Supporting Statement – Part A

Submission of Information for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program: CY 2018 OPPS/ASC Final Rule

A. Background

The Centers for Medicare & Medicaid Services' (CMS') quality reporting programs promote higher quality, more efficient health care for Medicare beneficiaries. CMS has implemented quality measure reporting programs for multiple settings, including for ambulatory surgical centers.

Section 109(b) of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109-432) amended section 1833(i) of the Social Security Act (the Act) by re-designating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).''

Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. This section also specifies that a reduction for one year cannot be taken into account in computing any annual increase factor for a subsequent year.

Section 1833(i)(7)(B) of the Act provides that, ''[e]xcept as the Secretary may otherwise provide,'' the hospital outpatient quality data provisions of subparagraphs (B) through (E) of section 1833(t)(17) of the Act shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the Hospital OQR Program and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC, respectively. Section 1833(t)(17)(B) of the Act requires that hospitals submit quality data in a form and manner, and at a time, that the Secretary specifies.

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

Section 1833(t)(17)(D) of the Act gives the Secretary the authority to replace measures or indicators as appropriate, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice. Section 1833(t)(17)(E) of the Act requires the Secretary to establish procedures for making data

submitted under the ASCQR Program available to the public. Such procedures include providing hospitals with the opportunity to review their data before these data are released to the public.

Section 3014 of the Affordable Care Act of 2010 (ACA) modified section 1890(b) of the Social Security Act to require CMS to develop quality and efficiency measures through a "consensus-based entity." To fulfill this requirement, the Measure Applications Partnership (MAP) was formed to review measures consistent with these requirements. MAP is convened by the National Quality Forum (NQF), a national consensus organization, with current organizational members including the American Association of Retired Persons (AARP), America's Health Insurance Plans, the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), the American Hospital Association, the American Medical Association, the American Nurses Association, the Federation of American Hospitals, and the Pacific Business Group on Health. Nationally recognized subject matter experts are also voting members of the MAP. CMS consulted with the MAP and received its formal recommendations before identifying ASCQR measures to be included in the CY 2018 OPPS/ASC rule. The CY 2018 final rule includes newly finalized measures and measure-related policies for the CY 2020 payment determination and subsequent years as well as a listing of previously adopted measures.

The CMS program established under these amendments is referred to as the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. As required, to date, CMS has adopted a set of 19 quality of care measures for the ASC setting; data has been collected for calendar years (CYs) 2014 through 2016 and has made this data publicly available after providing ASCs the opportunity to review the data. Based on program feedback through our outreach and education activities, the identification of measure topics of interest and required data collection have raised awareness of quality improvement in the ASC community. Additionally, as discussed below, ASCs can utilize program measures for their required quality assessment and performance improvement (QAPI) programs. The information collection requirements for the CY 2014 through CY 2018 payment determinations are currently approved under OMB Control Number 0938-1270. This information collection request covers the existing measure set to be collected for CYs 2019 and 2020.

In implementing this and other quality reporting programs, CMS' overarching goal is to support the National Quality Strategy's goals of better health for individuals, better health for populations, and lower costs for health care. The National Strategy for Quality Improvement in Health Care (National Quality Strategy) was released by the U.S. Department of Health and Human Services. The strategy was required under the Affordable Care Act and is an effort to create national aims and priorities to guide local, State, and national efforts to improve the quality of health care in the United States.

The ASCQR Program supports these goals by making collected clinical quality of care information publicly available and by fostering quality improvement. Taking into account the need to balance breadth with minimizing burden, program measures address as fully as possible, the six domains of measurement that arise from the National Quality Strategy: clinical care, person and caregiver centered experience and outcomes, safety, efficiency and cost reduction, care coordination, and community/population health.

B. ASCQR Quality Measures and Forms

1. Introduction

ASCQR Program payment determinations are made based on ASCQR quality measure data reported and supporting forms submitted by ASCs as specified through rulemaking. To reduce burden, a variety of different data collection mechanisms are employed, with every consideration taken to employ existing data and data collection systems. The complete list of measures and data collection forms are organized by type of data collected and data collection mechanism.

The Medicare program has a responsibility to ensure that Medicare beneficiaries receive the health care services of appropriately high quality that are comparable to that received by those under other payers. The ASCQR Program seeks to encourage care that is both efficient and of high quality in the ambulatory outpatient setting through collaboration with the ASC community to develop and implement quality measures that are fully and specifically reflective of the quality of ambulatory outpatient services.

2. CY 2014 through CY 2018 Payment Determinations

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70537), CMS finalized quality measures, administrative processes and data submission requirements for the CYs 2014 through 2018 payment determinations. The information collection requirements for the CY 2014 through CY 2018 payment determinations are currently approved under OMB Control Number 0938-1270.

