ASC Quality Collaboration

August 29, 2011

VIA ELECTRONIC SUBMISSION

Donald Berwick, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1525-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1525-P; Proposed ASC Quality Reporting Program

Dear Administrator Berwick:

On behalf of the ASC Quality Collaboration (ASC QC), a cooperative effort of organizations and companies interested in ensuring ambulatory surgical center (ASC) quality data is appropriately developed and reported, please accept the following comments regarding CMS-1525-P, Section XIV. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting, as it pertains to ASCs (76 Fed. Reg. 42313, July 18, 2011). The ASC Quality Collaboration's stakeholders include ASC corporations, the ASC industry association, 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 quality reporting. Our commitment is reflected in the steps we have taken independently to facilitate quality reporting by ASCs – all without federal incentive or penalty. This includes developing and securing the endorsement of the National Quality Forum (NQF) for six ASC facility-level quality measures, as well as developing and publishing a quarterly public report of ASC quality data that is 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. Over 1200 centers, representing more than 20 percent of all Medicare certified ASCs, participated in the 1Q2011 report.

We are pleased the agency has begun to present its proposals for the ASC Quality Reporting Program. We are grateful to see the measures we developed included in these proposals and appreciate the consideration the agency has given to our prior suggestions on implementing a quality reporting system for ASCs. We are pleased to have this opportunity to continue to provide information regarding the characteristics and operational capabilities of the

ASC industry pertinent to quality reporting, share our perspective on facility-level quality measures appropriate to ASCs, offer recommendations regarding implementation of the ASC Quality Reporting Program, and share our thoughts on effective ways of presenting ASC quality data to the public.

I. Timeline for the Implementation of the ASC Quality Reporting Program

While we appreciate the agency taking its first steps toward putting an ASC Quality Reporting Program in place by publishing proposals for selected aspects of the program in this rule, the time ASCs will have to respond to and prepare for whatever new requirements are finalized in the rulemaking process is inadequate. Specifically, CMS has proposed that ASCs begin to submit quality data on selected measures to the agency on January 1, 2012 for the CY 2014 payment determination. We anticipate that, as in years past, CMS will issue the ASC/OPPS final rule at the end of October or the beginning of November 2011. This would give ASCs two months to become versed in the new quality reporting program requirements finalized in the rule, to develop and implement the changes in daily processes and operational systems needed to meet the new CMS requirements, to educate staff regarding the new requirements and the new processes for meeting those requirements, and to initiate data reporting. The unreasonableness of this proposed timeline cannot be overemphasized. Indeed, our review of the implementation periods for other quality reporting programs indicates this compressed timeline is unprecedented.

Placing this proposal in the context of the timeframe CMS allows for changes in existing quality reporting programs highlights how inappropriate it would be to allow two months of advance notice for implementation of an entirely new quality reporting program. As an example we point to the sub-regulatory process CMS has established for updates to technical specifications for measures under existing quality reporting programs, such as those for inpatient hospitals and hospital outpatient departments. Here, the agency provides "at least 3 months of advance notice for substantial changes such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months notice for substantive changes to data elements that would require significant systems changes" [See, for example, 73 FR 48622 and 76 FR 42348]. We believe implementation of a new quality reporting program deserves even more advance notice, and certainly no less than the minimum of 6 months of advance notice extended when measure specifications under existing programs require significant system changes.

We strongly recommend CMS revise its timeline for implementation of the ASC Quality Reporting Program in order to allow ASCs a reasonable amount of time to prepare to collect and submit data for measures finalized for reporting in 2012. CMS should delay implementation of data collection and submission for measures finalized for claims-based reporting until dates of service on or after October 1, 2012. We do not anticipate this postponement would prevent CMS from incorporating claims-based quality reporting data in the CY 2014 payment determination. We also believe it would be prudent for the agency to allow ASCs to initiate claims-based reporting on a trial basis from January 1, 2012 through September 30, 2012. This would allow ASCs the opportunity to test operational system changes and electronic data interchange processes prior to the implementation of formal data reporting on October 1, 2012.

II. Considerations in the Selection of Measures for the ASC Quality Reporting Program

CMS has outlined a set of principles the agency applies for the development and use of measures in its quality reporting programs. These principles are generally sound, but must be applied with an appreciation for factors that distinguish each provider/supplier from others. Some important attributes that impact quality measure selection for the ASC industry are outlined below.

First, the case mix across ASCs is very diverse. Centers range from those providing services related to a single subspecialty (such as gastroenterology or ophthalmology), while other centers provide services in two or more subspecialties. In order to promote broad participation in the quality reporting system, this diversity must be considered in the selection of the measure set. Depending on the particular measure being considered, this diversity also has important implications for the development of data completeness standards and the need for exemptions based on case mix or low volume.

Second, of the providers that offer surgical services to Medicare beneficiaries (acute inpatient hospitals, hospital outpatient departments (HOPDs), ASCs and physicians), ASCs are the most constrained in the range of services that can be performed and reimbursed. This poses challenges to the alignment and harmonization of measures across these providers, as ASCs provide a subset of the services offered by the others. Depending on the measure specifications, this often means that what may be a pertinent measure of quality based on the scope of services for one provider is largely irrelevant in the ASC.

Third, of the facility providers of surgical services, ASCs receive the lowest reimbursement for the services they perform. As a result, ASCs must be "lean"; CMS has estimated that approximately 73 percent of ASCs would be classified as small businesses according to the Small Business Administration size standards [72 Fed. Reg. 66901]. The predominance of small facilities is corroborated by CMS data indicating a median of two operating/procedure rooms per facility (mean = 2.5). Not only do the facilities tend to be small, they also employ smaller number of individuals as compared to hospitals and HOPDs. The ASC Association's 2010 ASC Salary & Benefits Survey shows the majority (63%) of ASCs have 20 or fewer total full time equivalents, including both clinical and non-clinical staff. As a practical matter, this means that ASCs are acutely sensitive to administrative burdens. Both the quality measures and data submission requirements adopted for ASCs should be as streamlined as possible. As individual centers weigh the costs of participating in a quality reporting program against potential penalties, unnecessary complexity could have the unintended consequence of reducing ASC participation in the program – an outcome to be avoided.

Finally, the use of electronic health records (EHR) is limited in the industry as a whole. ASCs were not included in provisions of the American Recovery and Reinvestment Act of 2009 establishing an incentive and penalty program to encourage physicians and hospitals to implement health information technology. Although ASCs were eligible to apply for a very limited portion of $2 billion in grant and loan money available to states for investment in health information technology, this eligibility has not resulted in a significant increase in the use of EHRs in the ASC industry.

Turning to specific principles for guiding the selection of quality measures for surgical facilities, we believe the following additional concepts are important: comprehensive evaluation and testing prior to implementation, appropriate attribution of accountability, and results that are meaningful to the general public. These are described in more detail below.

Whenever possible, facility-level measures of surgical quality for the ASC Quality Reporting Program should be selected from among those endorsed by the National Quality Forum (NQF) through its national multi-stakeholder consensus approval process. While CMS states that consensus among affected parties can be achieved in other ways – including through the measure development process, through broad acceptance and use of the measure, and through public comment – we do not believe these proxies are equivalent or entirely satisfactory. These alternative approaches lack a consistently comprehensive and rigorous measure evaluation process and often bypass the requirements for actual testing that characterize the NQF process for achieving full (as opposed to time-limited) endorsement of a measure. We believe there are sufficient numbers of NQF endorsed measures to select from when developing the measure set for ASCs to make a criterion of endorsement by a national, multi-stakeholder organization "practical and feasible".

In addition, the selected outpatient surgical facility quality measures should reflect aspects of patient care that are directly attributable to the facility itself - its staff, equipment, environment of care, and its roles in the delivery of patient care - and for which the facility, by virtue of its specific functions in patient care, may reasonably be held accountable. We do not believe it is appropriate to implement physician-level quality measures for non-physician provider types, such as ASCs.

