E. Proposed Quality Reporting Requirements for Ambulatory Surgical Centers (ASCs)

1. Background

Section 109(b) of the Medicare Improvements and Extension Act of 2006 under Division B, Title I of the Tax Relief and Health Care Act of 2006, Pub. L. 109-432 (MIEA-TRHCA) amended section 1833(i) of the Act by redesignating 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)." Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit "data required to be submitted on measures selected under this paragraph with respect to a year" to the Secretary in accordance with this paragraph 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 this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year.

Subparagraph (B) of paragraph (7) states "[e]xcept as the Secretary may otherwise provide," the provisions of subparagraphs (B) through (E) of paragraph (17) of section 1833(t) of the Act, which contain requirements for quality reporting for hospital outpatient services, "shall apply with respect to services of [ASCs] under this paragraph in a similar manner to the manner in which they apply under such paragraph" 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. Pertinent to this proposed rule are subparagraphs (B) and (E) of section 1833(t)(17) of the Act. Subparagraph (B) of section 1833(t)(17) of the Act requires subsection (d) hospitals to "submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph." Subparagraph (E) of section 1833(t)(17) of the Act requires the Secretary to "establish procedures for making data submitted under this paragraph available to the public." Further, these procedures shall ensure that hospitals have the opportunity to review the data before these data are made public. Additionally, the Secretary must "report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals" on CMS' Internet Web site.

Thus, subsections (i)(7)(B) and (t)(17)(B) of section 1833 of the Act, read together, require that ASCs submit quality data in a form and manner, and at a time, that the Secretary specifies. Pertinent to this proposed rule, subsections (i)(7)(B) and (t)(17)(B) of section 1833 of the Act, read together, require the Secretary to establish procedures for making data submitted available to the public and to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and cost of care that relate to services furnished in ASCs on CMS's Internet Web site. Subsection (i)(7)(B) of section 1833 of the Act also specifies that these provisions apply except as the Secretary may otherwise provide.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to implement the ASC Quality Reporting Program beginning with the CY 2014 payment determination (76 FR 74492 through 74517). We adopted claims-based measures for the CY 2014 payment determination for services furnished between October 1, 2012 and December 31, 2012. For the CY 2015 payment determination, we adopted the same claims-based measures as adopted for the CY 2014 payment determination and two structural measures. We did not specify the data collection period for the claims-based measures for the CY 2015 payment determination, but specified that reporting for the structural measures would be between July 1, 2013 and August 15, 2013 for services furnished between January 1, 2012 and December 31, 2012 using an online measure submission Web page available at: http://www.QualityNet.org. For the CY 2016 payment determination, we adopted the same claims-based and structural measures as adopted for the CY 2015 payment determination and one process of care measure. We did not specify the data collection period for the claims-based or structural measures, but specified that data collection for the process of care measure would be via the National Healthcare Safety Network beginning on October 1, 2014 and continuing through March 31, 2015.

In the CY 2012 OPPS/ASC final rule with comment period, we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration and appeals processes in the FY 2013 IPPS/LTCH PPS proposed rule rather than in the CY 2013 OPPS/ASC proposed rule (76 FR 74515), because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to be

finalized earlier and prior to data collection for the CY 2014 payment determination, which is to begin with services furnished on October 1, 2012.

Below we are issuing proposals for administrative requirements, data completeness requirements, extraordinary circumstance waiver or extension requests, and a reconsideration process. As discussed below, we are not proposing to validate claims-based and structural measures. Further, we intend to address appeals of reconsideration decisions in a future rulemaking. To be eligible to receive the full annual increase, we are proposing that ASCs must comply with the requirements specified below for the respective payment determination year.

We invite public comment on these proposals.

2. Proposed Requirements for Reporting of ASC Quality Data

a. Proposed Administrative Requirements

(1) Proposals Regarding QualityNet Account and Administrator for the CYs 2014 and 2015 Payment Determinations

A QualityNet account is required to submit quality measure data to the QualityNet Web site and, in accordance with CMS policy, a QualityNet administrator is necessary to set-up a user account for the purpose of submitting this information to the QualityNet Web site. The main purpose of a QualityNet administrator is to serve as a point of contact for security purposes for quality reporting programs. We believe from our experience that a QualityNet administrator typically fulfills a variety of tasks related to quality reporting, such as creating, approving, editing, and terminating QualityNet user accounts within an organization, and monitoring QualityNet usage to maintain proper