ASCQR PROGRAM MEASURES FOR THE CY 2014 THROUGH CY 2018 PAYMENT DETERMINATIONS

NQF No.	Measure Name	Data Collection Mode
0263	ASC-1: Patient Burn	Quality Data Codes via Claims
0266	ASC-2: Patient Fall	Quality Data Codes via Claims
0267	ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	Quality Data Codes via Claims
0265†	ASC-4: Hospital Transfer/Admission	Quality Data Codes via Claims
0264†	ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing	Quality Data Codes via Claims
N/A	ASC-6: Safe Surgery Checklist Use	Web-based (CMS)
N/A	ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures	Web-based (CMS)

0431	ASC-8: Influenza Vaccination Coverage among Healthcare Personnel	Web-based (NHSN)
0658	ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Web-based (CMS)
0659	ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use	Web-based (CMS)
1536	ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (CMS; Voluntary)
2539	ASC-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data	Claims

† We note that NQF endorsement for this measure was removed.

Measures that have data collected via Quality Data Codes (QDCs) are submitted on Part B Medicare claims submitted on the CMS-1500 form for payment; the CMS-1500 revised form received OMB approval on March 29, 2017, (OMB Control Number 0938-1197). Data collected in this manner requires nominal, additional effort for ASC facilities.

Web-based measures labeled as "CMS" require ASCs to submit non-patient level data directly to CMS via a web-based tool located on a CMS website. The web-based measure labeled as "NHSN" is submitted through the CDC's National Healthcare Safety Network (NHSN); CDC then supplies this information to CMS.

One measure, ASC-11, is reported voluntarily; reporting or not reporting data for this measure does not affect an ASC's payment determination under the program.

Measures labeled as having an information collection mode of "Claims" have information derived through analysis of administrative Medicare claims data and do not require additional effort or burden from ASCs.

3. CY 2019 Payment Determination

In the CY 2018 OPPS/ASC final rule, CMS is removing three measures from the ASCQR Program measure set: (1) ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing, a claims-based measure; (2) ASC-6: Safe Surgery Checklist Use, a Web-based measure; and (3) ASC-7: ASC Facility Volume Data on Selected Procedures, a Web-based measure for the CY 2019 payment determination.

The entire measure set finalized for the CY 2019 measure set is:

ASCQR PROGRAM MEASURES FOR THE CY 2019 PAYMENT DETERMINATION

NQF No.	Measure Name	Data Collection Mode
0263	ASC-1: Patient Burn	Quality Data Codes via Claims
0266	ASC-2: Patient Fall	Quality Data Codes via Claims
0267	ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	Quality Data Codes via Claims
0265†	ASC-4: Hospital Transfer/Admission	Quality Data Codes via Claims
0431	ASC-8: Influenza Vaccination Coverage among Healthcare Personnel	Web-based (NHSN)
0658	ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Web-based (CMS)
0659	ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use	Web-based (CMS)
1536	ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (CMS; Voluntary)
2539	ASC-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data	Claims

† We note that NQF endorsement for this measure was removed.

Measures that have data collected via Quality Data Codes (QDCs) are submitted on Part B Medicare claims submitted on the CMS-1500 form for payment; the CMS-1500 revised form received OMB approval on March 29, 2017, (OMB Control Number 0938-1197). Data collected in this manner requires nominal, additional effort for ASC facilities.

Web-based measures labeled as "CMS" require ASCs to submit non-patient level data directly to CMS via a web-based tool located on a CMS website. The web-based measure labeled as "NHSN" is submitted through the CDC's National Healthcare Safety Network (NHSN); CDC then supplies this information to CMS.

One measure, ASC-11, is reported voluntarily; reporting or not reporting data for this measure does not affect an ASC's payment determination under the program.

Measures labeled as having an information collection mode of "Claims" have information derived through analysis of administrative Medicare claims data and do not require additional effort or burden from ASCs.

4. CY 2020 Payment Determination

In the CY 2017 OPPS/ASC final rule, CMS added two additional measures collected and reported via a CMS online data submission tool and five measures collected via the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey. These are highlighted below. The data for these measures will be collected during CY 2018 and reported in CY 2019 for the measures reported via a CMS online data submission tool and on a rolling basis during CYs 2018 and 2019 for the OAS CAHPS survey-based measures. In the CY 2018 OPPS/ASC final rule, CMS is delaying implementation of the OAS CAHPS survey and the five survey-based measures collected via the survey until further action in future rulemaking.

