VIA ELECTRONIC DELIVERY

October 11, 2010

Secretary Kathleen Sebelius
Office of the Secretary
Department of Health and Human Services
200 Independence Ave, SW.
Room 719B
Washington, DC 20201

Attention: Draft Tier 2 Modules

Dear Secretary Sebelius:

Ambulatory Surgery Centers (ASCs) are committed to patient safety and providing high-quality, patient-centered care at a low cost to the health care system. On behalf of the ASC Association, the ASC Advocacy Committee, and the ASC Quality Collaboration (ASCQC), we submit these comments regarding the US Department of Health and Human Service's *Action Plan to Prevent Healthcare-Associated Infections: Ambulatory Surgical Centers*. As the Workgroup continues to develop its recommendations, it should seek to

- Build upon current activities of the ASC industry and others,
- Build a foundation of research to support an evidence-based plan,
- Work to create transparency across surgical settings,
- Incentivize providers to make investments that will reduce HAIs, and
- Ensure that the "Candidate measures" are most effective by considering how they align with industry needs and capabilities.

ASCs are an integral part of the health care system, providing critical access to surgical and diagnostic care, including preventive services. Advances in the practice of surgery and anesthesia have allowed ASCs to move more services out of hospitals into less expensive and clinically appropriate settings: from about 100 procedures in 1982 when Medicare began to cover care in ASCs, to the thousands of procedures Medicare currently covers in both hospital outpatient departments (HOPDs) and ASCs.

ASCs provide about 40 percent of all outpatient surgeries, more than 22 million procedures, in 5,300 ASCs across the United States. By far the most common services performed for Medicare beneficiaries are cataract and related surgeries, gastrointestinal endoscopies and pain management. Gastrointestinal endoscopies and pain management are also the most common services performed for non-Medicare patients.

With the passage of comprehensive health care reform legislation in early 2010, there is an increased focus on access to quality care, cost savings, and preventive care as the nation begins the process of expanding participation in private and public insurance options. ASCs are often the most cost-effective surgical setting for patients and payers. Many ASCs focus on services that are recommended by the U.S. Preventive Services Task Force and Healthy People 2010 & 2020, such as colonoscopy screening. ASCs reduce costs: Compared to the HOPD, every procedure performed in an ASC saves the Medicare program more than 40 percent and usually saves Medicare beneficiaries between 50 and 60 percent on their co-payments. The use of ASCs has likely slowed growth in total Medicare spending for outpatient surgical services because they offer a low-cost alternative to HOPDs, a goal that is consistent with the Administration’s health reform priorities.

ASCs are an important part of meeting the health reform objectives articulated by the Congress and the Administration: to increase value in health care by ensuring access, promoting the efficient use of services, and improving quality. We look forward to continuing to work with CMS, accrediting organizations, state ASC associations, medical and nursing professional organizations, and leaders in quality measurement towards the elimination of healthcare-associated infections (HAIs).

We appreciate the forum provided by the Department at their September 23-24 stakeholder meeting to discuss the proposed action plan. As the agency has provided with other health care settings, we urge HHS to schedule a second stakeholder meeting with broad participation of ASC industry stakeholders before finalizing their recommendations.

BUILD UPON CURRENT ACTIVITIES

In reviewing the draft HHS Action Plan, we identified several areas in which the industry's current, independent initiatives to promote the delivery of high quality care and best practices appear to have been overlooked. We believe a second stakeholder meeting with much broader ASC participation would help to build relationships with the industry's quality leaders and to identify efforts to eliminate HAIs which are already underway. New efforts to reduce HAIs should be built upon existing ones to leverage resources, avoid redundancies, and capitalize on current positive momentum. The Workgroup should recommend that resources be dedicated to maintain or expand current efforts which are now supported by the industry.

