Medicaid EHR Incentive Programs; and (4) use QRDA Category I format data transmission.

K. ASC Quality Reporting Program

1. Background

Section 109(b) of the MIEA TRHCA amended section 1833(i) of the Act by re-designating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system "in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7)." Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that a reduction for one year cannot be taken into account in computing any annual increase factor for a subsequent year.

Section 1833(i)(7)(B) of the Act provides that, "[e]xcept as the Secretary may otherwise provide," the hospital outpatient quality data provisions of subparagraphs (B) through (E) of section 1833(t)(17) of the Act shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the Hospital OQR Program and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC,

respectively. Section 1833(t)(17)(B) of the Act requires that hospitals submit quality data in a form and manner, and at a time, that the Secretary specifies.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Section 1833(t)(17)(C)(ii) of the Act allows the Secretary to select measures that are the same as (or a subset of) the measures for which data are required to be submitted under the Hospital IQR Program.

Section 1833(t)(17)(D) of the Act gives the Secretary the authority to replace measures or indicators as appropriate, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice. Section 1833(t)(17)(E) of the Act requires the Secretary to establish procedures for making data submitted under the Hospital OQR Program available to the public. Such procedures include providing hospitals with the opportunity to review their data before these data are released to the public. For a more detailed discussion of the provisions in section1833(t)(17) of the Act, please see the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) and this final rule with comment period.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780), the CY 2010

OPPS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 72109), we did not implement a quality data reporting program for ASCs. We determined that it would be more appropriate to allow ASCs to acquire some experience with the revised ASC payment system, which was implemented for CY 2008, before implementing new requirements, such as public reporting of quality measures. However, in these rules, we indicated that we intend to implement the provisions of section 109(b) of the MIEA-TRHCA in the future.

In preparation for proposing an ASC Quality Reporting Program, in the CY 2011 OPPS/ASC proposed rule, we solicited public comment on the following measures under consideration for ASC quality data reporting: (1) Patient Fall in the ASC; (2) Patient Burn; (3) Hospital Transfer/Admission; (4) Wrong Site, Side, Patient, Procedure, Implant; (5) Prophylactic IV Antibiotic Timing; (6) Appropriate Surgical Site Hair Removal; (7) Surgical Site Infection; (8) Medication Administration Variance (MAV); (9) Medication Reconciliation; and (10) VTE Measures: Outcome/Assessment/Prophylaxis (75 FR 46383).

In addition to preparing to propose implementation of an ASC Quality Reporting Program, HHS developed a plan to implement a value-based purchasing (VBP) program for payments under the Medicare program under title XVIII of the Act for ASCs as required by section 3006(f) of the Affordable Care Act, as added by section 10301(a) of the Affordable Care Act. We also submitted a Report to Congress, as required by section 3006(f)(4) of the Affordable Care Act, entitled "Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan" that contains this plan. This report is

found on our Web site at:

http://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf. Currently, we do not have express statutory authority to implement an ASC VBP program. Should there be legislation to authorize CMS to implement an ASC VBP program, we will develop the program and propose it through rulemaking.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42336 through 42349), we proposed to implement the ASC Quality Reporting Program beginning with the CY 2014 payment determination, with data collection beginning in CY 2012 for most of the measures to be used for the CY 2014 payment determination.

Comment: One commenter stated that it was unclear if there are any payment penalties for not participating in ASC quality data reporting and that if there are payment penalties, how would they be calculated. Several commenters stated their belief that the payment penalty for non-reporting or not meeting reporting requirements be lowered for at least the initial payment penalty year, recommending a 0.4 percentage point reduction for CY 2014, rather than a 2 percentage point reduction. Some of these commenters noted that a 0.4 percentage point reduction is consistent with the Hospital IQR Program.

Response: The payment reduction for not participating in ASC quality reporting is set by statute. Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary as specified will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. We intend to propose in the CY 2013 OPPS/ASC proposed rule the method for how these payment penalties will be calculated. We note

that although the payment reduction under the Hospital IQR Program was initially a 0.4 percentage point reduction to the applicable percentage increase, the payment reduction has, since FY 2007, been 2.0 percentage points. (Beginning with FY 2015, the payment reduction will be one-quarter of the applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act).)

Comment: Many commenters appreciated CMS' plan to implement an ASC Quality Reporting Program but strongly urged CMS to delay the start of required data submission from the proposed January 1, 2012 to October 1, 2012 at the earliest, in order for ASCs to have sufficient time to prepare and adapt to the new reporting procedures. A few commenters noted that a new quality reporting program warrants at least 6 months of advance notice to providers, who would have to make substantive changes to data elements and operation systems. Commenters cited the example of ASCs' inexperience in reporting data using Quality Data Codes (QDCs) as well as reporting to NHSN as efforts that would require tremendous time, training and resources to initiate.

Many commenters believed it would be prudent for CMS to allow ASCs to submit quality data initially on a trial basis for a time period from January 1, 2012 through September 30, 2012. Commenters asserted that ASCs need this trial period to test their systems and resolve any problems that may arise.

Response: We thank the commenters for their support for the ASC Quality Reporting Program. We strongly believe this program is an important milestone in the alignment of quality of care across HOPDs and ASC settings. We acknowledge the new challenges faced by ASCs in preparation for this quality reporting program. Based on

public comments, we will delay required data submission until October 1, 2012 for the CY 2014 payment determination. More information regarding measure submission timeframes and other program requirements can be found in the "Form, Manner and Timing" section of this final rule with comment period.

After consideration of the public comments we received, we are finalizing the ASC Quality Reporting Program, with data collection to begin on October 1, 2012.

- 2. ASC Quality Reporting Program Measure Selection
- a. Timetable for Selecting ASC Quality Measures

In the CY 2012 OPPS/ASC proposed rule (76 FR 42337), we proposed to adopt measures for three CY payment determinations for the ASC Quality Reporting Program in this rulemaking. We proposed to adopt measures for the CYs 2014, 2015, and 2016 payment determinations. We stated, to the extent that we finalize some or all of the measures for future payment determinations, we would not be precluded from adopting additional measures or changing the list of measures for future payment determinations through annual rulemaking cycles so that we may address changing program needs arising from new legislation or from changes in HHS and CMS priorities. Under this approach, in the CY 2013 or CY 2014 rulemaking cycle, we could propose any additions or revisions to the measures we adopted in the CY 2012 rulemaking cycle for the CY 2014 payment determination or for future payment determinations. This is consistent with our approach to proposing measures for multiple payment determinations for the Hospital IQR and Hospital OQR Programs. We believe this proposed process will assist ASCs in planning, meeting future reporting requirements, and implementing quality

improvement efforts. We also would have more time to develop, align, and implement the infrastructure necessary to collect data on the measures and make payment determinations. This flexibility would enable us to adapt the program to support changes in HHS and CMS priorities and any new legislative requirements. In the proposed rule, we invited public comments on this proposal.

<u>Comment</u>: A few commenters supported the multi-year approach which is perceived as great opportunities for ASCs to gain understanding of measure specifications, data collection and data submission methodologies while CMS develops needed infrastructure to collect quality data on ASCs.

Response: We thank the commenters for the support of the multi-year proposals for ASC quality measures.

After consideration of the public comments we received, we are finalizing our proposal to adopt quality measures for the CY 2014, CY 2015, and CY 2016 payment determinations. We discuss the quality measures that we are finalizing for these CYs below.

b. Considerations in the Selection of Measures for the ASC Quality Reporting Program Section 1833(i)(7)(B) of the Act states that section 1833(t)(17)(C) of the Act shall apply with respect to ASC services in a similar manner in which they apply to hospitals for the Hospital OQR Program, except as the Secretary may otherwise provide. The requirements at section 1833(t)(17)(C)(i) of the Act state that measures developed shall "be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected

parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities."

In selecting proposed measures for the ASC Quality Reporting Program and other quality reporting programs, we have focused on measures that have a high impact on and support HHS and CMS priorities for improved health care outcomes, quality, safety, efficiency and satisfaction for patients. Our goal for the future is to expand any measure set adopted for ASC quality reporting to address these priorities more fully and to align ASC quality measure requirements with those of other reporting programs as appropriate, including the Hospital OQR Program, the Hospital IQR Program, the PQRS, and reporting requirements implemented under the HITECH Act so that the burden for reporting will be reduced. In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a welldocumented and rigorous approach to consensus development. However, as we have noted in previous rulemaking for the Hospital OQR Program (75 FR 72065), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment.

In developing this and other quality reporting programs, as well as the Hospital VBP Program, we applied the following principles for the development and use of measures. In the proposed rule, we invited public comment on these principles in the ASC quality reporting context.

• Pay-for-reporting, public reporting, and value-based purchasing programs should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider/supplier characteristics.

- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider/supplier category that reflects the level of care and the most important areas of service and measures for that provider/supplier.
- The collection of information should minimize the burden on providers/
 suppliers to the extent possible. To this end, we will continuously seek to align our
 measures with the adoption of meaningful use standards for HIT, so that data can be
 submitted and calculated via certified EHR technology with minimal burden.
- To the extent practicable and feasible, and within the scope of our statutory authorities for various quality reporting and value-based purchasing programs, measures used by CMS should be endorsed by a national, multi-stakeholder organization.

 Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We believe that ASC facilities are similar, insofar as the delivery of surgical and related nonsurgical services, to HOPDs. Similar standards and guidelines can be applied between hospital outpatient departments and ASCs with respect to surgical care improvement, given that many of the same surgical procedures are provided in both settings. Measure harmonization assures that comparable care in different settings can be evaluated in similar ways, which further assures that quality measurement can focus more on the needs of a patient with a particular condition rather than on the specific program or policy attributes of the setting in which the care is provided. In general, our goal is to adopt harmonized measures that assess the quality of care given across settings and providers/suppliers and to use the same measure specifications based on clinical evidence and guidelines for the care being assessed regardless of provider/supplier type or setting. This harmonization goal is also supported by a commenter to the CY 2011 OPPS/ASC proposed rule, who recommended CMS align ASC quality measures with State and other Federal requirements (75 FR 72109).

Our CY 2014 measure proposals for ASCs align closely with those discussed in the Report to Congress entitled "Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan" and with those proposed for future consideration in the CY 2011 OPPS/ASC proposed rule (75 FR 46383). Furthermore, the measures that we proposed for ASCs fall into the parameter of our stated framework for the ASC Quality Reporting Program, discussed above. The initial measure set that we proposed for the CY 2014 payment determination addresses outcome measures and infection control process measures. Six of the eight initial measures that we proposed for the CY 2014

payment determination are recommended by the ASC Quality Collaborative (ASC QC) and are NQF-endorsed. The seventh measure that we proposed is appropriate for measuring ambulatory surgical care, is NQF-endorsed, is currently in use in the PQRS, and is similar to a measure that is being used in the Hospital OQR Program, and therefore aligns across settings in which outpatient surgery is performed. We proposed collecting these seven measures via "quality data codes" to be placed on Part B claims submitted by ASCs for Medicare fee-for-service patients beginning January 1, 2012. The eighth measure we proposed for the CY 2014 payment determination is an outcome measure of surgical site infection to be submitted in 2013 via the CDC's NHSN. Similarly, hospital inpatient departments will begin reporting this measure to the CDC under the Hospital IQR Program in 2012, and we also proposed that hospital outpatient departments begin reporting this measure to the CDC under the Hospital OQR Program in 2013. Thus, this measure would be aligned across quality reporting programs for facilities performing surgery.

<u>Comment</u>: Several commenters supported all the proposed NQF-endorsed measures for ASCs and also believed that all ASC quality reporting measures should be NQF-endorsed, regardless of the measures' endorsement by other national multi-stakeholder organizations. Some commenters noted that ASC measures should focus on facility-level data and not physician-level data.

Response: Under section 1833(i)(7)(B) and (t)(17)(C)(i) of the Act, except as the Secretary may otherwise provide, the Secretary must develop measures that reflect consensus among affected parties and, to the extent feasible and practicable, must include

measures set forth by a national consensus building entity. Whenever possible, we strive to adopt NOF-endorsed measures because these measures will meet these requirements. as discussed above. However, we believe that the requirement that measures reflect 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 comments. Further, it may not be feasible or practicable to adopt an NOF-endorsed measure, such as when an NOF-endorsed measure does not exist. Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt measures that do not reflect consensus among affected parties and are not endorsed by a national consensus building entity. We wish to clarify that these measures would be submitted by facilities, not physicians, and that the data for the measures will be displayed at the facility level.