The entire measure set finalized for the CY 2020 payment determination is:

ASCQR PROGRAM MEASURES FOR THE CY 2020 PAYMENT DETERMINATION

NQF No.	Measure Name	Data Collection Mode
0263	ASC-1: Patient Burn	Quality Data Codes via Claims
0266	ASC-2: Patient Fall	Quality Data Codes via Claims
0267	ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	Quality Data Codes via Claims
0265†	ASC-4: Hospital Transfer/Admission	Quality Data Codes via Claims
0431	ASC-8: Influenza Vaccination Coverage among Healthcare Personnel	Web-based (NHSN)
0658	ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Web-based (CMS)
0659	ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use	Web-based (CMS)
1536	ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (CMS; Voluntary)
2539	ASC-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data	Claims
N/A	ASC-13: Normothermia Outcome	Web-based (CMS)
N/A	ASC-14: Unplanned Anterior Vitrectomy	Web-based (CMS)
N/A	ASC-15a: OAS CAHPS – About Facilities and Staff*	Survey-based
N/A	ASC-15b: OAS CAHPS – Communication About Procedure*	Survey-based

NQF No.	Measure Name	Data Collection Mode
N/A	ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery*	Survey-based
N/A	ASC-15d: OAS CAHPS – Overall Rating of Facility*	Survey-based
N/A	ASC-15e: OAS CAHPS – Recommendation of Facility*	Survey-based

† We note that NQF endorsement for this measure was removed.
* Measure reporting delayed beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking.

Quality Data Codes are collected via Part B Medicare claims and require nominal, additional effort for ASC facilities.

Web-based measures labeled as "CMS" require ASCs to submit non-patient level data directly to CMS via a web-based tool located on a CMS website. The web-based measure labeled as "NHSN" is submitted through the CDC's National Healthcare Safety Network (NHSN); CDC then supplies this information to CMS.

One measure, ASC-11, is reported voluntarily; reporting or not reporting data for this measure does not affect an ASC's payment determination under the program

Measures labeled as having an information collection mode of "Claims" have information derived through analysis of administrative Medicare claims data and do not require additional effort or burden from ASCs.

Measures labeled as having an information collection more of "Survey-based" have information derived through analysis of data submitted via the OAS CAHPS Survey and do not require additional effort or burden from ASCs beyond administering the survey and submitting survey data to CMS. These survey administration burdens are captured under a previously finalized PRA Package, OMB Control Number 0938-1240.

5. CY 2022 Payment Determination and Subsequent Years

In the CY 2018 OPPS/ASC final rule, CMS is adding two measures collected via Part A and Part B Medicare administrative claims and Medicare enrollment data to the ASCQR Program measure set: (1) ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures. These measures are highlighted below. The data for these measures will be collected during CY 2020 and reported in CY 2021.

The entire measure set finalized for the CY 2022 payment determination and subsequent years is:

ASCQR PROGRAM MEASURES FOR THE CY 2022 PAYMENT DETERMINATION

NQF No.	Measure Name	Data Collection Mode
0263	ASC-1: Patient Burn	Quality Data Codes via Claims
0266	ASC-2: Patient Fall	Quality Data Codes via Claims
0267	ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	Quality Data Codes via Claims
0265†	ASC-4: Hospital Transfer/Admission	Quality Data Codes via Claims
0431	ASC-8: Influenza Vaccination Coverage among Healthcare Personnel	Web-based (NHSN)
0658	ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Web-based (CMS)
0659	ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use	Web-based (CMS)
1536	ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (CMS; Voluntary)
2539	ASC-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data	Claims
N/A	ASC-13: Normothermia Outcome	Web-based (CMS)
N/A	ASC-14: Unplanned Anterior Vitrectomy	Web-based (CMS)
N/A	ASC-15a: OAS CAHPS – About Facilities and Staff*	Survey-based
N/A	ASC-15b: OAS CAHPS – Communication About Procedure*	Survey-based
N/A	ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery*	Survey-based
N/A	ASC-15d: OAS CAHPS – Overall Rating of Facility*	Survey-based
N/A	ASC-15e: OAS CAHPS – Recommendation of Facility*	Survey-based
N/A	ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures	Claims
N/A	ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures	Claims

† We note that NQF endorsement for this measure was removed.

* Measure reporting delayed beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking.

Measures that have data collected via Quality Data Codes (QDCs) are submitted on Part B Medicare claims submitted on the CMS-1500 form for payment; the CMS-1500 revised form

received OMB approval on March 29, 2017, (OMB Control Number 0938-1197). Data collected in this manner requires nominal, additional effort for ASC facilities.

Web-based measures labeled as "CMS" require ASCs to submit non-patient level data directly to CMS via a web-based tool located on a CMS website. The web-based measure labeled as "NHSN" is submitted through the CDC's National Healthcare Safety Network (NHSN); CDC then supplies this information to CMS.

One measure, ASC-11, is reported voluntarily; reporting or not reporting data for this measure does not affect an ASC's payment determination under the program.

Measures labeled as having an information collection mode of "Claims" have information derived through analysis of administrative Medicare claims data and do not require additional effort or burden from ASCs.

