregious since the HAC-POA policy applies to conditions that often are not "reasonably preventable."

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.
Rather, the AMA supports a better approach to improving patient safety and quality. As such, the AMA promotes efforts to enhance and strengthen the patient-physician relationship, as well as those efforts aimed at the education of patients and families so that they can engage in the safe management of their care as they are treated in a variety of care settings. By leading and supporting national patient safety efforts, such as the Making Strides in Safety® program, confidential, error-reporting systems and patient education messaging, the AMA is working diligently to promote a culture of patient safety. Moreover, the AMA has a long and successful track record in developing and promoting the use of quality measures. The AMA-convened Physician Consortium for Performance Improvement (PCPI) to date has developed approximately 270 quality measures covering 43 clinical conditions, and many of these measures have been adopted by the Centers for Medicare and Medicaid Services for use in the PQRI and Medicare demonstration projects. In addition, the PCPI is forging ahead to develop the next generation of measures so that quality can improve at the point of care. To achieve its goals, the PCPI has developed coordination of care measures that are now in the testing stage, and is focusing on the development of appropriate use measures as well as e-measure specifications to help physicians comply with pending government health IT incentive programs.

Accordingly, we continue to urge CMS to choose a more effective approach to balancing risk and improving quality and patient safety by encouraging physician adoption of quality improvement tools.

Thank you for your consideration of our comments, and we stand ready to continue working with CMS to improve quality and patient safety while balancing risk and cost to patients, the Medicare program, and the health care system overall.

Sincerely,

Michael D. Maves, MD, MBA