<u>Comment</u>: A commenter stated that several distinct factors should be considered in the selection of measures for ASCs: (1) the diversity in the case mix across ASCs (that is, a single subspecialty ASC (for example, endoscopy centers) versus a "multi-specialty" ASC may require exemptions based on case mix or low volume); (2) Hospital OQR Program measure specifications may not be relevant for all ASCs; (3) the reporting

burden for most ASCs which are classified as small business; and (4) the use of EHRs in ASCs is not widespread.

Response: We have considered these factors in selecting measures for the ASC Quality Reporting Program. In general, we have sought to select measures that are broadly applicable to ASCs, given the diversity in case mix and ASC specialty. The majority of the measures selected for CY 2014, CY 2015 and CY 2016 for this program are applicable regardless of the types of procedures performed at a particular facility. We will consider the usefulness of specialty-specific measures as well as exemptions based on case mix or low volume for ASCs as we gain experience with the measures we are adopting and as we develop future measures. We also sought to align the ASC measures with measures selected for other settings/providers that perform surgeries, such as HOPDs. However, we acknowledge that not all procedures that are performed in HOPDs are performed in ASCs, and hence that some Hospital OQR measures may not be as relevant for ASCs or may need to be tailored to the types of procedures approved to be performed in ASCs. We also understand that most ASCs are small businesses for which data collection burden or EHR adoption may pose challenges. Therefore, in order to reduce burden, we proposed and are finalizing only claims-based measures for the first year of the program and adding only structural measures in the second year of the program.

<u>Comment</u>: A few commenters were disappointed that no patient experience of care measures were proposed for ASCs. The commenters encouraged CMS to facilitate voluntary patient experience of care measures for ASCs.

Response: We are considering a patient experience of care survey for the ASC Quality Reporting Program, and will also consider the operational feasibility of allowing voluntary reporting of such a measure in the future.

- 3. ASC Quality Measures for the CY 2014 Payment Determination
- a. Claims-Based Measures Requiring Submission of Quality Data Codes (QDCs)
 beginning January 1, 2012

In the CY 2012 OPPS/ASC proposed rule (76 FR 42338 through 42342), we proposed to adopt seven NQF-endorsed claims-based measures, six of which were developed by the ASC QC. The ASC QC is a cooperative effort of organizations and companies formed in 2006 with a common interest in ensuring that ASC quality data is measured and reported in a meaningful way. Stakeholders in the ASC QC include ASC corporations, ASC associations, professional societies and accrediting bodies that focus on ASC quality and safety. The ASC QC initiated a process of standardizing ASC quality measure development through evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. The ASC QC in its ASC Quality Measure Implementation Guide version 1.4 states that "it focused on outcomes and processes that ASC facilities could influence or impact, outcomes that ASC facilities would be aware of given their limited contact with the patient, and outcomes that would be understandable and important to key stakeholders in ASC care, including patients, providers and payers."

The ASC QC developed and pilot-tested five facility-level measures (Patient Burn; Patient Fall in the ASC; Wrong Site, Wrong Side, Wrong Patient, Wrong

Procedure, Wrong Implant; Hospital Transfer/Admission, and Prophylactic IV Antibiotic Timing) for feasibility and usability. On November 15, 2007, these five measures were endorsed by the NQF. On September 25, 2008, a sixth ASC QC-developed facility-level measure, "Appropriate Surgical Site Hair Removal" was NQF-endorsed as "Ambulatory Surgery Patients with Appropriate Method of Hair Removal." Of the six ASC QC measures, the Prophylactic IV Antibiotic Timing and Ambulatory Surgery Patients with Appropriate Method of Hair Removal measures are infection control process measures, and the rest are outcome measures. All six of these measures were listed as under consideration in the CY 2011 OPPS/ASC proposed rule (75 FR 46383). We proposed these six measures for use in the CY 2014 payment determination.

The seventh claims-based measure we proposed for the CY 2014 payment determination is Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin. This measure was developed by the AMA's Physician Consortium for Performance Improvement, a national, diverse, physician-led group that identifies, develops, and promotes implementation of evidence-based clinical performance measures that reflect best practices. This measure is NQF-endorsed. It is an infection control process measure and is currently adopted in the Hospital IQR Program and the PQRS.

We proposed to collect all seven measures using the claims-based quality data codes (QDCs) data collection mechanism. We proposed to require ASCs to report on ASC claims a quality data code (QDC) to be used for reporting quality data. We proposed that an ASC would need to add a QDC to any claim involving a proposed claims-based quality measure. We stated that CMS is in the process of developing QDCs

for each proposed claims-based quality measure and the QDC would be a CPT Category II code or a HCPCS Level II G-code if an appropriate CPT code is not available. We stated that more information on the QDCs that would be associated with the proposed quality measures will be provided in this CY 2012 OPPS/ASC final rule with comment period. Additionally, we proposed to create a new ASC payment indicator "M5" (Quality measurement code used for reporting purposes only; no payment made) for assignment to the QDC to clarify that no payment is associated with the QDC for that claim. We stated that, if one or more of these measures are finalized as proposed, an ASC would need to begin submitting these QDCs on any Medicare Part B claims pertaining to the measures on January 1, 2012.

For the first six measures listed, the ASC QC measures specifications can be found at

http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pd <u>f.</u> ³⁷ For the seventh measure, the specifications can be found on the PQRS Web site at: http://www.cms.gov/pqrs/downloads/2011_PhysQualRptg_MeasuresGroups_Specificatio nsManual_033111.pdf?agree=yes&next=Accept.

<u>Comment</u>: Commenters generally supported most of the proposed measures for CY 2014 and requested harmonization of the measures with the Hospital OQR Program as appropriate, so that comparative quality data is available to consumers. A commenter requested that CMS provide measure benchmarks for ASCs to assess how they stack up against their peers.

³⁷ ASC Quality Measures: Implementation Guide Version 1.4, ASC Quality Collaboration, December 2010.

Response: We thank the commenters for the support of our intent to align and harmonize measures across Hospital OQR and ASC Quality Reporting Programs to keep consumers better informed when making outpatient care decisions. When publicly displaying measures, we provide State and national averages whenever possible for comparative purposes. For the Hospital IQR Program, we provide benchmarks using the Achievable Benchmarks of Care methodology at:

http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage
%2FQnetTier2&cid=1228768205297. We also provide such benchmarks for the
Hospital OQR measures at:

http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage %2FQnetTier2&cid=1228768205213. However, such information is provided for informational purposes and quality improvement purposes and should not be interpreted as performance standards.

<u>Comment</u>: Several commenters believed that the number of measures proposed for ASCs is excessive and recommended that CMS adopt three patient safety measures initially to allow ASCs more time to gain experience with quality reporting.

Response: We are mindful of the potential burden on ASCs when we contemplated measures for ASCs. We determined that the initial adoption of claims-based measures would ease the data collection burden on ASCs while providing sufficient time for ASCs to gain experience with quality reporting. To that end, instead of proposing chart-abstracted measures, we proposed seven claims-based measures and 1 NHSN-based reporting measure for the first year of ASC Quality Reporting Program.

As discussed below, in this final rule with comment period, we are finalizing only five of the seven claims-based measures we proposed for CY 2014 payment determination. In addition, we are delaying the data collection until October 1, 2012 for the claims-based measures for the CY 2014 payment determination.

Comment: Several commenters supported the submission of QDCs on administrative claims which they believed are less burdensome, given that ASCs already submit a CMS-1500 form for each Medicare beneficiary served. A few commenters were concerned about the potential burden caused by the use CPT II codes -QDCs and questioned why CMS cannot adopt the same data collection code process used in Hospital OQR Program claims-based measures. Some commenters were very concerned that proposed method of collection via QDCs has not been tested for the ASC setting. One commenter believed that the PQRS experienced problems using QDCs.

Response: We agree with the commenters that stated that QDCs are a low-burden method of collecting quality data. The information needed for the current claims-based measures used in the Hospital OQR Program can be captured using solely ICD-9 codes and CPT-I codes placed on claims submitted to CMS. This is not the case for the ASC quality measures, because the type of information needed to assess whether numerator events occurred for these measures (and for some of the measures, events that help define the denominator) are not captured in these two coding systems. This type of information can be captured using the CPT-II and G-codes that would be placed on claims in addition to the ICD-9 codes and CPT-I codes used to capture diagnoses and procedure codes.

The other method that could have been used to collect information for these measures is submission of retrospectively chart-abstracted data elements to CMS separately from claims. However, we determined that this method of data collection for these measures may be more burdensome for ASCs than submitting CPT-II codes and G-codes on the claims for these measures in addition to the ICD-9 and CPT-I codes that they submit to CMS for payment purposes. In order to submit quality data using CPT-II and HCPCS codes, ASCs would need to add the appropriate QDCs for measure numerators and denominators on Medicare Part B claim forms. Based on the public comments we received, we are deferring the start date of required submissions of QDCs for the ASC Quality Reporting Program to October 1, 2012.

The QDCs are a means of data collection for quality measures that is already in use in PQRS. PQRS has received quality measure information via QDCs reported via claims since the program's inception in 2007. From 2007 through 2008, there were instances where QDCs were reported incorrectly and therefore deemed invalid due to a number of reasons. These reasons included: diagnosis mismatch; gender mismatch; reporting the QDC on a denominator code not contained within the measure; and reporting an invalid modifier (PQRS uses 1P, 2P, 3P and 8P modifiers to represent performance exclusions and performance not met instances). However, in recent reporting years, we have seen the QDC errors decrease to a very low percentage (less than 1 percent errors are QDC-related) attributed to providers' progressive experience with QDCs, our education and outreach efforts, as well as our streamlining of diagnosis-

specific QDCs. Therefore, we believe that over time, ASCs will have the same success as PQRS with QDC-based measures.

<u>Comment</u>: For future options for data submission, a commenter suggested using ASC-specific registry which is under consideration for development by registry developers.

Response: We thank the commenter for the suggestion. In our search for future quality measures for ASCs, we will consider ASC-specific registry-based measures.

The seven proposed claims-based measures are discussed in more detail below:

(1) Patient Burns (NQF #0263)

The ASC Quality Measures: Implementation Guide Version 1.4 states that every patient receiving care in an ASC setting has the potential to experience a burn during an episode of care, given the multitude of factors that could pose risks for patient burns in the surgical and procedural settings. The Guide cited a recent publication from the ECRI Institute that relates an increased risk of burns associated with newer electrosurgical devices due to their application of higher electrical current for longer time intervals. Other common sources of burns in a surgical setting include chemical and thermal sources, and radiation, scalds, and fires. Clinical practice guidelines for reducing the risk of burns have been established by the American Society of Anesthesiologists (ASA) and Association of Operating Room Nurses (AORN).

This NQF-endorsed measure assesses the percentage of ASC admissions experiencing a burn prior to discharge. The specifications for this NQF-endorsed measure developed by the ASC QC can be found at:

f. The ASC QC in their ASC Quality Measure Implementation Guide version 1.4 defines a "burn" for purposes of this measure as "[u]nintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation (for example, warming devices, prep solutions, and electrosurgical unit or laser)." We believe that this measure would allow stakeholders to develop a better understanding of the incidence of these events and further refine means to ensure prevention.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs since they serve surgical patients who may face the risk of burns during ambulatory surgical procedures. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42339). While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use

information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if this measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

<u>Comment</u>: Several commenters supported the proposed measure, but noted that this measure does not apply to GI ASCs since the risk of burn in conjunction with endoscopic procedures is rare and minor.

Response: We thank the commenters for the support of the measure. The denominator for the NQF-endorsed measure is all ASC admissions. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure. Therefore, the measure is applicable to all Medicare Part B ASC admissions It addresses "[u]nintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation (for example, warming devices, prep solutions, and electrosurgical unit or laser)." Although

patient burns may be rare in GI ASCs, we believe that inclusion of the measure in the ASC Quality Reporting Program will help ensure that such burns never happen. We refer commenters to the specifications for this measure for more information.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to begin on October 1, 2012 (as discussed in section XIV.K.1. of this final rule with comment period).