Measures labeled as having an information collection more of "Survey-based" have information derived through analysis of data submitted via the OAS CAHPS Survey and do not require additional effort or burden from ASCs beyond administering the survey and submitting survey data to CMS. These survey administration burdens are captured under a previously finalized PRA Package, OMB Control Number 0938-1240.

7. Forms Used in ASCQR Program Procedures

Two administrative forms are utilized by the ASCQR Program: the Extraordinary Circumstance Extension or Exemptions form and Reconsideration Request form. Neither of these forms is completed on an annual basis; all are completed on a need-to-use, exception basis and most ASCs will not need to complete any of these forms in a given year.

In the event of extraordinary circumstances not within the control of an ASC, such as a natural disaster, an ASC can request a waiver or extension for meeting program requirements. For the ASC to receive consideration for an extension or waiver, an Extraordinary Circumstances Extensions or Exemption Request must be submitted. CMS provides this form to ASCs on-line and facilities may submit the form electronically, by mail, or fax. We note that the burden associated with completing and submitting an Extraordinary Circumstance Extension/Exemption Request is already accounted for in a separate PRA package, OMB Control Number 0938-1022.[1] Therefore, the burden associated with completing and submitting and Extraordinary Circumstance Extension/Exemption Request is not addressed in this PRA Package. We note that in the CY 2018 OPPS/ASC final Rule, we note that we intend to begin referring to the process as the extraordinary circumstances exceptions process.

[1] This burden is captured under another package because the quality reporting and value-based purchasing programs currently housed under the Division of Value, Incentives, and Quality Reporting all use a single request form, and these requests are reviewed by an independent group within the Division. Accounting for this burden under a single package ensures that all programs are using the same form, process, and burden estimates and avoids the risk of inconsistency or misalignment in CMS policies on this issue, as well as reducing inefficiencies in form updates and request processing.

When an ASC is determined by CMS to not have met program requirements and has had a 2-percentage point reduction in their APU, the ASC may submit a request for reconsideration to CMS. This request must be submitted by the first business day in February in the year the payment reduction has occurred. CMS provides this form to ASCs on-line and facilities may submit the form by mail or by fax. While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations exclude collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions. Therefore, the burden associated with submitting a reconsideration request is not accounted for in this PRA package.

C. Justification

1. Need and Legal Basis

Section 109(b) of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109-432) amended section 1833(i) of the Act by re-designating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system ‘‘in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).’’ Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. Sections 1833(t)(17)(C) (i) and (ii) of the Act require the Secretary to develop measures appropriate for the measurement of the quality of care furnished in outpatient settings.

Continued improvement of the quality measure set is consistent with the letter and spirit of the authorizing legislation, TRCHA, to collect and make publicly available ASC-reported information on the quality of care delivered in the ASC outpatient setting and to utilize a formal, consensus process as defined under the ACA. Efforts are made to reduce burden by limiting the adoption of measures requiring the submission of patient-level information that must be acquired through chart abstraction and to employ existing data and data collection systems, such as the NHSN network and Medicare claims.

2. Information Users

The Ambulatory Surgical Center Quality Reporting Program views an effective pay-for-reporting program as having a streamlined measure set that provides meaningful measurement that serves to differentiate facilities by quality of care while limiting burden to the fullest extent possible.

This information gathered by the program is used by CMS to direct activities of Quality Improvement Organizations (QIOs) to focus on specific areas for improvement and to develop quality improvement initiatives. In addition, ASCs can utilize program measures as metrics for required quality assessment and performance improvement (QAPI) programs under ASC conditions for coverage (CfCs). As described in 42 CFR §416.43, these programs must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcome and by the identification and reduction of medical errors. The current ASCQR Program measure set includes measures that can be used for these efforts.

Most importantly, this information is available to Medicare beneficiaries, as well as to the general public, to provide information to assist them in making decisions about their health care. ASCQR Program data is published on the *Hospital Compare* Web site at https://data.medicare.gov/ in a form that allows reviewers to review both facility-level and national performance on quality measures selected for use in the ASCQR Program.

3. Improved Information Technology

To assist ASCs in this initiative, CMS provides a secure data warehouse and use of the My QualityNet website for storage and transmittal of data prior to the release of data to the CMS website. ASCs also have the option of using other vendors to transmit the data. CMS has engaged a national support contractor to provide technical assistance with the data collection tool, other program requirements, and to provide education.

For the claims-based measures, this section is not applicable as claims-based measures are calculated from administrative claims data that result from claims submitted by ASCs to Medicare for reimbursement. Therefore, no additional information technology will be required for ASCs for these measures.

4. Duplication of Similar Information

The information to be collected is not duplicative of similar information collected by the CMS or other efforts to collect quality of care data for outpatient ASC care. As required by statute, CMS required ASCs to submit quality measure data for services provided.

Once an ASC submits quality measure data to the ASCQR Program, they are considered to be participating in the program. In order to withdraw from the program after submitting quality measure data, an ASC must complete and submit an online withdrawal form requesting withdrawal from the program.

