VIA ELECTRONIC DELIVERY

Secretary Kathleen Sebelius
Department of Health and Human Services
Office of Healthcare Quality
Room 445-G
200 Independence Avenue, SW
Room 711G
Washington, DC 20201
Attention: Draft National HAI AP

June 25, 2012

Re: Revised Draft National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Prevention; Chapter 5. Ambulatory Surgical Centers

Dear Secretary Sebelius:

On behalf of the ASC Quality Collaboration (ASC QC), a cooperative effort of organizations focused on the development and reporting of ambulatory surgical center (ASC) quality data, please accept the following comments regarding the revised draft National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Prevention; Chapter 5. Ambulatory Surgical Centers. The ASC QC’s stakeholders include ASC corporations, ASC industry associations, physician and nursing professional societies, and accrediting bodies with an interest in ASCs. Please see Appendix A for a list of the ASC QC’s participants.

The ASC QC strongly advocates high-quality care, quality measurement and reporting, and strong infection prevention practices. Our commitment is reflected in the steps we have taken independently to facilitate quality reporting and support best practices in infection prevention. Since its formation in 2006, the ASC QC has:

- Developed and secured the endorsement of the National Quality Forum (NQF) for six ASC facility-level quality measures, including two measures that assess processes related to the prevention of surgical site infection (SSI).
- Developed a quarterly public report of ASC quality data that is published and freely available to all online. These quarterly reports are made possible through the voluntary efforts of participants in the ASC QC and may be accessed at the ASC QC’s website at: [http://www.ascquality.org/qualityreport.html](http://www.ascquality.org/qualityreport.html). Over 1300 centers, representing more than 20 percent of all Medicare certified ASCs, participated in the 4Q2011 report.
- Developed ASC Tools for Infection Prevention (ASC TIPs), designed to support the ASC industry’s focus on high quality care by bringing infection prevention resources together in one location and making them available free of charge. These toolkits focus on several key areas...
related to infection prevention, and, since our last communication, have been expanded to include additional topics. The toolkits now address hand hygiene, safe injection practices, point of care devices, environmental infection prevention, single-use device reprocessing, endoscope reprocessing, and sterilization and high-level disinfection.

We appreciated the opportunity to discuss the Department’s HAI Action Plan at the recent HAI Data Summit held in Kansas City, Missouri on May 30-31, 2012, and present our further reflections and feedback here for your consideration.

I. Identify High Priority HAIs for Outpatient Surgical Settings

In its initial Action Plan, the Department of Health and Human Services (HHS) focused on six high priority healthcare-associated infections (HAIs) pertinent to care provided in the acute care hospital setting. These HAIs were surgical site infection (SSI), central-line associated bloodstream infection, ventilator-associated pneumonia, catheter-associated urinary tract infection, *Clostridium difficile* infection, and methicillin-resistant *Staphylococcus aureus* infection. While the current draft chapter for ASCs makes frequent reference to SSI and various infection prevention practices, HHS has not articulated a set of target HAIs for ASCs. HHS should develop a list of high priority HAIs for outpatient surgical settings in order to ensure the Action Plan is focused on efforts likely to have a significant public health impact.

We believe this step is essential, particularly in light of information shared by representatives from State Health Departments at the HHS HAI Data Summit and in National Healthcare Safety Network (NHSN) Workgroup sessions regarding their current state-level SSI reporting initiatives for ASCs. Considerable resources – both on the part of states and ASC providers – have been invested in reporting SSIs following selected outpatient surgeries to the National Healthcare Safety Network (NHSN), sponsored by the Centers for Disease Control and Prevention (CDC). Yet it is now becoming apparent that the surgeries initially selected by the states for surveillance and reporting are not appropriate to the outpatient surgical setting. In addition, the data generated has lacked sufficient power for analysis and has not been found actionable. These experiences highlight the need for careful development, including pilot testing where appropriate, of new initiatives to help ensure they will make meaningful contributions to the elimination of HAIs.

In the event that the current evidence in the medical literature and other data sources regarding the incidence of HAIs related to care in the outpatient surgical setting is inadequate to allow the creation of a list of outpatient HAI priority areas, HHS may need to support basic HAI outcomes research in order to identify appropriate HAI targets. This incidence data would also be essential to judging the success of any interventions the Department undertakes to reduce the level of target HAIs.