(2) Patient Fall (NQF #0266)

Falls, particularly in the elderly, can cause injury and loss of functional status, and falls in healthcare settings can be prevented through assessment of risk, care planning, and patient monitoring. Healthcare settings are being called upon to report patient falls and to take steps to reduce the risk of falls. The ASC QC indicates in their ASC quality measure implementation guide the use of anxiolytics, sedatives, and anesthetic agents may put patients undergoing outpatient surgery at increased risk for falls. Guidelines and best practices for the prevention of falls, and management of patients after falls have been made available by the Agency for Healthcare Research and Quality (http://www.ahrq.gov/qual/transform.htm), and the National Center for Patient Safety (http://www.patientsafety.gov).

This NQF-endorsed measure assesses the percentage of ASC admissions experiencing a fall in the ASC. The specifications for this NQF-endorsed measure developed by the ASC QC can be found at:

http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pd f.

The ASC QC in its ASC Quality Measure Implementation Guide version 1.4 defines a "fall" as "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", which is consistent with the definition set forth by the National Center for Patient Safety.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs because it was specifically developed to measure quality of surgical care furnished by ASCs, as measured by patient falls. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is NOF-endorsed.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare fee-for-service beneficiaries from January 1, 2012 through December 31, 2012 (76 FR 42339). While

the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate the measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if this measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

<u>Comment</u>: All the commenters who commented on this measure supported the proposed measure but were concerned about the proposed data collection starting on January 1, 2012.

Response: We thank the commenters for the support of the measure. As stated in XIV.K.1. of this final rule with comment period, we are delaying the beginning of the data collection until October 1, 2012.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to begin on October 1, 2012.

(3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)

Surgeries and procedures performed on the wrong site/side, and wrong patient can result in significant impact on patients, including complications, serious disability or death. While the prevalence of such serious errors may be rare, such events are considered serious reportable events, and are included in the NQF's Serious Reportable Events in Healthcare 2006 Update. The Joint Commission has issued a Universal Protocol to prevent such serious surgical errors. The proposed NQF-endorsed measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. The ASC QC in its ASC Quality Measures: Implementation Guide Version 1.4 defines "wrong" as "not in accordance with intended site, side, patient, procedure or implant." The specifications for this NQF-endorsed measure developed by the ASC QC can be found at:

http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pd <u>f.</u>

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the

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http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx

³⁹ Joint Commission. Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. Available at http://www.jointcommission.org/standards_information/up.aspx. Last accessed December 14, 2010.

extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs because the measure assesses the quality of surgical care provided in ASCs as measured by the percentage of surgical errors. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42340). While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if this measure is finalized, ASCs would need to place QDCs relevant to this measure on

Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

Comment: All of the commenters who commented on this measure supported the proposed measure. However, some commenters indicated that this measure may not apply to GI ASCs since the risk of performing wrong site, wrong side, wrong patient, wrong procedure, and wrong implant in ASC endoscopic procedures is rare (for example, confusion over an upper GI endoscopy and colonoscopy, or a single procedure in one encounter versus both an upper endoscopy and colonoscopy in the same encounter).

Also, commenters were concerned about the proposed data collection starting on January 1, 2012.

Response: We thank the commenters for the support of the measure. As discussed above, this measure is applicable to all Medicare Part B ASC admissions. Although this type of mishap may be rare, we believe that inclusion of the measure in the ASC Quality Reporting Program will help ensure they will never happen. Note that, as stated in section XIV.K.1. of this final rule with comment period, we are delaying the beginning of the data collection until October 1, 2012.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to being on October 1, 2012.

(4) Hospital Transfer/Admission (NQF #0265)

The transfer or admission of a surgical patient from an outpatient setting to an acute care setting can be an indication of a complication, serious medical error, or other

unplanned negative patient outcome. While acute intervention may be necessary in these circumstances, a high rate of such incidents may indicate suboptimal practices or patient selection criteria. The proposed NQF-endorsed measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC. The ASC QC defines "hospital transfer/admission" as "any transfer/admission from an ASC directly to an acute care hospital, including hospital emergency room."

The specifications for this NQF-endorsed measure developed by the ASC QC measure can be found at:

http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pd f. The ASC QC believes that this "measure would allow ASCs to assess their guidelines for procedures performed in the facility and patient selection if transfers/admissions are determined to be at a level higher than expected. If commonalities are found in patients who are transferred or admitted, guidelines may require revision."

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses outpatient surgical care quality in the form of the rate of surgical outpatients needing acute care interventions. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a

national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42340). While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQFendorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if the measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

<u>Comment</u>: All of the commenters who commented on this measure supported the proposed measure. However, one commenter noted that the measure should be expanded to include patients who return home after ASC procedure, but are then admitted to a

hospital shortly after for a procedure-related issue. The commenter urged CMS to create methods to track the adverse outcomes of these patients.

Response: We thank the commenters for their support. We also thank the commenter for the suggestion, and will consider it in future measure development and refinement.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to begin on October 1, 2012 (as discussed in section XIV.K.1. of this final rule with comment period).

(5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

Timely preoperative administration of intravenous antibiotics to surgical patients is an effective practice in reducing the risk of developing a surgical site infection, which in turn is associated with reduced health care burden and cost, and better patient outcomes. 40 41 42 The measurement of timely antibiotic administration for surgical patients is occurring in the Hospital IQR Program, Hospital OQR Program and the PQRS. The NQF-endorsed ASC QC measure assesses the rate of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time. The specifications for this NQF-endorsed measure developed by the ASC QC measure can be found at:

⁴⁰ Classen, D. et al.: The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. NEJM. 1992;326(5):281-286.

⁴¹ Silver, A. et al.: Timeliness and use of antibiotic prophylaxis in selected inpatient surgical procedures. The Antibiotic Prophylaxis Study Group. Am J Surg. 1996;171(6):548-552.

⁴² Dounis, E., Tsourvakas, S., Kalivas, L., and Giamacellou, H.: Effect of time interval on tissue concentrations of cephalosporins after tourniquet inflation. Highest levels achieved by administration 20 minutes before inflation. Acta Orthop Scand. 1995;66(2):158-60.

 $\frac{http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pd}{f.}$

The ASC QC measure implementation guide defines "antibiotic administered on time" as "[a]ntibiotic infusion ... 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 fluoroguinolones are administered." The measure also defines "prophylactic antibiotic" as "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, Ertapenem, Erythromycin, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin and Vancomycin." All prophylactic IV antibiotics administered for surgical site infection would need to have their infusion initiated within the one hour time frame, except for vancomycin or fluoroguinolones, where infusion must be initiated within the two hours time frame. The ASC QC Guide states that "[i]n cases involving more than one antibiotic, all antibiotics must be given within the appropriate time frame in order for the case to meet criteria." The timing of the antibiotic starts at the time the antibiotic is initiated with a preoperative order.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication

errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses the quality of care for surgical patients in an outpatient setting as measured by timely antibiotic administration. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NOF.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDCs data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42341). While the NQF-endorsed specification for this measure includes all ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of surgical site infection, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if the measure

is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

<u>Comment</u>: A few commenters opposed the measure and believed that this measure is not applicable to ASC GI endoscopic centers. A few commenters considered the proposed data collection to begin on January 1, 2012 unreasonable.

Response: The measure assesses whether an antibiotic is given on time prior to a procedure if it was ordered. We note that the specifications for the measure list endoscopy as one of the examples of procedures. As stated in section XIV.K.1. of this final rule with comment period, we are delaying the beginning of data collection until October 1, 2012 for the CY 2014 payment determination.

<u>Comment</u>: A few commenters did not believe this measure is burdensome since it is a claims-based measure, but urged that CMS provide training to ASCs regarding when to enter the specific QDCs appropriately. A commenter asked for clarification whether the proposed QDC-codes should be reported with every claim for an ASC procedure or only if the adverse event has occurred. One commenter suggested that CMS provide education to ASCs regarding whether QDCs need to be reported with every claim, or only for those where an adverse event occurred.

Response: We also do not believe submitting QDCs on claims is burdensome. In order to submit quality data using CPT-II and HCPCS codes, ASCs would need to add the appropriate QDCs for measure numerators and denominators on Medicare Part B claim forms. We intend to provide education and outreach on data submission for the

reporting program, and we will publish details about the QDCs and whether they will need to be submitted for numerators and denominators in the ASC Quality Reporting Program Specifications Manual. We anticipate releasing this manual in second quarter 2012

<u>Comment</u>: One commenter noted that CMS incorrectly stated that the NQF-endorsed specification for this measure includes all ASC admissions. The commenter stated that the NQF specification limits the denominator to all ASC admissions with a pre-operative order for a prophylactic IV antibiotic for the prevention of surgical site infection.

The commenter recommended giving the public the opportunity to comment on the QDC descriptors that CMS develops in the future. Specifically, the commenter requested the following corrections: (1) the required timing of antibiotics begins with the initiation of the IV antibiotic, not the pre-operative order; and (2) the specifications limit the denominator to all ASC admissions with a preoperative order for IV antibiotics, not all ASC admissions. The commenter believed that three QDCs are needed to describe: (1) timely administration; (2) untimely administration; and (3) circumstances where no prophylactic was ordered.

Response: The commenter is correct, the denominator for the NQF-endorsed measure is all ASC admissions with a pre-operative order for a prophylactic IV antibiotic for prevention of surgical site infections. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure.

We correctly described the measure initially but then did not state it completely when describing the application of the measure to a subset of patients. As the commenter stated, the assessment of appropriateness of timing begins with the initiation of IV antibiotics relative to the initial surgical incision or the beginning of the procedure. We will ensure these aspects of the measure are clarified in the Specifications Manual CMS issues for this program.

<u>Comment</u>: A commenter recommended the discontinuation of this measure once the proposed surgical site infection measure is implemented to include additional ASC procedures.

Response: We thank the commenter for the suggestion. As discussed in section XIV.K.3.b. below, for the ASC Quality Reporting Program, we are not finalizing the surgical site infection measure in this rulemaking.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to begin on October 1, 2012 (as discussed in section XIV.K.1 of this final rule with comment period).

(6) Ambulatory Surgery Patients with Appropriate Method of Hair Removal (NQF #0515)

The ASC QC⁴³ cited evidence that "[r]azors can cause microscopic cuts and nicks to the skin, not visible to the eye. Use of razors prior to surgery increases the incidence of wound infection when compared to clipping, depilatory use or no hair removal at

⁴³ ASC QC Quality measures: Implementation Guide version 1.4. ASC Quality Collaboration. December 2010.

all."⁴⁴ A 1999 guideline issued by the CDC suggests that if hair must be removed from a surgical site, that it preferably be done with clippers rather than razors in order to minimize cuts and nicks to the skin which may increase the risk of a surgical site infection.⁴⁵ In 2002, the Association of Operating Room Nurses published similar guidelines for appropriate hair removal.⁴⁶ While a similar measure is being considered for retirement from the Hospital IQR Program because it displays a high degree of performance with little variability or room for improvement, we believe that there is significant variability in practice and the level of adherence to this guideline in outpatient surgical settings such as ASCs is not known. Therefore, we believe that this measure is still appropriate for use in the ASC setting. In the CY 2012 OPPS/ASC proposed rule (76 FR 42341 through 42342), we proposed to adopt the NQF-endorsed measure to capture the percentage of ASC admissions with appropriate surgical site hair removal. The specifications for this NQF-endorsed measure developed by the ASC QC can be found at:

http://www.ascquality.org/documents/ASCOualityCollaborationImplementationGuide.pd

f. Read together, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national

⁴⁴ Seropian, R., Reynolds, B.M.: Wound infections after preoperative depilatory versus razor preparation. Am J Surg.1971 Mar;121(3):251-4.

⁴⁵ http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf

⁴⁶ Association of Operating Room Nurses. Recommended practices for skin preparation of patients. AORN J. 2002 Jan;75(1):184-7.

consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses quality of surgical care performed in ASCs, as measured by appropriate surgical site hair removal. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42341). While the NQF-endorsed specification for this measure includes all ASC admissions with surgical site hair removal, our proposal to use information submitted on claims to calculate these measures necessitates that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if the measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of CY 2014 payment determination.