5. Small Business

There are 3,937 ASCs eligible to participate in the program (as compared to 5,260 ASCs estimated to be eligible in the previously finalized PRA package under this OMB control

number); these facilities have an average of twenty-eight employees and many would be considered to be small businesses. All of the program information collection requirements are designed to allow maximum flexibility to facilities possible to encourage participation in the program. We have designed the collection of quality of care data to be the minimum necessary for the calculation of summary figures that are reliable estimates of ASCs' performance. We have also incorporated measures that use data collected on Medicare claims whenever possible to ease burden. This program will assist all ASCs, especially those of smaller size in gathering information for their own quality improvement efforts.

6. Less Frequent Collection

We have designed the collection of quality of care data to be the minimum necessary for data validation and calculation of summary figures to be reliable estimates of ASCs performance. Under the ASCQR Program, participating ASCs are required to submit data for web-based measures to CMS on an annual basis. In addition, for submission of claims-based measures, participating ASCs are required to submit paid Medicare Fee-for-Service claims from the 12-month data collection period. CMS collects the data submitted by participating ASCs for the chart-abstracted measures, web-based measures, and claims-based measures to determine the Annual Payment Updates (APUs) to ASCs, which are determined on a yearly basis. To collect the information less frequently would compromise the timeliness of any calculated estimates.

7. Special Circumstances

All ASCs reimbursed under the ASC Payment System must meet ASCQR Program Requirements, including administrative and data submission requirements, to receive the full annual increase provided under the revised ASC payment system for a given calendar year. Failure to meet all requirements may result is a 2.0 percentage point reduction in the APU.

8. Federal Register Notice/Outside Consultation

The CY 2018 Outpatient Prospective Payment System and Ambulatory Surgical Center final rule displayed at the Office of the Federal Register on November 1, 2017. It published in the Federal Register on November 13, 2017 (82 FR 52356). The document is available on both the Federal Register and CMS web sites.

CMS is supported in this program's efforts by the Joint Commission, NQF, MAP, and CDC. These organizations collaborate with CMS on an ongoing basis, providing technical assistance in developing and identifying quality measures, and assisting in making collected information accessible, understandable, and relevant.

9. Payment/Gift to Respondent

ASCs are required to submit these data in order to receive the full annual increase provided under the revised ASC payment system for a given calendar year. No other payments or gifts will be given to respondents for participation.

10. Confidentiality

All information collected under the ASCQR Program will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for CMS data, including the Privacy Act of 1974 (5 U.S.C. 552a), the Health Insurance Portability and Accountability Act, and the Quality Improvement Organizations confidentiality requirements, which can be found at 42 CFR Part 480. CMS maintains this information in the CMS data warehouse, which contains all information collected under this and other quality data reporting programs. In addition, the tools used for transmission and storage of data are considered confidential forms of communication and are HIPAA-compliant.

11. Sensitive Questions

This program does not collect information on "sexual behavior and attitudes, religious beliefs, etc.," but it does collect health information, which could be considered "matters that we commonly considered private." This includes clinical data elements that will be collected and are necessary to calculate statistical measures. These statistical measures are the basis of subsequent improvement activities for ASC facilities and cannot be calculated without the case specific data. Case specific data will not be released to the public and is not releasable by requests under the Freedom of Information Act. Only ASC-specific data will be made publicly available as mandated by statute. In addition, the tools used for transmission of data are considered confidential forms of communication and are HIPAA-compliant.

12. Burden Estimate (Total Hours & Wages)

For the ASCQR Program, the burden associated with meeting program requirements includes the time and effort associated with completing administrative requirements and collecting and submitting data on the required measures. As noted previously, the ASCQR Program utilizes two forms in its administrative activities: Extraordinary Circumstances Extensions/Exemptions Requests and Reconsideration Requests. Neither of these forms is completed on an annual basis; both are on a need to use, exception basis and most ASCs will not need to complete either of these forms in any given year. The burden associated with submitting an Extraordinary Circumstances Extension/Exemption Request is accounted for in OMB Control Number 0938-1022, and is therefore excluded from this burden estimate. Consistent with 5 CFR 1320.4 (44 USC 3518(c)(1)(b)), the burden associated with filing a reconsideration request is excluded from this package because this collection occurs during the conduct of an administrative action.

The burden estimates for data collection and submission related to the measures for the ASCQR Program are calculated for participating ASCs based on the following data:

- Unless otherwise specified, we estimate that there are approximately 3,937 facilities eligible to participate in the ASCQR Program (as compared to 5,260 ASCs estimated to be eligible in the previously finalized PRA package under this OMB control number).
- We estimate that it takes an ASC approximately 15 minutes (0.25 hours) for chart abstraction of a measure for collection based on new reporting requirements.
- We estimate an hourly labor cost (wage plus fringe and overhead) of $36.58/hour.

