

quality data for the FY 2016 payment determination.

TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION AND SUBSEQUENT FISCAL YEAR PAYMENT DETERMINATIONS

Data collection timeframe: CY 2014	Final submission deadlines for the LTCHQR Program FY 2016 payment determination
Q1 (January–March 2014) .....	May 15, 2014
Q2 (April–June 2014) .....	August 15, 2014
Q3 (July–September 2014) .....	November 15, 2014
Q4 (October–December 2014) .....	February 15, 2015

7. Public Display of Data Quality Measures

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs under section 1886(m)(5)(C) of the Act available to the public. In addition, section 1886(m)(5)(E) of the Act requires that such procedures shall ensure that a LTCH has the opportunity to review the data that is to be made public with respect to its facility, prior to such data being made public. In addition, the statute requires that the Secretary shall report quality measures that relate to services furnished in LTCHs on our Internet Web site. Therefore, the Secretary will publicly report quality measure data that is reported under the LTCHQR Program. We did not propose procedures or timelines for public reporting of LTCHQR Program data in the proposed rule.

*Comment:* One commenter urged CMS to publicly report the LTCHQR Program data on *Hospital Compare*. This commenter further noted that the lack of established procedures or timelines for public reporting of these data is inappropriate and does not reflect the commitment to accountability and transparency CMS has shown in other quality reporting programs. Another commenter noted that a preview period of quality reports prior to their being made public must be present.

*Response:* We agree with these commenters. We appreciate the need for accountability and transparency for the LTCHQR Program similar to our other quality reporting programs. To this end, we are continuing to undertake efforts to establish procedures and a timeline for the public reporting of data for the LTCHQR Program and we will communicate this information as soon as it is available. Further, similar to our other quality reporting programs, we will provide for a preview period of quality reports under the LTCHQR

Program prior to making quality data public.

*E. Quality Reporting Requirements Under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program*

**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, Public Law 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 final 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’ 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 OPPI/ASC final rule with comment period, we finalized our proposal to implement the ASC Quality Reporting (ASCQR) 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 OPPI/ASC final rule with comment period (76 FR 74515), 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 OPPI/ASC proposed rule because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to be finalized earlier and before data collection for the CY 2014 payment determination, which is to begin with services furnished on October 1, 2012.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105), we issued proposals for administrative requirements, data completeness requirements, extraordinary circumstance waiver or extension requests, and a reconsideration process. As discussed below, we did not propose 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 proposed that ASCs must comply with the requirements specified below for the respective payment determination year.

We invited public comment on these proposals.

## 2. Requirements for Reporting Under the ASCQR Program

### a. Administrative Requirements

#### (1) Requirements 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, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28102), we did not propose 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 OPPI/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 our data system, we proposed that ASCs will need to identify and register a QualityNet 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 proposed 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 did not propose 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 proposed 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.

We invited public comment on these proposals.

*Comment:* Some commenters supported not requiring ASCs to maintain a QualityNet administrator until 2013, but recommended that the inactivity deactivation window be extended to one year because many ASCs will need to access their accounts solely on an annual basis.

*Response:* We appreciate the commenters' support. We understand the commenters' concerns that the QualityNet accounts may be deactivated because ASCs would not be submitting data frequently. As a commenter noted in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74515), QualityNet accounts are automatically deactivated after a 120-day period of inactivity in accordance with CMS security policy. Both the length of this timeframe and the requirement to maintain a QualityNet administrator when a facility is submitting data to a CMS system are dictated by our 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.

After consideration of the public comments we received, we are finalizing our proposals without modification that ASCs will need to identify and register a QualityNet

administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site and 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.

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

We finalized in the CY 2012 OPPTS/ASC final rule with comment period a policy to consider an ASC as participating in the ASCQR 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).

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28103), we proposed that once an ASC submits any quality measure data, it would be considered as participating in the ASCQR Program. Further, we proposed that, once an ASC submits any quality measure data and is considered to be participating in the ASCQR 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 ASCQR 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 ASCQR 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 ASCQR 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 ASCQR Program.

We proposed that any and all quality measure data submitted by the ASC while participating in the ASCQR 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 proposed that, once an ASC submits quality measure data indicating its participation in the ASCQR 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 proposed that an ASC would indicate on the form the initial payment determination year to which the withdrawal applies. We proposed a different process for ASCs to withdraw from participation than the process we proposed for an ASC to participate in the ASCQR Program because of the payment implications of withdrawal. We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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. Because 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 proposed that these administrative requirements would apply to all ASCs designated as open in the CASPER system for at least 4 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 ASCQR Program's initial implementation year.