Comment: A few commenters stated that the measure does not apply to endoscopy centers. Several commenters opposed this measure because they stated that there is no conclusive clinical evidence that clipping, rather than other hair removal techniques, reduces surgical site infections across a broad spectrum of surgical procedures. Furthermore, the scrotal surgery exclusion does not appear to be present in the ASC specifications. Two commenters found it confusing that CMS has currently suspended this measure from the Hospital IQR Program due to the measure's "topped-out" status.

Response: CMS agrees with these comments, and is not finalizing this measure for the ASC Quality Reporting Program. A recently published systematic review by Alexander JW et al. (Annals of Surgery.2001;253(6):1082-1093) also indicates that not removing hair is associated with the least probability of infection.

Comment: One commenter indicated that CMS incorrectly stated that the NQF-endorsed specification for this measure includes all ASC admissions. The commenter clarified that the NQF specifications limit the denominator to all ASC admissions with surgical site hair removal. A commenter noted that the public should have the opportunity to comment on the descriptors CMS develops. The commenter believed that a correction that needs to be made in the rule: the specifications limit the denominator to all ASC admissions with surgical site hair removal, not all ASC admissions. Additionally, the commenter believed that a set of three QDCs would be needed to describe: (1) appropriate hair removal; (2) inappropriate hair removal; and (3) circumstances where no hair was removed or other exclusions.

Response: As discussed above, we are not finalizing this measure for the ASC Quality Reporting Program.

After consideration of the public comments we received, we are not finalizing this measure for CY 2014 payment determination.

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

Surgical outcomes are affected by the selection of appropriate antibiotics. Current guidelines indicate that first or second generation cephalosporins are effective for prevention of surgical site infections in most cases. The goal of this proposed measure is to ensure safe, cost-effective, broad spectrum antibiotics are used as a first line prophylaxis unless otherwise indicated. This measure was developed by the AMA's Physician Consortium for Performance Improvement, a national, diverse, physician-led group that identifies, develops, and promotes implementation of evidence-based clinical performance measures that reflect best practices. This measure received NQF endorsement under a 2008 project entitled "Hospital Care: Specialty Clinician Performance Measures," and it assesses the percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin or cefuroxime for antimicrobial prophylaxis. While we recognize that this measure is not specifically endorsed for the ASC setting, we believe that this measure is highly relevant for use in ASCs because it assesses adherence to best practices for use of prophylactic antibiotics for outpatient surgical patients. Accordingly, we proposed to adopt an application of this

NQF-endorsed measure for use in the ASC Quality Reporting Program. The measure specifications for this proposed measure can be found at:

http://www.cms.gov/pqrs/downloads/2011_PhysQualRptg_MeasuresGroups_SpecificationsManual_033111.pdf?agree=yes&next=Accept.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate for measurement of quality care in an ASC because it specifically assesses quality care, as measured by adherence to best practices for prophylactic antibiotics provided for outpatient surgical patients. We believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment.

The measure development process employed the same process used by the American Medical Association Physician Consortium for Performance Improvement (AMA-PCPI). The AMA PCPI is a consortium of physicians dedicated to improving patient safety by developing evidence based performance measures, promoting the implementation of effective and relevant clinical performance improvement activities, and advancing the science of clinical performance measurement and improvement. The

AMA-PCPI develops many measures for the PQRS program. The AMA-PCPI development process for this measure is a consensus-based process that involves stakeholder input, including surgeons performing procedures in outpatient settings such as ASCs. Because of this, we believe this measure meets the requirement of reflecting consensus among affected parties.

Further, it is not feasible or practicable to adopt an NQF-endorsed measure of prophylactic antibiotic selection specifically for ASCs because there is no such NQF-endorsed measure. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt measures that are not NQF-endorsed or measures that have not been endorsed for the ASC setting.

The proposed adoption of this measure in the ASC Quality Reporting Program also is consistent with our goal to align measures across settings, as it is also used in the PQRS, and a similar measure (NQF #0528) has been implemented in the Hospital OQR Program and the Hospital IQR Program.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from

January 1, 2012 through December 31, 2012 (76 FR 42342). While the NQF-endorsed specification for this measure includes all surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if the measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

<u>Comment</u>: Several commenters expressed various concerns regarding this measure: A commenter believed this is a physician-level measure and not an ASC-level measure. Therefore, the commenter suggested that CMS report the antibiotic selection data submitted by physicians for this measure by place of service (POS) and aggregate physician performance data across surgical settings, including hospital inpatient and outpatient settings, and ASC setting.

A commenter believed that this measure does not represent the most prevalent area of services provided by ASCs. A commenter stated that data collection for this measure is very burdensome. One commenter requested clarification on what procedure codes would allow for the best comparison since very few codes in the current denominator set are relevant to the ASC setting (according to the commenter, ASCs only accounted for 0.16 percent of total Medicare procedures in 2009). A commenter asked that CMS clarify and educate ASCs as to whether the proposed QDC-codes should be reported with every claim for an ASC procedure or only if the adverse event has occurred. A commenter stated that this measure should be phased out after the surgical site infection measure has been expanded to include additional ASC procedures. Given the NQF's endorsement for this measure is non-ASC-specific, another commenter encouraged CMS to seek NQF endorsement specific to the ASC setting to ensure accuracy in data collection and implementation.

Response: We agree that the measure may not address the most prevalent procedures performed by ASCs and we will need to examine how the measure may be modified in order to capture those procedures most commonly performed in ASCs.

Therefore, we are not finalizing this measure for the CY 2014 payment determination at this time

After consideration of the public comments we received, we are not finalizing the selection of prophylactic antibiotic: first OR second generation cephalosporin measure for ASCs for the CY 2014 payment determination.

b. Surgical Site Infection Rate (NQF #0299)

HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths. ⁴⁷ It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. HAIs are largely preventable for surgical patients through application of perioperative best practices such as those listed in the CDC's Surgical Site Infection prevention guidelines. Therefore, many health care consumers and organizations are calling for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and gives hospitals an incentive to improve infection control efforts. This proposed measure is currently collected by the NHSN as part of State-mandated reporting and surveillance requirements for hospitals in some States. Additionally, data submission for this measure through EHRs may be possible in the near future.

This measure is NQF-endorsed and we proposed to adopt it for the CY 2014 Hospital OQR Program. It also has been adopted for the FY 2014 Hospital IQR Program. Because we proposed the same measure for Hospital OQR Program, we refer readers to the discussion of this measure in sections XIV.C.2.a. of the proposed rule and this final rule with comment period. The measure specifications can be found at http://www.cdc.gov/nhsn/psc.html. The NQF describes this measure as the "percentage

⁴⁷ McKibben. L., Horan, T.: Guidance on public reporting of healthcareassociated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005;33:217-26.

of surgical site infection events occurring within thirty days after the operative procedure if no implant is left in place, or [within] one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure."

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. Increasingly, surgical procedures are being performed in hospital outpatient department settings and ASCs. We believe this measure is appropriate for measuring quality of care in ASCs because it applies to outcomes for surgical patients undergoing procedures that are performed in ASCs.

Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is endorsed by the NQF. The proposed adoption of this measure in the ASC Quality Reporting Program also is consistent with our goal to align measures across settings because we have proposed this measure for the Hospital OQR Program for CY 2014 payment determination and have previously adopted it for Hospital IQR Program for the FY 2014 payment determination. Therefore, we proposed to adopt the Surgical Site Infection Rate measure that is collected by the CDC via the NHSN for the ASC Quality Reporting Program for the CY 2014 payment determination.

Data submission for this measure for the CY 2014 payment determination would begin with infection events occurring on or after January 1, 2013 through June 30, 2013. The proposed reporting mechanism for this proposed HAI measure via the NHSN is discussed in greater detail in sections XIV.C.2.a. of the proposed rule and this final rule with comment period. In the proposed rule, we invited public comment on this proposed measure and the reporting mechanism.

<u>Comment</u>: Some commenters requested clarification on how infections will be identified by ASCs in cases where patients go home on the same day or go to another hospital for the infection. Commenters believed that it would be challenging to survey outpatients, including ASC patients, to determine whether an infection has developed and if it meets the NHSN definition for surgical site infection.

Some commenters believed that the NHSN module was not relevant for ASCs. A commenter cited the measure specification that "SSI [surgical site infections] are to be identified on original admission or upon readmission to the facility of the original operative procedures" and concluded this measure is inappropriate for ASCs due to patients' short length of stay and their likely admission to a hospital when an infection occurs. Because the commenter believed that the 10 NHSN-defined operative procedure categories have little relevance to the predominant procedures performed in ASCs, the commenter recommended that CDC re-specify the measure to include common ASC-specific procedures to identify related infections in the numerator.

One commenter urged CMS to consider facility exemptions in implementing this measure. The commenter stated that ASCs seldom perform operative procedures as

defined by the CDC: "an operative procedures as the one 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."

Another commenter stated that ASCs normally do not have an ongoing relationship with patients and recommended that CMS require ASCs to conduct follow-up phone calls with patients, caregivers or physicians within 30 days of procedures to identify patients who have developed surgical site infections. Commenters also recommended that CMS require that ASCs include this information in medical records as part of the data submission to NHSN, preferably via electronic submission.

Several commenters supported the surgical site infection measure but the disparate codes used by hospital outpatient departments and ASCs and the ICD codes used in the NHSN module would create potential inaccurate data submission. The commenters believed that the uncommon use of NHSN in ASCs would add challenges to follow-up surveillance.

Response: We thank the commenters for their views. As discussed below, we are not finalizing this proposed measure.

<u>Comment</u>: One commenter encouraged CMS to accelerate the timeframe for making the surgical site infection measure data for ASCs publicly available. The commenter believed that once this outcome measure is implemented, two ASC surgical infection control measures (ASC-5: Prophylactic IV antibiotic timing, and ASC-7: Prophylactic antibiotic selection for surgical patients) can be eliminated from the

Hospital OQR Program. The commenter suggested harmonization of this measure across different HOPD surgical and ASC settings.

Response: We appreciate this supportive comment. At this time, we are not finalizing surgical site infection measures for the Hospital OQR Program or the ASC Quality Reporting Program. We will consider proposing a surgical site infection measure for the ASC Quality Reporting Program in the future. We agree with the commenters that a number of procedures frequently performed in outpatient surgical settings like ASCs are not addressed in the current surgical site infection measure adopted for the Hospital IQR Program, and that a follow-up and collection protocol that is better suited to outpatient surgical settings for such a measure should be developed. We also agree with the suggestion that we harmonize measures between the ASC Quality Reporting Program and the Hospital OQR Program, to the extent feasible. These comments will be taken into consideration in future surgical site infection measurement proposals for the ASC Quality Reporting Program.

<u>Comment</u>: A commenter believed that the measure should facilitate comparisons across ASCs and hospital outpatient surgery setting by making the data more patient-centered for easy comprehension.

Response: We appreciate the input from the commenter. Although we are not adopting this measure at this time, we will take this view into consideration as we consider proposing a surgical site infection measure in the future.

<u>Comment</u>: A commenter was very concerned about the burden to report to NHSN and cited that 40 ASCs that are currently participating in NHSN reported

registration and data submission are very time-consuming. The commenter urged CDC to streamline these processes to make them more user-friendly.

Response: We appreciate the input from the commenter regarding potential burden and the need for user-friendly processes. As stated above, we are not finalizing this measure for the CY 2014 payment determination.

<u>Comment</u>: Some commenters requested that CMS delay implementation of the surgical site infection measure to the CY 2015 payment determination with data collection starting on January 1, 2014 through June 30, 2014 to allow ASC to gain experience with the NHSN module.

Response: As stated above, we are not finalizing the surgical site infection measure for the CY 2014 payment determination.

After consideration of the public comments we received, we are not finalizing the surgical site infection measure for ASCs for CY 2014 payment determination. We will consider proposing the measure once a suitable set of procedures and a protocol for ASCs and HOPDs has been developed.