II. Develop Resource-Efficient HAI Surveillance Methods

Once priority outpatient HAI outcomes have been identified, resource-efficient surveillance methods will need to be developed. As HHS has indicated in the past, research is needed to understand how definitions and surveillance protocols that have been used in hospital settings can be translated for the outpatient environment.
The delayed onset of many of the HAI outcomes of interest poses a significant challenge for case detection for inpatient and outpatient care alike. Rather than using resource-intensive methods such as patient and physician surveys, we believe it would be prudent to further explore ways that administrative claims data can be used to alert providers to HAI outcomes. For example, CDC and the ASC QC are currently discussing the development of a measure that would evaluate hospitalizations following an ASC admission. As part of this project, we are exploring the use of claims for subsequent hospitalizations with subsequent validation by the ASC as a method of case detection. We believe that, with further development and refinement, administrative claims data also offer a potential avenue for the detection of delayed HAI outcomes that lead the patient to seek additional medical care. To fully realize this potential, continued refinements to ICD diagnosis coding to more clearly identify HAI outcomes and policy changes, such as requiring a consistent claims-based reporting method for HAIs, would need to be implemented. In addition, methods for payers to share claims-based HAI data with providers would need to be developed. HHS, through its oversight and administration of the Medicare program, is in a position to lead further exploration of this resource-efficient approach to case detection.

Regardless of the methodology ultimately selected, the surveillance methodology chosen should be one that could be implemented in a consistent fashion across surgical sites of service. The methodology should support the development of SSI rates that could be compared on a facility-by-facility basis across providers of outpatient surgical services. We are pleased to have been included in a recent Healthcare Infection Control Practices Advisory Committee (HICPAC) NHSN Workgroup discussion regarding outpatient surveillance and look forward to continued inclusion in these deliberations.

### III. Streamline Reporting Systems

The CDC's NHSN has been an important tool for the collection of hospital HAI data. We believe the system will require further development and refinement in order to achieve the same level of utility for outpatient providers.

CDC personnel have indicated approximately 40 ASCs reported data to NHSN as of early 2010. ASCs in Colorado - where State requirements for quality reporting have included reporting to the NHSN since October 2008 for abdominal hernia repairs, hip replacements and knee replacements - have gained the greatest amount of experience. These centers report that the system is difficult to use – everything from registration to data submission is challenging, and consumes a significant amount of time. To submit data, participating facilities must first prepare a monthly reporting plan. Then detailed patient-level data must be prepared for all patients undergoing the specified operative procedures, with a minimum of 15 required data fields per patient, and the possibility of additional conditionally required elements for selected operative procedure categories. If the patient develops an SSI, 17 additional required data fields must be completed, with the possibility of one additional conditionally required element. We believe NHSN should be evaluated for opportunities to simplify and streamline the platform for outpatient use, including an evaluation of the current enrollment process, opportunity for data uploads from patient accounting systems to populate demographic data fields, and a detailed analysis of the required data fields to determine whether all should be retained for outpatient data collection and reporting purposes.
We appreciate CDC’s willingness to work with stakeholders to develop an outpatient procedure module and to evaluate ways in which the NHSN enrollment and reporting processes can be simplified and made more relevant to the ASC setting. We look forward to additional dialogue on this matter.

IV. Other Areas Proposed for Collaboration

We appreciate the efforts of the Department to coordinate the various HAI initiatives undertaken by its numerous subordinate agencies. We encourage HHS to continue its outreach to stakeholders in the outpatient surgical community in order to ensure that HAI-related activities are well coordinated and appropriately designed to advance best practices and quality measurement, and to ensure broad-based and effective communication.

A. Culture of Safety and Patients’ Perspectives of Care Surveys

In updating the original draft Action Plan, HHS has proposed a number of new priority areas. Among these are adapting the Agency for Healthcare Research and Quality’s (AHRQ) Medical Office Survey on Patient Safety Culture for the ASC setting. HHS has also proposed to develop a related ASC Patient’s Perspectives of Care Survey. We support both these activities, but believe AHRQ’s Hospital Survey on Patient Safety Culture should also be considered in creating a safety culture survey for ASCs. We look forward to providing detailed input in these areas as these projects are initiated.

B. Process of Care Measures

We agree that existing process measures that address surgical care should be evaluated for their relevance to the ASC setting. In fact, when the ASC Quality Collaboration was formed, our clinicians undertook a detailed evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. We found that although several existing measures addressed surgical care, none had been developed specifically for the outpatient surgical setting. Our analysis determined that many of these measures are specific to procedures that are either never or uncommonly performed in outpatient facilities. Other measures expressly excluded patients with a stay of less than 24 hours, effectively eliminating the entire ASC patient population.

The ASC QC did identify two areas of focus under the Surgical Care Improvement Project (SCIP) that are also important to ASCs: the timely administration of prophylactic intravenous antibiotics and appropriate surgical site hair removal. We developed and secured NQF endorsement for ASC-specific measures for these two SSI prevention processes. These measures are currently in use and being voluntarily reported to the public in aggregate form on the ASC QC’s website at [www.ascquality.org](http://www.ascquality.org). The Prophylactic IV Antibiotic Timing measure has been selected by CMS for inclusion in its ASC Quality Reporting Program (ASC QRP). We believe these ASC-specific measures, which have been harmonized to the corresponding SCIP measures to the extent feasible and practicable, are the most appropriate for measuring SSI prevention processes in the ASC setting.