The ASC industry voluntarily began its own efforts at collecting and reporting quality data several years ago. Since 2006, the ASCQC has developed quality measures appropriate for the industry, six of which were endorsed by the National Quality Forum (NQF). Absent any incentive or requirement to do so, with infrastructure costs entirely supported by the industry, more than 20 percent of ASCs voluntarily collect and report data on the six NQF-endorsed ASC measures on a quarterly basis. Quarterly data for 2010 is now available for public review on their website at www.ascquality.org. The group is continuing to develop new measures, with measures for surgical site infections and medication administration variance recently submitted to the NQF.

Data aggregated from the most recent ASCQC 2010 Second Quarter Report shows that ASCs have low rates of medical error and few complications related to common procedures performed in the outpatient setting. Similarly, national data collected by the ASC Association from more than 650 ASCs through its Outcomes Monitoring Project shows that 80 percent of ASCs report fewer than 1.5 post-surgical wound infections per 1,000 patients encountered. Comparable information from the outpatient hospital department setting would enable valuable comparisons across settings.

In addition to measure development, the ASCQC is also an integral resource promoting best practices on infection control. To date, the group has released four modules in a series of educational toolkits aimed at helping facilities address infection control standards. The toolkits make infection prevention resources readily accessible to ASCs by bringing them together in one location and distributing them at no cost to the users. The first four modules address hand hygiene, safe injection practices, point of care devices, and environmental infection prevention. Each toolkit provides ASCs with essential resources. For example, the *Safe Injection Practices Toolkit* includes

- Assessment Tools
- Implementation Aids
- Training Materials
- Monitoring Tools
- Workplace Reminders
- Guidelines from Leading Authorities

The ASCQC continues to develop new materials to promote best practices and improve compliance with the revised ASC Conditions for Coverage.

We urge the Workgroup to consider opportunities to promote additional provider education and recommend applying additional resources to meet the industry's educational needs. The ongoing results of research, especially any surveys or surveillance conducted in the field, could be an effective tool for education if they were provided as confidential feedback in real time to the ASCs.

BUILD A FOUNDATION OF RESEARCH

We believe investing in research should be a core element of the HHS HAI plan for ASCs. Many of the metrics proposed in this draft Action Plan are based on evidence developed in the inpatient surgical setting and may not be the most appropriate ones for the outpatient setting. The outpatient surgical setting differs from the inpatient setting in many respects, most notably in case mix and patient mix. Developing the evidence base in ASCs is vital to informed planning and decision-making with respect to outpatient HAIs.

Defining the extent of HAIs is an essential first step. Rates of HAI-related outcomes in ASCs and other outpatient surgical settings have not been established. Industry experience suggests that SSIs resulting from ambulatory surgical procedures are relatively rare. This baseline should be validated through formal study and serve as a benchmark to measure future successes in, and to determine the appropriate allocation of resources to, reducing HAIs in ASCs.

Going forward, it will be essential to formally study outcomes and use this information to focus public health policy and target resource allocation. Research specific to the outpatient setting should guide the selection, development and implementation of the "Candidate measures": there should be a solid evidence base for determining which outcomes should be targeted for improvement, which process changes are linked to improving those outcomes, and which methods are best suited to measuring adherence to those processes and measuring changes in those outcomes.

Clinical and research experts with backgrounds in ASCs should be part of these research efforts, as well as efforts to eliminate HAIs across healthcare settings. Engaging ASC experts will help in the design of experiments and development of best practices that are appropriate for all providers of surgery. We encourage this Workgroup and others like it to continue to involve ASC experts in their important work.

CREATE TRANSPARENCY ACROSS SURGICAL SETTINGS

Comparable information about patient safety and care quality in ASCs and HOPDs can empower consumers and their physicians to chose the most valuable and appropriate setting for their outpatient surgical care. Thousands of procedures can be performed in either setting; comparisons based on quality could incentivize substantial improvements in both settings. Research is needed to develop methods that will allow comparisons of HAI outcomes to be made across providers – not only across ASCs with their widely varying

case mix, but also across the full spectrum of providers of outpatient surgical care. These comparisons are important to expanding the level of transparency for consumers and also to allowing providers to understand their level of performance in relation to their peers. To this end, we ask the Workgroup to put significant effort into developing risk adjustment models that will allow comparisons of HAIs in both ASCs and HOPDs.

