



ASC Quality Collaboration

September 2, 2008

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1404-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1404-P; Reporting Quality Data for Annual Payment Rate Updates

Dear Acting Administrator Weems:

On behalf of the ASC Quality Collaboration, 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-1404-P, Section XVI. Reporting Quality Data for Annual Payment Rate Updates, particularly as it pertains to ASCs (73 Fed. Reg. 41539, July 18, 2008). The ASC Quality Collaboration's stakeholders include ASC corporations, the ASC industry association, professional societies, accrediting bodies and government entities. Please see Appendix A for a list of the ASC Quality Collaboration's participants.

The ASC Quality Collaboration strongly advocates quality reporting. Sharing reliable quality information with the public gives consumers the opportunity to make informed health care choices. Quality data is also an important performance improvement tool. ASCs have a long history of commitment to high-quality care, and we are eager to make quality data available to the public. Recognizing that Medicare beneficiaries have a choice of providers and settings for many of the most common outpatient surgical services, we look forward to the time when direct comparisons between surgical care delivered in hospital outpatient departments and ASCs will be possible.

Over the last few years, the ASC Quality Collaboration has communicated regularly with CMS through formal comments, letters, conference calls and a face-to-face meeting. We have shared news of our progress in the development of ASC facility-level quality measures endorsed by the National Quality Forum (NQF), provided information regarding the characteristics and operational capabilities of the ASC industry, provided recommendations regarding the structure of the future ASC quality reporting system, and offered our thoughts on the most effective

manner of sharing quality information with the public. We appreciate this opportunity to continue to discuss our recommendations for the future ASC quality reporting system.

I. ASC Quality Reporting System

Last year we stated our appreciation for the consideration the Centers for Medicare & Medicaid Services (CMS) demonstrated in its decision not to introduce quality measures for ASC reporting in CY 2008. With the implementation of the revised ASC payment system earlier this year, the ASC community faced a significant transition, and we agreed with the decision not to introduce additional requirements simultaneously. A further barrier to implementation at that time was the absence of nationally endorsed ASC quality measures designed for public reporting and accountability.

However, this year we are disappointed in the lack of progress concerning agency proposals for an ASC quality reporting system for CY 2009. The ASC industry has anticipated and actively prepared for a CY 2009 implementation based on the statutory reference that would allow payment reductions to non-compliant ASCs for dates of service on or after January 1, 2009. Collection of quality data is a common practice in ASCs, and has been a feature of the industry since its inception. When the first ASC was established in 1970, there was considerable skepticism surrounding the ambulatory model of delivering surgical care. This skepticism compelled the collection and reporting of data regarding safety, quality and outcomes from the earliest days of ASC existence. ASCs now collect this data not only for internal quality assurance and performance improvement, but also report it for purposes of external benchmarking and to fulfill various requirements for state licensure, certification and accreditation. In light of these activities, we do not agree with CMS's characterization of ASCs as "facilities which do not have prior experience with quality reporting" [73 Fed. Reg. 41547].

We do not share CMS's opinion that the revised ASC payment system will pose ongoing challenges of such magnitude as to prevent the reporting of quality data in 2009. The ASC industry has a longstanding history of quality measurement and is ready to move ahead. We encourage CMS to move forward by issuing its proposals as expeditiously as possible. Significant further delay in issuing proposals for the ASC quality reporting system is not helpful to the Medicare program, the public or the ASC provider community, all of whom have a significant stake in timely progress in this area.

If the agency is not able to publish proposals for a comprehensive quality reporting system for implementation in 2009, we request that it begin to develop a claims-based infrastructure based on the following recommendations regarding quality measures, data submission and public reporting. This would allow ASCs to become familiar with reporting the new HCPCS Level II quality codes in 2009, and give the agency the opportunity to develop experience with the claims-based ASC quality reporting mechanism prior to the implementation of payment reductions for non-compliance.

A. Quality Measures for Outpatient Surgery

We believe that measures for the evaluation of outpatient surgical facility quality should reflect processes or outcomes of 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, can reasonably be held accountable.

When the ASC Quality Collaboration was formed, we 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 outpatient surgical setting. In fact, many of the 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 nationally endorsed 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 outpatient surgical 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 and was able to confirm their feasibility and usability. Five of these measures have now been endorsed by the NQF.

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 similar measures already being reported by inpatient hospitals and hospital outpatient departments. 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.”

Please see Appendix B for detailed information on the five NQF-endorsed outpatient surgical facility-specific quality measures. We strongly recommend CMS implement these facility-specific measures for ASC reporting.

The ASC Quality Collaboration has been mindful of the need to ensure that the measures developed through our efforts are applicable to all facilities offering ambulatory surgery. The ASC facility-level measures currently endorsed by the NQF are appropriate for all outpatient

surgical settings. We therefore encourage CMS to apply these measures for reporting by other providers of outpatient surgical services. Applying the same facility-level quality measures to all settings offering outpatient surgery would expand the points of comparison available to Medicare beneficiaries and would represent an important step forward in improving their ability to assess quality among different providers.