We invited public comment on these proposals.

*Comment:* Commenters supported the CMS proposal that ASCs would indicate their participation in the ASCQR Program solely by beginning to submit QDCs to CMS because they believe this is the least burdensome means for ASCs to indicate their participation status.

*Response:* We appreciate the commenters' support. We believe this is the least burdensome means for ASCs to indicate their participation status.

*Comment:* Commenters supported the CMS proposal to have an active mechanism for ASCs to withdraw from the ASCQR Program. Commenters also agreed quality measure data should not be publicly available for a payment determination year and any subsequent payment determination year(s) for which an ASC is withdrawn from the Program. One commenter stated that this active mechanism will help distinguish those ASCs who are aware of the requirements, but choose not to participate, from those that are participating unsuccessfully or who are not aware of the Program, and could allow for more targeted educational efforts.

*Response:* We appreciate the commenters' support.

*Comment:* Commenters agreed that CMS had the right to make any data collected under the ASCQR Program publicly available, but made suggestions regarding various facets of public reporting including the ability of facilities to preview data, delaying public reporting, the ability of facilities to resolve accuracy concerns, limiting

the information reported for the first years of the Program to whether the ASC successfully participated in the ASCQR Program, and including explanatory narrative for individual measures.

*Response:* We thank the commenters for their views and suggestions. Regarding public reporting, we only proposed that any and all quality measure data submitted by the ASC while participating in the ASCQR Program could be made publicly available; commenters agreed with this proposal. We did not make any other proposals regarding public reporting. We will consider these additional comments addressing public reporting of ASCQR Program data in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposals without modification regarding participation in and withdrawing from the ASCQR Program as discussed above.

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

##### (1) Background

In the CY 2012 OPPTS/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.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), we proposed 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 stated that we intended to do so in the CY 2013 OPPTS/ASC proposed rule.

We invited public comments on these proposals.

*Comment:* Some commenters agreed with the CMS proposal that claims for services furnished between October 1, 2012 and December 31, 2012 that are paid by April 30, 2013 be included in the data used for the CY 2014 payment determination stating that they believed that this April 30, 2013 date would allow for sufficient time for claims processing. However, other commenters believed the proposed period for the collection of claims data may be too abbreviated to capture all pertinent data. Because ASCs have up to 1 year to submit claims for services rendered, some commenters suggested that the period for the collection of claims data be as close to 1 year from the date the service was provided to be included in a payment determination. Some of the commenters that suggested that a longer time period for claims be included, suggested that claims for services furnished between January 1, 2013 and December 31, 2013 be processed by June 30, 2014 for the CY 2015 payment determination.

*Response:* We appreciate the commenters' support of our proposals that claims for services furnished between October 1, 2012 and December 31, 2012 that are paid by April 30, 2013 be included in the data used for the CY 2014 payment determination. We agree that sufficient time should be allowed for claims processing to obtain complete data. We have conducted an internal analysis of claims submission by ASCs and have found that over 90 percent of ASC claims are submitted and paid in our proposed timeframe. Therefore, we believe that our proposed April 30 paid date provides sufficient time for claims to be submitted. In addition, while we appreciate that a longer timeframe, for example to June 30, may be desirable, we believe that April 30 is the latest date that would still allow us to acquire and analyze the claims data, make payment determinations, and importantly, allow sufficient time for the administrative contractors to program their systems.

We did not make any proposals regarding a data collection and processing period for the CY 2015 payment determination, but have done so in the CY 2013 OPPTS/ASC proposed rule.

*Comment:* One commenter expressed concern with the lag between the quality data reporting period and the payment reductions in the ASCQR Program, noting that CMS finalized its proposal to reduce ASC payments in 2014 based on data submitted in 2012. This commenter believed that CMS should align the penalty reporting period with the penalty year.

*Response:* We understand the commenter's concern with the lag between when data are reported and when payment is affected, and we will strive to reduce this lag without significant adverse effects on data completeness and quality. We interpret the commenter's desire to align the penalty reporting period with the penalty year to mean that, for example, claims for services furnished in CY 2014 would be used to affect CY 2014 payment. This could only be accomplished if we applied any reduction retroactively and recouped funds for any such reduction. We do not believe this a feasible approach because it could cause undue financial hardship on an ASC to have to refund monies and it would be administratively burdensome for us.

After consideration of the public comments we received, we are finalizing our proposal, without modification, that claims for services furnished between October 1, 2012, and December 31, 2012 be paid by the administrative contractor by April 30, 2013, to be included in the data used for the CY 2014 payment determination.