INCENTIVIZE INVESTMENTS TO ACCELERATE CHANGE

We support the action plan's call for rapid, decisive progress towards reducing HAIs. Unifying the effort to collect and disseminate information and incentivizing investment in health information technology will increase the immediate impact of these efforts.

Healthcare providers are increasingly being asked to provide quality and other related data to a wide variety of stakeholders to support diverse activities such as licensure, certification, payment incentives and accreditation. However, there is no consistency from one stakeholder to the next in terms of data set, definition of metrics or data collection approaches. This lack of consistency is imposing an ever larger burden on providers as they attempt to satisfy various requirements. A similar type of situation was seen in the 1960s with the proliferation of billing forms and data sets required for filing of health claims. The situation was resolved with the creation of the National Uniform Billing Committee and the adoption of a national claim form and standard data set.

A similar effort is needed in the collection of quality data. The industry, researchers, consumers and others would be best served by a unified effort to gather data and report it, create a one-stop shop for comprehensive information. As CMS considers data collection and reporting on HAI-prevention measures, we encourage CMS to also consider coordinating these activities with similar activities by accrediting bodies, states, and others and to develop a harmonized, non-redundant data collection.

Health information technology can enable better, more efficient data collection. We agree with the Workgroup's proposal that ASCs should be eligible for bonuses or financial support to encourage wider use of electronic health information technology. Data from the April 2010 National Health Statistics Report No. 22 indicates that 22.3% of freestanding ASCs reported using any form of electronic medical record (EMR); 3.2% of freestanding ASCs have basic EMRs, while only 0.5% have fully functional EMRs. ASCs were not included in provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) establishing an incentive program to encourage physicians and hospitals to implement health information technology. The industry has been under a Medicare payment freeze for six of the last seven years, and anticipates that 2011 will also result in a rate freeze, presenting economic barriers to adoption of costly new technologies. Financial incentives similar to those provided to physicians and hospitals under the ARRA are essential to promote ASC investments in such systems.

COMMENTS ON THE HHS PROPOSED CANDIDATE MEASURES

We appreciate the opportunity to comment on the other points raised in the Workgroup's "Candidate measures" list and timeline. We agree that surveillance of HAIs across surgical settings is important. Information on HAIs should be transparent and available to providers for quality improvement and to the public. We agree that measures from the Surgical Care Improvement Project and the NQF serious reportable events sets should be considered and encourage the Workgroup to identify which of the measures are applicable to ASCs. As the Workgroup continues to develop the candidate measures, we encourage goal-

setting and a timeline built upon similar efforts currently underway. We have addressed each candidate measure below.

By December 31, 2011, identify selected common ambulatory surgical center surgical procedures for which surgical site infection definitions and methods should be developed and develop a multi-year plan and phased approach to support routine surveillance; and,

By December 31, 2013, all certified/accredited ASCs will have in place a surveillance system for procedure-related adverse events, including no less than 30 days post-discharge surveillance for all patients.

We agree that surveillance efforts should include a range of high-volume procedures in order to engage the industry broadly, reach across ASC surgical specialties, and develop a reliable measurement of the incidence of HAIs related to care that is provided in ASCs. Some ASCs provide multi-specialty services while many others are single specialty, especially ophthalmic and gastro-intestinal ASCs. If surveillance efforts are too narrowly focused by specialty then the results will not be representative of the industry.

Surveillance for HAIs in ambulatory patients presents well-recognized challenges. Many ASCs survey the performing surgeon to determine patient outcomes in the post-operative period following discharge. As noted, this method can be efficient and has good specificity, but it can be resource intensive and may not always capture all SSIs.

Several alternative SSI surveillance methodologies exist, but each has its own limitations. Research is needed to determine a standardized method which optimizes sensitivity and specificity while minimizing resource utilization for case detection. It will be important to ensure that costs associated with surveillance do not exceed the potential public health impact.

