AMA
AMERICAN
MEDICAL
ASSOCIATION

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Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicaid Program; Payment Adjustment for Provider-Preventable Conditions Including Health Care-Acquired Conditions; Proposed Rule; 76 *Fed. Reg.* 9283 (Feb. 17, 2011).

Dear Administrator Berwick:

The American Medical Association (AMA) appreciates the opportunity to provide our views to the Centers for Medicare and Medicaid Services (CMS) regarding the Medicaid proposed rule on *Payment Adjustment for Provider-Preventable Conditions (PPCs) Including Health Care-Acquired Conditions (HCACs)*, 76 *Fed. Reg.* 9283 (Feb. 17, 2011). This rule proposes to implement section 2702 of the Patient Protection and Affordable Care Act of 2010 (ACA) regarding prohibiting federal payment expended for providing medical assistance for HCACs. The rule also proposes to authorize states to identify other PPCs for which Medicaid payment would be prohibited.

Section 2702 of the ACA directs the Secretary of the Department of Health and Human Services (HHS) to identify current state practices that prohibit payment for HCACs and incorporate the practices identified, or elements of such practices, which the Secretary determines appropriate for application to the Medicaid program in regulations. These regulations are to be effective as of July 1, 2011, and will prohibit payments to states under section 1903 of the Social Security Act for any amounts expended for providing medical assistance for health care-acquired conditions specified in the regulations. **Section 2702 also requires that the regulations ensure that the prohibition on payment for HCACs does not result in a loss of access to care or services for Medicaid beneficiaries.**

CMS proposes in the rule that in identifying an HCAC, the Medicare criteria for inpatient hospital acquired conditions (HACs), as established under the Deficit Reduction Act of 2005 (DRA), would be the floor for state HCACs, but states could still go beyond Medicare. (Under the DRA, HACs are codes (for medical conditions) 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.) CMS further proposes that states may identify

similar "other PPCs" (OPPCs) related to other conditions that states identify and approve for nonpayment through Medicaid in hospital and other settings.

The AMA maintains strong concerns about the existing inpatient hospital HAC policy, and therefore we are equally concerned about simply extending this policy, as is, as a floor for the states. In addition, we have grave concerns about states extending the existing HAC policy beyond the conditions on the Medicare HAC list, especially without resolving existing issues with the HAC policy or conducting any in-depth study of the impact of the policy on patient access and <u>total</u> cost to the health care system. We also have serious concerns about CMS' proposal that states extend the HAC policy to other provider settings. Section 3008 of the ACA contains a provision requiring the Secretary of HHS to conduct a study on expanding the HAC policy to other settings, including inpatient rehabilitation facilities, long-term care hospitals, hospital outpatient departments, and other hospitals excluded from the inpatient prospective payment system, skilled nursing facilities, ambulatory surgical centers, and health clinics. This study is required to include an analysis of how such policies could impact quality of patient care, patient safety, and Medicare spending, and is due to Congress by January 1, 2012. It is much too premature for CMS to suggest that states extend a federal policy which is currently limited to the hospital inpatient setting, to other provider settings, especially before this study is completed.

CONCERNS ABOUT EXISTING HOSPITAL INPATIENT HAC POLICY

As the AMA has previously commented to CMS, we have strong concerns about the overall existing hospital inpatient HAC policy. 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 basic criteria, which was stipulated in the DRA, 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 specific 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 with multiple co-morbid conditions may develop the conditions on the HAC list regardless of the preventive measures in place. **CMS, therefore, should use a more effective approach to balancing risk and improving patient safety by encouraging compliance with evidence-based guidelines, rather than adopting a non-payment policy for HACs. CMS should also apply this approach to the Medicaid program.**

Further, CMS' decision to apply the HAC 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, and unpredictably, cause an increase in other infections, *e.g.*, *Clostridium difficile.* The AMA is also concerned that the HAC 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 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 a blunt approach that is not effective or wise for patients or the Medicare or Medicaid program. **If CMS, as proposed, simply extends the current unproven hospital inpatient HAC policy to the states as a floor, this will simply extend a flawed policy to a program that is already underfunded and covers a vulnerable patient population with frequent co-morbid conditions and life circumstances that can increase the risk for HACs. This policy will place Medicaid patients at further risk of reduced access to care and increased financial costs, with unproven benefits, on an already over-stretched Medicaid program.**

CONSISTENCY ACROSS HEALTH CARE PAYERS

The AMA appreciates that CMS acknowledges in the proposed rule the need for implementing Medicaid regulations in a manner that would provide some consistency across health care payers, including Medicare and Medicaid. This consistency is essential. As discussed below, the HAC policy is extremely costly to implement, and the benefit of this policy is unknown at this time, especially since a cost-benefit analysis has never been conducted. The administrative burden of complying with varying federal and state regulations simply increases implementation costs, and this is further complicated by the fact that many private payers follow Medicare and Medicaid requirements, yet have their own and often separate implementing requirements. As CMS balances the need for consistency, as proposed in the rule, against state "flexibility to design individual HCAC policies for nonpayment, quality-related programs," we urge CMS to set this balance more toward consistency, especially as states initially implement the HAC policy and quality related programs. This will help ease administrative burdens and help minimize unnecessary costs to the overall health care system, patients, and providers. **There is a critical need for consistency with respect to quality initiatives, including HAC policies and quality reporting programs. There are currently numerous different programs and federal, state, and private entities involved in developing quality initiatives, all with different requirements. Consistency across payers and government entities, as we move forward, is vital to avoid mass confusion and unnecessary and duplicative administrative and implementation costs that may not result in improved care and likely will reduce patient access or even harm patients, all of which would undermine the intended goals of any quality-related program.**