We have previously utilized the maximum estimate of 5,260 ASCs in estimating the burden associated with participation with the ASCQR Program. However, per 42 CFR § 416.305(c), some ASCs are exempt from all program requirements if they have low Medicare claim numbers (fewer than 240 Medicare claims per year). Based on an analysis of the CY 2018 payment determination data, we found that of the 5,461 ASCs submitting measure data to CMS, only 3,937 were required to participate in the ASCQR Program. In order to more accurately capture the burden associated with mandatory participation in the ASCQR Program, we believe it is most appropriate to estimate that 3,937 ASCs are submitting data as mandated by the Secretary. We note that the decrease in the number of estimated ASCs contributes to a decrease in our total burden estimate for the ASCQR Program. We note that for some measures, such as ASC-11, we use a different estimate for the number of ASCs submitting data. This is because these measures are subject to unique circumstances that warrant use of a different baseline participation estimate, as discussed in more detail below.

We estimate that it takes approximately 15 minutes for chart abstraction of a measure for collection. We reached this number based on an analysis of historical data from the Hospital Inpatient Quality Reporting Program's data validation contractor. Based on this contractor's validation activities, we believe that the average time required to chart-abstract data for each measure is approximately 15 minutes.

We estimate an hourly wage of $18.29/hour for data collection and submission for the ASCQR Program, which is based on the Bureau of Labor Statistics (BLS) Wage for a Medical Records and Health Information Technician (29-2071);[2] however, obtaining data on overhead costs is challenging. Overhead costs vary greatly across industries and facility sizes. In addition, the precise cost elements assigned as "indirect" or "overhead" costs, as opposed to direct costs or employee wages, are subject to some interpretation at the facility level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary from study-to-study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. In calculating the labor cost, we estimate an hourly labor cost of $36.58/hour ($18.29 base salary + $18.29 fringe and overhead).

a. CY 2019 Payment Determination and Subsequent Years: Previously Finalized Measures

For the CY 2019 payment determination and subsequent years, we previously adopted 12 measures. CMS finalized some changes to these measures or their associated burden estimates for the CY 2019 payment determination, as discussed in further detail in section 12.b.i. below. The following section outlines the previously estimated and finalized burdens associated with measures.

[2] We note that in the previous ASCQR Program PRA package we used an hourly wage of $16.52/hour. We are updating this wage estimate to $18.29/hour in the CY 2018 OPPS/ASC final rule to reflect the most current wage rate data published by the BLS.

Estimated Burden for Claims-Based Measures Using Quality Data Codes (QDCs)

For the five claims-based measures included in the CY 2019 payment determination that require ASCs to use quality data codes (QDCs) on Medicare claims (ASC-1, ASC-2, ASC-3, ASC-4, and ASC-5), we believe that the reporting burden will be nominal. Based on our data for CY 2014 payment determinations for the ASC-1, ASC-2, ASC-3, ASC-4, and ASC-5 claims-based measures, extrapolating to 100 percent of ASCs reporting, there would be an average of 11.8 events per year. Therefore, we estimated the burden to report QDCs on this number of claims per year to be nominal due to the small number of cases (approximately one case per month per ASC) for the CY 2019 payment determination and subsequent years.

Estimated Burden for Claims-Based Measures Not Using QDCs

For the ASC-12 measure, which is calculated by CMS based on Medicare claims and does not require ASCs to use QDCs, we estimated that any burden would be nominal for the CY 2019 payment determination and subsequent years.

Estimated Burden for Measures Submitted Via an Online Data Submission Tool

ASCs will incur a financial burden associated with the web-based ASC-6 and ASC-7 measures. We estimate that each participating ASC will spend 10 minutes per year (0.167 hours) to collect and submit the required data for each of these measures, making the estimated annual burden associated with each measure 0.167 hours and $6.11 per facility. Accordingly, we estimate the total annual burden to be 657 hours (3,937 ASCs × 1 measures × 0.167 hours per ASC) and $24,050.58 annually (657 hours x $36.58 per hour) each for ASC-6 and ASC-7.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-6	3,937	0.167	1	3,937	657	$36.58	$24,050.58
ASC-7	3,937	0.167	1	3,937	657	$36.58	$24,050.58