We urge the Department to engage professionals with expertise in HAI surveillance such as the department's internal experts, the Association for Professionals in Infection Control and Epidemiology (APIC), and the ASC industry signatories to this letter to develop definitions and best practices around HAI surveillance practices that are effective and produce the least administrative burden to patients and providers. We look forward to such dialogue and welcome Department representatives to visit our centers and engage with the industry to develop consensus recommendations that can be embraced by all providers of outpatient surgical services.

By December 31, 2013, all certified/accredited ASCs will demonstrate 100% adherence to the measures contained within the infection control worksheet.

We agree that the processes of care on the infection control worksheet should continue to be part of the effort to eliminate HAIs in ASCs and all surgical settings.

Similar indicators of adherence to evidence-based processes of care are used for many healthcare services, such as inpatient and outpatient hospital services. After years—and in some cases close to a decade—of widespread measurement and quality improvement efforts, there is still variation in adherence among hospitals and HOPDs. We encourage the Workgroup to consider the experience of other healthcare providers and set attainable milestones and goals for adherence across the ASC industry. Milestones should acknowledge both substantial improvements towards the goal and attainment of the highest standards. In addition, public reporting of data should be comparable across sites of care to provide consumers meaningful points of comparison when selecting a facility for their outpatient surgical needs.

Use of the worksheet in other settings should be promoted to encourage a focus on best practices across surgical settings and also to allow for meaningful comparisons across settings. Effective ways to use the worksheet to increase compliance should include additional focus on education and adherence to worksheet processes in every certified/accredited ASC's quality assurance and improvement plan.

By December 31, 2015, all certified/accredited ASCs will be reporting surveillance data in standardized formats to both Patient Safety Organizations and to the National Healthcare Safety Network.

We agree that transparency and public reporting are effective steps towards eliminating HAIs.

Patient Safety Organizations (PSOs) are relatively new, not yet widespread, and have a scope of responsibilities well beyond ASCs. The rule to establish the framework for reporting to PSOs became effective in January 2009. There are fewer than 90 PSOs in only 30 states and the District of Columbia. They are charged with assisting hospitals, physicians, and other healthcare providers on a full range of safety issues, well beyond HAIs and ASCs. The Workgroup should consider the capacity and the role of PSOs.

The CDC's National Healthcare Safety Network is an important program for the collection of HAI data and one that we believe, with further development and refinement to improve utility for outpatient providers, could be a very useful tool for reliable determination of risk-adjusted HAI incidence data in the ASC and HOPD settings. However, the process to enroll and participate in this program can be very challenging for ASCs lacking information technology support. The majority of ASCs do not have access to an IT support department. We appreciate CDC's willingness to evaluate ways in which the NHSN enrollment and reporting processes can be simplified and look forward to additional dialogue on this matter.

As we noted earlier, reporting the same information to multiple entities is counter-productive, redirecting resources toward redundant efforts instead of using the resources for wider or deeper data collection and reporting. Also, it is less effective than providing consumers and researchers information in a single, comprehensive resource.

By December 31, 2015, all certified/accredited ASCs will demonstrate 100% adherence to Surgical Care Improvement Project/National Quality Forum infection control process measures.

As the ASCQC began its work on ASC measure development, they set out to harmonize ASC quality indicators with indicators from other surgical settings, such as the Surgical Care Improvement Project (SCIP). They identified two areas of focus under SCIP which are also important to ASCs: the timely administration of prophylactic intravenous antibiotics and appropriate surgical site hair removal. The ASCQC developed and secured NQF endorsement for ASC-specific measures of these two SSI prevention processes. These measures are currently in use and being voluntarily reported to the public in aggregate form on the ASCQC's website. We believe these ASC-specific measures—which have been harmonized to the corresponding SCIP measures—are the most appropriate for measuring performance in the ASC setting. We would support the use of these measures in workgroup's proposed metric. It is worth noting that the ASC industry has asked CMS for several years to develop a national infrastructure to allow ASCs to voluntarily report these measures and other quality indicators.

