ASC Quality Collaboration

September 14, 2007

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P; Quality Data

Dear Acting Administrator Weems:

On behalf of the ASC Quality Collaboration, a cooperative effort of organizations and companies interested in ensuring that ASC quality data is appropriately developed and reported, please accept the following comments regarding CMS-1392-P, Section XVII. Reporting Quality Data for Annual Payment Rate Updates as it pertains to ambulatory surgical centers (ASCs). Early in 2006, the ASC Quality Collaboration came together to initiate the process of developing standardized ASC quality measures. The organization's stakeholders include ASC corporations, ASC associations, professional societies, accrediting bodies and government entities. We are pleased that Section 109 of the Tax Relief and Health Care Act of 2006 (TRHCA) will afford ASCs the opportunity to share standardized quality indicators with CMS and the public.

We appreciate the consideration CMS demonstrated in its decision to introduce quality measures for ASC reporting beginning January 1, 2009. With the implementation of the revised ASC payment system in 2008, the ASC community will face a significant transition and we are pleased additional requirements will not be introduced simultaneously. The current absence of any nationally endorsed ASC quality measures designed for public reporting and accountability would have been a further barrier to implementation in 2008. However, we anticipate ASC quality measures will be endorsed by the National Quality Forum by the end of the year and will be available for implementation in 2009.

I. Quality Measures for Outpatient Surgery

The quality of facility services for outpatient surgery is most appropriately evaluated by measures specifically designed to assess processes or outcomes of care germane to the specific services rendered by facilities that provide ambulatory surgical services. It is crucial that measures selected for the evaluation of facility quality reflect processes or outcomes of care that are attributable to and reasonably the responsibility of the facility itself -- its staff, the equipment, the environment of care offered to its patients, and its roles in the delivery of patient care.

When the ASC Quality Collaboration was formed, our clinicians undertook a detailed evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. Though several existing measures addressed surgical care, none had been developed specifically for the ambulatory surgical center setting. In fact, many of these measures are specific to procedures that are either uncommonly performed in outpatient facilities, or not performed at all for Medicare beneficiaries in the outpatient surgical setting. Other measures expressly exclude patients with a stay of less than 24 hours, effectively eliminating the entire ASC patient population. Still other measures focus on processes of care that are specific responsibilities of physicians, such as the selection and ordering of antibiotics.

Finding no measures designed for public reporting and accountability specific to facilities performing outpatient surgery, the ASC Quality Collaboration developed a number of facility-level measures of ASC quality. These measures were based on those already commonly used by the ASC community for internal quality assessment and external benchmarking. After refining these standardized measures, the ASC Quality Collaboration piloted them in a sample of twenty ASCs and was able to confirm their feasibility and usability. To date, these measures have been reviewed by a technical advisory panel and a steering committee of the National Quality Forum (NQF). As a result of these evaluations, five measures have been recommended for endorsement and have recently been open to public and NQF member comment. We anticipate that final action on these measures could be taken as early as November 2007.

Of the five measures, four are outcome measures that have applicability to all outpatient surgical facilities and thereby ensure broad facility participation regardless of case mix. These measures focus on 1) patient falls, 2) patient burns, 3) hospital transfer/admission and 4) wrong site/wrong side/wrong patient/wrong procedure/wrong implant. The fifth measure is a process measure which evaluates the timing of the administration of intravenous antibiotics for prophylaxis of surgical site infection. This prophylactic antibiotic timing measure has been specifically designed to harmonize with, and be complementary to, similar measures (PQRI #20 and PQRI #21) developed to evaluate physician performance in this area. Please see Attachment A for detailed information on the five outpatient surgical facility-specific quality measures.

The prophylactic antibiotic timing measure also addresses the statutory requirement under TRHCA for evaluation of medication errors. In their recent *MEDMARX® Data Report: A Chartbook of Medication Error Findings from the Perioperative Settings from 1998-2005*, the U.S. Pharmacopeia detailed the various types of medication errors in outpatient surgery, one of which was "wrong time." The report specifically recommended "[d]eveloping strategies to ensure that medications, especially antimicrobial agents, are administered at the correct time."

As of this writing, we are not aware of any other measures specifically addressing facility quality in the delivery of outpatient surgical services that have either been nationally endorsed for public reporting and accountability or are in the process of evaluation for endorsement. Therefore, we strongly recommend CMS consider these five facility-specific measures for ASC reporting if they are endorsed by the NQF.