Our measure development activity is ongoing. We welcome input from CMS regarding processes or outcomes of care for which the agency is interested in seeing facility-level outpatient surgery quality measures developed.

B. ASC Data Collection

We believe one of the shared goals of CMS and the ASC Quality Collaboration is to foster high levels of participation in the future ASC quality reporting system. To achieve that goal, CMS should implement a reporting mechanism that allows reliable reporting while minimizing the imposition of new costs and processes.

As CMS develops its proposals for an ASC quality reporting system, the administrative and financial burden of reporting quality measures should be given all due consideration. 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 which indicates a median of two operating/procedure rooms per facility (mean = 2.5). Further, the ASC Association's 2008 ASC Salary & Benefits Survey shows the majority (61%) of ASCs have 20 or fewer total full time equivalents, including both clinical and non-clinical staff.

With the goal of maximizing participation in mind, we recommend the use of administrative claims as the data collection methodology for the ASC industry. CMS has already developed a roadmap for claims-based quality data collection under the Physician's Quality Reporting Initiative (PQRI). Using either HCPCS Level II G codes or AMA Category II CPT codes developed specifically for quality reporting, the physician is able to submit quality data in conjunction with codes for services rendered on the CMS-1500. ASCs currently submit their Medicare claims using the CMS-1500 and are therefore in a position to report quality data in the same manner as physicians. This would allow CMS to leverage the processes it has already developed under PQRI. In the event ASCs are required to submit claims using the UB-04 in the future, these codes can continue to be reported in the same format.

By comparison, internet-based reporting of patient-level quality data involves many of the same disadvantages of the challenging quality reporting system the agency has implemented for the hospital setting, in that it would represent a new process requiring additional resource use, training, and expense. Given the very limited use of electronic medical records in the ASC setting at the present time, the preparation of patient-level data for internet-based reporting would require chart abstraction, entry of significant amounts of data into an electronic format and a new data submission process.

It is not reasonable to saddle an industry that is composed predominantly of small providers with such a cumbersome process when a viable and extant alternative offers a much simpler approach to robust data collection. A claims-based system offers the opportunity to use an existing process modified only by the addition of new codes designed for quality reporting. We shared our specific recommendations for HCPCS quality codes and descriptors with the agency in earlier correspondence dated November 21, 2007. For your reference, we abstract the suggested descriptors from that letter in Appendix C.

C. Public Reporting of Quality Data

The ASC Quality Collaboration supports transparency 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. 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 by assuring that the information made available is correct, up-to-date, and clearly presented. Specifically, internet-based presentation of quality and cost data should address or incorporate the following principles.

- 1) Consumers should be able to directly compare providers of outpatient surgical services, such as a hospital outpatient department and an ASC.
- 2) There should be a mechanism for providers to raise concerns with any information to be posted prior to its publication.
- 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.

II. Reporting Quality Data for Annual Payment Rate Updates

In this rule, CMS has described its proposals for hospital outpatient department reporting of quality data for annual payment rate updates. Given the possibility CMS may offer similar proposals for some aspects of the ASC quality reporting system, we offer comments on selected details of the hospital outpatient department (HOPD) proposals.

We are in agreement with the proposal to update the technical specifications of quality measures through a sub-regulatory process with the stated caveats. Sub-regulatory revisions to the technical specifications must be limited to those changes in a given measure made through the consensus approval process. As indicated, timely advance communication of any such changes would be important. However, we recommend that CMS expand its communication efforts beyond the Quality Net site and the specifications manuals. CMS should also give notice of these changes in the Federal Register and utilize other established channels for sharing

information with providers, such as the agency's list serves and MLN Matters articles, to ensure broad and effective communication of changes.

In this proposed rule, CMS proposes to adopt claims-based imaging measures in the HOPD, measures CMS indicates it "can calculate using Medicare Part B claims data without imposing on hospitals the burden of additional chart abstraction [73 Fed. Reg. 41541]". We are supportive of the development and implementation of measures that can be calculated using Medicare Part B claims data, provided those measures have been endorsed by a voluntary consensus building entity. We appreciate the sensitivity CMS has shown in these proposals to the burdens of chart abstraction and separate data reporting and encourage the agency's further exploration of gathering data through claims.

We appreciate the attention to detail CMS has shown in developing its proposed method of applying the required reduction to OPDS payments for hospitals that do not meet requirements and would welcome an equally careful approach to the development of a method appropriate to ASC payments. However, we note that the agency's proposals to proportionately reduce the beneficiary copayment liability may have the unintended consequence of influencing beneficiaries, particularly those most affected by the constraints of a limited and fixed income, to choose non-compliant hospitals in order to save money.

We support the implementation of a mandatory reconsideration and appeals process, similar to that proposed for application to the hospital outpatient setting. However, we recommend that data which under is reconsideration or appeal not be publicly displayed until such reconsideration or appeal is fully resolved.