In summary, we are finalizing five claims-based measures total using the QDC data collection mechanism for the CY 2014 payment determination. Based upon the public comment we received, we are finalizing the data submission for these five claims-based measures to begin on October 1, 2012. This issue is discussed in more detail in the Form, Manner and Timing section for this program. The quality measures we are adopting for ASCs for the CY 2014 payment determination are listed below with the ASC prefix:

ASC Program Measurement Set for the CY 2014 Payment Determination (Data submission to begin on October 1, 2012)

ASC-1: Patient Burn

ASC-2: Patient Fall

ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

ASC-4: Hospital Transfer/Admission

ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing

- 4. ASC Quality Measures for CY 2015 Payment Determination
- a. Retention of Measures Adopted for the CY 2014 Payment Determination in the
 CY 2015 Payment Determination

In general, unless we otherwise specify in the retirement section of a rule, we proposed to retain measures from one CY payment determination to another. In the CY 2012 OPPS/ASC proposed rule (76 FR 42343), we proposed to retain the measures we proposed to adopt for the CY 2014 payment determination, if they are finalized in the CY 2012 OPPS/ASC final rule with comment period, for the CY 2015 payment determination. In the proposed rule, we invited public comments on this proposal.

<u>Comment</u>: One commenter supported the proposed retention of the measures we finalized for the CY 2014 payment determination for the CY 2015 payment determination.

Response: We thank the commenter for supporting the retention of these measures.

After consideration of the public comment we received, we are finalizing our proposal to retain measures from one CY payment determination to the next. For the

CY 2014 payment determination, as discussed above, we are finalizing five claims-based measures. Therefore, we will retain these five measures for the CY 2015 payment determination

b. Structural Measures for the CY 2015 Payment Determination

In the CY 2012 OPPS/ASC proposed rule (76 FR 42343 through 42346), for the CY 2015 payment determination, we proposed to adopt two structural measures: Safe Surgery Checklist Use, and ASC Facility Volume Data on Selected ASC Surgical Procedures. We discuss these proposals below.

(1) Safe Surgery Checklist Use

A sound surgery safety checklist could minimize the most common and avoidable risks endangering the lives and well-being of surgical patients. The purpose of this proposed structural measure is to assess whether ASCs are using a safe surgery 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. The use of such checklists has been credited with dramatic decreases in preventable harm, complications and post-surgical mortality.⁴⁸ In November 2010, the New England Journal of Medicine published a study concluding that surgical complications were reduced by one-third, and mortality by nearly half, when a safe surgery checklist was used.⁴⁹

Haynes, A.B.; Weiser, T.G.; Berry, W.G. et. al (2009). "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population". New England Journal of Medicine. 360: 491-499.
 de Vries EN, Prins HA, Crolla RMPH, et al. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010;363: 1928-37

We believe that effective communication and the use of safe surgical practices during surgical procedures will significantly reduce preventable surgical deaths and complications. Some examples of safe surgery practices that can be performed during each of these three perioperative periods are shown in the table below:

First critical point (prior to	Second critical point (prior	Third critical point (prior to
administering anesthesia)	to skin incision)	patient leaving the operating
		room)
Verbal confirmation of patient	Confirm surgical team	Confirm the procedure
identity	members and roles	 Complete count of surgical
Mark surgical site	 Confirm patient identity, 	instruments and accessories
Check anesthesia	procedure, and surgical	 Identify key patient concerns
machine/medication	incision site	for recovery and management of
Assessment of allergies, airway	Administration of antibiotic	the patient
and aspiration risk	prophylaxis within 60 minutes	
	before incision	
	 Communication among 	
	surgical team members of	
	anticipated critical events	
	 Display of essential 	
	imaging as appropriate	

For example, mistakes in surgery can be prevented by ensuring that the correct surgery is performed on the correct patient and at the correct place on the patient's body. A safe surgery checklist would reduce the potential for human error, which would increase the safety of the surgical environment. Another example of a checklist that employs safe surgery practices at each of these three perioperative periods is the World Health Organization Surgical Safety Checklist, which was adopted by The World Federation of Societies of Anesthesiologists as an international standard of practice. This

⁵⁰ Hospital National Patient Safety Goals. The Joint Commission Accreditation Hospital Manual, 2011. http://www.jointcommission.org/standards_information/npsgs.aspx

checklist can be found at:

http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html.

The adoption of a structural measure that assesses Safe Surgery Checklist Use would align our patient safety initiatives with those of several surgical specialty societies including: the American College of Surgeons' Nora Institute for Patient Safety, the American Society of Anesthesiologists, TJC, the National Association for Healthcare Quality and the AORN. The measure would assess whether the ASC uses a safe surgery checklist in general, and would not require an ASC to report whether it uses a checklist in connection with any individual procedures.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. This measure is appropriate for the measurement of quality of care furnished by ASCs because it pertains to best practices for surgeries, and ASCs perform ambulatory surgeries. It also reflects consensus among affected parties. As stated in sections XIV.C.2.c.1 of the proposed rule and this final rule with comment period, we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment.

The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federation of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety⁵¹, which is comprised of the American Association of Nurse Anesthetists, the American College of Surgeons, the American Association of Surgical Physician Assistants, the American Society of Anesthesiologists, the American Society of PeriAnesthesia Nurses, AORN, and the Association of Surgical Technologists. Two State agencies (Oregon, South Carolina), the Veterans Health Administration⁵², numerous hospital systems, State hospital associations (such as California and South Carolina), national accrediting organizations and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.^{53, 54} Because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist Use reflects consensus among affected parties. We also note that TJC has included safe surgery checklist practices among those to be used to achieve NPSGs adopted for 2011 for surgeries performed in ambulatory settings and hospitals⁵⁵.

⁵¹ http://www.cspsteam.org/safesurgerychecklist/safesurgerychecklist.html

⁵² Neily, J; Mills, PD, Young-Xu, Y. (2010). "Association between implementation of a Medical Team Training Program and Surgical Mortality". JAMA. 304 (15): 1693-1700.

⁵³ Haynes, AB; Weiser, TG; Berry, WR et al (2009) "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population". NEJM. 360:491-499.

⁵⁴ Birkmeyer, JD (2010) "Strategies for Improving Surgical Quality – Checklists and Beyond." NEJM. 363: 1963-1965.

⁵⁵ http://www.jointcommission.org/standards information/npsgs.aspx

The Safe Surgery Checklist Use structural measure is not NQF-endorsed, and there is no NQF-endorsed measure of safe surgery checklist use despite the broad acceptance and widespread endorsement of this practice. Therefore, it is not feasible or practicable to adopt an NQF-endorsed measure of safe surgery checklist use because there is no such NQF-endorsed measure. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. We note that the proposed adoption of this measure in the ASC Quality Reporting Program is consistent with our goal to align measures across settings because we also proposed the same measure for the Hospital OQR Program for CY 2014 payment determination.

For the CY 2015 payment determination, we proposed that data collection for this structural measure for ASCs would begin on July 1, 2013 and end on August 15, 2013 for the entire time period from January 1, 2012 through December 31, 2012. In other words, an ASC would report whether their facility employed a safe surgery checklist that covered each of the three critical perioperative periods for the entire calendar year of 2012 during the 45-day window from July 1 through August 15, 2013. The information for this structural measure would be collected via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. This collection mechanism is also

used to collect structural measures and other information for other programs, specifically for the Hospital IQR and Hospital OQR Programs.

In the proposed rule, we invited public comments on our proposal to add this new structural measure to the ASC quality measurement set and the submission process for the CY 2015 payment determination.

Comment: Several commenters fully supported the Safe Surgery Checklist measure and believed the measure helps to ensure safe surgical practices prior to administration of anesthesia, incision, and the patient's departure from the operating room. A commenter did not believe this measure would impose substantial burden on ASCs because the data is collected via a Web-based tool. Some commenters appreciated the flexibility given to ASCs in the design and use of a specific checklist to meet their needs. Commenters urged CMS to revise the measure name to include, "safe surgery/procedure checklist" and modify its purpose statement to indicate the intent of the measure as "an assessment whether ASCs use 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: (1) prior to the administrative of anesthesia or sedation; (2) prior to incision or the beginning of the procedure; and (3) prior to the patient leaving the operating or procedure room." Commenters urged harmonization with the same measure proposed in the Hospital OQR Program.

Response: We agree with the commenter that this measure would impose minimal burden because the data are submitted using a Web-based data submission tool.

The ASC safe surgery checklist measure is aligned with the safe surgery checklist measure that we are adopting for HOPDs.

Comment: A few commenters recommended a 60-day time period for data submission rather than the 45-day window and suggested that CMS change this measure into a claims-based measure rather than using an online tool. Commenters recommended changing the proposed collection time period from January 1, 2012 through December 31, 2012 to January 1, 2013 through December 31, 2013 and delay the data submission period until early 2014. The commenters did not provide a rationale for this suggestion.

Response: The goal of this measure is to assess whether a particular ASC is using a safe surgery checklist from January 1, 2012 until December 31, 2012, requiring one yes/no response for this measure, not to assess whether a safe surgery checklist is used for each Medicare Part B patient. Therefore, a claims-based measure would not be appropriate to measure whether an ASC is using a safe surgery checklist because we are not measuring its use on an individual claims-based level.

We note that the Web based reporting tool is a minimally burdensome method of collecting this facility level information, and is currently in use for similar types of measures for both the Hospital IQR and Hospital OQR Programs. We seek to align the reporting periods for the reporting programs and currently, a 45-day window is being used for data collection for some structural measures in the Hospital IQR and Hospital OQR Programs. At this time, we are not changing the time periods for the structural measures because there is minimal burden and advance preparation to collect and report this information to CMS.

Comment: A few commenters did not support this measure for different reasons. Some commenters believed that the use of a checklist cannot be validated by CMS, and therefore, it should not be considered as a measure. Some commenters noted that it is not NQF-endorsed. Some commenters objected to the collection of patient- or procedure-detailed level data. Commenters were also concerned about the implementation of this measure simultaneously with ICD-10 conversion would further tax facilities' resources. A commenter stated this measure is duplicative because all accredited ASCs are already required to use a safe surgery checklist. Another commenter noted that the safe surgery checklist as required in the Conditions for Coverage could also meet the criteria for this measure. A few commenters stated this measure does not apply to ASCs performing GI surgical procedures and requested the adoption of a safe surgery checklist that is specific to GI procedures performed in ASCs.

Response: We acknowledge that this measure cannot be validated because it does not use charts or claims. Nonetheless, we believe the measure would heighten ASCs' awareness of patient safety during surgical procedures and safeguard against preventable human errors. As discussed above, we believe this measure meets the statutory requirements, even if it is not NQF-endorsed. There is no NQF-endorsed measure for safe surgery checklist use despite the broad acceptance and widespread endorsement of this practice. Therefore, it is not feasible or practicable to adopt an NQF-endorsed measure of safe surgery checklist use because there is no such NQF-endorsed measure. As stated in previous rulemaking, we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved

during measure development processes, consensus shown through broad acceptance and use of measure; and consensus through public comment. The use of a safe surgery checklist has been adopted by the World Federation of Societies of Anesthesiologists, and is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety which is comprised of multiple medical professional organizations.

We disagree with the commenters who suggested that a safe surgery checklist would not apply to GI procedures. Some GI procedures are performed under anesthesia, and wrong site surgery and wrong procedure is possible for GI procedures, all of which are general topics that would be covered under a safe surgery checklist. Therefore, we believe that a well-designed, comprehensive generic safe surgery checklist should cover GI-specific surgical procedure elements as well.

We do not believe that the reporting of this structural measure to CMS for this quality reporting program and subsequent public reporting is duplicative of accreditation requirements or conditions of coverage for ASCs, because these other requirements do not require the reporting this information to CMS annually by each eligible facility and the subsequent public reporting of this information on a CMS Web site. As stated previously, this measure is not collected on an individual patient or procedure level and does not involve the use of ICD-9 codes or ICD-10 codes.

After consideration of the public comments we received, we are finalizing this measure for CY 2015 payment determination. We are finalizing our proposal for the CY 2015 payment determination that ASCs would report their yes/no response regarding use of a safe surgery checklist between July 1, 2013 and August 15, 2013 for the time

period from January 1, 2012 through December 31, 2012 using an online measure submission Web page available on http://www.qualitynet.org. Details regarding measure submission timelines and collection periods are discussed in the Form, Manner and Timing section for this program in this final rule with comment period.