One of the principles that guided the ASC Quality Collaboration was harmonization – the idea that the measures developed through our efforts should be applicable to all facilities offering ambulatory surgery, allowing comparison of quality across sites of service. The ASC measures currently under consideration for endorsement by the NQF are appropriate for other outpatient surgical settings, effectively addressing the need to harmonize quality measures whenever possible.

II. ASC Data Collection

To date, CMS has implemented a number of quality reporting systems that employ a variety of methods to collect patient-level quality data. Most of these systems require that data be submitted electronically to a repository. As proposed in this rule, hospital outpatient departments would adopt the same methodology currently used by hospitals for inpatient reporting. That process requires abstraction of clinical data based on chart review, followed by compilation and submission in specific XML format to an approved data submission vendor. This vendor then transmits the data to the QIO Clinical Warehouse.

On the other hand, under the Physician's Quality Reporting Initiative (PQRI), physicians report patient-level quality data using administrative claims. Using either HCPCS Level II G codes or AMA Category II CPT codes adopted specifically for quality reporting, the physician is able to submit quality data in conjunction with codes for services rendered on the CMS-1500. Given the administrative burden of medical record extraction, physicians are likely to continue using a claims-based approach to quality reporting in the future.

We have carefully evaluated these alternative approaches, taking into account the characteristics and resources of the typical ASC. Though there is significant variability, CMS data indicates a median of two operating/procedure rooms per facility (mean = 2.5). FASA's 2006 ASC Salary & Benefits Survey shows that the majority (62.2%) of ASCs have 20 or fewer total full time equivalents, including both clinical and non-clinical staff. It is unusual for an ASC to have a medical records department staffed with multiple individuals.

Our evaluation of alternative reporting methodologies has focused on their complexity, staff resources needed for implementation, requirements for hardware and software, training requirements, and additional expenses, particularly related to contracting with data submission vendors. In all these areas, we find the administrative claims data approach to be the most practical, feasible and economical solution for ASCs.

The administrative and financial burden of reporting quality measures should be fully considered. CMS has estimated that approximately 73 percent of ASCs would be considered small businesses according to the Small Business Administration (SBA) size standards (see 72 Fed. Reg. 42538 (August 2, 2007) and 72 Fed. Reg. 42812 (August 2, 2007)). In this respect, ASCs more closely resemble individual physician practices than hospitals.

Further, ASCs will continue submitting their Medicare claims using the CMS-1500 at least through 2008. Therefore, ASCs are in a position to report quality data in the same manner as physicians, which will allow CMS to leverage the processes it has already developed under

PQRI. If ASCs move to the UB-04 in the future (a change we support), these codes can continue to be reported on the new form and comparisons made across multiple years remain feasible.

We request CMS work with ASC leaders to develop HCPCS Level II G codes that would allow facility-level quality measures to be reported using a claims-based approach. Reporting data on the claim form using HCPCS codes is achievable across ambulatory settings and can be accommodated on both the CMS-1500 and the UB-04.

III. Publication of Quality Data Collected

The demand for more publicly available health care information is being driven by federal and some state actions and by employers in an effort to control escalating health insurance costs and improve quality. Generally these transparency oriented efforts are motivated by a desire to provide consumers with information they can use in a meaningful way to improve their health and lower the cost of their care. As the health insurance industry moves to more consumer driven health care through Health Savings Accounts (HSAs), Health Reimbursement Accounts (HRAs) and Flexible Spending Accounts (FSAs), access to cost and quality information will become even more important to consumers. The ASC Quality Collaboration supports the development of transparency regarding health care information and welcomes a fair presentation of ASC cost and quality information to assist consumers in making decisions.

The success of transparency efforts is closely linked to how effectively information is shared with the public. A data reporting infrastructure should allow patients and payers to compare quality across Medicare's payment silos when a service or procedure can be delivered in multiple ambulatory settings.

Consumers should be able to access quality and cost information on websites that are organized to allow easy comparisons, while also protecting the rights of providers to assure the information is correct, up-to-date, and clearly presented. Specifically, web-based presentation of quality and cost data should address or incorporate the following principles.

1) Information should be presented on all available sites of service so consumers can compare a hospital outpatient department and an ASC for a procedure that could be performed in both locations.

2) There should be a mechanism for providers to raise concerns with any information to be posted prior to its public presentation.

3) There should 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.

4) In addition to reporting quality measures, other useful information such as accreditation status, state licensure and Medicare certification should be made available.