Further, in light of the urgent need for consistency, the AMA urges CMS to provide such consistency in the criteria used to determine an OPPC. The Medicare policy by statute must adhere to the DRA criteria listed above in identifying a HAC in a hospital inpatient setting. CMS applies these same criteria to Medicaid HCACs (i.e., those conditions on the Medicare HAC list), but authorizes states to identify OPPCs (for conditions and settings beyond those specified in Medicare) and apply payment prohibitions the same as would apply to HCACs. As discussed further below, the AMA opposes such extension of this policy. To exacerbate matters, CMS is proposing criteria for OPPCs that are different than the federal criteria for HCACs. CMS proposes the following criteria for states to use in identifying additional OPPCs:

- A condition or event identified by a State for inclusion under this provision must be a discrete, auditable, quantifiable, and clearly defined occurrence.

- A condition or event must be clearly adverse, resulting in a negative consequence of care that results in unintended injury or illness.

- A condition or event identified must be reasonably preventable, meaning an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.

These differing criteria undermine the consistency that CMS acknowledges is needed in the system. Further, these criteria are very broad based, and do not even require use of evidence-based guidelines in determining whether a condition is reasonably preventable. The AMA opposes this proposal, and we urge CMS to withdraw it.

THE PRESENT ON ADMISSION POLICY IS FLAWED

The Present on Admission Policy Increases Medicare and Medicaid Program Spending

Under the proposed rule, CMS asks for comments on the efficiency of present on admission (POA) indicators, and discusses that tools that require standardized medical record reviews may be more effective in detection than the POA system. As discussed above, the AMA believes that use of the POA system is extremely problematic. **To determine whether a condition exists when the patient enters the hospital will increase Medicare and Medicaid 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.**

In considering whether to allow use of the POA system at the state level, CMS should immediately assess amounts that have been saved through application of the HAC policy in the inpatient hospital setting and compare those amounts with implementation costs for hospitals, including the costs of increased tests to determinate whether a condition is POA. In September 2009, CMS contracted with Research Triangle Incorporated (RTI) to study the impact of the 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. **While this study was also for the purpose of evaluating additional conditions for future selection, it did not 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 a payment setting, including higher copayments for patients. There is a fine line between limiting harm and promoting quality health care that improves the value of services delivered under Medicare and

Medicaid. To achieve "value," a desired quality outcome for patients must be produced at a reasonable cost to the system.

Present on Admission Documentation is Confusing and Onerous

The POA documentation process causes 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 causes unnecessary friction between hospitals and physicians, as well as creates concerns 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. 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 should establish an exception process to account for these circumstances, and this should apply at the state level as well.**

RELIABLE, VALID RISK ADJUSTMENT TECHNIQUES MUST BE USED IN A HAC PAYMENT POLICY

As discussed above, some medical conditions put patients at higher risk of a HAC than other medical conditions. **CMS must consider adequate risk adjustment techniques to address this critical factor, and these should apply at the state level as well.** 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.

Further, 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.

APPLICATION OF NONPAYMENT FOR HACS TO OTHER SETTINGS

CMS should conduct a cost/benefit analysis and develop effective risk adjustment techniques before providing that states may extend the HAC approach to other settings.

It is unacceptable that CMS is providing that states expand the inpatient HAC policy when it clearly is not ready to be extended at the federal level, especially considering that the ACA study on extending the HAC policy to other settings is still being conducted. Extending the HAC policy to other providers at the state level while a federal study on this same issue is pending is clearly premature, particularly when there are strong reasons to be concerned that the HAC policy approach will not achieve its quality improvement goals and, in fact, may cost significantly more money in proportion to overall program benefits, while also causing delays or denying access to needed care for patients.

Further, the AMA would be extremely concerned about states expanding the HAC policy to other settings, especially in physician offices, because the payment approach is completely different from the hospital setting. For example, in a physician's office, 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, and because each patient might receive care from multiple physicians, identifying and valuing the work attributable to a preventable condition managed by any particular physician at any particular 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 adherence to treatment recommendations 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 physician's control could cause a patient to acquire various conditions while under a physician's care, CMS should instead encourage states to require compliance with evidence-based guidelines rather than extending the HAC policy.**

ACCESS TO CARE

As discussed above, section 2702 of the ACA requires that the Secretary ensure that the prohibition on payment for HCACs does not result in a loss of access to care or services for Medicaid beneficiaries. The AMA is disappointed in CMS' response to this statutory requirement. In the rule, CMS merely proposes that "any reduction in payment would be limited to the amounts directly identifiable as related to the PPC and the resulting treatment." CMS states it is proposing this method of protecting access because it limits states' ability to unduly reduce provider rates. **The AMA believes the ACA requirement to ensure that the HAC policy does not result in a loss of access for Medicaid beneficiaries requires far more than is proposed by CMS. We urge CMS to actively monitor and conduct a study of the impact of extending the HAC policy to the states and to conduct a detailed cost/benefit analysis, as discussed above.**

CMS studied various reports to comply with the section 2702 requirement that the Secretary identify current state practices that prohibit HCACs and incorporate these practices, as appropriate, into the

Medicaid regulations. Yet CMS did not study an HHS Office of Inspector General (OIG) report addressing key issues in implementing the HAC policy (*Adverse Events in Hospitals: Overview of Key Issues* (OEI-06-07-00470)). **In this report, 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." CMS must follow up on these findings and incorporate adjustments into the Medicaid regulations to address access issues, along with increased costs and reduced provider revenue, which also impact access.**

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

Sincerely,

Michael D. Maves, MD, MBA