(2) ASC Facility Volume Data on Selected ASC Surgical Procedures

There is substantial evidence in recent peer-reviewed clinical literature that volume of surgical procedures, particularly of high risk surgical procedures, is related to better patient outcomes, including decreased surgical errors and mortality. 56, 57, 58 This may be attributable to greater experience and/or surgical skill, greater comfort with and hence likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. For this reason, the National Quality Forum has endorsed measures of total all-patient surgical volume for Isolated CABG and Valve Surgeries (NQF #0124), Percutaneous Coronary Intervention (PCI) (NQF #0165), Pediatric Heart Surgery (NQF #0340), Abdominal Aortic Aneurism Repair (NQF #357), Esophageal Resection (#0361), and Pancreatic Resection (NQF #0366). Additionally, many consumer-oriented Web sites reporting health care quality information sponsored by States (California, New York, Texas, Washington, Florida, Illinois, Michigan, Oregon) and private organizations (Leapfrog Group, U.S. News & World Report) are reporting procedure volume, in addition to

⁵⁶ Livingston, E.H.; Cao, J "Procedure Volume as a Predictor of Surgical Outcomes". JAMA. 2010:304(1):95-97.

⁵⁷ David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. "Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures". *JAMA*. 2005;294(15):1903-1908.

⁵⁸ Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B "Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer" *JAMA*. 2000; 284 (23): 3028-3035.

provider performance on surgical process (SCIP measures) and outcome measures (surgical site infection, Patient Safety Indicators, and Mortality), because it provides beneficial performance information to consumers choosing a health care provider,. The currently NQF-endorsed measures of procedure volume (noted above) relate to surgeries only performed in inpatient settings, and would not be applicable to the types of procedures approved to be performed in HOPDs and ASCs.

The recently issued Report to Congress entitled "Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan" included an analysis of CY 2009 ASC claims for Medicare beneficiaries. When stratified by specialty category, CMS identified six procedure categories that historically constitute 98.5 percent of the total volume of procedures performed in ASCs: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. In the CY 2012 OPPS/ASC proposed rule (76 FR 42345), we proposed that ASCs submit all patient volume data on these six broad categories of surgical procedures as a structural measure to be used for the ASC Quality Reporting Program CY 2015 payment determination. In section XIV.C.2.c.(2) of the proposed rule, we also proposed that HOPDs submit similar all patient volume data for eight broad procedure categories.

Structural measures assess whether a provider/facility possesses conditions for the care of patients that are associated with better quality. Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors)

furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. Because surgical volume is associated with better quality, and surgical procedures are performed in ASCs, we believe that surgical volume is appropriate for measuring the quality of these six categories of surgical procedures performed in ASCs. We have previously established for other programs that we believe consensus among affected parties can be reflected through various means including widespread use among industry stakeholders. We believe that the ASC Facility Volume Data on Selected ASC Surgical Procedures structural measure reflects consensus among affected parties as being associated with quality of surgical care because of recent evidence published in well-respected and widely circulated peer-reviewed clinical literature, and because of its widespread reporting among States and private stakeholders on Web sites featuring quality information. Because the current volume measures are endorsed for inpatient procedures, many of which are not performed in outpatient settings such as ASCs, it is not feasible or practicable to use NQF-endorsed measures of volume for ASCs. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures.

For the CY 2015 payment determination, we proposed that ASCs would report these data with respect to these six categories between the dates July 1, 2013 and August 15, 2013 with respect to the time period January 1, 2012 through December 31, 2012. In

other words, under this proposal, an ASC would report its CY 2012 all-patient volume data for these six categories of procedures during the 45-day window of July 1 to August 15, 2013. In the CY 2012 OPPS/ASC proposed rule (76 FR 42346), we included a table which listed the HCPCS codes for which hospitals would be required to report all-patient volume data. Like the structural measures in the Hospital OQR Program, data on this proposed measure would be collected via an online Web-based tool that would be made available to ASCs via the QualityNet Web site. This collection mechanism is also used to collect structural measures and other information for other programs (Hospital IQR and Hospital OQR). In the proposed rule, we invited public comment on this proposal.

<u>Comment</u>: A commenter questioned why cardiovascular and respiratory codes are included for the same measure proposed in the Hospital OQR Program and not in the ASC Quality Reporting Program. The commenter recommended harmonizing the same categories for both programs for consistency.

Response: The procedures approved for HOPDs and for ASCs are not the same in type or frequency. For HOPDs, an analysis of prior years' data indicated that procedures performed in the eight broad categories that we proposed (eye, cardiovascular, gastrointestinal, genitourinary, musculoskeletal, nervous, respiratory, and skin systems) accounted for 99 percent of the procedures performed in HOPDs. When we assessed the frequency of procedures performed by ASCs using prior year's claims, we found that the six procedure categories of gastrointestinal, eye, nervous system, musculoskeletal, skin and genitourinary constitute 98.5 percent of the total volume of

procedures performed in ASCs. Therefore, unlike HOPDs, cardiovascular and respiratory system procedures were not included in the list of most common procedures performed in ASCs. These two categories combined would account for 1.5 percent of procedures performed in ASCs. This is the reason why procedures performed in these two anatomic areas were not included in the ASC procedure volume list of procedure codes. We will continue to examine claims data on an ongoing basis, and should we become aware of commonly performed procedures in the Cardiovascular and Respiratory categories for which we should collect volume in the future, we will propose to collect ASC procedures for those categories in a future rule.

Comment: A few commenters fully supported the collection of all-patient volume data on surgical procedure measure and urged harmonization with the same measure adopted in the Hospital OQR Program. Another commenter noted that the provision of data on high volume procedures across hospital outpatient setting and ASC setting would facilitate comparisons and subsequent informed decisions. A commenter believed that this measure would create incentives for ASCs to increase their procedure volumes and improve their performance.

Response: We appreciate the commenters' support and their insights and recommendations. We will continue to work towards harmonizing measures, when possible, between different settings and facilities.

<u>Comment</u>: A few commenters believed that the measure is poorly specified, and should be refined to provide meaningful information to the consumer. Commenters recommended clarification on the most common ASC specialty-specific procedures

performed, prior to creation of a clearly specified measure. Commenters also urged CMS to solicit input from the ASC community to determine how to make publication of volume data meaningful prior to implementation. A commenter stated this measure is unwarranted as volume data is already available on many State-supported or hospital-specific Web sites. Commenters believed that reporting volume without providing pertinent information on outcomes or patient-reported assessments of care may mislead patients about the quality of care delivered.

Response: Although this measure is not NQF-endorsed, we believed it reflects consensus among affected parties as evidenced by peer reviewed literature and widespread use on Web sites featuring quality information. We believe it is important to provide this information to consumers. We agree with commenters that information on outcomes should be provided to consumers as well, and we have adopted several surgical outcome measures in the ASC Quality Reporting Program so that this information can be provided to consumers. As discussed in the proposed rule, our goal for this measure is to provide consumers with useful information on surgical procedure volume in order to assist patients in making informed healthcare decisions. We are aware of Web sites reporting volume for some procedures performed in hospitals. However, we are not aware of Web-sites that are reporting ASC volume by facility for commonly performed procedures. We want to create a standardized platform for consumers to be able to compare volume information based on procedure types commonly performed in ASCs within the 6 broad categories.

However, we agree with commenters that collecting and displaying information on the broad categories as currently specified may not be meaningful to consumers. Based on the public comments we received that the six broad categories will not be meaningful to consumers, we will further refine the specification for the categories by grouping the codes into procedure types commonly performed in ASCs within the 6 broad categories so that they are more meaningful to consumers. The codes in the 6 broad categories that ASCs would use to collect volume remain the same, but the information would be reported to CMS in the subcategories that will be defined in the Specifications Manual. We will include these refinements in the specifications for the measure that will be in an upcoming release of the ASC Specifications Manual. We agree with the commenter that obtaining stakeholder input as well as consumer testing prior to public reporting of the volume information will be beneficial, and will strive to do so, as we have done previously for information made available to the public from other quality reporting programs.

<u>Comment</u>: A commenter believed the proposed volume data submission via the QualityNet Web site is cumbersome and the implementation should be delayed to allow ASCs to gain experience with the online tool.

Response: The online tool is a low burden method of collecting facility level structural measures, and is currently in use for structural measures for both the Hospital IQR and Hospital OQR Programs. While the time period for the measure for CY 2015 would be calendar year 2012, the information would not be submitted by ASCs until

mid-2013. Therefore, we do not believe further delay in the collection and submission of the measure is necessary.

After consideration of the public comments we received, we are finalizing the proposed ASC facility volume data on selected ASC surgical procedures measure for the CY 2015 payment determination, with a modification. Based upon public comment received, we will further group the codes for commonly performed procedure types within the 6 broad categories. This information will be provided in an upcoming Specifications Manual release. We are finalizing our proposal for the CY 2015 payment determination that ASCs would report data with respect to these six categories between July 1, 2013 and August 15, 2013 for the entire time period from January 1, 2012 through December 31, 2012 using an online measure submission Web page available on http://www.qualitynet.org. More information regarding the collection and submission requirements for this measure can be found in the Form, Manner and Timing section for this program in this final rule with comment period.

In summary, for the CY 2015 payment determination, we are retaining the five claims-QDC-based measures finalized for the CY 2014 payment determination, and adding two structural measures, safe surgery checklist use and ASC facility volume data on selected ASC surgical procedures, for a total of 7 measures.

The measures for ASCs for the CY 2015 payment determination are listed below:

ASC Program Measurement Set
for the CY 2015 Payment Determination

ASC-1: Patient Burn

ASC-2: Patient Fall

ASC Program Measurement Set		
for the CY 2015 Payment Determination		
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant		
ASC-4: Hospital Transfer/Admission		
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing		
ASC-6: Safe Surgery Checklist Use*		
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures*		
, and the second		
Procedure Category	Corresponding HCPCS Codes	
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716,	
	C9724, C9725, 0170T	
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T,	
	0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T,	
	0191T, 0192T, 76510, 0099T	
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T,	
	0215T, 0216T, 0217T, 0218T, 0062T	
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T,	
	0201T	
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127,	
	C9726, C9727	
Genitourinary	50000 through 58999, 0193T, 58805	

^{*}New measures for CY 2015 payment determination.

- 5. ASC Quality Measures for the CY 2016 Payment Determination
- a. Retention of Measures Adopted for the CY 2015 Payment Determination in the
 CY 2016 Payment Determination

In general, unless otherwise specified in the retirement section of a rule, we proposed to retain measures from one CY payment determination to the next. In the CY 2012 OPPS/ASC proposed rule (76 FR 42346), we proposed to retain the measures we proposed to adopt for the CY 2015 payment determination, if they are finalized in an OPPS/ASC final rule with comment period, for the CY 2016 payment determination. In the proposed rule, we invited public comment on this proposal.

As discussed previously, we finalized our proposal to retain measures from one CY payment determination to another. We did not receive any comments objecting to the retention of the measures finalized for the CY 2015 payment determination for the CY 2016 payment determination. Thus, we are finalizing the retention of the seven measures finalized in the CY 2015 payment determination for the CY 2016 payment determination.

b. HAI Measure: Influenza Vaccination Coverage among Healthcare Personnel (HCP)(NQF #0431)

The Influenza Vaccination among Healthcare Personnel measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. The specifications for this measure are available at http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS Manual.pdf.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42346), for the ASC CY 2016 payment determination, we proposed to adopt this NQF-endorsed HAI measure. We also proposed to adopt this measure for the Hospital OQR Program for the CY 2015 payment determination. We refer readers to the discussion in sections XIV.C.3.b. of the proposed rule and this final rule with comment period for detailed descriptions of this measure.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national

consensus building entities. We believe this measure is appropriate for measuring quality of care in ASCs due to the significant impact of HCP influenza vaccination on the spread of influenza among patients. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is endorsed by the NQF.

We proposed that ASCs use the NHSN infrastructure and protocol to report the measure for ASC Quality Reporting Program purposes. Collection of data via the NHSN for this measure would begin with immunizations from October 1, 2013 to March 31, 2014 for the CY 2016 payment determination. In the proposed rule, we invited public comment on our proposal to adopt this HAI measure into the ASC Quality Reporting Program for the CY 2016 payment determination.

<u>Comment</u>: A few commenters supported the measure, but were concerned that ASCs will require many resources to initiate this reporting process since they are not accustomed to reporting to NHSN. A commenter recommended that the measure be re-specified for the ASC setting to include only those employees for which ASCs can reasonably report vaccination status. The commenter recommended that CMS postpone data collection for immunizations from the proposed October 1, 2013 to March 31, 2014 to October 1, 2014 through March 31, 2015 for the CY 2016 payment determination.