security and confidentiality measures. Thus, we highly recommend that ASCs have and maintain a QualityNet administrator. However, we are not proposing that ASCs be required to do so for the CY 2014 payment determination because ASCs are not required to submit data to the quality data warehouse for the CY 2014 payment determination (76 FR 74504) and we do not want to unduly burden ASCs by requiring ASCs to have a QualityNet administrator. We note that a QualityNet account is not necessary to access information that is posted to the QualityNet Web site, such as specifications manuals and educational materials.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74509), for the CY 2015 payment determination, we require ASCs to submit structural measure data to the QualityNet Web page. To enter these data into the CMS data system, we are proposing that ASCs will need to identify and register a Quality Net administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. Because submission of structural measure data is not required until the July 1, 2013 to August 15, 2013 time period, we are proposing that ASCs would be required to have a QualityNet administrator at the time facilities submit structural measure data in 2013 for the CY 2015 payment determination, which is no later than August 15, 2013. ASCs may have a QualityNet administrator prior to this date, but we are not proposing that ASCs be required to do so.

We note that there are necessary mailing and processing procedures for having a QualityNet administrator assigned by CMS separate from completion of the forms by the ASC that can require significant time to complete and we strongly caution ASCs to not

wait until the deadline to apply; instead, we recommend allowing a minimum of 2 weeks, while strongly suggesting allowing additional time prior to the deadline to submit required documentation in case of unforeseen issues. Because ASCs will need a QualityNet administrator only to have the ability to set up a user account for the purpose of submitting structural measure data once a year, we are proposing that ASCs would not be required to maintain a QualityNet administrator after the entry of the structural measure data in 2013 for the CY 2015 payment determination. Although we highly recommend that ASCs have and maintain a QualityNet administrator, we believe that requiring an ASC to maintain a QualityNet administrator throughout the year would increase the burden on ASCs.

As a commenter noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), QualityNet accounts are automatically deactivated after a 120-day period of inactivity per CMS security policy. If an account is deactivated due to inactivity, it can be reactivated by contacting the QualityNet Help Desk; contact information for the QualityNet Help Desk is located on the QualityNet Web site.

(2) Proposals Regarding Participation Status for the CY 2014 Payment Determination and Subsequent Payment Determination Years

We finalized in the CY 2012 OPPS/ASC final rule with comment period a policy to consider an ASC as participating in the ASC Quality Reporting Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the program on their CY 2012 claims relating to the finalized measures (76 FR 74516).

We are proposing that once an ASC submits any quality measure data, it would be considered as participating in the ASC Quality Reporting Program. Further, we are proposing that, once an ASC submits any quality measure data and is considered to be participating in the program, an ASC would continue to be considered participating in the program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the program by indicating on a participation form that it is withdrawing, as discussed below. For example, if an ASC includes any QDCs on its claims for the CY 2014 payment determination, it would be considered participating in the ASC Quality Reporting Program for the CY 2014 payment determination and for every subsequent payment determination unless the ASC withdraws. Likewise, if an ASC did not submit any QDCs for the CY 2014 payment determination, but submitted quality measure data for the CY 2015 payment determination, the ASC would be considered participating in the ASC Quality Reporting Program starting with the CY 2015 payment determination and continuing for subsequent payment determinations unless the ASC withdraws from the program.

We considered whether to propose that an ASC be required to complete and submit a notice of participation form for the CY 2015 payment determination or subsequent payment determination years to indicate that the ASC is participating in the program as we require for hospitals, but decided against this proposal because we were concerned about the burden on ASCs. We believe these proposals will reduce burden on ASCs while accomplishing the purpose of notifying CMS of an ASC's participation in the ASC Quality Reporting Program.

We are proposing that any and all quality measure data submitted by the ASC while participating in the ASC Quality Reporting Program could be made publicly available. This policy would allow us to provide information on the quality of care provided to Medicare beneficiaries which promotes transparency.

We are proposing that once an ASC submits quality measure data indicating its participation in the ASC Quality Reporting Program an ASC must complete and submit an online participation form indicating withdrawal to withdraw from the program. This form would be located on the QualityNet Web site starting in July 2013. We are proposing that an ASC would indicate on the form the initial payment determination year to which the withdrawal applies. We are proposing a different process for ASCs to withdraw from participation than the process we are proposing for an ASC to participate in the ASC Quality Reporting Program because of the payment implications of withdrawal. We are proposing that, in withdrawing from the program, the ASC would incur a 2.0 percentage point reduction in its annual payment update for that payment determination year and any subsequent payment determination year(s) in which it is withdrawn.

We will not make quality measure data publicly available for that payment determination year and any subsequent payment determination year(s) for which the ASC is withdrawn from the program.