We request more detailed consideration and expanded description on this vital matter from CMS in future rulemaking.

IV. Summary of Recommendations

The ASC Quality Collaboration fully supports public reporting of facility-level quality measures that evaluate outcomes or processes of care specific to the facility services rendered in the outpatient surgical setting. CMS should adopt measures of quality for public reporting and accountability that have been developed specifically for application in the outpatient surgical facility.

CMS should implement a claims-based reporting system for ASCs, similar to the quality reporting system the agency has implemented for physicians. Such a system would allow patient-level data collection without undue financial and administrative burden.

Presentation of quality data deserves careful consideration to achieve the most effective communication of information. At a minimum, the method CMS selects for sharing data should allow interested parties to directly compare measures of outpatient surgical facility services across facility types.

Thank you for considering these comments. I would be happy to assist with questions or provide additional information at your request.

Sincerely,

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Appendix A

ASC Quality Collaboration Measures "*Recommended for Endorsement*" by the National Quality Forum (NQF)

PLEASE NOTE: These measures are subject to change pending additional action by the NQF.

Patient Burn	
Intent	To capture the number of admissions (patients) who experience a burn prior to discharge
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions experiencing a burn prior to discharge Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: ASC admissions experiencing a burn prior to discharge Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Burn: Unintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation, (e.g. warming devices, prep solutions, electrosurgical unit or laser); Allowable values: The count for this data element would be represented by any whole number 0 or greater

Prophylactic IV Antibiotic Timing	
Intent	To capture whether antibiotics given for prevention of surgical site infection were administered on time
Numerator/Denominator	Numerator: Number of Ambulatory Surgery Center (ASC) admissions with an order for a prophylactic IV antibiotic for prevention of surgical site infection who received the prophylactic antibiotic on time Denominator: All ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of surgical site infection
Inclusions/Exclusions	Numerator Exclusions: None Denominator Exclusions: ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of infections other than surgical site infections (e.g. bacterial endocarditis); ASC admissions with a preoperative order for a prophylactic antibiotic not administered by the intravenous route
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Antibiotic administered on time: Antibiotic infusion is initiated within one hour prior to the time of the initial surgical incision or the beginning of the procedure (e.g., introduction of endoscope, insertion of needle, inflation of tourniquet) or two hours prior if vancomycin or fluoroquinolones are administered; Allowable values: 0 minutes to 24 hours reporting in military time format from 0:00 to 23:59; hours from 00 to 23 and minutes from 00 to 59. If unable to determine (UTD), "UTD" is assigned. Prophylactic antibiotic: an antibiotic prescribed with the intent of reducing the probability of an infection related to an invasive procedure. For purposes of this measure, the following antibiotics are considered prophylaxis for surgical site infections: Ampicillin/sulbactam, Aztreonam, Cefazolin, Cefmetazole, Cefotetan, Cefoxitin, Cefuroxime, Ciprofloxacin, Clindamycin, Erythromycin, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin and Vancomycin

Patient Fall in the ASC

Intent	To capture the number of admissions (patients) who experience a fall within the ASC
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions experiencing a fall within the confines of the ASC Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusion: ASC admissions experiencing a fall within the confines of the ASC Numerator Exclusion: ASC admissions experiencing a fall outside the ASC Denominator Inclusion: All ASC admissions Denominator Exclusion: ASC admissions experiencing a fall outside the ASC
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Fall: a sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object, excluding falls resulting from violent blows or other purposeful actions. (National Center for Patient Safety)

Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

Intent	To capture any ASC admissions (patients) who experience a wrong site, side, patient, procedure or implant
Numerator/Denominator	Numerator: All Ambulatory Surgery Center (ASC) admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure or wrong implant Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: All ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure or wrong implant Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports, quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Wrong: not in accordance with intended site, side, patient, procedure or implant; Allowable values: The count for this data element would be represented by any whole number 0 or greater

Hospital Transfer/Admission

Intent	To capture any ASC admissions (patients) who are transferred or admitted to a hospital prior to discharge from the ASC
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions requiring a hospital transfer or hospital admission prior to being discharged from the ASC Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: ASC admissions requiring a hospital transfer or hospital admission prior to being discharged from the ASC Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Hospital transfer/admission: any transfer/admission from an ASC directly to an acute care hospital including hospital emergency room; Allowable values: The count for this data element would be represented by any whole number 0 or greater Discharge: occurs when the patient leaves the confines of the ASC