Response: CMS and CDC recognize the potential challenges faced by ASCs in data collection for this measure. Recently, CDC submitted a revised measure proposal to NQF, based on results of field testing. The revised measure proposal reduces denominator data collection to employee healthcare personnel, defined as staff on facility

payroll, and two categories of non-employee healthcare personnel: (1) licensed independent practitioners, that is, physicians, advance practice nurses, and physician assistants; and (2) student trainees and adult volunteers.

Based on the public comments we received, we are changing the proposed initial reporting period for HCP influenza vaccination coverage so that a less burdensome, updated CDC protocol for the measures as well as infrastructure upgrades can be incorporated into the collection system and ASCs will have enough time to obtain training to collect and report the updated measure to NHSN. The reporting period will begin October 1, 2014 and continue through March 31, 2015 for ASCs as recommended by commenters. Further details on the submission requirements for this measure will be proposed in the Form Manner and Timing section for this program in a future rulemaking.

<u>Comment</u>: A commenter cautioned potential duplicative reporting efforts since some States already mandate vaccination of healthcare workers and public reporting of healthcare vaccination rates.

Response: We appreciate the commenter's cautionary note and recognize that requirements for measurement and reporting of HCP vaccination rates, as is the case for other measureable healthcare processes and outcomes, may exist at the State and federal levels. Standardizing reportable healthcare quality measurements is a priority because that reduces reporting burden while preserving the opportunities to use those data for different purposes at the State and federal levels.

<u>Comment</u>: A commenter stated that the measure should allow healthcare personnel to choose the vaccination type or brand most appropriate for them.

Response: The measure does not require healthcare personnel to receive a specific type or brand of influenza vaccine in order to be included in the measure.

After consideration of the public comments we received, we are finalizing the proposed Influenza Vaccination Coverage among Healthcare Personnel measure for the CY 2016 payment determination, with a modification. Because NQF's final review and an endorsement decision are pending with respect to the CDC's revised measure proposal and at the request of commenters, as discussed above, we are changing the data collection timeframe from what we proposed. Data collection via NHSN will begin on October 1, 2014 and continue through March 31, 2015. Details for submission of this measure will be proposed in a future rulemaking.

In summary, for the CY 2016 payment determination, we are retaining the seven measures that we adopted for the CY 2015 payment determination and are adding one NHSN HAI measure for a total of eight measures.

The measures for ASCs for the CY 2016 payment determination are listed below:

ASC Program Measurement Set for the CY 2016 Payment Determination
ASC-1: Patient Burn
ASC-2: Patient Fall
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4: Hospital Transfer/Admission
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing
ASC-6: Safe Surgery Checklist Use
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures

ASC Program Measurement Set for the CY 2016 Payment Determination		
Procedure Category	Corresponding HCPCS Codes	
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716,	
	C9724, C9725, 0170T	
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T,	
	0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T,	
	0191T, 0192T, 76510, 0099T	
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T,	
	0215T, 0216T, 0217T, 0218T, 0062T	
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T,	
	0201T	
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127,	
	C9726, C9727	
Genitourinary	50000 through 58999, 0193T, 58805	
ASC- 8: Influenza Vaccination Coverage among Healthcare Personnel *		

^{*}New measure for CY 2016 payment determination.

6. ASC Measure Topics for Future Consideration

Below is a list of future measurement areas that we are considering for future ASC Quality Reporting Program payment determinations for which we sought comment in the CY 2012 OPPS/ASC proposed rule (76 FR 42347 through 42348).

In particular, we sought comment on the inclusion of Patient Experience of Care Measures in the ASC Quality Reporting Program measure set for a future payment determination, such as existing Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups and the CAHPS Surgical Care Survey, sponsored and submitted by the American College of Surgeons (ACS) and the Surgical Quality Alliance (SQA). We also, in particular, sought comment on the inclusion of procedure-specific measures for cataract surgery, colonoscopy and endoscopy, and for

measures of Anesthesia Related Complications in the ASC Quality Reporting Program measure set.

Measures and Measurement Topics under Consideration for Future Paymen Determinations		
Patient Experience of Care:		
Consumer Assessment of Healthcare Providers and Systems (CAHPS) surv	yous for	
clinicians/groups	veys 101	
CAHPS Surgical Care Survey		
Procedure Specific Measures		
Colonoscopy and other Endoscopy measures		
Cataract Surgery measures		
Anesthesia Related Complications:		
Death		
Cardiac Arrest		
Perioperative Myocardial Infarction		
Anaphylaxis		
Hyperthermia		
Transfusion Reaction		
Stroke, Cerebral Vascular Accident, or Coma following anesthesia		
Visual Loss		
Medication Error		
Unplanned ICU admission		
Patient intraoperative awareness		
Unrecognized difficult airway		
Reintubation		
Dental Trauma		
Perioperative aspiration		
Vascular access complication, including vascular injury or pneumothorax		
Pneumothorax following attempted vascular access or regional anesthesia		
Infection following epidural or spinal anesthesia		
Epidural hematoma following spinal or epidural anesthesia		
High Spinal		
Postdural puncture headache		

Major systemic local anesthetic toxicity

Measures and Measurement Topics under Consideration for Future Payment Determinations

Peripheral neurologic deficit following regional anesthesia

Infection following peripheral nerve block

Additional Future Measurement Topics:

NQF Serious Reportable Events in Healthcare

Medication administration variance

Medication reconciliation

Venous thromboembolism measures: outcome/assessment/prophylaxis.

Presence of Physician during Entire Recovery Period

Post-discharge follow up

Post-discharge ED visit within 72 hours

In the proposed rule, we invited public comment on these quality measures and measurement topics so that we may consider proposing to adopt them for future ASC Quality Reporting Program payment determinations beginning with the CY 2015 payment determination. We also sought suggestions for additional measures and rationales for the ASC Quality Reporting Program that are not listed in the table above.

• Patient's experience of care measure

<u>Comment</u>: One commenter noted that the CAHPS surgical care survey was not appropriate for ASCs since it may not address the short patient experience with staff performance at ASCs.

Response: We thank the commenter for the input and we will take it into consideration in future measure selection efforts for this program.

• Anesthesia related complications measures

<u>Comment</u>: A commenter supported the anesthesia related complications measures listed, including, Use of Reversal Agents, Type of Anesthesia and Credentials

of the Professional Administering Anesthesia When a Complication is Reported,
Presence of Physician During Entire Recovery Period, and Post Discharge ED Visit
within 72 Hours.

Response: We thank the commenter for the input on anesthesia related complications. We will take this input into consideration in future measure selection efforts for this program.

• Additional future measurement topics

<u>Comment</u>: A commenter recommended CMS taking a cautious approach for the venous thromboembolism measures: outcome/assessment/prophylaxis measure because the incidence of deep vein thrombosis (DVT) and pulmonary embolism (PE) following total knee and hip replacement can be reduced but not eliminated. The commenter noted the trade off for lower DVT/PE rates is more wound complications, including surgical site infections.

Response: We thank the commenter for the input and recommendation. We will take them into consideration in future measure selection efforts for this program.

• Other measure topics

<u>Comment</u>: A commenter recommended the future inclusion of ASC specialty-specific measures, especially ASC-specific GI measures, plan for reprocessing endoscope, more measures related to safe injection practices, accreditation status, participation in a registry, sedation safety, and nursing sensitive structural measures.

Response: We thank the commenter for the input and recommendations for future measurement topics. We will take them into consideration in future measure selection efforts for this program.

- 7. Technical Specification Updates and Data Publication
- a. Maintenance of Technical Specifications for Quality Measures

In the CY 2012 OPPS/ASC proposed rule (76 FR 42348), we proposed to provide technical specifications, and in some cases, links to technical specifications hosted on external third party Web sites, for the ASC Quality Reporting Program measure in a Specifications Manual, to be posted after publication of the CY 2012 OPPS/ASC final rule with comment period, on the CMS QualityNet Web site at http://www.QualityNet.org. Currently, the specifications for the proposed ASC measures for the CY 2014, CY 2015 and CY 2016 payment determinations, with the exception of the two structural measures, can be found at:

http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pd f;

http://www.cms.gov/pqrs/downloads/2011_PhysQualRptg_MeasuresGroups_SpecificationsManual_033111.pdf?agree=yes&next=Accept; http://www.cdc.gov/nhsn/psc.html; and http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf. The specifications for the two structural measures are included in the discussion.

We proposed to maintain the technical specifications for the measures adopted for the ASC Quality Reporting Program by updating this Specifications Manual, including updating the detailed instructions and the calculation of algorithms as appropriate. In

some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. We currently use this same process for Hospital OQR Program measures, as discussed in sections XIV.A.3.a. of the proposed rule and this final rule with comment period. We proposed to follow the same technical specification maintenance process for the ASC Quality Reporting Program measures as for the Hospital OQR Program measures and we invited public comments on this proposal.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for updates to the technical specifications that we use to calculate Hospital OQR Program measures. This process is used when changes to the measure specifications are necessary due to changes in scientific evidence or other substantive changes, thereby giving CMS the option to seek re-endorsement of that measure. The legal standard for adopting Hospital OQR measures is the measure must be appropriate to measure quality of care in the setting, there must be consensus among affected parties, and to the extent feasible and practicable, measures must be set forth by a consensus building entity. We note that NQF endorsement of an OQR measure is not required under sections 1833(i)(2)(D)(iv), (i)(7) or (t)(17) of the Act. The legal standard for adopting ASC measures is this same standard, except as the Secretary may otherwise provide. Changes of this nature to measures adopted for the ASC Quality Reporting Program may not coincide with the timing of our regulatory actions, but nevertheless require inclusion in the measure specifications so that measures are

calculated based on the most up-to-date scientific standards and, in some instances, consensus standards.

For the Hospital OQR Program, we indicated that notification of changes to the measure specifications is available on the QualityNet Web site,

http://www.QualityNet.org, and in the Hospital OQR Specifications Manual and would occur no less than 3 months before any changes become effective for purposes of reporting under the Hospital OQR Program. The Hospital OQR Specifications Manual is released every 6 months and addenda are released as necessary providing 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. We proposed to follow the same subregulatory process for the ASC Quality Reporting Program for updates to the technical specifications. In the proposed rule, we invited public comments on this proposal.

<u>Comment</u>: A few commenters expressed appreciation of the technical specifications maintenance timeline, which proposes that at least 6 months of advance notice will be provided to participants for substantive changes to data elements that would require significant system changes and at least three months for substantial changes. A commenter noted that the implementation of a new reporting program requires even more advance notice and no less than a minimum of 6 months.

Response: We appreciate the commenters' support for our proposed technical specifications maintenance timeline. We will strive to provide as much advance notice as

possible when substantive changes to technical specifications are made. We are providing more start up time for the program by delaying the start of required data submission for the program to October 1, 2012.

After consideration of the public comment we received, we are finalizing the policy of providing technical specifications and links to technical specifications in a Specifications Manual to be posted after publication of this final rule with comment period. However, we are finalizing a policy of posting it not only the CMS QualityNet Web site as we proposed, but also on a CMS Web site such as http://www.cms.gov because we wish to utilize multiple Web sites to increase ASC awareness of our technical and measure specifications in our outreach and education. We believe that posting the information on the QualityNet Web site would increase ASC awareness of our program's specifications. However, we also believe that many ASC's will review the CMS Web site, since CMS posts claims processing manuals and other documentation that are used by providers and practitioners to submit claims to CMS.

We also are finalizing our proposal to follow the same maintenance process used for the Hospital OQR Program, including maintenance of the technical specifications for the measures adopted by updating the Specifications Manual, and updating the detailed instructions and the calculation of algorithms as appropriate. We also are finalizing our policy to follow the same subregulatory process for the ASC Quality Reporting Program as used for the Hospital OQR Program for updates to the technical specifications, including issuing regular manual releases at six month intervals, to provide addenda as necessary, and providing 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.

b. Publication of ASC Quality Reporting Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. These requirements under section 1833(t)(17)(E) of the Act also apply to the ASC Quality Reporting Program except as the Secretary may otherwise provide. In the CY 2012 OPPS/ASC proposed rule (76 FR 42348), we proposed to make data that an ASC has submitted for the ASC Quality Reporting Program available on a CMS Web site after providing an ASC an opportunity to preview the data to be made public. We proposed that these data would be displayed at the CMS Certification Number (CCN) level. Publishing this information encourages beneficiaries to work with their doctors and ASCs to discuss the quality of care ASCs provide to patients, thereby providing an additional incentive to ASCs to improve the quality of care that they furnish. We intend to propose more detail on the publication of data in a later rulemaking. In the proposed rule, we solicited public comment on these proposed processes of making ASC quality data available to the public.