We are proposing that an ASC would continue to be deemed withdrawn unless the ASC starts submitting quality measure data again. Once an ASC starts submitting quality measure data, the ASC would be considered participating unless the ASC

withdraws, as discussed above. Again, we believe that these proposals would reduce the burden on ASCs of having to notify CMS as to when they are participating.

We are proposing that an ASC can withdraw from the program at any time up to August 31, 2013 for the CY 2014 payment determination; we anticipate that this will be the latest date possible to allow an ASC to withdraw before payment determinations affecting CY 2014 payment are made. We are proposing that an ASC can withdraw from the program at any time up to August 31, 2014 for the CY 2015 payment determination. We will propose withdrawal dates for later payment determinations in future rulemakings.

We are proposing that these administrative requirements would apply to all ASCs designated as open in the CASPER system before January 1, 2012 for the CY 2014 payment determination. Since ASCs are not required to include QDCs on claims until October 2012 for the CY 2014 payment determination, an ASC designated as open in the CASPER system before January 1, 2012 would be operating for at least 10 months before having to report any data. We believe this would be a sufficient amount of time for ASCs to be established to report quality data for the CY 2014 payment determination.

For the CY 2015 payment determination, we are proposing that these administrative requirements would apply to all ASCs designated as open in the CASPER system for at least four months prior to January 1, 2013. We believe that this date and length of operations experience would provide new ASCs sufficient time before having to meet quality data reporting requirements after the program's initial implementation year.

We invite public comment on these proposals relating to administrative requirements.

b. Proposals Regarding Form, Manner, and Timing for Claims-Based Measures for CYs 2014 and 2015 Payment Determinations

(1) Background

In the CY 2012 OPPS/ASC final rule with comment period, we adopted claims based measures for the CYs 2014 and 2015 payment determinations (76 FR 74504 through 74509). We also finalized 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 (76 FR 74515 through 74516). Further, we finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. We did not finalize a date by which claims would be processed to be considered for CY 2014 payment determinations.

We are now proposing that claims for services furnished between October 1, 2012 and December 31, 2012 would have to be paid by the administrative contractor by April 30, 2013 to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date would allow ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

We did not finalize a data collection and processing period for the CY 2015 payment determination, but intend to do so in the CY 2013 OPPS/ASC proposed rule.

(2) Proposed Minimum Threshold for Claims-Based Measures Using QDCs

In the CY 2012 OPPS/ASC final rule with comment period, we finalized 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. In other words, the numerator will be the total number of claims meeting measure specifications that have QDCs and the denominator will be the total number of claims meeting measure specifications. We stated our intent to propose how we would assess data completeness for claims-based measures in this proposed rule (76 FR 74516). For the initial reporting years, we believe that a lower threshold for data completeness should be established for data collection because ASCs are not familiar with how to report quality data under the ASC Quality Reporting Program, and because many ASCs are relatively small and they may need more time to set up their reporting systems. For the CYs 2014 and 2015 payment determinations, we are proposing that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe 50 percent is a reasonable minimum threshold based upon the considerations discussed above for the initial implementation years of the ASC Quality Reporting Program. We intend to propose to increase this percentage for subsequent payment determination years

as ASCs become more familiar with reporting requirements for this quality data reporting program.

As stated in CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), ASCs will add the appropriate QDCs on their Medicare Part B claim forms, the Form CMS-1500s submitted for payment, to submit the applicable quality data. A listing of the codes with long and short descriptors is available in transmittal 2425, Change Request 7754 released March 16, 2012 (http://www.cms.gov/transmittals/downloads/R2425CP.pdf). Details on how to use these codes for submitting numerators and denominator information will be available in the ASC Quality Reporting Program Specifications Manual located on our Web site (http://www.cms.hhs.gov) beginning in April 2012.

We invite public comment on these proposals relating to form, manner, and timing for claims-based measures.

c. ASC Quality Reporting Program Validation of Claims-Based and Structural Measures

We received comments on the CY 2012 OPPS/ASC proposed rule requesting that rules for data validation be adopted as soon as possible (76 FR 74515). We noted that claims-based and structural measures historically have not been validated through independent medical record review in our quality reporting programs for either hospitals or physicians due to the lack of relevant information in medical record documentation for specific data elements of the measures, such as use of a safe surgery checklist. Thus, consistent with other CMS quality reporting programs, we are not proposing to validate claims-based measures (beyond the usual claims validation activities conducted by our

administrative contractors) and structural measures for the ASC Quality Reporting Program.

3. Proposed Extraordinary Circumstances Extension or Waiver for the CY 2014 Payment Determination and Subsequent Payment Determination Years

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. Therefore, we are proposing procedures for extraordinary circumstance extension or waiver requests for the submission of information, including but not limited to, QDCs submitted on claims, required under the ASC Quality Reporting Program.

