

(b) *Who may submit a request.* Any individual, partnership, corporation, association, society, scientific or academic establishment, or professional or trade organization able to furnish the information required in paragraph (c) of this section may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the criteria of a new technology IOL under § 416.195.

(c) *Content of a request.* In order to be accepted by CMS for review, a request for review of the ASC payment amount for insertion of an IOL must include all the information as specified by CMS.

(d) *Confidential information.* In order for CMS to invoke the protection allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905), the requestor must clearly identify all information that is to be characterized as confidential.

**§ 416.195 Determination of membership in new classes of new technology IOLs.**

(a) *Factors to be considered.* CMS uses the following criteria to determine whether an IOL qualifies for a payment adjustment as a member of a new class of new technology IOLs when inserted at an ASC:

(1) The IOL is considered new. CMS will evaluate an application for a new technology IOL only if the IOL type has received initial FDA premarket approval within the 3 years prior to the new technology IOL application submission date.

(2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The labeling, which must be approved by FDA, shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.

(3) The IOL is not described by an active or expired class of new technology IOLs; that is, it does not share a predominant, class-defining characteristic associated with improved clinical outcomes with members of an active or expired class.

(4) Any specific clinical benefit referred to in paragraph (a)(2) of this sec-

tion must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:

- (i) Reduced risk of intraoperative or postoperative complication or trauma;
- (ii) Accelerated postoperative recovery;
- (iii) Reduced induced astigmatism;
- (iv) Improved postoperative visual acuity;
- (v) More stable postoperative vision;
- (vi) Other comparable clinical advantages.

(b) *CMS determination of eligibility for payment adjustment.* CMS reviews the information submitted with a completed request for review, public comments submitted timely, and other pertinent information and makes a determination as follows:

(1) The IOL is eligible for a payment adjustment as a member of a new class of new technology IOLs.

(2) The IOL is a member of an active class of new technology IOLs and is eligible for a payment adjustment for the remainder of the period established for that class.

(3) The IOL does not meet the criteria for designation as a new technology IOL and a payment adjustment is not appropriate.

[71 FR 68226, Nov. 24, 2006, as amended at 77 FR 68558, Nov. 15, 2012; 80 FR 70604, Nov. 13, 2015]

**§ 416.200 Payment adjustment.**

(a) CMS establishes the amount of the payment adjustment for classes of new technology IOLs through proposed and final rulemaking in connection with ASC facility services.

(b) CMS adjusts the payment for insertion of an IOL approved as belonging to a class of new technology IOLs for the 5-year period of time established for that class.

(c) Upon expiration of the 5-year period of the payment adjustment, payment reverts to the standard rate for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to a class of new technology IOLs must submit claims using billing codes specified by

CMS to receive the new technology IOL payment adjustment.

### Subpart H—Requirements Under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

SOURCE: 80 FR 70604, Nov. 13, 2015, unless otherwise noted.

#### §416.300 Basis and scope of subpart.

(a) *Statutory basis.* Section 1833(i)(2)(D)(iv) and (i)(7) of the Act authorizes the Secretary to implement a revised ASC payment system in a manner so as to provide for a 2.0 percentage point reduction in any annual update for an ASC's failure to report on quality measures in accordance with the Secretary's requirements.

(b) *Scope.* This subpart contains specific requirements and standards for the ASCQR Program.

#### §416.305 Participation and withdrawal requirements under the ASCQR Program.

(a) *Participation in the ASCQR Program.* Except as provided in paragraph (c) of this section, an ambulatory surgical center (ASC) is considered as participating in the ASCQR Program once the ASC submits any quality measure data to the ASCQR Program and has been designated as open in the Certification and Survey Provider Enhanced Reporting system for at least four months prior to the beginning of data collection for a payment determination.

(b) *Withdrawal from the ASCQR Program.* (1) An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the CMS-designated information system.

(2) An ASC may withdraw from the ASCQR Program any time up to and including August 31 of the year preceding a payment determination.

(3) Except as provided in paragraph (c) of this section, an ASC will incur a 2.0 percentage point reduction in its ASC annual payment update for that payment determination year and any subsequent payment determinations in which it is withdrawn.

(4) An ASC will be considered as rejoining the ASCQR Program if it begins to submit any quality measure data again to the ASCQR Program.

(c) *Minimum case volume for program participation.* ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year.

(d) *Indian Health Service hospital outpatient department participation.* Beginning with the CY 2017 payment determination, Indian Health Service hospital outpatient departments that bill Medicare under the Ambulatory Surgical Center payment system are not considered ASCs for the purposes of the ASCQR Program. These facilities are not required to meet ASCQR Program requirements and will not receive payment reductions under the ASCQR Program.

[80 FR 70604, Nov. 13, 2015, as amended at 88 FR 82179, Nov. 22, 2023]

#### §416.310 Data collection and submission requirements under the ASCQR Program.

(a) *Requirements for claims-based measures using quality data codes (QDCs).* (1) ASCs must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims.

(2) The data collection period for claims-based quality measures reported using QDCs is the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the Medicare Administrative Contractor (MAC) by April 30 of the following year of the ending data collection period will be included in the data used for the payment determination year.

(3) For ASCQR Program purposes, data completeness for claims-based measures using QDCs is determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure

specifications that contain the appropriate QDCs with the number of Medicare claims that meet measure specifications, but do not have the appropriate QDCs on the submitted Medicare claim. The minimum threshold for successful reporting is that at least 50 percent of Medicare claims meeting measure specifications contain the appropriate QDCs. ASCs that meet this minimum threshold are regarded as having provided complete data for the claims-based measures using QDCs for the ASCQR Program.

(b) *Requirements for claims-based measures not using QDCs.* The data collection period for claims-based quality measures not using QDCs is paid Medicare fee-for-service claims from the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the MAC by April 30 of the following year of the ending data collection period will be included in the data used for the payment determination.

(c) *Requirements for data submitted via an online data submission tool—(1) Requirements for data submitted via a CMS online data submission tool—(i) CMS-designated information system account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain an account for the CMS-designated information system in order to submit quality measure data to the CMS-designated information system for all web-based measures submitted via a CMS online data submission tool. A security official is necessary to set up such an account for the CMS-designated information system for the purpose of submitting this information.

(ii) *Data collection requirements.* The data collection period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Beginning with the CY 2017 payment determination year, data collected must be submitted during the period of January 1 to May 15 in the year prior to the payment determination year.

(iii) *Review and corrections period.* For measures submitted to CMS via a CMS

online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed.

(2) *Requirements for data submitted via a non-CMS online data submission tool.* The data collection period for ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel is from October 1 of the year 2 years prior to the payment determination year to March 31 during the year prior to the payment determination year. Data collected must be submitted by May 15 in the year prior to the payment determination year.

(d) *Extraordinary circumstances exceptions.* CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or if CMS determines that a systemic problem with one of its data collection systems directly affected the ability of the hospitals to submit data. CMS may grant an exception as follows:

(1) *Upon request of the ASC.* Specific requirements for submission of a request for an exception are available on the CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to ASCs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Ambulatory surgical centers must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS survey as a vendor on behalf of