Data generated by appropriately selected quality measures should provide information that can be readily understood by the consumer and that can be used in their evaluation of the quality of care offered by the facility. Measures that do not result in clear and helpful data should not be considered for inclusion in a provider measure set. This consumer aspect has been the generally acknowledged reason for the existence of public quality data reporting programs and CMS should include this as a guiding principle for measure selection.

III. Proposed Timetable for the Selection of ASC Quality Measures

In its existing quality reporting programs, CMS has established a practice of proposing and finalizing measure sets in advance for a series of three calendar year payment determinations. As noted above, we find the specific timeline for the CY 2014 payment determination unreasonable and in need of significant revision. However, we support the general idea of giving providers a significant period of advance notice by publishing measure sets several calendar years in advance. This allows providers to gain understanding of measure specifications, data completeness expectations and data submission methodologies, and to gain experience with collecting data for the required measures prior to the reporting period.

IV. Quality Data Reporting Mechanisms and Quality Measures Proposed for the CY 2014 Payment Determination

A. Submission of Quality-Data Codes for Claims-Based Measures

We support the agency's proposal to collect quality data through the submission of quality data codes (QDCs) on administrative claims. CMS has already developed a claims-based quality data collection infrastructure under the Physician's Quality Reporting System (PQRS), which it is expanding for use by other providers. Using either HCPCS Level II G codes or AMA Category II CPT codes developed specifically for quality reporting, providers are able to submit quality data in conjunction with codes for services rendered on the claim form. Given that ASCs already submit a CMS-1500 form for each Medicare beneficiary served, ASCs would be able to use a familiar process to report quality data using QDCs.

We believe this data submission approach is preferable to other existing options, such as retrospective chart abstraction, which is cumbersome and expensive. In its April 2007 report to the U.S. Senate Committee on Finance (GAO-07-320), the Government Accountability Office (GAO) found the collection of hospital quality data via chart abstraction required six steps, two of which were complex. Hospitals studied reported they had to increase the amount of staff resources devoted to abstracting quality data for the CMS quality measures as the number of measures on which they reported expanded and found no economies of scale as they expanded the scope of quality data abstraction. Study hospitals estimated that staff resources devoted to abstracting data for the CMS quality measures ranged from 0.7 to 2.5 full-time equivalents, typically registered nurses. ASCs are lean, efficient providers, and this level of staff burden would represent a significant hardship.

Given that Medicare-certified ASCs are predominantly small providers, any process that is cumbersome and resource-intensive would have a significant impact on day-to-day operations, and may lead some ASCs to consider foregoing quality reporting as they consider the balance between the costs incurred to report quality measures against the payment penalty for not reporting. As compared to chart abstraction, the use of claims-based QDCs offers a much simpler, yet effective, approach to data submission and we appreciate its inclusion in these proposals. The Accreditation Association for Ambulatory HealthCare (AAAHC) dissents, believing quality data should be developed for all patients, not just Medicare beneficiaries.

We note that CMS has provided physicians with several data reporting options under PQRS. In addition to reporting data to the agency on their Medicare Part B claims, physicians have two other options: reporting via a qualified registry and reporting using a qualified EHR product. The ASC QC has a strong interest is developing an ASC-specific registry. An AHRQ grant application to support the development of an ASC registry was submitted by the industry earlier this year, and the ASC QC has initiated discussions with registry developers with the goal of identifying a registry development partner later this year. Therefore, while the majority of the industry does not currently participate in registry-based data reporting and lacks EHRs, we believe these should remain options CMS should make available to ASCs as the quality reporting program matures.

B. Outcome Measures Endorsed by the NQF for the ASC Setting

CMS has proposed to include the following four outcome measures for the CY 2014 payment determination: Patient Burn (NQF #0263), Patient Fall in the ASC (NQF #0266), Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267), and

Hospital Transfer/Admission (NQF #0265). These outcome measures were developed by ASC QC and have been endorsed by the NQF as facility-level measures of quality appropriate to the ASC setting. By virtue of their specifications, these measures are expected to be applicable to the care provided in all outpatient surgical facilities, allowing broad ASC participation regardless of case mix.

We support the inclusion of these four NQF-endorsed facility-level outcome measures in the ASC Quality Reporting Program. However, we reiterate our concerns regarding the timing of the implementation of data collection and submission for these measures for the CY 2014 payment determination as noted above.

As the agency has stated, the specifications for these measures include all ASC admissions in the denominator statement. We agree with the opinion of the NQF that restricting the denominator to the Medicare beneficiaries for which CMS receives ASC claims would be appropriate for the purposes of the Medicare ASC Quality Reporting Program.

These measures are appropriate for all outpatient surgical facilities. We encourage CMS to consider these measures for other facility providers of outpatient surgical services, such as hospital outpatient departments. Applying the same facility-level quality measures to all settings offering outpatient surgery expands the comparative data available to Medicare beneficiaries and would represent an important step toward full transparency.

C. Process Measures Developed by the ASC QC and Endorsed by the NQF for the ASC Setting

CMS has proposed to include Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264) and Appropriate Surgical Site Hair Removal (NQF #0515) in the measure set for the ASC Quality Reporting Program. These process measures were developed by ASC QC and have been endorsed by the NQF as facility-level measures of quality appropriate to the ASC setting. They evaluate processes believed to be important in minimizing the risk of surgical site infection. While not applicable to all ASCs, such as single-specialty centers that provide gastrointestinal endoscopies, these measures are applicable to a broad range of services in a significant percentage of ASCs.

We support the inclusion of these two ASC QC NQF-endorsed facility-level process measures in the ASC Quality Reporting Program. However, as was the case for the outcome measures discussed above, we have significant concerns regarding the proposed timing of the implementation of data collection and submission for these measures.

As with the ASC QC's outcome measures, these measures were developed envisioning data submission by both claims-based quality codes and registry-based reporting. We support the agency's proposal that these measures be reported on Medicare claims using QDCs. We hope there will be opportunity to make comment on the descriptors CMS develops when they become available.

1. Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

In its discussion of the ASC QC's Prophylactic Intravenous Antibiotic Timing measure at 76 FR 42341, the agency states, "[t]he timing of the antibiotic starts at the time the antibiotic is initiated with a preoperative order". This is not correct. The timing for this measure begins with the initiation of the intravenous infusion of the antibiotic. The timing of the preoperative order does not figure into the calculation of the one-hour (or two-hour, if the antibiotic administered is vancomycin or a fluoroquinolone) time interval prior to the initial surgical incision or the start of the procedure.

We note the agency also states in this proposed rule that "the NQF-endorsed specification for this measure includes all ASC admissions". This statement is incorrect. The measure specifications limit the denominator to "[a]ll ASC admissions with a preoperative order for a prophylactic IV antibiotic for the prevention of surgical site infection".

We agree with the opinion of the NQF that restricting the denominator to the Medicare patients for which CMS receives ASC claims would be appropriate for the purposes of the Medicare ASC Quality Reporting Program**.**

This measure is similar to other antibiotic timing measures already being reported by inpatient hospitals and hospital outpatient departments, but improves feasibility and usability in the ASC setting. While other commenters may suggest CMS implement the hospital measures in the ASC setting, we do not believe this would be appropriate.

For example, the specifications of Timing of Antibiotic Prophylaxis (ID# OP-6), currently reported as part of the Hospital OQR program, have little relevance to the ASC. If the measure were to be applied to the ASC setting, analysis shows that of the 108 procedure codes listed in the denominator code set, only 66 are performed for Medicare beneficiaries in the ASC setting. These 66 services had a volume of only 29,222 in 2009, which is less than 0.5% of the roughly 6.4 million total procedural service volume in 2009. Please see Table 1 in Appendix B for a code-by-code summary of this analysis.