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

In the CY 2012 OPPTS/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 ASCQR Program, and because many ASCs are relatively small and they

may need more time to set up their reporting systems.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), for the CYs 2014 and 2015 payment determinations, we proposed 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 ASCQR Program. We intend to propose to increase this percentage for subsequent payment determination years as ASCs become more familiar with reporting requirements for the ASCQR Program.

As stated in CY 2012 OPPTS/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 which can be found on our Web site at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2425CP-.pdf>. Details on how to use these codes for submitting numerators and denominator information has been available since April 2012 in the ASCQR Program Specifications Manual and the QualityNet Web site at <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228772323772>.

We invited public comment on these proposals.

*Comment:* Several commenters strongly supported the proposed 50 percent minimum threshold for data completeness of claims-based measures for the CYs 2014 and 2015 payment determinations. Some commenters recommended that claims where Medicare is the secondary payer should be excluded from calculations of data completeness for the CY 2014 payment determination because private payers will not be fully informed of the G-codes until the January 2013 tape release.

*Response:* We appreciate the commenters' support. We understand that, although CMS issued the G-codes for the ASCQR Program with the April 2012 HCPCS release, private payers will not have the files for use until January 1, 2013. When we finalized our policy for calculating data completeness for the CY 2014 payment determination in the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74516), we did

not specify whether claims where Medicare is the secondary payer would be included for data completeness. However, in the CY 2013 OPPTS/ASC proposed rule, we stated that we were proposing to use the same method for determining data completeness that was finalized for the CY 2014 payment determination for the CY 2015 payment determination and subsequent payment determination years and specified that, in calculating data completeness, claims where Medicare is the primary or secondary payer would be included. However, because private payers will not have the QDCs in their required HCPCS data files until January 1, 2013, claims with QDCs received prior to January 1, 2013, can be rejected for having invalid codes. As it is not possible for ASCs to submit differing codes on primary versus secondary payer claims for at least some payers, we are specifying that only claims where Medicare is the primary payer—not the secondary payer—will be used in the calculation of data completeness for the CY 2014 payment determination. We intend to finalize what claims would be included in calculating data completeness for the CY 2015 payment determination in the CY 2013 OPPTS/ASC final rule with comment period.

*Comment:* One commenter claimed that statistics from the PQRS Program, which uses G-codes on claims for quality measure reporting, show that claims-based reporting is much less accurate than registry-based reporting. This commenter recommended that ASCs not be subject to payment reductions for CY 2014, the first year when payment can be reduced under the ASCQR Program.

*Response:* We thank the commenter for this information. However, we do not know of any analysis for claims-based and registry-based data collected under the PQRS to support the claim that statistics from the PQRS Program show that claims-based reporting is less accurate than registry-based reporting. We are aware of a recently released competitive Request for Proposal (RFP) entitled "Physician Quality Reporting System and Electronic Prescribing Incentive Program Data Assessment, Accuracy and Improper Payments Identification Support" where we seek, among other purposes, to validate and verify the accuracy of Group Practice Reporting Option claims and registry data submitted by or on behalf of eligible professionals. This RFP is currently available and results from any connected work have not yet been initiated.

We do not agree that all ASCs should not be subject to payment reductions for

the first year of the Program. We delayed the start of required data collection for the CY 2014 payment determination until October 1, 2012 (76 FR 74516) as suggested by public comments. We have provided time for ASCs to practice using QDCs. QDCs for ASCQR Program reporting may be used beginning with April 2012 services. Based upon an internal analysis, ASCs are successfully submitting these codes on their Medicare claims. Therefore, we did not propose and are not delaying the implementation of the payment reduction under the ASCQR Program.

*Comment:* Many commenters expressed their views on and made suggestions for ASCQR Program measures and measure specifications.

*Response:* We thank the commenters for taking the time to express these views and suggestions. However, we did not make any proposals regarding measures or measure specifications. We will consider these comments when we make proposals regarding ASCQR Program measures or measure specifications.

After consideration of the public comments we received, we are finalizing our proposal that the minimum threshold for successful reporting for the CYs 2014 and 2015 payment determinations be that at least 50 percent of claims meeting measure specifications contain QDCs. As discussed above, only claims where Medicare is the primary payer will be used in the calculation of data completeness for the CY 2014 payment determination.

#### c. ASCQR Program Validation of Claims-Based and Structural Measures

We received comments on the CY 2012 OPPTS/ASC proposed rule requesting that rules for data validation be adopted as soon as possible (76 FR 74515). We noted that structural measures historically have not been validated through independent medical record review in our quality reporting programs for hospitals 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. Likewise, we have not historically validated claims-based measures for hospitals. Thus, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), consistent with other CMS quality reporting programs, we did not propose to validate claims-based measures (beyond the usual claims validation activities conducted by our administrative contractors) and structural measures for the ASCQR Program.

