AMA AMERICAN MEDICAL ASSOCIATION

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The Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: Ms. Julie Moreno
Ms. Rani Jeeva

The American Medical Association (AMA) appreciates the opportunity to comment on the United States Department of Health and Human Services (HHS) *Action Plan to Prevent Healthcare-Associated Infections* (HAIs). HHS has developed this "Action Plan" to move toward preventing and eliminating HAIs.

In the Action Plan, HHS identified certain potential "First Tier" partners, "who have been active and/or have synergistic efforts currently underway," with whom HHS wishes to collaborate in its efforts to reduce HAIs. The AMA appreciates HHS' recognition of the AMA as a potential "First Tier" partner, and we agree it is critical that HHS have direct and regular input from major stakeholders, including the AMA, as HHS moves forward with its HAI prevention "Action Plan."

The AMA applauds HHS' leadership in seeking to prevent HAIs. The AMA has long been committed to quality improvement and strongly supports innovative efforts to provide high quality, cost-effective care to patients. Further, as a leader in patient safety, we support HAI prevention efforts.

IMPACT OF HAI PREVENTION EFFORTS ON PUBLIC HEALTH

From a public health perspective, the intent of the Action Plan is laudable and the AMA appreciates the importance this Action Plan can have in reducing HAIs, thereby reducing morbidity and mortality. Indeed, the AMA has publicly supported the efforts of the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Disease Society of America (IDSA) in this area, and we are pleased that the Action Plan relies heavily on the

SHEA/IDSA Compendium of Strategies. The strong effort to correlate the prevention prioritizations with the SHEA/IDSA recommendations is to be applauded. Increasing the consistency of different guidelines, thus allowing better data comparison, increases compliance and uniformity.

The public health impact of success in achieving the Action Plan's prevention targets for five identified categories of HAIs will be enormous. There will be a substantial and dramatic reduction in morbidity and mortality that will inevitably be associated with a reduction in costs. Accordingly, it is essential that partners work together to identify the best methods for implementing interventions that will improve practice to reach these targets.

PRINCIPLES GOVERNING HAI PREVENTION EFFORTS

The Action Plan discusses key criteria related to development of a plan to prevent HAIs. **We urge HHS to fully engage stakeholders in the further discussion and development of an HAI Action Plan using these key criteria, as discussed below. The AMA believes these criteria are essential to developing health care policy.**

- **Research projects to address specific knowledge gaps about HAIs is a priority, and increased understanding of the basic science underlying HAIs will be critical for informing prevention efforts.**

  The Action Plan discusses that a broad, comprehensive research agenda to support a national effort to prevent HAIs needs to address the issue from a number of aspects, including an increased understanding of the basic science underlying HAIs and their associated pathogens, as this will be critical for informing prevention efforts.

  The Plan further discusses that in identifying initial types of research projects to help reduce HAIs, the following factors must be considered:

  - *Contribution to understanding evidence*—what level of evidence will the project yield and will it change behavior?
  - *Feasibility*—are resources available to perform the project and will the proposed study lead to interventions that could potentially reduce burden?
  - *Cost*—are the costs of the project justifiable for the potential health impact?
  - *Public impact*—are the project results easily understood and of value to policymakers and is the impact measured in cost, quality of life, and redirected resources?

We are pleased that the Action Plan acknowledges the breadth and complexity of the recommendations in the scientific literature for practices to reduce HAIs, in addition to recognizing the importance of understanding the basic science underlying HAIs in relation to developing prevention initiatives. We further applaud consideration of cost, feasibility, public impact, and level of evidence yielded when determining the types of research projects to initiate. These factors are critical for identifying research projects that can produce findings that translate into effective public policy, which, in turn, must also turn on these factors.