Other SCIP measures have either limited or no applicability to the ASC setting. Of the SCIP measures addressing infection, we have made the following observations:
The SCIP measure evaluating antibiotic selection has an equivalent PQRS measure; we see no value in duplicating physician-level reporting in this area.

The SCIP measure addressing post-operative glucose control focuses on cardiac surgery, which is not performed in ASCs, and has a measurement period of 48 hours, which exceeds the maximum length of stay in the ASC setting (which is 23 hours, 59 minutes).

The SCIP normothermia measure is measured for patients undergoing surgical procedures under general or neuraxial anesthesia of greater than or equal to 60 minutes duration. Although the majority of ASC procedures do not require general or neuraxial anesthesia, we are currently evaluating the feasibility of adapting this measure to the ASC setting.

The SCIP antibiotic discontinuation measure evaluates post-operative discontinuation at time points that exceed the maximum length of stay in the ASC setting.

The SCIP measure evaluating postoperative urinary catheter removal excludes patients whose length of stay was less than two days postoperatively.

Endoscope reprocessing has been another suggested area of focus for the development of process measures. This type of measure would represent an opportunity for measurement across sites of service offering endoscopic services; such a cross-setting measure could be very helpful to consumers. However, we note that a series of three measures related to colonoscope processing developed by the AAAHC Institute for Quality Improvement were not endorsed by the NQF in a recent consensus development project. The three measures addressed the frequency of personnel instruction in colonoscope processing, whether or not facilities reviewed processing guidelines at appropriate intervals and made any necessary revisions to their colonoscope processing protocols, and documentation of personnel competency at appropriate time intervals. NQF has stated that the decision not to endorse these measures was based on the following:

- Lack of adequate consensus across stakeholders.
- The opinion that these measures are more appropriate for quality improvement activities and not for public reporting and accountability.
- The opinion that these measures are more appropriate as basic accreditation standards and should be considered a competency and safe practice issue.

In light of this, we suggest the Department convene a diverse group of stakeholders as it considers appropriate topics for, and approaches to, measurement surrounding endoscope reprocessing.

C. **Outcomes Measures**

The ASC QC remains keenly interested in opportunities for ASCs to share data regarding their surgical site infection (SSI) rates with the public. We are especially interested in any SSI measure that would allow for direct comparisons across the facility settings that provide outpatient surgical services.

CDC and the American College of Surgeons have collaborated to develop an SSI outcome measure appropriate to surgeries performed in the acute inpatient setting. To be appropriate to the outpatient setting, this measure would need to be revised. The development of an outpatient-appropriate approach to the detection of cases for inclusion in the numerator will be essential, as will a determination of the outpatient procedures most appropriate for inclusion in the measure denominator. These refinements to the existing measure will improve the opportunity for ASC participation, ensure
the data developed is representative of the performance of ASCs and other outpatient surgical service providers, and provide a broader spectrum of meaningful information for prospective consumers of outpatient surgical services.

CDC is already well aware of the limitations of the existing SSI measure for the outpatient setting. We continue to appreciate their willingness to work with stakeholders to address the challenges inherent in developing an outpatient SSI measure.

V. Measurable Goals

HHS has proposed, with stakeholder input, to accomplish a number of goals by December 31, 2013. Among these are to:

- Identify existing quality measures (e.g., serious reportable events, SCIP measures) that have been endorsed and are applicable to ASCs,
- Identify areas where additional quality measures are needed for ASCs,
- Establish a timeline and methods for adoption and implementation of select measures within ASCs,
- Identify a set of ASC procedures for which SSI definitions and methods should be developed, and
- Establish a multi-year plan and phased approach to support their routine surveillance.

The ASC QC supports these goals and, as a stakeholder, looks forward to actively participating in these initiatives.

***

Thank you for considering these comments. We look forward to continuing our interactions with HHS and its agencies. Please do not hesitate to contact us if we can assist with questions or provide additional information.

Sincerely,

Donna Slosburg, BSN, LHRM, CASC
Executive Director, ASC Quality Collaboration
727-367-0072
donnaslosburg@ascquality.org
Appendix A
Current Participants in the Activities of the ASC Quality Collaboration

Accreditation Association for Ambulatory HealthCare
Ambulatory Surgery Foundation
Ambulatory Surgical Centers of America
American College of Surgeons
American Osteopathic Association, Healthcare Facilities Accreditation Program
AmSurg
Association of periOperative Registered Nurses
Florida Society of Ambulatory Surgery Centers
Health InVentures
Hospital Corporation of America, Ambulatory Surgery Division
Nueterra Healthcare
Outpatient Ophthalmic Surgery Society
Surgical Care Affiliates
Symbion
The Joint Commission
United Surgical Partners International