*Comment:* Several commenters urged CMS to reconsider the need for data validation to ensure standardization and accuracy. Some of these commenters believed that such a data validation process should involve independent review of medical records. One commenter stated that, although it may be acceptable at this time to not perform validity testing on the data, it recommended that prior to using ASC measures for accountability purposes (for example, public reporting, pay for performance), CMS develop and deploy a plan for such testing. The commenter believed that scientific acceptability of the measure is, in part, based on the quality of the data that is used. Having taken such a validation step would be informative in both refining the measure and arriving upon a set of ASC measures.

*Response:* We appreciate and share the commenters' concern about standardization and the desire for accuracy. We agree that, before using data collected for a quality data reporting program for such activities as public reporting, it is preferable to be able to assess the accuracy of the data reported (we note that the ASCQR Program is a pay for reporting program and not pay for performance program). However, this preference is counterbalanced by the feasibility of being able to do so. Structural measures historically have not been validated through independent medical record review in our quality reporting programs for hospitals (the Hospital IQR and Hospital OQR Programs). We have not validated structural measures 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. Because we do not believe at this time that there is a method for us to effectively validate structural measure data, we are not requiring a data validation process for our current structural measures under the ASCQR Program.

In regard to the current ASCQR Program claims-based measures, the number of events expected to be reported is small because most of the measures are for adverse or rare events. In this situation, any random selection of cases would require a burdensome sample size. Further, we expect the accuracy for reported adverse events to be high. Because we do not believe at this time that any results that could be obtained justify the burden associated with a data validation process which would necessitate an independent validation effort, we also are not

requiring a data validation process for our current claims-based measures.

As we gain more experience with the ASCQR Program, we will reassess whether a data validation process for claims-based and structural measures is needed.

### 3. 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, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104 through 28105), we proposed 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 ASCQR Program.

In the event of extraordinary circumstances, such as a natural disaster, that is not within the control of the ASC, we proposed 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 proposed 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 proposed 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, email 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 ASCQR Program information, and a reasonable basis for the proposed date.

We proposed 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 proposed 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 proposed 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 proposed 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, emails and notices on the QualityNet Web site.

We invited public comment on this proposed process for granting extraordinary circumstances extensions or waivers for the submission of information for the ASCQR Program.

*Comment:* Many commenters supported having a process for ASCs to apply for an extension or waiver of the submission of information under the ASCQR Program in the event of extraordinary circumstances. Some of these commenters recommended that the period of time an ASC can apply be extended, for example, to 90 days after such an event, rather than 45 days as proposed.

*Response:* We appreciate the commenters' support. Regarding the timeframe to request an extension or waiver, we have found that 45 days is sufficient time for hospitals to make such a request under the Hospital OQR Program. We believe that 45 days also would be sufficient time for ASCs to make such requests. We believe that more than 45 days to complete and submit a form will only serve to delay the process. We also proposed and are finalizing a policy that we would 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.

*Comment:* Some commenters noted unforeseen issues related to information technology failures that could prevent ASCs from participating in the ASCQR Program. Examples of such included clearinghouses stripping the QDCs from claims before the claims go to the MAC for processing and problems with billing software not allowing the reporting of a code with a zero dollar charge.

*Response:* We are aware of situations where clearinghouses are removing QDCs from claims as well as of non-Medicare payers rejecting claims with QDCs as having invalid codes. We note that we issue an update tape containing all valid HCPCS codes and that clearinghouses should abide by the complete listing of HCPCS codes and should not remove these HCPCS codes from claims. However, we would consider inappropriate removal or rejection of QDCs by clearinghouses as well as private payers an extraordinary circumstance if the ASC was able to sufficiently document refusal by a clearinghouse or private payer to follow our HCPCS usage standards that could result in the ASC suffering substantial risk of having a payment reduction under the ASCQR Program. This documentation must include substantive efforts made by the ASC to inform the clearinghouse or private payer of the need to follow our HCPCS usage standards. We also are aware of the need for the placement of a nominal value in the payment field for some billing software and we have issued guidance on this issue. This guidance is currently available in the Question and Answer Tool on the QualityNet Web site located at <http://www.Qualitynet.org> under the question with Answer ID 158904 entitled "What are the G-codes for the ASC measures, and where and how do I use them?"

After consideration of the public comments we received, we are finalizing our proposals without modification regarding a process for an extension or waiver of the submission of information required under the ASCQR Program.