<u>Comment</u>: Commenters overwhelmingly supported transparency in ASC quality reporting and cost information and some recommended CMS publish the ASC quality data at the earliest opportunity.

Commenters believed the ASC quality information should be displayed in a manner that allows easy comparisons for quality and cost between HOPDs and ASCs. Commenters expressed concerns regarding potential inappropriate data displayed on Hospital Compare. These commenters suggested that, in publicly displaying ASC data, CMS should: (1) provide contact information for program content area experts; (2) provide a provider-specific narrative section that would allow providers to advise consumers on any concerns the provider has regarding the reliability or accuracy of data posted; (3) provide each ASC's accreditation status; (4) display Medicare rates and patients' out-of-pocket costs for services provided in both HOPD and ASC settings; (5) distinguish ASCs where only GI procedures are done, those where they are also done, and those where they are not done; and (6) stratify performance data when it is publicly posted based on risk profiles.

Response: We thank the commenters for their support and suggestions. We will take the suggestions into consideration for future public reporting of the data.

<u>Comment</u>: Some commenters believed that ASCs should have one year of confidential feedback on measure participation, data completeness, QDC submission errors, and performance details at CCN level, prior to publication of the data. Some commenters recommended that an appeals process should be put in place for dispute of data accuracy.

Response: We will consider these suggestions. We are required to make the data submitted under this program available to the public. Prior to making the data available to the public, we also are required to provide facilities with the opportunity to review

their data. We intend to propose a reconsideration and appeals process in future rulemaking.

<u>Comment:</u> A few commenters urged CMS to strive for user friendly data on the CMS Web site for the ASC Quality Reporting Program.

Response: We thank the commenters for their suggestion; we intend to make the display as consumer friendly as possible.

After consideration of the public comments we received, we are finalizing our proposed policy to make data that an ASC has submitted for the ASC Quality Reporting Program available on a CMS Web site after providing an ASC an opportunity to preview the data to be made public. As we proposed, these data will be displayed at the CCN level.

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

In the CY 2012 OPPS/ASC proposed rule (76 FR 42348 through 42349), to participate in the ASC Quality Reporting Program for the CY 2014 payment determination, we proposed that ASCs must meet data collection and data submission requirements. We stated that we intend to propose administrative requirements, data validation and data completeness requirements, reconsideration and appeals processes, and CY 2015 payment determination reporting requirements in the CY 2013 OPPS/ASC proposed rule.

<u>Comment</u>: Several commenters stated their concern that administrative requirements, data validation and data completeness requirements, and reconsideration

and appeal processes were not proposed or provided in detail. Several commenters suggested that rules for data validation and completeness as well as the proposed process for reconsideration and appeals be specified in an interim rule in the first quarter of 2012. One commenter stated their belief that since the use of claims-based quality data codes is a new approach to quality data reporting, data validation procedures must be included in a final ASC Quality Reporting Program. One commenter wished to consider the more detailed proposals intended for publication in later rulemaking and encouraged CMS to issue these proposals at the earliest opportunity. One commenter believed that the uncertainty associated with not knowing what is necessary to be a successful participant in the program is an unwanted deterrent to full participation.

Response: We thank these commenters for expressing their concerns regarding the deferring of proposals for administrative requirements, data validation and data completeness requirements, and reconsideration and appeals processes requirements until the CY 2013 OPPS/ASC proposed rule. We fully intend to put forth these proposals as soon as possible using the public comments we received on the CY 2012 OPPS/ASC proposed rule.

We agree that it is preferable to issue these proposals as soon as possible and based upon the comments received intend to do so in the FY 2013 IPPS/LTCH PPS proposed rule rather than the CY 2013 OPPS/ASC proposed rule. We intend to take this approach because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to finalize earlier and prior to data collection beginning with October 2012 services. We disagree with the comment that the use of claims-based quality codes is a new approach to quality

data reporting; this mechanism is used to collect such information under the PQRS. However, regarding the necessity to include data validation procedures in a final ASC Quality Reporting Program, we will consider these comments for future rulemaking. We note that claims-based and structural measures historically have not been validated through independent medical record review in our hospital and physician quality reporting programs due to the lack of relevant information in medical record documentation for specific data elements, such as use of a safe surgery checklist.

<u>Comment</u>: One commenter stated that QualityNet accounts are automatically deactivated after a 120-day period of inactivity and yet as proposed, ASCs would only use the QualityNet for data submission infrequently. This commenter urged CMS to establish a process to avert account deactivation.

Response: We thank the commenter for raising this issue. While we did not make any proposals specifically addressing the need for a QualityNet account, we made proposals regarding the entering of structural measure data which may necessitate the need for a QualityNet account. In finalizing our proposals regarding structural measure data entry, we note that we have deferred the data entry for structural measure data until 2013; note that a QualityNet account is not necessary to access information that is posted to the Web site, such as specifications manuals and educational materials. We intend to address any QualityNet account requirements for the ASC Quality Reporting Program for program requirements in later rulemaking.

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

In the CY 2012 OPPS/ASC proposed rule (76 FR 42348 through 42349), we proposed that, to be eligible for the full CY 2014 ASC annual payment update, ASCs would be required to submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. For the CY 2014 payment determination, we proposed to use Medicare fee-for-service ASC claims for services furnished between January 1, 2012 and December 31, 2012.

We proposed to consider an ASC as participating in the ASC Quality Reporting Program for CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to the proposed measures if finalized. As no determinations will be made affecting payment until the CY 2014 annual payment update, we proposed this approach in order to reduce ASC burden. We stated that we intend to provide additional details regarding participation notification and other administrative requirements in CY 2013 rulemaking.

We proposed that data completeness 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. We stated that we intend to propose how we will assess data completeness for claims-based measures in the CY 2013 OPPS/ASC proposed rule. In the CY 2012 OPPS/ASC proposed rule, we requested public comment on these proposals and were specifically

interested in receiving public comment on what constitutes complete data in regard to our proposed ASC claims-based measures utilizing QDCs and methods to assess completeness.

<u>Comment</u>: Some commenters supported the proposal 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 submitted claim forms during the reporting period for the CY 2014 payment determination as this approach was seen as reasonable and reduced burden.

Response: We thank these commenters for their support. We agree that this method is reasonable and will reduce burden.

<u>Comment</u>: Many commenters expressed their belief that the time line for beginning the reporting of quality data was too aggressive, citing issues of time to adapt billing systems and personnel training. Many commenters suggested that data collection be delayed, beginning with October 1, 2012 services, rather than January 1, 2012 services as proposed.

Response: We thank the commenters for their views. Based upon the many comments received regarding the data collection time period for the CY 2014 payment determination, we are delaying the beginning of the data collection until October 1, 2012. Thus, we will be using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from October 1, 2012 through December 31, 2012 for the CY 2014 payment determination measures, as discussed in sectionXIV.K.3.a. of this final rule with comment period.

Comment: One commenter believed that a low threshold for data completeness should be established for data collection during CY 2012 because ASCs will not know the rules by which they are being judged until late in 2012 and that reporting thresholds of less than 100 percent for initial reporting periods are consistent with other CMS reporting programs. Some commenters suggested, that due to ASCs not being familiar with reporting, successful reporting on a limited number of claims, for example, 50 percent should be permitted, a level similar to that in the PQRS.

Response: We thank these commenters for responding to our request on what constitutes complete data for our proposed ASC claims-based measures. We agree that for the initial year of the program, a low threshold should be used and that a level such as the 50 percent used in the PQRS would be reasonable. As previously stated, we intend to propose how we will assess data completeness for claims-based measures in the FY 2013 IPPS/LTCH PPS proposed rule and will consider the comments when developing our proposals.

Comment: Some commenters believed that, given the variability in ASC case mix, it can reasonably be anticipated that some measures will not apply to all ASCs, and, therefore, that CMS should consider the need for exemptions based on case-mix. One commenter believed that some smaller facilities may not have any cases for the proposed ASC quality measures and that to maintain a process that limits burden, waiving data submission requirements when a facility has 5 or fewer cases for a measure as is done under the Hospital IQR and Hospital OQR Programs could be implemented.

Response: We thank the commenters for their views regarding criteria for reporting exemptions under the ASC Quality Reporting Program. We will consider these comments as we develop our proposals in future rulemaking. As stated above, based upon the comments received, we intend to make further proposals on data completeness in the FY 2013 IPPS/LTCH PPS proposed rule rather than the CY 2013 OPPS/ASC proposed rule as the former rule is scheduled to finalize earlier. We agree that waiving data submission requirements for low case loads is reasonable and we will consider this comment with all others when developing our proposals.

Comment: One commenter believed that, since the full complement of measures are not applicable to all ASCs, G-codes that ASCs can submit once during a performance period that indicates the measure is not applicable to the ASC should be developed, thereby exempting the ASC from data submission for the measure. One commenter believed that it is unclear how a facility should report with respect to a measure that may not be applicable to the services furnished by that type of ASC. One commenter sought clarification that ASCs would not need to report on all measures, but only those measures that applied.

Response: We thank the commenters for their views regarding methods to report when an ASC does not have cases for a quality measure. We understand that a measure may not be applicable to the services furnished by a type of ASC. For the reporting of quality data using QDCs, as stated in Section XIV.K.1.a.5, ASCs would add the appropriate QDCs for measure numerators and denominators on Medicare Part B claim forms to submit quality data. We intend to provide education and outreach on data

submission for the reporting program, and we will publish details about the QDCs and whether they will need to be submitted for numerators and denominators in the ASC Quality Reporting Program Specifications Manual. We anticipate releasing this manual in second quarter 2012.

<u>Comment</u>: Some commenters believed that what CMS proposed as constituting "successful" reporting, that is complete submission, was vague.

Response: We are finalizing our proposals to assess the completeness of reporting 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 claims. We will be using public comments we received that addressed this issue in the development of our future proposals. As stated above, we intend to propose a specific definition of reporting completeness in the FY 2013 IPPS/LTCH PPS proposed rule in order to provide opportunity for notice and comment prior to October 2012 services.

After consideration of the public comments received, we are finalizing our proposals with some modification. As proposed, we are finalizing our proposal that, to be eligible for the full CY 2014 ASC annual payment update, an ASC must submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. Further, as proposed, we are finalizing our proposal that data completeness for claims-based measures 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. Finally, we are deferring the data collection time period for the CY 2014 payment determination to a later date, beginning data collection with services beginning October 1, 2012, rather than January 1, 2012, while maintaining the end date of December 31, 2012.

We also are finalizing our proposal to consider an ASC as participating in the ASC Quality Reporting Program for CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to finalized measures

b. Data Submission Deadlines for the Surgical Site Infection Rate Measure

As discussed above, we proposed to adopt a HAI measure, Surgical Site Infection Rate, for the CY 2014 payment determination. We proposed to use the data submission and reporting standard procedures that have been set forth by the CDC for NHSN participation in general and for submission of this measure to the NHSN. We referred readers to the CDC's NHSN Web site (http://www.cdc.gov/nhsn) for detailed data submission and reporting procedures. Our proposal seeks to reduce ASC burden by aligning CMS data submission and reporting procedures with NHSN procedures currently used by healthcare providers and suppliers. The submission timeframes for the CY 2014 payment determination that we proposed to use for the proposed Surgical Site Infection Rate measure were shown in the CY 2012 OPPS/ASC proposed rule (76 FR 42349). We stated that ASCs must submit their quarterly data to the NHSN for ASC Quality Data Reporting purposes within the date intervals shown in the table set out in

the proposed rule (76 FR 43249) (any updates to this schedule would be posted on the QualityNet and CMS Web sites).

In the proposed rule, we requested public comments on these proposals. We did not receive any comments specifically on the proposed timeframes. However, as discussed above, we are not finalizing this measure at this time; therefore, we are not finalizing this time table for data collection.