February 5, 2009

Donald Wright, MD, MPH
Principal Deputy Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, SW 716-G
Washington, DC 20201

Dear Dr. Wright:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international association comprised of 12,000 infection prevention and control specialists, wishes to thank the Department of Health and Human Services (HHS) for the opportunity to provide input into the HHS Action Plan to Prevent Healthcare-Associated Infections (The Action Plan).

APIC supports the efforts of our members as they work to prevent healthcare-associated infections through a variety of avenues. Among these efforts are: sharing best practices for preventing, identifying, monitoring, and treating healthcare-associated infections, as well as the collection of meaningful data for internal improvement and public reporting.

We applaud HHS for its collaborative process with all relevant agencies in producing this document. We agree that success will only be achieved through maintaining agency engagement and urge HHS to reach out to other federal departments that have experience running healthcare facilities such as the Department of Veterans Affairs and the Department of Defense. We also appreciate the efforts of HHS to reach out to organizations like ours which bring significant experience in the mission to prevent infection and improve the safety of patients.

Further, we appreciate the recognition of the importance of healthcare-associated infections by HHS, as well as the focus on the need to identify gaps in our knowledge base. The Action Plan outlines the challenges we are facing in our efforts to eliminate all preventable infections. However, we believe as HHS moves forward in gathering stakeholder input through comments and public meetings, more defined action items should be developed that have clear deliverables for a true national plan. We are hopeful that the current plan, with its set of metrics and associated targets, will develop into a clear roadmap on each agency's role, either alone or as part of a collaborative. This would include a description of how the specific targets will be achieved, and a specific timeline. Further, we look forward to further refinement of how alignment among agencies will be implemented.

We understand that in an attempt to outline the importance of healthcare-associated infections, the policy statement may be a bit fragmented, comprised of various components of existing documents. Perhaps a more cohesive approach focusing on basic science, coupled with epidemiology, may better serve in this instance.
Below are our comments, which we hope will support your efforts to develop a cohesive policy statement to prevent HAIs.

**Executive Summary**

We appreciate the Action Plan’s focus on the four categories that account for 75 percent of all infections. However, there was some concern that the executive summary then veered into highlighting specific pathogens.

**Prevention – Targets and Metrics**

We agree with the plan to revisit the *Clostridium difficile (C. diff)* target in two years based on anticipated additional information when it becomes available. Further, we support developing best practices for urinary tract infection (UTI) and *C. diff*. In addition, we support the Action Plan’s recommendation of conducting a survey of U.S. hospitals to identify whether or not they have an antibiotic stewardship team in place and, if so, what the team’s purpose and function is at that institution. Finally, we support the Action Plan’s statement regarding the challenges with resource allocation.

We recommend the following:

- Clarification of whether all healthcare facilities or the population served should be expected to collect and report data on all of the metrics.

- Utilizing National Healthcare Safety Network (NHSN) definitions and formulas without comparison to administrative (i.e. coding) data.

- Providing guidance for a healthcare facility for a meaningful implementation of the methicillin resistant *staphylococcus aureus* (MRSA) metric 1 for their population. Our concern is the challenge for application to the local level of a 50% target reduction of MRSA incidence as measured by the Centers for Disease Control and Prevention (CDC) Emerging Infections Program (EIP)/Active Bacterial Core (ABC) surveillance.

- Clarification of the catheter-associated urinary tract infection (CAUTI) 2 definition: Number of UTIs (ICD9 + not present on admission) / (#major surgery ICD9 + urinary catheter ICD9)}* 100 discharges. Infection preventionists use the NHSN definition listed initially. Is this measure intended as a surrogate measure for CAUTI?

- Addressing the possible self-reported bias when reporting compliance with the prevention bundles, such as those for central line insertion.

- When viewing nurse/patient ratio, that information is collected on resources available to the Infection Prevention Department (i.e., staffing, clerical, computer integrations, etc).
• Diverting the focus from 100% performance of the central line bundle to a somewhat more realistic approach for those outside the infection prevention arena, such as quality and management leaders.

Prevention – Prioritized Recommendations

We agree with the Action Plan’s statement which acknowledges the importance of “decreasing the burden of data collection”. Electronic resources are of assistance; however currently with NHSN Procedure Module, this does not always limit the amount of data that must be collected. In addition, we support the criteria for evaluation of proposed projects prior to initiation of the projects.

We recommend the following:

• A definition of “large drape” related to “Priority Module 1 for Recommendations for Aseptic Insertion of Vascular Catheters” would assist with compliance. The infection preventionist’s interpretation of a large drape means a full body drape; but since the standards do not specify the drape size, infection preventionists may be challenged by anesthesia, medical staff, and leadership to employ a smaller, less expensive drape for the vascular site.

