June 14, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

The Society for Healthcare Epidemiology of America (SHEA) and the Association for Professionals in Infection Control and Epidemiology (APIC) would like to thank you for your continued leadership and commitment to the prevention and reduction of healthcare-associated infections (HAIs) through the National Action Plan.

SHEA and APIC are pleased to be among the stakeholders working closely with the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) to translate agency goals and objectives for HAI funds into actions at the bedside that can achieve meaningful reductions in preventable HAIs and promote patient safety. As you know, there is a critical need for ongoing support of a national prevention strategy to address this problem, estimated by CDC to be one of the top ten causes of death in the nation and one that poses a significant economic burden on the nation's healthcare system.

While we applaud the commitment of the federal agencies involved in building this national strategy, we are very concerned about plans by the Agency for Healthcare Research and Quality (AHRQ) to prepare and release a public report entitled "Healthcare-Associated Infections: HCUP State – Level Discharge Rates." SHEA and APIC first learned about these plans following a June 7 webinar with Healthcare Cost & Utilization Project (HCUP) partners arranged by AHRQ. We understand that AHRQ has subsequently delayed its release as a result of concerns raised during the webinar, recognized several flaws in its approach to the data and intends to re-evaluate the methods used to calculate the rates for HAIs and the presentation of the state-level information. **We are pleased with this decision and urge you to ensure that there is adequate discussion and consultation with all HHS agencies contributing HAI data to the National Action Plan concerning the methodology and the findings prior to any further action related to this report.**

SHEA and APIC represent the leaders in the science and implementation efforts to eliminate HAIs. We support the national priority attention on measurement and elimination of HAIs as a quality imperative, as well as the transparency of these efforts. However, we believe that the **methodology being used by AHRQ is deeply flawed and entirely inconsistent** with approaches being utilized by other federal agencies and state health departments. Moreover, SHEA and APIC consider that the initial planned release of this report demonstrates **a serious lack of interagency cooperation and collaboration in this area.** Finally, we believe it is remarkable that this effort was done absent **input or consideration of the perspectives of professionals with expertise in HAI prevention, and surveillance and public health departments.**

Our specific concerns are as follows:

- ***The methodology being used by AHRQ is flawed and inconsistent.***

Despite the acknowledgement on June 9 by AHRQ of several methodology problems, we believe it is important to fully delineate our organizations' concerns regarding the methodology used. The HCUP report is based on the use of hospital administrative discharge data summaries. Decades of published scientific research in the field of hospital epidemiology and infection control demonstrate that administrative data are not sufficiently accurate and not cost-effective for HAI surveillance. Administrative data frequently misclassifies HAIs and has a very low positive predictive value. At best, the positive predictive value of this data is 23%, meaning that 3 of every 4 infections (75%) detected by this method are not truly HAIs.[1,2,3] The Government Accountability Office acknowledged the limitations of administrative data in the detection of HAIs in its 2008 report.[4]

The proposed public report relies upon HCUP data that:

- cannot distinguish which infections are acquired during hospital care and which are acquired in the community (present on admission);
- includes no risk stratification or risk adjustment;
- are not uniform formal surveillance definitions;
- are not validated for accuracy;
- vary from state to state in the number of diagnoses per chart that are submitted to HCUP (so the higher the number of such diagnoses, the higher the HAI "rate");
- express CLABSI, CAUTI and VAP infection rates as infections per 1,000 discharges rather than infections per 1,000 device-days (since HCUP data do not include the number of device-days at risk). This ignores a seminal CDC publication (Infection Control and Hospital Epidemiology, 1991;12(10):609-21) that led the hospital epidemiology community to abandon use of infections per 1,000 admissions (or discharges) for inter-hospital comparisons as device usage is the true exposure risk; and,
- are inconsistent with the metrics outlined in the National Action Plan in that administrative data cannot be seen as a proxy for surveillance-derived rates, on which the Action Plan is based.

SHEA and APIC are concerned that AHRQ would issue a report based solely on administrative data that are acknowledged to be limited in accuracy and scope. We support a national standard for data reporting, collection and dissemination of HAI data, and CDC's National Healthcare Safety Network (NHSN) is acknowledged by experts in the field to be the best and most accurate source of this information. As you are aware, NHSN is now in use in the majority of U.S. hospitals and is an important tool used in the Comprehensive Unit-based Safety Program (CUSP) initiative you have strongly supported throughout the states.

- ***There is a lack of interagency cooperation and collaboration in this area***

SHEA and APIC understand that the Centers for Medicare & Medicaid Services (CMS), CDC, AHRQ and other agencies within HHS have an important leadership role to play in preventing HAIs. But there is clear redundancy, lack of communication, and a seeming competition to provide the "silver bullet" solution that is fundamentally detrimental to the effort.