#### 4. ASCQR 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, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28105), we proposed to implement a reconsideration process for the ASCQR Program modeled after the reconsideration processes we implemented for the Hospital IQR and Hospital OQR Programs.

We proposed 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 proposed 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 proposed 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 proposed 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 ASCQR Program requirements as provided in any CMS notification to the ASC;
- ASC basis for requesting reconsideration. We proposed that the ASC must identify the ASC's specific reason(s) for believing it met the affected payment year's ASCQR 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, email 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 ASCQR Program requirements. With regard to information submitted on claims, we proposed that 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 proposed that we would:

- Provide an email 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 stated that 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 stated that we intend to issue proposals regarding appeals of ASCQR Program reconsideration decisions in a future rulemaking.

We invited public comment on our proposed reconsideration procedures.

*Comment:* Several commenters supported the CMS proposal to have a reconsideration process. Some of these commenters recommended longer timeframes for an ASC to submit a request than the proposed March 17th deadline, including April 15th and a minimum of 90 days.

*Response:* We appreciate the commenters' support. We also appreciate suggestions by some commenters to extend the time to submit a reconsideration request. However, we believe the March 17 deadline to submit a reconsideration request provides ASCs with sufficient time to assess the effects of a payment reduction on their January claims. We also note that the March 17 deadline is later than the February 2 deadline that the Hospital OQR Program allows and the Hospital OQR Program also involves a calendar year payment determination.

*Comment:* Some commenters believed that the need for appeals could be mitigated if CMS incorporates a reporting feedback program that periodically updates ASCs on their reporting status.

*Response:* We thank these commenters for expressing this view. An automated reporting system with feedback reports as is supplied for the Hospital IQR and OQR Programs will be available for the ASCQR Program. We plan to begin a reporting feedback program during 2013. We intend to provide feedback on the October 1, 2012, to December 31, 2012 claims-based measures, via a report that will be supplied via an ASC's QualityNet account. ASCs will be able to access these automated reports via their QualityNet accounts beginning in 2013. Information regarding feedback reports will be available on the QualityNet Web site (<http://www.QualityNet.org>).

After consideration of the public comments we received, we are finalizing our proposals regarding ASCQR Program reconsideration procedures for the CY 2014 payment determination and subsequent payment determination years.

*Comment:* Commenters expressed views and suggestions regarding additional topics including mechanisms to increase ASC awareness of the ASCQR Program and alternate reporting mechanisms.

*Response:* We thank these commenters for their suggestions for improving the ASCQR Program. Although we did not make proposals on these topics, we will consider these views for future rulemaking and program development. We have been making efforts to supply information to ASCs regarding the ASCQR Program including information posted on the QualityNet Web site (<http://www.QualityNet.org>), an educational mailing to ASCs, and an online question and answer tool (<http://cms-ocsq.custhelp.com>) which is also accessible via the QualityNet Web site.

#### *F. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program*

##### 1. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for rate year (RY) 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during such rate year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable rate year.

We note that section 1886(s)(4)(A)(i) of the Act uses the term "rate year." Beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD-9-CM codes, which are effective on October 1 of each year. The change allows for annual payment updates and the ICD-9-CM coding update to occur on the same schedule and appear in the same **Federal Register** document, thus making updating rules more administratively efficient. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the 12-month period of October 1 through September 30 is referred to as a fiscal year (76 FR 26435). For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435). For purposes of the discussion below, the term "rate year" and "fiscal year" both refer to the period beginning October 1 and ending September 30. To avoid any confusion that may be caused by using the term "rate year" with respect to the inpatient psychiatric hospitals and psychiatric units quality reporting program, we will use the term "fiscal year" rather than "rate year" throughout this proposed rule, even when we are referring to statutory provisions that refer to "rate year."

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than such payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality

measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. The NQF is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We generally prefer to adopt NQF-endorsed measures in our reporting programs with some exceptions as provided by law.

For purposes of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Finally, pursuant to section 1886(s)(4)(D)(iii) of the Act, the Secretary shall publish the measures applicable to the FY 2014 IPFQR Program no later than October 1, 2012.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the quality reporting program. Such procedures must ensure that a facility has the opportunity to review its data prior to such data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on a CMS Web site.

##### 2. Application of the Payment Update Reduction for Failure To Report for FY 2014 Payment Determination and Subsequent Years

Beginning in FY 2014, section 1886(s)(4)(A)(i) of the Act requires the application of a 2.0 percentage point reduction to the applicable annual update to a Federal standard rate for those psychiatric hospitals and psychiatric units that fail to comply with the quality reporting requirements implemented in accordance with