We note that the 2008 design [Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) section 101] for the Physician Quality Reporting Initiative (PQRI) incorporated flexibility in reporting periods to address the burden of data collection on physician practices. The flexibilities offered in the PQRI system include alternative, shorter reporting periods and an option to intensively measure 15 consecutive patients as an alternative to sampling 80 percent of all eligible patients. We urge CMS to give equal consideration to the data collection burden on ASCs and consider similar options for flexibility in reporting.

In conclusion, we wish to emphasize that the ASC Quality Collaboration believes CMS was incorrect in asserting ASCs are unprepared to participate in quality reporting due to changes in the ASC payment system. Over the last few years, through the efforts of this collaboration and many others in the industry, ASCs have learned about and been anticipating this next step.

We encourage CMS to move promptly to develop and issue its proposals for the ASC quality reporting system. If the agency is not able to issue its proposals for a quality reporting system for a 2009 implementation, we request the agency develop and implement a claims-based reporting infrastructure based upon the specific recommendations outlined above, allowing ASCs that wish to do so to voluntarily report quality data on their 2009 claims.

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Thank you for considering these comments. We look forward to future opportunities to continue our dialogue with the agency on this very important matter. 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 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 Nurses
Hospital Corporation of America, Outpatient Services Group
National Surgical Care
Novamed
Nueterra Healthcare
Surgical Care Affiliates
Symbion
The Joint Commission
United Surgical Partners, Inc.

Appendix B

ASC Quality Collaboration Measures Currently Endorsed by the National Quality Forum (NQF)

Patient Burn	
<i>Intent</i>	To capture the number of admissions (patients) who experience a burn prior to discharge
<i>Numerator/Denominator</i>	Numerator: Ambulatory Surgery Center (ASC) admissions experiencing a burn prior to discharge Denominator: All ASC admissions
<i>Inclusions/Exclusions</i>	Numerator Inclusions: ASC admissions experiencing a burn prior to discharge Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
<i>Suggested Data Sources</i>	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
<i>Data Element Definition and Allowable Values</i>	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	
<i>Intent</i>	To capture whether antibiotics given for prevention of surgical site infection were administered on time
<i>Numerator/Denominator</i>	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
<i>Inclusions/Exclusions</i>	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
<i>Suggested Data Sources</i>	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
<i>Data Element Definition and Allowable Values</i>	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

<i>Intent</i>	To capture the number of admissions (patients) who experience a fall within the ASC
<i>Numerator/Denominator</i>	Numerator: Ambulatory Surgery Center (ASC) admissions experiencing a fall within the confines of the ASC Denominator: All ASC admissions
<i>Inclusions/Exclusions</i>	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
<i>Suggested Data Sources</i>	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
<i>Data Element Definition and Allowable Values</i>	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

<i>Intent</i>	To capture any ASC admissions (patients) who experience a wrong site, side, patient, procedure or implant
<i>Numerator/Denominator</i>	Numerator: All Ambulatory Surgery Center (ASC) admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure or wrong implant Denominator: All ASC admissions
<i>Inclusions/Exclusions</i>	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
<i>Suggested Data Sources</i>	ASC operational data, including administrative records, medical records, incident/occurrence reports, quality improvement reports
<i>Data Element Definition and Allowable Values</i>	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

<i>Intent</i>	To capture any admissions (patients) who are transferred or admitted to a hospital upon discharge from the ASC
<i>Numerator/Denominator</i>	Numerator: Ambulatory Surgery Center (ASC) admissions requiring a hospital transfer or hospital admission upon discharge from the ASC Denominator: All ASC admissions
<i>Inclusions/Exclusions</i>	Numerator Inclusions: ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
<i>Suggested Data Sources</i>	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
<i>Data Element Definition and Allowable Values</i>	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

Appendix C

Suggested G Code Descriptors for Reporting ASC Quality Measures

1. Patient Burn

GXXXX – ASC patient documented to have received a burn prior to discharge

GXXXX – ASC patient documented not to have received a burn prior to discharge

2. Prophylactic IV Antibiotic Timing

GXXXX – ASC patient with order for prophylaxis for surgical site infection documented to have received antibiotic within one hour prior to incision time (two hours for vancomycin or fluoroquinolones)

GXXXX – ASC patient with order for prophylaxis for surgical site infection documented not to have received antibiotic within one hour prior to incision time (two hours for vancomycin or fluoroquinolones)

GXXXX – ASC patient without order for prophylaxis for surgical site infection

3. Patient Fall

GXXXX – ASC patient documented to have experienced a fall within the ASC

GXXXX – ASC patient documented not to have experienced a fall within the ASC

4. Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

GXXXX – ASC patient documented to have experienced a wrong site, wrong side, wrong patient, wrong procedure or wrong implant event

GXXXX – ASC patient documented not to have experienced a wrong site, wrong side, wrong patient, wrong procedure or wrong implant event

5. Hospital Transfer/Admission

GXXXX – ASC patient documented to have required a hospital transfer or hospital admission upon discharge from the ASC

GXXXX – ASC patient documented not to have required a hospital transfer or hospital admission upon discharge from the ASC