In addition, Timing of Antibiotic Prophylaxis (ID# OP-6) is more complex, largely due to the manner in which the included and excluded populations are constructed to determine the denominator. The ASC QC's measure answers the question of whether or not the prophylactic intravenous antibiotic was delivered timely in a simpler way, and because it imposes less burden, is preferable. The ASC QC's measure could readily be applied in the HOPD setting as well, allowing harmonization across settings and giving consumers the opportunity to compare quality metrics across settings.

2. Appropriate Surgical Site Hair Removal (NQF #0515)

We note the agency states in this proposed rule that "the NQF-endorsed specification for this measure includes all ASC admissions". This is incorrect. The measure specifications limit the denominator to '[a]ll ASC admissions with surgical site hair removal".

We agree with the opinion of the NQF that restricting the denominator to the Medicare patients for which CMS receives ASC claims would be appropriate for the purposes of the Medicare ASC Quality Reporting Program.

This measure is similar to SCIP INF-6 Appropriate Hair Removal, a measure that has been reported by inpatient hospitals. The ASC-specific measure improves feasibility and usability in the ASC setting. While other commenters may suggest CMS implement the hospital measure in the ASC setting, we do not believe this would be appropriate.

As currently specified, the SCIP INF-6 measure has little relevance to services performed in ASCs. When the ICD-9 procedure codes specified for the denominator are crosswalked to their corresponding CPT-4 and HCPCS Level II codes, only 64 services performed for Medicare beneficiaries in the ASC setting are identified. These 64 services had a volume of only 14,895 in 2009, which is less than 0.25% of the roughly 6.4 million total procedural service volume in 2009. Please see Table 2 in Appendix B for a summary of this analysis. This measure does not reflect important service areas for ASCs.

We note the agency has proposed to retire the SCIP INF-6 measure from the Hospital IQR program for FY 2014 based on an analysis indicating the measure is "topped out" in the inpatient setting (76 FR 2460). We concur with the agency's assessment that level of adherence to this infection prevention practice in the outpatient setting is unknown, and makes the measure appropriate for use in ASCs. At this time, there is little data regarding ASC performance in this area, and the available data is subject to sample bias. ASC data for this measure should be collected and reported until broader measurement, as would occur if it is included in the measure set for the ASC quality reporting system as proposed, allows an unbiased determination of ASC performance levels. Hospital inpatient performance levels indicate what may be achieved through measurement and reporting; ASCs should have the opportunity to demonstrate their performance in this area as well.

D. Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin (NQF #0268)

The AMA's Physician Consortium for Performance Improvement developed this process measure as a physician-level performance measure. The ASC QC does not support the inclusion of this measure for collection and reporting under the ASC Quality Reporting Program for a number of reasons.

First, the ASC QC does not believe that physician-level measures are appropriately applied to facilities (the AAAHC holds the minority opinion that physician-level measures could be aggregated to represent facility-level performance). This measure evaluates whether or not a physician prescribed an appropriate prophylactic antibiotic for patients undergoing the surgical procedures included in the denominator statement. Prescribing medications is an individual professional activity that is reserved to physicians and other licensed independent practitioners as determined by State scope of practice determinations. Facilities cannot and do not prescribe medications. Therefore it is not appropriate to hold facilities accountable for prescribing decisions on a patient-by-patient basis. This opinion is consistent with the NQF determination that the level of analysis for this measure is the individual clinician.

Secondly, evaluation of the measure specifications reveals that it has little relevance to the services offered in the ASC setting. Of the 445 codes specified in the current denominator

set, only 52 of those, or less than 12 percent, are services that are currently included in the Medicare list of ASC services. Further analysis shows that those 52 services had a total volume of 10,355 in 2009, which is a miniscule 0.16 percent of the slightly more than 6.4 million total Medicare procedural service volume in 2009. Please see Table 3 in Appendix B. In this proposed rule, CMS states the principles the agency applies in development and use of measures. Among these is the principle that a measure set should reflect "the most important areas of service and measures for that provider/supplier" (76 FR 42337). Our analysis indicates this measure falls short in reflecting the most important service areas for ASCs.

Similarly, the specifications of a related measure, Prophylactic Antibiotic Selection for Surgical Patients (ID# OP-7), which is currently reported as part of the Hospital OQR program, has little relevance to the ASC. The denominator population for this measure is identified as "[p]atients with a *CPT® Code* of selected surgeries as defined in Appendix A, OP Table 6.0". This is the same table used to specify the denominator for OP-6 discussed in section IV.C.1. above, and therefore the analysis yields identical results. Specifically, of the 108 procedure codes listed in the denominator code set, only 66 are performed for Medicare beneficiaries in the ASC setting. These 66 services had a volume of only 29,222 in 2009, which is less than 0.5% of the roughly 6.4 million total procedural service volume in 2009. Please refer to Table 4 in Appendix B for a code-by-code summary of this analysis. This measure, though associated with slightly more volume than the similar PQRS measure, also fails to target a significant area of ASC service.

Finally, physicians currently report the Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin (NQF #0268) measure under the PQRS. We do not see the value in having data for the same measure collected and reported for the same patient by both the physician and the ASC. This potential for duplicate reporting would increase provider burden without adding new information to the pool of quality data available to the public. Because this is a physician-level measure, physicians, not ASCs, are the appropriate submitters of the data for this measure. While ASC reporting would be limited to 52 of the 455 services specified, physicians as a provider group are able to report on all 455 of the service codes specified by the denominator. If the agency wishes to do so, it could report the antibiotic selection data submitted by physicians for this measure by place of service (POS). Using the POS information on claims, CMS could aggregate physician performance data across surgical settings, including the hospital inpatient and outpatient settings, and ASCs.

In addition to the issues outlined above, we do not believe Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin is feasible and usable in the ASC setting. The complexity of the measure specifications would require significant resources to implement in the ASC. We provide a detailed discussion of this matter in Section V.A. below. As efficient, low-cost providers of outpatient surgical services, ASCs are not in a position to absorb the expenses associated with the additional investment of personnel time that would be required to collect and report data for this measure.

E. Surgical Site Infection Rate (NQF #0299)

The ASC QC is 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, so the agency's proposal to adopt the Surgical Site Infection Rate measure for both the ASC Quality Reporting Program and the Hospital OQR program was initially appealing.

The measure was developed by the Centers for Disease Control and Prevention (CDC), tested for the hospital setting and endorsed by the NQF as appropriate for hospital use. Unfortunately, our analysis of this measure revealed specifications that do not translate well to the ASC setting.

The numerator specifications indicate instances of SSI are to be "identified on original admission or upon readmission to the facility of the original operative procedure". This approach to the identification of SSI events is appropriate to the hospital setting, but not to the ASC setting. The maximum length of stay in an ASC is 23 hours and 59 minutes, and the typical stay is much shorter. Therefore, it is unlikely that an SSI would be "identified on the original admission" given the brief length of stay. Further, ASC patients are expected to return to their usual place of residence following surgery, and to visit their surgeon's office for follow-up. If complications – such as a deep incisional or organ/space SSI - develop following the procedure and require admission for management, the patient would not be readmitted to the ASC, but rather to a hospital. As a result, ASCs are not in a position to identify instances of SSI "upon readmission to the facility of the original operative procedure". Taken together, the two specified methods of identifying SSIs – upon original admission and upon readmission – would not be expected to identify any SSIs at all when applied to the ASC setting.

CMS should request that CDC re-specify the measure to include an ASC-appropriate approach to the identification of infections for inclusion in the numerator. The surveillance methodology chosen should be one that could be implemented in a consistent fashion across surgical sites of service. The process should be one that could be expected to lead to the development of facility-specific SSI rates that could be compared on a facility-by-facility basis across providers of outpatient surgical services.