Further, the Plan identifies current concern that the national 5-year targets for reducing HAIs may be used for performance incentives. **Until the science base for the feasibility of these targets is established, along with improved surveillance and measurement systems and an improved health care infrastructure to facilitate proper intervention, use of any national target for payment or accreditation purposes would be inappropriate as well as undermine HAI prevention efforts.**

- **Stakeholder involvement (including the physician community) is necessary for developing HAI policy.** As discussed above, we agree that all relevant stakeholders must have a critical role in the development of HAI prevention policy. Without the involvement and support of physicians and other front-line providers with first-hand knowledge of and experience in treating HAIs, effective public policy for HAI prevention will be impossible to achieve.

- **Education of best practices for providers, other healthcare personnel, and patients is critical to prevent HAIs.** The AMA agrees with this important principle, and believes that education efforts must be broad-based, timely, and aggressive to ensure optimal compliance with best practices, especially if new payment and coverage policy governing HAIs is ultimately established. Otherwise, providers, healthcare personnel, and patients will not have the needed time or knowledge to implement appropriate systems to comply with the policy.

In addition to the above principles, the Action Plan identifies a number of considerations and challenges in making progress toward meeting HAI prevention targets, as noted on pages 19 through 21 of the Action Plan. The AMA agrees with these considerations, and we urge HHS to build HAI prevention efforts with these in mind. Several of these considerations are particularly critical, as noted below:

- **There is concern over the potential use of national, aspirational five-year targets as performance incentives without adequate development of the science base for prevention and feasibility, along with improved measurements systems and increased infrastructure.** We agree with this concern, and urge HHS to ensure that oversight, incentive, and measurement are not based upon an unreasonable outcome that has not yet been vetted scientifically nor has an appropriate infrastructure for implementation.

- **Challenges remain related to resource allocation and workforce development. As HAIs are reduced, the cost of detecting each event will become increasingly great. New methods of collecting and evaluating data will require staff and financial resources. It is important to limit the additional data collection burden on staff and healthcare facilities to ensure that the focus of the professionals will be the implementation of prevention interventions that have an impact.** The AMA believes that resource allocation is also an important consideration for HHS and CMS for purposes of ensuring that they have appropriate resources and time to collect and analyze data and implement well-developed, scientifically-based and valid policies in an appropriate timetable.

- **It is important that existing national data sources identified for metric systems are validated. They need to avoid gaps in data for age groups and other population groups. The feasibility of use of various systems must also be carefully evaluated and used to inform research.**

IMPORTANT CONSIDERATIONS IN IMPLEMENTING THE EXISTING HEALTHCARE-ASSOCIATED CONDITION MEDICARE POLICY

Finally, the Action Plan discusses a variety of tools within its statutory and regulatory authority to encourage the prevention of HAIs. One potential tool discussed in the plan is the Centers for Medicare and Medicaid Services' (CMS) new policy on healthcare-associated conditions (HACs). Under this policy, Medicare denies payment for a CMS-designated HAC that is acquired in the hospital and is not identified as present on admission to the hospital. CMS has established this policy pursuant to statutory authority granted by Congress with regard to the inpatient hospital setting only.

If HHS ultimately considers applying this policy to additional HAIs, we urge HHS to recognize several key principles:

- **The Medicare HAC non-payment policy should only apply to events that should never happen.** These events should be those that are "reasonably preventable" in that there is solid evidence that occurrence of the event can be reduced to zero or near zero by following evidence-based guidelines developed by appropriate medical specialty organizations based on non-biased, well-designed, prospective, randomized studies.

  In developing the current HAC policy, CMS has confused events that should never happen in a hospital, like surgery on the wrong body part, with often unavoidable conditions, like surgical site infections. There is strong, broad disagreement with CMS throughout the medical community that the conditions covered under the inpatient HAC non-payment policy are "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.

As discussed above, we strongly agree with the discussion in the Action Plan that understanding the basic science underlying HAIs will be critical for informing prevention efforts, and therefore we urge HHS to ensure that there is broad agreement in the medical community with the scientific evidence underlying any resultant HAI policy.

- **The HAC policy will increase Medicare spending on tests and screenings with questionable benefit to patients.** The HAC policy requires hospitals to ensure that certain medical conditions are not present on admission. 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.