Of particular note is the fact that AHRQ has contracted with Battelle Memorial Institute to lead a project exploring what value, if any, administrative data adds over and above the clinical data used by the CDC's NHSN surveillance system. The Battelle project invited recognized leaders in the field of hospital epidemiology and infection control (many nominated by our organizations), along with allied health professionals in all pertinent disciplines, to build on an extensive review of the literature, and should provide informative results before the end of this year. For HCUP data to be compiled into a public report prior to completion of the Battelle

project demonstrates poor coordination *even within* AHRQ. On this note, SHEA and APIC recommend that the AHRQ-Battelle project be used to determine whether administrative data might add value *as a supplement* to clinical data and NHSN for guiding HAI control efforts. Premature release of the proposed HCUP-based public report as planned would have undermined confidence in government reporting of HAI information, would not have added meaningful information for those with expertise in hospital epidemiology, and would have mislead the public who are not familiar with the technical deficiencies that will render AHRQ results so different from NHSN results.

- ***There is little input from experts in HAI surveillance and prevention***

Stakeholders such as SHEA and APIC with expertise in the field of HAI prevention and surveillance are not being engaged by AHRQ in the design and development of reports such as this. Moreover, expert advice that is offered in advisory meetings and focus groups with AHRQ contractors is being ignored. During the June 7 webinar, it was clear that AHRQ had not considered coordinating the invitation with CDC, the Council of State and Territorial Epidemiologists (CSTE), nor with SHEA or APIC.

The message around HAIs conveyed through the potential release of this report does a tremendous disservice to the work being done and progress being made on this critical issue by misrepresenting the status of HAIs in the United States. SHEA and APIC believe it is time for the agencies to look outward to collaborate with the true leaders of change in HAI prevention who are the front line practitioners and scientists – members of SHEA, APIC, CSTE and other professional societies.

SHEA and APIC value our respective roles as stakeholders, resources, and partners with governmental agencies in transparency efforts and achieving the goals outlined in both Healthy People 2020 and the National Action Plan. In this effort we feel it is vital that the consumers and payors have the most accurate and reliable data available.

SHEA and APIC request that AHRQ/HHS consider how future decisions will be made to produce and publish such reports, and ask that more concerted efforts are made in the future to coordinate early planning of such efforts with the hospital epidemiology and infection control communities, as well as with HHS agencies such as CDC. Ultimately, this latest chapter confirms the critical need for a national standard for defining and reporting HAIs that ensures validated data and measures that accurately portray infection rates across geographic and health status-based risk categories. Without such a standard and associated coordination among data collecting entities, patients and healthcare facilities lack comparable information on rates of infection that can inform their decision-making and improve the quality of care.

Sincerely,

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President, SHEA

Russell Olmsted, MPH, CIC
President, APIC

cc: Carolyn M. Clancy, MD
William Munier, MD, MBA
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About the Society for Healthcare Epidemiology of America

SHEA is a professional society representing more than 1,900 physicians and other healthcare professionals around the world with expertise in healthcare epidemiology and infection prevention and control. SHEA's mission is to prevent and control healthcare-associated infections and advance the field of healthcare epidemiology. The society leads this field by promoting science and research and providing high-quality education and training in epidemiologic methods and prevention strategies. SHEA upholds the value and critical contributions of healthcare epidemiology to improving patient care and healthcare worker safety in all healthcare settings. www.shea-online.org

About the Association for Professionals in Infection Control and Epidemiology (APIC)

APIC's mission is to improve health and patient safety by reducing risks of infection and other adverse outcomes. The association's more than 14,000 members direct infection prevention programs that save lives and improve the bottom line for hospitals and other healthcare facilities around the globe. APIC advances its mission through education, research, collaboration, practice guidance, public policy and credentialing. www.apic.org

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1 Sherman E, Heydon K, et al. Administrative Data Fail to Accurately Identify Cases of Healthcare-Associated Infection. *Infection Control and Hospital Epidemiology 2006*; 27.4: 332-37.

2 Stevenson K, Khan Y, Dickman J, et al. Administrative coding data, compared with CDC/NHSN criteria, are poor indicators of health care-associated infections. *American Journal of Infection Control 2008*; 36:155-64.

3 Jhung M, Banerjee, S. Administrative Coding Data and Health Care–Associated Infections. *Healthcare Epidemiology;* 2009:49:949-55.

4 United States Government Accountability Office. *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*, April 2008.