Turning to the denominator, the specifications for this measure identify ten NHSN-defined operative procedure categories as the base population for reporting:

1. Abdominal aortic aneurysm repair (AAA),
2. Coronary artery bypass graft with both chest and donor site incisions (CBGB),
3. Coronary artery bypass graft with chest incision only (CBGC),
4. Colon surgery (COLO),
5. Hip prosthesis (HPRO),
6. Abdominal hysterectomy (HYST),
7. Knee prosthesis (KPRO),
8. Peripheral vascular bypass surgery (PVBY),
9. Rectal surgery (REC), and
10. Vaginal hysterectomy (VHST).

These operative procedure categories have little relevance to the predominant services performed in ASCs. When the ICD-9 procedure codes specified for the denominator are crosswalked to

their corresponding CPT-4 and HCPCS Level II codes, only eleven (11) of these operations are performed for Medicare beneficiaries in the ASC setting. These 11 operations had a service volume of only 791 in 2009, which is approximately 0.012% of the roughly 6.4 million total ASC procedural service volume in 2009. Please see Table 5 in Appendix B for a summary of this analysis. As a result of the manner in which the denominator is specified, the total number of ASCs participating in the measure is likely to be quite low. Those facilities that do participate may only be able to report on a handful of different operative procedures, with the possibility of very low volumes precluding public reporting due to the need to protect confidential health information. We believe the denominator should be revised to include key outpatient operative procedures, thereby improving the opportunity for ASC participation and ensuring that the data developed is more representative of ASC performance.

Data for the measure is to be reported to the CDC's National Healthcare Safety Network (NHSN). CDC personnel have indicated approximately 40 ASCs were participating as of early 2010, indicating limited ASC experience with NHSN. Many hospitals are already familiar with NHSN, but this would represent a new process for most ASCs. 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 a detailed analysis of the required data fields should be undertaken to determine whether all should be retained for outpatient reporting purposes. In addition, NHSN as a whole should be evaluated for opportunities to simplify and streamline the system.

CMS will also need to consider the matter of facility exemptions when implementing this measure. The specifications limit the measure to operative procedures in which a surgeon makes at least one incision through the skin or mucous membrane, including laparoscopic approach, and closes the incision before the patient leaves the operating room. This is entirely appropriate, but means this measure is not applicable to common ASC services such as endoscopies, no-stitch cataract surgeries and pain management injections. In fact, many ASCs do not perform any operations or procedures that would meet the CDC's definition of an operative procedure. These facilities should be exempt from reporting on this measure.

In summary, and in light of the issues with the current measure specifications identified above and the significant burden associated with current NHSN data entry requirements, we recommend CMS postpone implementation of the Surgical Site Infection measure. Taking additional time to resolve important matters - such as identifying outpatient surgical procedures appropriate for SSI tracking to allow greater ASC participation, determining the most effective procedures for outpatient surveillance to allow consistent SSI identification across surgical settings, and streamlining the NHSN system to minimize burden – would be highly desirable and beneficial to all stakeholders. These focus areas are similar to those HHS identified in its recent

draft report entitled "HHS Action Plan to Prevent Healthcare-Associated Infections: Ambulatory Surgical Centers". In this draft report, HHS acknowledges "guidance is lacking as to which procedures should be prioritized for surveillance activities", states "research is needed to understand how definitions and surveillance protocols that have been developed for use in hospital settings can be translated for the ASC environment", and indicates that evaluation of the experiences of ASCs with NHSN in states such as Colorado "will be needed to determine how the system might be tailored to better fit the needs of outpatient settings". We would be pleased to provide any input CMS and CDC might find helpful to facilitate timely resolution of these matters.

Once the needed revisions are adopted, we recommend CMS phase in reporting for the measure as is being done under the Hospital IQR program. Under the hospital program, collection of infection data will be limited to two operative procedure categories for the FY 2014 hospital payment determination and then expanded in subsequent years. A similar approach should be applied to the ASC program. This will allow ASCs to gain experience with NHSN over time and will help ensure a smooth transition as CDC simultaneously manages significant increases in provider enrollment and even greater increases in data volume.

V. Proposed Requirements for Reporting of ASC Quality Data for the CY 2014 Payment Determination

A. Data Collection and Submission Requirements for the Proposed Claims-Based Measures

CMS has not proposed the administrative requirements for the ASC Quality Reporting Program in this proposed rule, though it intends to do so in its CY 2013 OPPS/ASC rulemaking. Consequently, details regarding participation notification are not available. The agency proposes to consider an ASC as participating in the ASC Quality Reporting Program if the ASC includes the QDCs established for finalized claims-based measures on its claim forms during the reporting period for the CY 2014 payment determination. We agree this is a reasonable manner of determining participation.

In order to be eligible for the full CY 2014 ASC annual payment update, an ASC would be required to submit complete data on finalized claims-based measures by submitting the appropriate QDCs on the ASC's Medicare claims for services furnished during the reporting period. CMS states the completeness of the data submission for claims-based measures "would be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claim". This definition of complete data is somewhat vague.

The denominator for each of the proposed claims-based outcome measures (Patient Burn, Patient Fall in the ASC, Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and Hospital Transfer/Admission) is "all ASC admissions". To be complete, the appropriate QDC for each one of these measures should be submitted on each Medicare claim for dates of service during the reporting period, including claims for discontinued services. The following illustrative codes include recommended descriptors for each measure.

Patient Burn
Gxxx1 – Patient documented to have received a burn prior to discharge
Gxxx2 – Patient documented not to have received a burn prior to discharge

Patient Fall in the ASC
Gxxx3 – Patient documented to have experienced a fall within the ASC
Gxxx4 – Patient documented not to have experienced a fall within the ASC

Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
Gxxx5 – Patient documented to have experienced a wrong site, wrong side, wrong patient, wrong procedure or wrong implant event
Gxxx6 – Patient documented not to have experienced a wrong site, wrong side, wrong patient, wrong procedure or wrong implant event

Hospital Transfer/Admission
Gxxx7 – Patient documented to have required a hospital transfer or hospital admission upon discharge from the ASC
Gxxx8 – Patient documented not to have required a hospital transfer or hospital admission upon discharge from the ASC

For data submission to be complete, each Medicare claim should include Gxxx1 or Gxxx2, and Gxxx3 or Gxxx4, and Gxxx5 or Gxxx6, and Gxxx7 or Gxxx8.

Because the occurrence of any of these events is unusual, reporting alternatives such as sampling or reporting a predetermined number of consecutive patients could lead to inaccurate information, and are not recommended.

The data submission protocol for the proposed Prophylactic IV Antibiotic Timing measure must account for two items. First, the specifications limit the denominator to "[a]ll ASC admissions with a preoperative order for a prophylactic IV antibiotic for the prevention of surgical site infection". It is well recognized that both patient factors and procedure factors play a role in determining the risk of SSI and the need for prophylaxis. We believe it is important to measure timely administration in all eligible circumstances in order to provide accurate performance data. As a result, the measure denominator does not identify the population for measurement using procedure codes because this would not completely define the population for whom a preoperative order for IV antibiotic prophylaxis could be given.

To allow for, and subsequently assess, complete data submission for this measure, a set of three QDCs would be needed: one to describe timely administration of prophylaxis, a second to describe untimely administration of prophylaxis, and a third to describe the circumstance in which no prophylaxis is ordered preoperatively. Sample G-codes with recommended descriptors are provided below.

Gxxx9 – Patient with a preoperative order for IV antibiotic prophylaxis for surgical site infection documented as initiated on time
Gxx10 – Patient with a preoperative order for IV antibiotic prophylaxis for surgical site

infection documented as not initiated on time
Gxx11 – Patient without a preoperative order for IV antibiotic prophylaxis for surgical site infection

The second item to be considered is that the measure is not applicable to all ASCs, as previously noted. While it would be possible to require those facilities to submit the sample code Gxx11 on all their claims, that approach would impose unnecessary burden for affected ASCs. Instead, we recommend CMS develop a G-code to be submitted by ASCs that do not administer intravenous antibiotic prophylaxis for SSI. This code would allow the ASC to claim an exemption from data submission for this measure. We suggest the following descriptor: Gxxxx – This facility does not administer intravenous antibiotic prophylaxis for SSI. Submission of such a code would trigger a confirmation notice to the facility. Non-exempt facilities would report Gxxx9, Gxx10 or Gxx11 on all Medicare claims.