ASCs will also incur a burden to collect and submit the information on the NHSN HAI measure, ASC-8. The burden associated with successful reporting of ASC-8 data includes registering with the NHSN system, collecting influenza vaccination status data from healthcare personnel (HCP) working at a facility, and submitting the summary influenza data to NHSN using a standardized form. We estimated that each participating ASC will spend approximately five minutes (0.083 hours) on NHSN registration. We further estimated that it takes approximately 15 minutes (0.167 hours) per HCP to collect vaccination status data, and that ASCs maintain an average of 20 HCP per facility.[3] As a result, we estimate the facility-level burden for ASC-8 to be 3.423 hours (0.083 hours registration + (0.167 hours x 20 HCP responses)) and $125.21 (3.423 hours x $36.58/hour). We further estimate that the total annual burden associated with this measure for ASCs, including NHSN registration and data submission would be 13,476.351 hours (326.771 hours NHSN registration [3,937 ASCs x 0.083 hours HCP responses] + 13,149.58 hours NHSN

[3] This estimate is based upon burden estimates from the CDC (OMB No. 0920–0666) and reported numbers for the average number of workers per ASC.

data submission [3,937 ASCs x 20 HCPs per ASC x 0.167 hours]) and $492,964.92 (13,476.351 hours x $36.58 per hour) across all ASCs.

Measure	Respondents	Hours per Case[4]	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-8	3,937	3.423	1	3,937	13,476.351	$36.58	$492,964.92

ASCs will incur a financial burden associated with the chart-abstracted web-based measures, ASC-9 and ASC-10. For the chart-abstracted measures, we estimated that each participating ASC would spend 15 minutes per case to collect and submit the data for the minimum required yearly sample size of 63 as designated in the Ambulatory Surgical Center Quality Reporting Specifications Manual. We therefore estimated the reporting burden for an ASC with 63 cases would be 16 hours (0.25 hours x 63 cases) and $576.14 (16 hours x $36.58/hour). We further estimated a total burden of 62,008 hours (3,937 ASCs x 16 hours) and $2,268,243.50 (62,008 hours x $36.58/hour) each for ASC-9 and ASC-10.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-9	3,937	0.25	63	248,031	62,008	$36.58	$2,268,243.50
ASC-10	3,937	0.25	63	248,031	62,008	$36.58	$2,268,243.50

Some ASCs will incur a financial burden associated with reporting the chart-abstracted web-based ASC-11 measure, which is a voluntary measure, which would not impact any ASC's payment determination. We estimated that each participating ASC would spend 15 minutes per case to collect and submit the data for this measure. We expect that ASCs will vary greatly as to the number of cases per ASC due to ASC specialization. We estimated that approximately 20 percent of ASCs nationwide, or 1,052 ASCs (5,260 ASCs nationwide x .20) will elect to report this measure on a voluntary basis, and so we estimate the total estimated burden for a single ASC with an average of 63 cases to be 16 hours (0.25 hours x 63 cases) and $576.14 (16 hours x $36.58/hour). We further estimated a total burden of 16,569 hours (1,052 ASCs x 16 hours) and $606,094.02 (16,569 hours x $36.58/hour) across all ASCs.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-11	1,052	0.25	63	66,276	16,569	$36.58	$606,094.02

The following table summarizes the previously finalized burden estimates for the CY 2019 payment determination (note that the burden for all other measures is estimated to be nominal):

[4] For the ASC-8 measure, the ASCQR Program considers the successful reporting to NHSN of summary influenza vaccination status data as the "sample" for a facility. Therefore, the burden estimate provided uses a "Sample" of 1 submission and accounts for all estimated hours of work at the facility level to submit this single form.

Measure	Hour Burden	Cost
ASC-6	657	$ 24,050.58
ASC-7	657	$ 24,050.58
ASC-8	13,476	$ 492,964.92
ASC-9	62,008	$ 2,268,243.50
ASC-10	62,008	$ 2,268,243.50
ASC-11	16,569	$ 606,094.02
Total	**155,375**	**$ 5,683,647.10**

b. CY 2019 Payment Determination and Subsequent Years: New Measure Policies

The sections below detail both previously finalized and newly finalized changes to the ASCQR Program measure set and reporting requirements.

i. CY 2019 Payment Determination

In the CY 2018 OPPS/ASC final rule, CMS is removing three previously finalized measures from the ASCQR Program beginning with the CY 2019 payment determination. These measures are:

- ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing
- ASC-6: Safe Surgery Checklist Use
- ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures

One of these measures, ASC-5, is submitted via CMS claims using QDCs. As discussed above, we estimate the burden to report QDCs on this number of claims per year to be nominal due to the small number of cases reported; therefore, we estimate a nominal reduction in ASC burden associated with the removal of ASC-5 from the ASCQR Program measure set.