In the event of extraordinary circumstances, such as a natural disaster, that is not within the control of the ASC, we are proposing to adopt a process for an extension or waiver for submitting information for meeting program requirements that is similar to the one adopted for the Hospital OQR Program because this process has been effective for hospitals, and we believe such a process also would be effective for ASCs. We are proposing that an ASC would complete a request form that would be made available on the QualityNet Web site and submit the request to CMS. We are proposing that the following information must be noted on the form:

- ASC CMS Certification Number (CCN) and related National Provider Identifier(s) [NPI(s)];
- ASC Name;

- Contact information for a person at the ASC with whom CMS can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- ASC's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the ASC would be able to submit required ASC Quality Reporting Program information, and a reasonable basis for the proposed date.

We are proposing that the request form would be signed by a person who has authority to sign on behalf of the ASC and a request form would be required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, we are proposing that CMS would—

(a) Provide a written acknowledgement using the contact information provided in the request, notifying the ASC contact that the ASC's request has been received;

(b) Provide a formal response to the ASC contact using the contact information provided in the request notifying the ASC of our decision; and

(c) Complete its review of any request and communicate its response within 90 days following CMS's receipt of such a request.

We are proposing that we would also have discretion to grant waivers or extensions to ASCs that have not been formally requested by them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane)

affects an entire region or locale. We are proposing that, if we make the determination to grant a waiver or extension to ASCs in a region or locale, we would communicate this decision to ASCs and vendors through routine communication channels, including, but not limited to, e-mails and notices on the QualityNet Web site.

We invite public comment on this proposed process for granting extraordinary circumstances extensions or waivers for the submission of information for the ASC Quality Reporting Program.

4. Proposed ASC Quality Reporting Program Reconsideration Procedures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

We have established similar processes by which participating hospitals can submit requests for reconsideration of quality reporting program payment determinations for the Hospital IQR Program and the Hospital OQR Program. We believe these reconsideration processes have been effective in the hospital quality reporting programs and such a process would be effective for ASC quality reporting. Therefore, we are proposing to implement a reconsideration process for the ASC Quality Reporting Program modeled after the reconsideration processes we implemented for the Hospital IQR and Hospital OQR Programs.

We are proposing that an ASC seeking reconsideration would be required to submit to CMS a Reconsideration Request form that would be made available on the QualityNet Web site. We are proposing that the request form would be signed by a person who has authority to sign on behalf of the ASC and that this form must be

submitted by March 17 of the affected payment year (for example, for the CY 2014 payment determination, the request must be submitted by March 17, 2014).

We are proposing to use a deadline of March 17 to provide sufficient time for an ASC to see the effects of a payment reduction on its January claims. Administrative contractors have 30 days to process (pay or deny) clean claims. Administrative contractors have 45 days to process claims other than clean ones (that is, claims that require the contractor to query for more information, look at medical documentation, among others) (Claims Processing Manual, Chapter 1, Section 80; sections 1869(a)(2), 1816(c)(2) and 1842(c)(2) of the Act). We are proposing March 17 because this date is 45 days after an ASC would have had the opportunity to provide one full month of services (that is, March 17 is 45 days after January 31).

This Reconsideration Request form would contain the following information:

- ASC CCN and related NPI(s);
- ASC Name;
- CMS-identified reason for not meeting the affected payment year's ASC Quality Reporting Program requirements as provided in any CMS notification to the ASC;
- ASC basis for requesting reconsideration. We are proposing that the ASC must identify the ASC's specific reason(s) for believing it met the affected payment year's ASC Quality Reporting Program requirements and should receive the full ASC annual payment update;

- Contact information for a person at the ASC with whom CMS can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include physical address, not just a post office box); and

- A copy of all materials that the ASC submitted to comply with the affected payment year's ASC Quality Reporting Program requirements. With regard to information submitted on claims, we are proposing ASCs would not be required to submit copies of all submitted claims, but instead would focus on the specific claims at issue. Thus, ASCs would submit relevant information, which could include copies of the actual claims at issue.

Following receipt of a request for reconsideration, we are proposing that we would:

- Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the ASC contact notifying the ASC that the ASC's request has been received; and

- Provide a formal response to the ASC contact, using the contact information provided in the reconsideration request, notifying the ASC of the outcome of the reconsideration process.

We intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration.

We intend to issue proposals regarding appeals of ASC Quality Reporting Program reconsideration decisions in a future rulemaking.

We invite public comment on our proposed reconsideration procedures.