The data submission protocol for the proposed Appropriate Surgical Site Hair Removal measure must account for the same two items. The specifications limit the denominator to "[a]ll ASC admissions with surgical site hair removal". Again, both patient factors and procedure factors play a role in determining the need for hair removal and it is important to measure all eligible circumstances in order to provide accurate performance data. Procedure codes are not used to define the denominator because this would not completely identify the population for whom hair removal might be performed.

Similar to the IV antibiotic prophylaxis measure, a set of three QDCs would be needed to allow for, and subsequently assess, complete data submission: one to describe appropriate surgical site hair removal, a second to describe inappropriate surgical site hair removal, and a third to describe circumstances in which no hair removal is performed at all or the patient performs his or her own surgical site hair removal (a denominator exclusion). Sample G-codes with recommended descriptors follow:

Gxx12 – Patient with surgical site hair removal documented as performed with a razor or clippers in the scrotal area, or with clippers or depilatory cream at all other surgical sites
Gxx13 – Patient with surgical site hair removal documented as performed with a razor at surgical sites other than the scrotal area
Gxx14 – Patient documented to have no surgical site hair removal or to have performed his or her own surgical site hair removal

Again, this is a measure that is not applicable to all ASCs. Instead of requiring those facilities that do not perform surgical site hair removal at all to submit the sample code Gxx14 on all their claims, CMS should develop a G-code to be submitted by these ASCs claiming an exemption from data submission for this measure. We suggest the following descriptor: Gxxxx – This facility does not perform surgical site hair removal. Submission of such a code would trigger a confirmation notice to the facility. Non-exempt facilities would report Gxx12, Gxx13 or Gxx14 on all Medicare claims.

For both measures, facilities claiming exemption could be readily audited by reviewing their Medicare claims. Any facility submitting codes for services that would typically require antibiotic prophylaxis or hair removal could be flagged for an in-depth review.

As discussed in detail in IV.D. above, we oppose the inclusion of the proposed Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin in the measure set for ASCs for several reasons. The matter of complete data submission for this measure raises another concern we have reserved for discussion here. The denominator for this measure is specified using procedure codes. As the agency knows, a procedure code may not be assigned for billing until the documentation for the case has been reviewed to determine appropriate code assignment. Because this documentation is completed after the procedure itself has been completed, and the CPT or HCPCS code for billing is assigned after review of that documentation, it is unlikely that all cases eligible for inclusion in the denominator would be identified in advance. In order to ensure it has submitted complete data for this measure, the ASC would need to have a process in place to retrospectively identify and review all claims that include the codes specified in the denominator to determine if a QDC has been assigned too. Because this is done retrospectively, it adds burden. The same is true of the related measure, Prophylactic Antibiotic Selection for Surgical Patients (ID# OP-7). By comparison, the ASC QC process measures have been specified in a manner that allows for concurrent data collection, thereby reducing provider burden.

B. Data Submission Deadlines for the Proposed Surgical Site Infection Rate Measure

We are concerned by CMS's proposal that timing of data submission "begin with infection events occurring on or after January 1, 2013 through June 30, 2013". The CDC defines an SSI as an infection that "occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place". The proposed timing is stated relative to "infection events", meaning that the index operative procedure for the January 1 through June 30, 2013 data submission period could take place as early as January 1, 2012 if an implant is left in place. As stated previously, we do not support the implementation of ASC data collection and submission requirements until October 1, 2012.

In addition, tying the requirement to "infection events" is potentially confusing. The CDC SSI definition uses the date of the operative procedure as the reference point for the reporting periods specified in the measure. For consistency and clarity, CMS should consider restating its proposal in relation to the date of the operative procedure rather than the date of an "infection event". The reporting requirements must take the one-year surveillance period for operative procedures involving implants into consideration.

As previously noted, data submission for the proposed Surgical Site Infection Rate measure should be delayed until the needed revisions in the measure specifications discussed above are made.

VI. Quality Data Reporting Mechanisms and Quality Measures Proposed for the CY 2015 Payment Determination

A. Safe Surgery Checklist Use

CMS has proposed to include an assessment of safe surgery checklist use as a structural measure for inclusion in the ASC measure set for the 2015 payment determination. It is our understanding that CMS is not suggesting all ASCs use the same safe surgery checklist, but rather any checklist that "covers effective communication and helps ensure that safe practices are being performed at three critical perioperative periods: prior to administration of anesthesia, prior to incision, and prior to the patient leaving the operating room". We appreciate the flexibility the agency has shown in not prescribing the use of a specific checklist.

It is also our understanding that the agency intends to apply this measure to all ASCs. If this is the case, we believe it would be important for the agency revise the proposed statement of the measure so this intent is clearer. We suggest the agency refer to the checklist as a "safe surgery/procedure checklist" and modify its statement of the measure's purpose to the following: "to assess whether ASCs are using a safe surgery/procedure checklist that addresses effective communication and helps ensure that safe practices are being performed at three critical perioperative or periprocedural periods: prior to the administration of anesthesia or sedation, prior to incision or the beginning of the procedure, and prior to the patient leaving the operating or procedure room". These modifications could be made for the other providers for which CMS proposes to apply this measure.

We note this measure is intended to assess whether or not an ASC uses a safe surgery checklist as a matter of routine, and that CMS does not intend the measure to be reported in conjunction with individual procedures. We agree with this approach to measurement.

The proposed time period of January 1, 2012 through December 31, 2012 is of significant concern to us and is not something we can support, as it does not allow a sufficient period of advance notice on the heels of the publication of the CY 2012 OPPS/ASC final rule. CMS should modify this to January 1, 2013 through December 31, 2013 and delay the data submission period until early 2014. We also recommend a 60-day time period for data submission rather than the proposed 45-day window.

The proposed data submission for this measure via the QualityNet website adds complexity to the ASC Quality Reporting Program that is not needed. Please refer to VI.C. below for detailed comments on this matter.

B. ASC Facility Volume on Selected ASC Surgical Procedures

CMS has proposed a second structural measure for the CY 2015 payment determination: ASC Facility Volume Data on Selected ASC Surgical Procedures. As proposed, the measure would require an ASC to report its all-patient volume data for six very broad categories of procedures. This measure is not compelling: it is poorly specified and imposes provider burden without providing meaningful information to the consumer.

The term "volume" is ambiguous in the context of this measure. Does volume refer to the number of patients, the number of cases, or the number of procedures for the category? How are situations such as multiple visits by an individual patient for a series of patient management injections or for bilateral cataract procedures to be counted? How are cases involving bilateral procedures or those performed on multiple spinal levels to be counted? Are secondary

procedures to be counted in addition to the primary procedure? These are just a few of the methodological issues that would need to be addressed in order to create a clearly specified measure.

The consensus regarding measures of surgical volume is that they are best used to identify very low-volume providers, based on the belief this group tends to have, on average, the worst outcomes, although the strength of the association varies significantly. This information might aid consumer choice. Endorsed measures of surgical volume focus on narrowly defined types of procedures such as esophageal resection, aortic aneurysm repair and esophageal resection. Yet the proposed measure would look at very large, diverse categories of services. We do not believe there is any meaningful consumer information to be derived from this type of aggregated data. To illustrate this point, we pose the following sample questions regarding the data from each of the six proposed categories:

- How would a consumer needing a hernia repair use the data in the "Gastrointestinal" category to distinguish a facility that performs a high volume of gastrointestinal endoscopies from a facility that performs a high volume of general surgery?