The ASCQC has reviewed the two other indicators from the SCIP set mentioned by the workgroup: post-operative glucose control and normothermia. It is important to note that as currently specified, these measures are unlikely to be appropriate metrics for ASCs.

More specifically, the SCIP post-operative glucose control measure specifies that the glucose measurement is to be taken at 6am on postoperative days one and two. The Medicare standard for surgeries in ASCs precludes those procedures which require an overnight stay; thus, ASCs are usually prohibited from doing precisely the kinds of procedures which would require a patient to be under observation for two postoperative days. We also note that the Medicare SCIP measure specifies this indicator is to be used on patients undergoing "cardiac surgery", which is not representative of surgeries performed in ASCs.

The denominator for the SCIP normothermia measure is "patients undergoing surgical procedures under general or neuraxial anesthesia of greater than or equal to 60 minutes duration." Again, this measure is not applicable to the general population of ASC patients. The majority of ASC procedures do not require general or neuraxial anesthesia at all. Of the minority that do require general or neuraxial anesthesia, most do not require anesthesia of this duration.

By December 31, 2015, all certified/accredited ASCs will have achieved zero incidence of "Never Events" as defined by the National Quality Forum

We agree that the occurrence of a "wrong site/wrong patient/wrong procedure" is an important serious reportable event for all surgical providers. This has been the focus of several years of ASC industry efforts including sharing best practices, educational offerings, and ASCQC data collection. We have been encouraged by the extremely low incidence of this event in ASCs (see www.ascquality.org) and appreciate the Workgroup's support for continued work on this issue.

A few of the other serious reportable events may be relevant to HAIs; however, the majority are not, such as patient abductions and patient suicides. Other measures are simply not relevant to ASCs given the duration of the patient's time in the facility: for example "Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility" would never pertain to ASC patients having same-day surgery. We encourage the Workgroup to review the full list of serious reportable events and identify those which are relevant to HAIs in the ASC setting.

By December 31, 2015, and within two years of National Quality Forum endorsement, all certified/accredited ambulatory surgery centers will have implemented any new applicable healthcare-associated infection-related measures

The current system of notice and rulemaking is an important opportunity for all the stakeholders in quality measurement to review, comment-upon, and improve quality measures. This system is used in other settings (e.g. hospital outpatient department, inpatient hospital) and should be maintained for ASCs.

By December 31, 2015, all certified/accredited ASCs will have on staff or on contract services of a certified infection preventionist.

The Medicare Conditions for Coverage require an ASC to have a professional on staff trained in infection control. Like the hospital Conditions of Participation and interpretive guidelines, the ASC Conditions do not specify requirements for certification or specific training protocols. We believe that flexibility remains appropriate for professionals in both settings, as the training should correspond to the operations of the facility. Given the lower complexity of cases in the ASC setting, we do not believe infection control training should be more rigorous in the ASC setting than it is for professionals responsible for infection control in acute care hospitals.

We support improvement in the education and training of all ASC staff as appropriate to increase efforts to eliminate HAIs. The development of ASC-specific offerings, on-line training, and other flexible options are

needed. In addition, we urge the Secretary to pursue additional research designed to determine barriers to consistent adherence to infection prevention processes and effective methods to overcome those barriers.

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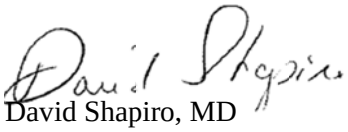
We will continue to work actively with CMS and our industry counterparts to ensure broad understanding and implementation of CMS's infection control standards in order to improve compliance. We look forward to engagement with the HHS team working on these recommendations and welcome the opportunity for ongoing dialogue. If you have any questions, please do not hesitate to contact us.

Sincerely,



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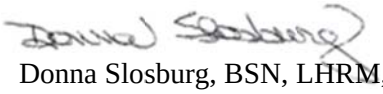

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