Research

Overall, APIC feels that this section should be strengthened to underscore the importance of conducting basic, epidemiological and translational studies to fill the basic and clinical science gaps. While the plan’s current focus on the conduct of health services research (i.e., successful implementation of strategies already known or suspected to be beneficial) will provide immediate short-term benefits, to achieve long-term and sustained success, a substantial investment in basic science, translational medicine, and epidemiology is needed. APIC also supports the need for translational research, taking known facts on infection prevention and deploying them effectively to change behavior, such as hand hygiene.

Recommendations:

• Additional research is necessary to identify the gaps in our understanding of what is best termed the preventability fraction – what proportion of healthcare-associated infections are preventable? What risk factors or characteristics define that group? APIC believes this distinction is critical to help guide subsequent research priorities and to help set realistic expectations.

• While the onset of HAIs in the community following discharge from a facility is discussed in regard to surveillance strategies, we believe coordination of both prevention and surveillance strategies needs to be studied across the full spectrum of the healthcare delivery system (acute care, rehabilitation, long term care, home care, dialysis, etc.). Although everyone agrees there are issues across the care system and interactions impacting HAIs that go
beyond acute care, there are large gaps in our understanding of interventions across this complex system that must to be addressed in order to develop a coordinated research agenda.

- We recommend a consideration of the contribution of patient factors in the development of HAIs. Patient condition, behavior and education deserves some attention as part of a coordinated response—as well as human factors/behavioral science critical to affecting caregiver behavior in preventing infection transmission.

- As HHS notes in its plan, the vast majority of central line-associated bloodstream infections (CLABSIs) occur outside of the intensive care unit (ICU) setting. However, studies of recent efforts to reduce these infections have focused exclusively in the ICU. We need to determine whether this research is generalizable. APIC believes a better understanding of evidence-base for all HAIs in both the non-ICU setting (oncology units, transplant units, etc.) as well as the non-hospital setting (long term care, home care, etc.) is necessary.

- The primary focus of research with respect to ventilator-associated pneumonia (VAP) should be on the development of a consistent surveillance definition of the infection (or reasonable surrogate markers) that is easy to apply and that is reproducible within and between entities. Progress toward preventing VAP cannot be achieved until this goal is accomplished.

- APIC believes the need for improved risk adjustment strategies is paramount to achieving any of the goals listed with respect to prevention of surgical site infections (SSI) and must be one of the primary research goals in this area.

- The emerging role of *C. difficile* as a community pathogen requires further study. In addition, the study of hand hygiene practices (alcohol-based hand sanitizers vs. soap and water) is missing from the list of gaps in prevention practices knowledge.

- The role of antimicrobial stewardship is to guarantee that patients receive appropriate anti-infective therapy and not to reduce overall use. A national focus to exclusively reduce antimicrobial use could result in a negative impact on the quality of care. A focus on appropriate use will eliminate unnecessary use without such risks.

**Information Systems and Technology**

Transitioning to electronic surveillance methodologies will bring greater consistency to data collection. The use of electronic case finding and surveillance systems as a screening tool can reduce inconsistency in data collection and reduce burden on staffing; however, any implemented measures should yield the same results regardless of data collection methodology and should be overseen by trained infection preventionists and epidemiologists. APIC would like to see closer alignment and building of electronic systems building on current use of NHSN now mandated or used in many states for surveillance, analysis and public reporting of HAIs.
In addition, we support the goal of using algorithms together with technology to shorten the gap in recognition of HAIs and combining outcome data with processes. This could facilitate data interpretation, identifying which processes were more effective than others. Often, these data are collected and reported in “silo” fashion without the association between compliance with prevention measures and outcome with an HAI.

We Recommend:

- Revisiting the goal of linking delivery of care from one facility to another to achieve success, beginning at a smaller level. While the goal is ideal, many systems do not currently have an interface between the laboratory system and data repository for review of potential infections. This remains a manual process for many facilities, even if they are relatively progressive in technology. Interfaces are not without costs both financial and labor.

- Defining what an “early warning” mechanism entails.

**Incentives and Oversight**

**Recommendations and Action Plans**

*Conditions of Participation –*
- APIC agrees with the comments that infection prevention and control requirements should be flexible and should avoid a prescriptive regulatory approach that would focus on specific infections.

- APIC supports the Center for Medicare and Medicaid Services’ (CMS) plans to consider increased partnering with CDC on surveyor enhancements, training and education.