- How would a consumer planning a corneal transplant determine if a facility performed a high or low volume of that operation by reviewing the data in the "Eye" category?

- How would a consumer planning carpal tunnel surgery distinguish a facility with a high volume of carpal tunnel repairs from a facility with a high volume of pain management injections by looking the data in the "Nervous System" category?

- How would a consumer needing a bunionectomy determine the relative volume (if any) of podiatric surgery as compared to arthroscopic surgery in a facility with high volume in the "Musculoskeletal" category?

- How would a consumer planning breast surgery determine what volume of breast surgery a facility performed by looking at the "Skin" category data? Would the consumer even realize that breast procedures were included in this category?

- How would a consumer planning prostate surgery determine whether a facility with high volume in the "Genitourinary" category performed a high volume of prostate surgery as compared to a high volume of hysteroscopies and laparoscopic gynecologic surgeries, which would be irrelevant to his decision?

These few examples illustrate how unhelpful - and potentially misleading - the proposed aggregate volume data could be from the consumer perspective.

On the other hand, the approach CMS has taken with its development of surgical volume data for its Hospital Compare website is helpful. Here, CMS offers the consumer an opportunity to choose from among many common inpatient operations, and then displays the volume of Medicare patients treated by each facility. This is the type of information that could be useful to a consumer trying to determine if a facility performs a procedure of interest, and if so, how often

it performs that service for the Medicare cohort. The consumer also has the opportunity to directly compare the volume for a procedure of interest across different facilities. The direct comparability of this data is assured because the agency uses a consistent process in developing these volume figures.

CMS should use the same approach to develop ASC volume data. This means sacrificing all patient data, but the results are clearly superior, and are achieved with absolutely no additional burden to the provider. Displaying data for 20 to 50 of the most common ASC procedures would cover the significant majority of ASC services.

In summary, we are strongly opposed to the inclusion of the ASC Facility Volume on Selected ASC Surgical Procedures measure in the ASC measure set, but have no concerns with the type of volume data developed and presented at Hospital Compare. We urge the agency to abandon the ASC Facility Volume on Selected ASC Surgical Procedures measure and adopt an approach to ASC volume that allows for consistent data development and the publication of meaningful consumer information.

C. Data Submission Via the QualityNet Website

CMS has proposed ASCs submit data for the proposed Surgical Safety Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures structural measures via the agency's QualityNet website. If finalized as proposed, this means ASCs must manage three different processes for submitting quality measure data to CMS for the CY 2015 payment determination. Use of the QualityNet website requires a mandatory registration process, meeting system requirements, installation of software, establishing accounts for each user, and specialized training to allow submission of the specified data in the prescribed format.

We believe a claims-based data submission method should be developed for the proposed Surgical Safety Checklist Use measure. This method should be based on the approach that CMS has developed and currently uses under the PQRS that allows physicians to make declarations to the agency via claims using HCPCS Level II G-codes. We refer specifically to G-codes such as those in the G8485-G8493 series, which allow the physician to communicate their intent to report quality data for selected measures groups. For example, physicians may report their intent to submit data on the PQRS perioperative care measures using the code G8492, I intend to report the perioperative care measures group. While this code is used to report intent, we believe a similar approach should be used to submit data for the proposed Surgical Safety Checklist Use measure via G-codes. We suggest the following:

Gxx15 - This facility employed a surgical/procedural safety checklist for the entire reporting period
Gxx16 - This facility did not employ a surgical/procedural safety checklist for the entire reporting period

An ASC would report the appropriate code on a claim during the designated data submission period for the measure.

We recognize this approach is not feasible for the proposed ASC Facility Volume Data on Selected ASC Surgical Procedures measure. However, as discussed in VI.B. above, there are compelling reasons why this measure should not be finalized.

In summary, we support the inclusion of the Safe Surgery Checklist Use measure with the modifications we have suggested in the CY 2015 payment determination measure set and recommend CMS employ claims-based data submission for this measure instead of the proposed use of QualityNet. We do not support the proposed ASC Facility Volume on Selected ASC Surgical Procedures, but rather CMS-developed Medicare volume data. Combined, these two recommendations obviate the need for data submission via QualityNet. Eliminating one of the three proposed methods of data submission would be an important step in streamlining and simplifying the ASC data submission process, and would reduce ASC burden.

If the agency determines it will not adopt these recommendations, we strongly recommend an implementation delay to allow ASCs the opportunity to become familiar with submission of quality data using QDCs on claims before having to turn their attention to learning an entirely new data submission process via QualityNet.

If the agency finalizes the use of QualityNet for ASC data submission, we also wish to highlight a potential issue that has been brought to our attention. As proposed, ASC use of QualityNet for data submission would occur on an infrequent basis - a 45-day period during each calendar year. It is our understanding that QualityNet accounts are automatically deactivated after a 120-day period of inactivity, and that account reactivation is a multi-step process. If the agency decides to require ASC use of QualityNet for data submission for the proposed structural measures, we recommend CMS take the necessary steps to avert widespread data submission issues related to account deactivation.

VII. Quality Data Reporting Mechanisms and Quality Measures Proposed for the CY 2016 Payment Determination

A. Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF #0431)

This measure has been proposed for inclusion in the Hospital IQR, Hospital OQR and ASC Quality Reporting Programs. We support the public reporting of vaccination rates among healthcare personnel. However, we are concerned regarding the magnitude of the data collection and submission burden that would be imposed if this measure were to be implemented as currently specified. Currently, the NHSN protocol requires detailed data on every healthcare worker, which is defined as an individual who works in the facility, whether paid or unpaid, and includes all employees, contractors, students, trainees, volunteers and physicians. The broad scope of this definition adds significantly to the data collection and submission burden.

We are pleased to note that the agency, in response to public comments on the FY 2012 Hospital IPPS proposed rule, has addressed these concerns for the hospital setting. CMS states the CDC is revising the measure to eliminate unnecessary burden by adding facility-level aggregate reporting of healthcare personnel influenza vaccination coverage to NHSN. In addition, the scope of the proposed measure is being revised to limit reporting to employees and

credentialed non-employees. We believe these are important and positive steps toward reducing facility data collection and submission burdens that do not detract from meaningful public reporting on this topic. We urge the agency to adopt these revisions when applying the measure to the ASC setting. We look forward to the opportunity to comment on the revised measure in future communications.

VIII. ASC Measure Topics For Future Consideration

The ASC QC continues to evaluate and develop other potential outpatient surgery quality measures, including topic areas such as patient experience, venous thromboembolism, normothermia and hospital admission in the 24 hours after discharge.

We are very interested in the development of a patient experience measure for outpatient surgical facilities similar to CAHPS survey tools currently in existence for other providers. We have developed a draft survey instrument, but currently lack the resources to complete the necessary testing. We continue to explore doing so in partnership with either CMS or AHRQ.

We note CMS has included the CAHPS Surgical Care Survey on its list of measures and measurement topics under consideration for future payment determinations. This survey was developed by the American College of Surgeons and solicits patient feedback regarding the surgeon (and anesthesiologist, if applicable) and the surgeon's office staff, including health providers, clerks and receptionists. Because it does not include questions that address the facility where the surgery was performed or the staff at that facility, we do not believe it is an appropriate survey for assessing patient experience in the ASC.

IX. Technical Specification Updates

CMS has proposed to provide technical specifications for the ASC Quality Reporting Program measures in a specifications manual posted on the CMS QualityNet website. The manual would include, where appropriate, links to technical specifications hosted on external third-party websites. The agency has also proposed to maintain the technical specifications using the same process it employs for the Hospital OQR Program and to allow the same advance notice periods before any changes become effective for purposes of reporting. Accordingly, ASCs could expect the release of an updated specifications manual every six months, with any interim addenda released on an as needed basis. These releases would occur with at least 3 months of advance notice for substantial technical specification changes such as changes to ICD–9, CPT, and HCPCS codes, and with at least 6 months of advance notice for changes to data elements that would require significant systems changes. We support this proposal.