  Prevention of HAIs is critical and we strongly support efforts to do so. Yet, policy to achieve HAI prevention should not add significant unneeded costs to the system, especially when those costs do not proportionately correlate to increased quality and health benefits for patients. Thus, in developing HAI prevention efforts, we urge HHS to apply the same principles discussed in the report relating to HAI research projects, including whether (i) resources are available to implement the policy and will the policy lead to appropriate interventions; (ii) policy implementation costs are justifiable for the potential health impact; and (iii) the policy is easily understood and of value to patients and providers; (iv) the policy impact is measured in terms of cost, quality of life, and redirected resources; and (v) the policy will effectively change behavior and outcomes.

- **Expanding the inpatient HAC nonpayment 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, 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. **Since many factors outside of a physicians' control could cause a patient to acquire various conditions while under a physician's care, HHS (and CMS) should instead encourage compliance with evidence-based guidelines rather than extending the HAC policy. We also recommend this approach as a tool for HAI prevention, rather than applying the misguided HAC policy.**

- **CMS should conduct an analysis of the current inpatient HAC policy, in consultation with technical experts, physician organizations, hospitals and other impacted providers. This analysis must occur before extending this approach to other conditions and settings.** CMS has not yet conducted any analysis of: (i) the impact of the current HAC inpatient policy with regard to such concerns as: 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; (iii) how to determine attribution issues with respect to when, where and why a condition has occurred; and (iv) 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.

  The HAC policy should not be further applied to any medical conditions or 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.

- **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 this policy were extended to other settings, CMS would likewise need similar statutory authority granted by Congress.

ADOPTION OF ICD-10

The Action Plan indicates that adoption of ICD-10 would provide a better infrastructure for the HAC payment policy, with more specific coding information.

The AMA supports the move to ICD-10. Moving from ICD-9 to ICD-10 is a significant change for the health care community and will require the establishment of a constructive implementation process and timeline that recognizes the challenges and requirements associated with a transition of this magnitude. An appropriate implementation process should also include checks along the way to ascertain whether health care providers (especially small physician offices), clearinghouses, and payers are able to successfully send and receive transactions using the 5010 standard (the electronic transactions standard that needs to be in place prior to the move to ICD-10). **We believe that significant physician outreach and education will also be critical to ensure a successful transition to the 5010 standard and to ICD-10. We look forward to working closely with HHS to help physicians and other health care professionals transition to ICD-10. A transition of this magnitude will require a workable implementation process and timeline for all HIPAA covered entities, and comprehensive outreach and education initiatives to support health care providers throughout this complex move to ICD-10.**

IMPLEMENTATION OF PATIENT SAFETY ACT

The AMA emphasizes that HAI data collection, analysis, and reporting must comply with existing federal privacy and patient safety laws and should not conflict with implementation of the *Patient Safety and Quality Improvement Act of 2005* (P.L. 109-41) (Patient Safety Act). The Patient Safety Act provides for the formation of Patient Safety Organizations (PSOs), which collect and analyze confidential information voluntarily reported by health care providers for the purpose of improving patient safety. A critical aspect of the Patient Safety Act is to ensure the confidentiality and legal protections of patient safety work product in order to encourage the voluntary reporting of patient safety events. As requested by the Secretary of HHS, the Agency for Healthcare Research and Quality (AHRQ) is tasked with coordinating the development of a set of common definitions and reporting formats (Common Formats), which would facilitate the voluntary collection of patient safety data and reporting of this information to PSOs. These forms allow for the voluntary reporting of patient safety events on a privileged and confidential basis. In order to instill trust and confidence in this patient safety reporting system and encourage patient safety reporting, we urge HHS to ensure that the data collected via the Common Formats remains privileged and confidential and only used or disclosed in accordance with federal privacy and patient safety laws.

We appreciate the opportunity to provide our views on these important matters and look forward to working with HHS regarding HAI prevention efforts.

Sincerely,

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