- We also strongly urge a systematic mechanism or process that involves both CDC and CMS in the review, revision and education on all standards and HAI-related related Interpretive Guidelines (IGs) for relevant standards, such as infection control (IC), Quality Assessment and Performance Improvement (QAPI), Physical plant etc. The public and other stakeholders need to be aware that there is such a process, ensuring the use of evidence-based guidelines.

*Accreditation*

We applaud CMS’s effort to refine and improve the current method of measuring the performance of Accreditation Organizations. We approve efforts to improve Joint Commission IC standards and elements of performance, as well as CMS Conditions of Participation. However, we note that The Joint Commission, in its propagation of National Patient Safety Goals (NPSG) and IC standards and elements of performance, is at risk of becoming increasingly prescriptive, contrary to CMS's stated goals. Even as CMS requires
The Joint Commission to incorporate some of its standards' language to maintain its deeming authority, it is clear CMS's Conditions of Participation (CoP) standards require substantial change to reduce current prescriptiveness that in some cases precludes improvement attempts that could further reduce HAIs. We strongly support CMS’ current efforts to make the CoP interpretive guidelines more performance based, resolving this issue to some degree.

**Survey and Certification**

- We agree with plans including conducting a pilot of a survey tool in conjunction with CDC. While the institutional expertise of the CDC is valuable and in fact essential to the development of such a tool, other stakeholders (e.g. APIC) have shared and at times offered complementary expertise that should also be accessed.

- If performance metrics are added, we agree they should be done in collaboration with CDC and Agency for Healthcare Research and Quality (AHRQ) and support use of NHSN.

**Value Based Purchasing (VBP) Financial Incentives**

We agree that positive incentives can have a powerful impact in driving quality improvements. Therefore, we agree that hospital VBP could provide a strong incentive to drastically reduce HAI rates. This plan also provides an opportunity to closely align current CDC initiatives with CMS incentives. APIC believes it is critical that the evidence-based measures selected in this HAI reduction plan align closely with CMS incentives. HHS/CMS validated quality measures including Surgical Care Improvement Project (SCIP) process measures through testing and reporting before attaching payment to such measures. HAI should be treated in the same way. As CMS moves into VBP systems there is great opportunity to align similar efforts with current outcome data collected via the NHSN system.

APIC also concurs that the Hospital-Acquired Conditions (HAC) payment policy could be made more precise in the future through “risk adjustment, implementation of a more sophisticated VBP model based on occurrence rates for conditions over time, and adoption of ICD-10.”

While we understand the urge to develop a hospital performance score that includes infection measures in a “rollup measure,” each time infection data are rolled into larger and larger aggregate measures, the refinement and precision of the data become more obscured. Developing and validating such a “rollup measure” will be a challenge but such careful steps are critical for this plan to be a success and achieve alignment between the economic incentives and tools to reduce HAIs.

Just as with quality measures, some HAI measures are useful for public reporting and some are better for internal performance improvement. In reviewing quality measures used in the current Hospital Compare report, there was no attempt to “rollup” various measures into a single domain. The variability is lost and therefore the capability to identify areas for improvement is
also lost. CLABSI and CAUTI for example, are as different as currently listed measures in Hospital Compare in terms of measures of underlying systems; Hospital Compare does not attempt to combine all measures, understanding they represent quite different events and opportunities to improve.

**Transparency and Associated Incentives**

We agree that transparency is a strong incentive for organizations to improve performance. However, there needs to be more research on the impact of public reporting on the quality of care, on the claim that public reporting drives patient choice, and on the unintended consequences of transparency. The recommendation and action plan section mentions that CAUTI, CLABSI, VAP, SSI, MRSA and *C. difficile* may be added to the Hospital Compare website. Before these measures are added, further research, particularly with the CDC, is needed to refine risk adjustment methodology and to ensure reliability of data collection. Developing standardized surveillance methodology that would allow inter-institutional comparison is problematic for some of these measures. CMS needs to make sure that measurement systems are validated before they are introduced.

**Conclusion**

We appreciate the Action Plan’s emphasis on the prevention of HAIs and improving the infrastructure in a national prevention effort, rather than simply the reporting of infections. The documented goals will be challenging; but if the members on the various committees are held to task with scheduled reports on the successes and barriers in implementation, the public health impact will be realized.

APIC appreciates the opportunity to provide comments on the HHS Action Plan to Prevent Healthcare-Associated Infections and looks forward to continuing to partner with the department to reduce healthcare-associated infection rates and save lives. We do believe that given the tremendous importance of this work and the impact on providers, states, and patients, that HHS should develop additional venues to invite stakeholder input into this plan and APIC welcomes such opportunities to continue working with HHS in furthering this important, collaborative work.

Sincerely,

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2009 APIC President