X. Publication of ASC Quality Reporting Program Data

The ASC QC supports transparency and welcomes a fair presentation of ASC quality and cost information that could assist consumers in making informed health care decisions. Consumers should be able to access this information on websites that are organized to allow easy comparisons, while also protecting the rights of providers by assuring that the information made available is correct, current, and clearly presented.

CMS has proposed to display data from the ASC Quality Reporting Program on a CMS website, and to present that information at the level of the CMS Certification Number (CCN). The agency has also proposed to provide ASCs an opportunity to preview any data to be made public. In addition to allowing ASCs to preview the data, CMS should also provide contact information for program content areas experts that ASCs can contact to ask questions or raise concerns with any information to be posted prior to its publication. There should also be a provider narrative section for each provider-specific item presented to the consumer. This narrative box would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented. In addition to reporting quality data, other useful information such as facility accreditation status should be made available to the consumer.

We look forward to the more detailed proposals on the publication of ASC quality program data the agency intends to publish in later rulemaking. We encourage CMS to issue these proposals at the earliest available opportunity.

XI. Additional Considerations

CMS intends to propose administrative requirements, data validation and data completeness requirements, reconsideration and appeals processes and payment determination reporting requirements in the CY 2013 OPPS/ASC proposed rule. We offer the following recommendations as the agency develops these additional proposals.

A. Exemptions

Given the variability in ASC case mix, it can reasonably be anticipated that there will continue to be instances in which measures implemented under the ASC Quality Reporting Program will not apply to all ASCs, as has been seen with a number of the quality measures CMS proposed in this rulemaking. The agency should consider the need for exemptions based on case mix as a matter of routine as it evaluates and proposes additional quality measures for inclusion in the ASC Quality Reporting Program. We also foresee the potential need for low volume exemptions when measures specify selected services.

B. Alternative Reporting Mechanisms

The ASC QC is actively pursuing the development of an ASC registry. CMS should allow ASCs the option of participating in the quality reporting program by reporting quality data to a qualified registry, which would in turn submit data on behalf of the ASC for a particular program year.

In addition to claims-based reporting and registry-based reporting, ASCs should also have the option of submitting quality data to CMS through an EHR-based reporting mechanism. While the penetration of EHRs in the ASC industry is limited at this time, there are centers that have implemented this technology that could benefit from this reporting option.

C. Feedback and Benchmarking

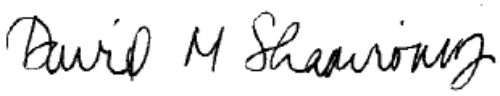
Following the end of each the reporting periods, CMS should provide confidential feedback reports based on the quality measures reported by individual ASCs for services provided during the reporting period. These reports should be provided at the CCN level and should address topics such as measure participation, data completeness, QDC submission errors and measure performance detail.

In addition to its use for public reporting purposes, the data collected through the ASC Quality Reporting Program should also be made available to participating ASCs for benchmarking purposes. We urge CMS to develop a process for establishing ASC benchmarks on a measure-by-measure basis. This information would be valuable as individual ASCs assess their performance relative to their peers and determine if performance improvement activities are needed. The Hospital-Specific Reports (HSRs) CMS currently prepares for individual hospitals participating in the Hospital IQR program could serve as a model.

***

Thank you for considering these comments. We look forward to continuing our dialogue with the agency on the ASC Quality Reporting Program. We would be happy to assist with questions or provide additional information at your request.

Sincerely,



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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
National Surgical Care
Nueterra Healthcare
Outpatient Ophthalmic Surgery Society
Surgical Care Affiliates
Symbion
The Joint Commission
United Surgical Partners International

Appendix B

Table 1
Summary of Analysis of Timing of Antibiotic Prophylaxis (ID# OP-6) Specifications: Codes Covered in the ASC Setting and Associated Volume

Code	Short Descriptor	2009 ASC Volume
21454	Treat lower jaw fracture	0
21461	Treat lower jaw fracture	0
21462	Treat lower jaw fracture	3
21465	Treat lower jaw fracture	0
27440	Revision of knee joint	0
27441	Revision of knee joint	2
27442	Revision of knee joint	2
27443	Revision of knee joint	1
27446	Revision of knee joint	516
27758	Treatment of tibia fracture	7
27759	Treatment of tibia fracture	2
28293	Correction of bunion	712
28415	Treat heel fracture	47
28420	Treat/graft heel fracture	0
28445	Treat ankle fracture	12
28465	Treat midfoot fracture each	28
28485	Treat metatarsal fracture	627
28505	Treat big toe fracture	81
28525	Treat toe fracture	53
28531	Treat sesamoid bone fracture	7
28555	Repair foot dislocation	9
28585	Repair foot dislocation	44
28615	Repair foot dislocation	82
28645	Repair toe dislocation	359
28675	Repair of toe dislocation	30
28705	Fusion of foot bones	8
28715	Fusion of foot bones	58
28725	Fusion of foot bones	206
28730	Fusion of foot bones	175
28735	Fusion of foot bones	23
28737	Revision of foot bones	57
33206	Insertion of heart pacemaker	4
33207	Insertion of heart pacemaker	8
33208	Insertion of heart pacemaker	86
33212	Insertion of pulse generator	49

33213	Insertion of pulse generator	151
33214	Upgrade of pacemaker system	0
33215	Reposition pacing-defib lead	3
33218	Repair lead pace-defib one	1
33220	Repair lead pace-defib dual	0
33222	Revise pocket pacemaker	8
33223	Revise pocket for defib	0
33233	Removal of pacemaker system	190
33234	Removal of pacemaker system	2
33235	Removal pacemaker electrode	1
33240	Insert pulse generator	29
33241	Remove pulse generator	30
33249	Eltrd/insert pace-defib	17
36830	Artery-vein nonautograft	326
43130	Removal of esophagus pouch	0
43246	Place gastrostomy tube	1745
54400	Insert semi-rigid prosthesis	2
54401	Insert self-contd prosthesis	1
54405	Insert multi-comp penis pros	130
54408	Repair multi-comp penis pros	23
54410	Remove/replace penis prosth	32
54416	Remv/repl penis contain pros	3
55700	Biopsy of prostate	20622
55705	Biopsy of prostate	30
57288	Repair bladder defect	1999
58550	Laparo-asst vag hysterectomy	9
58552	Laparo-vag hyst incl t/o	34
62230	Replace/revise brain shunt	2
62360	Insert spine infusion device	14
62361	Implant spine infusion pump	21
62362	Implant spine infusion pump	499

TOTAL PROCEDURE VOLUME: 29,222

Table 2
Summary of Analysis of SCIP INF-6 Appropriate Hair Removal Specifications: Codes Covered in the ASC Setting and Associated Volume

Code	Short Descriptor	2009 ASC Volume
13160	Late closure of wound	586
27437	Revise kneecap	15
27438	Revise kneecap with implant	5
27446	Revision of knee joint	516
29862	Hip arthr0 w/debridement	201
29914	Hip arthro w/femoroplasty	0
29915	Hip arthro acetabuloplasty	0
29916	Hip arthro w/labral repair	0
32420	Puncture/clear lung	0
43240	Esoph endoscope w/drain cyst	6
43250	Upper GI endoscopy/tumor	2326
43251	Operative upper GI endoscopy	8236
43258	Operative upper GI endoscopy	2048
43267	Endo cholangiopancreatograph	0
43268	Endo cholangiopancreatograph	61
43269	Endo cholangiopancreatograph	132
43271	Endo cholangiopancreatograph	13
43272	Endo cholangiopancreatograph	0
43273	Endoscopic pancreatoscopy	6
43761	Reposition gastrostomy tube	4
43886	Revise gastric port open	4
43887	Remove gastric port open	1
43888	Change gastric port open	3
44340	Revision of colostomy	26
44370	Small bowel endoscopy/stent	2
44379	S bowel endoscope w/stent	1
44383	Ileoscopy w/stent	21
44397	Colonoscopy w/stent	0
45000	Drainage of pelvic abscess	14
45005	Drainage of rectal abscess	10
45020	Drainage of rectal abscess	1
45160	Excision of rectal lesion	7
45321	Proctosigmoidoscopy volvul	0
45327	Proctosigmoidoscopy w/stent	0
45345	Sigmoidoscopy w/stent	1
45387	Colonoscopy w/stent	12

45541	Correct rectal prolapse	3
46706	Repr of anal fistula w/glue	3
46707	Repair anorectal fist w/plug	0
47510	Insert catheter bile duct	1
47511	Insert bile duct drain	0
47564	Laparo cholecystectomy/explr	7
49326	Lap w/omentopexy add-on	1
49402	Remove foreign body adbomen	7
49418	Insert tun ip cath perc	0
49419	Insert tun ip cath w/port	1
49426	Revise abdomen-venous shunt	2
50727	Revise ureter	0
50947	Laparo new ureter/bladder	1
50948	Laparo new ureter/bladder	0
51880	Repair of bladder opening	3
52355	Cystouretero w/excise tumor	39
52649	Prostate laser enucleation	0
55920	Place needles pelvic for rt	4
57320	Repair bladder-vagina lesion	1
57530	Removal of cervix	1
58550	Laparo-asst vag hysterectomy	9
58552	Laparo-vag hyst incl t/o	34
58661	Laparoscopy remove adnexa	339
58662	Laparoscopy excise lesions	177
59150	Treat ectopic pregnancy	1
59151	Treat ectopic pregnancy	0
61330	Decompress eye socket	3
61770	Incise skull for treatment	0
	TOTAL PROCEDURE VOLUME:	**14,895**

Table 3
Summary of Analysis of Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin (NQF #0268) Specifications: Codes Covered in the ASC Setting and Associated Volume

Code	Short Descriptor	2009 ASC Volume
15734	Muscle-skin graft trunk	275
15738	Muscle-skin graft leg	194
19301	Partial mastectomy	3026
19302	P-mastectomy w/ln removal	570
19303	Mast simple complete	243
19304	Mast subq	77
19366	Breast reconstruction	39
21805	Treatment of rib fracture	1
22524	Percut kyphoplasty lumbar	472
27440	Revision of knee joint	0
27441	Revision of knee joint	2
27442	Revision of knee joint	2
27443	Revision of knee joint	1
27446	Revision of knee joint	516
27704	Removal of ankle implant	13
27758	Treatment of tibia fracture	7
27759	Treatment of tibia fracture	2
27766	Optx medial ankle fx	111
27769	Optx post ankle fx	6
27792	Treatment of ankle fracture	438
27814	Treatment of ankle fracture	319
28192	Removal of foot foreign body	205
28193	Removal of foot foreign body	49
28415	Treat heel fracture	47
28420	Treat/graft heel fracture	0
28445	Treat ankle fracture	12
28465	Treat midfoot fracture each	28
28485	Treat metatarsal fracture	627
28505	Treat big toe fracture	81
28525	Treat toe fracture	53
28531	Treat sesamoid bone fracture	7
28555	Repair foot dislocation	9
28585	Repair foot dislocation	44
28615	Repair foot dislocation	82
28645	Repair toe dislocation	359

28675	Repair of toe dislocation	30
28705	Fusion of foot bones	8
28715	Fusion of foot bones	58
28725	Fusion of foot bones	206
28730	Fusion of foot bones	175
28735	Fusion of foot bones	23
28737	Revision of foot bones	57
36830	Artery-vein nonautograft	326
43130	Removal of esophagus pouch	0
43653	Laparoscopy gastrostomy	3
43870	Repair stomach opening	45
44100	Biopsy of bowel	0
47560	Laparoscopy w/cholangio	1
47561	Laparo w/cholangio/biopsy	4
49568	Hernia repair w/mesh	1499
62230	Replace/revise brain shunt	2
64746	Incise diaphragm nerve	1
	TOTAL PROCEDURE VOLUME:	**10,355**

Table 4
Summary of Analysis of Prophylactic Antibiotic Selection for Surgical Patients (ID# OP-7) Specifications: Codes Covered in the ASC Setting and Associated Volume

Code	Short Descriptor	2009 ASC Volume
21454	Treat lower jaw fracture	0
21461	Treat lower jaw fracture	0
21462	Treat lower jaw fracture	3
21465	Treat lower jaw fracture	0
27440	Revision of knee joint	0
27441	Revision of knee joint	2
27442	Revision of knee joint	2
27443	Revision of knee joint	1
27446	Revision of knee joint	516
27758	Treatment of tibia fracture	7
27759	Treatment of tibia fracture	2
28293	Correction of bunion	712
28415	Treat heel fracture	47
28420	Treat/graft heel fracture	0
28445	Treat ankle fracture	12
28465	Treat midfoot fracture each	28
28485	Treat metatarsal fracture	627
28505	Treat big toe fracture	81
28525	Treat toe fracture	53
28531	Treat sesamoid bone fracture	7
28555	Repair foot dislocation	9
28585	Repair foot dislocation	44
28615	Repair foot dislocation	82
28645	Repair toe dislocation	359
28675	Repair of toe dislocation	30
28705	Fusion of foot bones	8
28715	Fusion of foot bones	58
28725	Fusion of foot bones	206
28730	Fusion of foot bones	175
28735	Fusion of foot bones	23
28737	Revision of foot bones	57
33206	Insertion of heart pacemaker	4
33207	Insertion of heart pacemaker	8
33208	Insertion of heart pacemaker	86
33212	Insertion of pulse generator	49

33213	Insertion of pulse generator	151
33214	Upgrade of pacemaker system	0
33215	Reposition pacing-defib lead	3
33218	Repair lead pace-defib one	1
33220	Repair lead pace-defib dual	0
33222	Revise pocket pacemaker	8
33223	Revise pocket for defib	0
33233	Removal of pacemaker system	190
33234	Removal of pacemaker system	2
33235	Removal pacemaker electrode	1
33240	Insert pulse generator	29
33241	Remove pulse generator	30
33249	Eltrd/insert pace-defib	17
36830	Artery-vein nonautograft	326
43130	Removal of esophagus pouch	0
43246	Place gastrostomy tube	1745
54400	Insert semi-rigid prosthesis	2
54401	Insert self-contd prosthesis	1
54405	Insert multi-comp penis pros	130
54408	Repair multi-comp penis pros	23
54410	Remove/replace penis prosth	32
54416	Remv/repl penis contain pros	3
55700	Biopsy of prostate	20622
55705	Biopsy of prostate	30
57288	Repair bladder defect	1999
58550	Laparo-asst vag hysterectomy	9
58552	Laparo-vag hyst incl t/o	34
62230	Replace/revise brain shunt	2
62360	Insert spine infusion device	14
62361	Implant spine infusion pump	21
62362	Implant spine infusion pump	499
	TOTAL PROCEDURE VOLUME:	**29,222**

Table 5

Summary of Analysis of Surgical Site Infection Rate (NQF #0299) Specifications: Codes Covered in the ASC Setting and Associated Volume

Code	Short Descriptor	2009 ASC Volume
27437	Revise kneecap	15
27438	Revise kneecap with implant	5
27446	Revision of knee joint	516
37790	Penile venous occlusion	0
44340	Revision of colostomy	26
45100	Biopsy of rectum	179
45160	Excision of rectal lesion	7
45171	Exc rect tum transanal part	0
45172	Exc rect tum transanal full	0
58550	Laparo-asst vag hysterectomy	9
58552	Laparo-vag hyst incl t/o	34
	TOTAL PROCEDURE VOLUME:	**791**