The two remaining measures, ASC-6 and ASC-7, are submitted via a CMS online data submission tool. Because ASCs incur a financial burden in collecting and submitting data for these measures, we estimated a reduction in financial burden associated with their removal from the ASCQR Program. We estimate that each ASC will experience a reduction in burden of 0.167 hours and $6.11 based on this policy, for a total annual burden reduction of 657 hours (3,937 ASCs × 1 measures × 0.167 hours per ASC) and $24,050.58 annually (657 hours x $36.58 per hour) each for ASC-6 and ASC-7.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-6	3,937	0.167	1	3,937	657	$36.58	$24,050.58
ASC-7	3,937	0.167	1	3,937	657	$36.58	$24,050.58

The following table summarizes the estimated reduction in previously finalized burden, across participating ASCs, associated with CMS' policy to remove ASC-6 and ASC-7 beginning with the CY 2019 payment determination:

Measure	Hour Burden Reduction	Cost Reduction
ASC-6	- 657	- $ 24,050.58
ASC-7	- 657	- $ 24,050.58
Total	**- 1,315**	**- $ 48,101.16**

As a result of these policies, we estimate a total burden reduction of $48,101.16 for the CY 2019 payment determination. The following table summarizes the revised total burden estimates for the CY 2019 payment determination (note that the burden for all other measures is estimated to be nominal):

Measure	Hour Burden	Cost
ASC-8	13,476	$ 492,964.92
ASC-9	62,008	$ 2,268,243.50
ASC-10	62,008	$ 2,268,243.50
ASC-11	16,569	$ 606,094.02
Total	**154,061**	**$ 5,635,545.94**

ii. CY 2020 Payment Determination

In the CY 2017 OPPS/ASC final rule, CMS added seven additional measures to the ASCQR Program.[5] These previously finalized measures are:

- ASC-13: Normothermia Outcome
- ASC-14: Unplanned Anterior Vitrectomy
- ASC-15a: OAS CAHPS – About Facilities and Staff
- ASC-15b: OAS CAHPS – Communication About Procedure
- ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery
- ASC-15d: OAS CAHPS – Overall Rating of Facility
- ASC-15e: OAS CAHPS – Recommendation of Facility

In the CY 2018 OPPS/ASC final rule, CMS is delaying implementation of the five OAS CAHPS Survey-based measures until further action. The information collection requirements associated with measures ASC-15a – ASC-15e are currently approved under OMB Control Number 0938-1240; for this reason, we are not providing an independent estimate of the burden associated with the OAS CAHPS Survey administration for the ASCQR Program.

We believe ASCs will incur a financial burden associated with abstracting numerators, denominators, and exclusions for the two finalized measures collected and reported via a CMS online data submission tool, ASC-13 and ASC-14. For the chart-abstracted measures, we estimated that each participating ASC would spend 15 minutes per case to collect and submit the data, and a historic average sample of 63 cases per ASC to estimate the reporting burden. We

[5] We note that these measures were finalized in the CY 2017 OPPS/ASC final rule with comment period. CMS did not propose any additional changes to the CY 2020 payment determination.

therefore estimate that the reporting burden for an ASC with 63 cases would be 16 hours (0.25 hours x 63 cases) and $576.14 (16 hours x $36.58/hour). We therefore estimate a total burden of 62,008 hours (3,937 ASCs x 16 hours) and $2,268,243.50 (62,008 x $32.84/hour) each for ASC-13 and ASC-14 for the CY 2020 payment determination and subsequent payment determinations.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-13	3,937	0.25	63	248,031	62,008	$36.58	$2,268,243.50
ASC-14	3,937	0.25	63	248,031	62,008	$36.58	$2,268,243.50

The following table summarizes the additional burden for measure data collection and submission for the ASCQR Program for the CY 2020 payment determination and subsequent years:

Measure	Burden
ASC-13	$ 2,268,243.50
ASC-14	$ 2, 268,243.50
Total	**$ 4,536,487.00**

The following table summarizes the estimated total burden for measure data collection and submission for the ASCQR Program for the CY 2020 payment determination (note that the burden for all other measures is estimated to be nominal or captured in a separate PRA Package):

Measure	Hour Burden	Cost
ASC-8	13,476	$ 492,964.92
ASC-9	62,008	$ 2,268,243.50
ASC-10	62,008	$ 2,268,243.50
ASC-11	16,569	$ 606,094.02
ASC-13	62,008	$ 2,268,243.50
ASC-14	62,008	$ 2,268,243.50
Total	**278,076.351**	**$ 10,172,032.92**

iii. CY 2022 Payment Determination and Subsequent Years

In the CY 2018 OPPS/ASC final rule, CMS is adding two measures collected via Part A and Part B Medicare administrative claims and Medicare enrollment data to the ASCQR Program measure set: (1) ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures. Because these measures are collected via claims ASCs are already submitting for the purposes of payment and do not require any additional collection or reporting on the part of ASCs, we estimate that any burden would be nominal for the CY 2022 payment determination and subsequent years.

The following table summarizes the estimated total burden for measure data collection and submission for the ASCQR Program for the CY 2022 payment determination (note that the burden for all other measures is estimated to be nominal or captured in a separate PRA Package):

Measure	Hour Burden	Cost
ASC-8	13,476	$ 492,964.92
ASC-9	62,008	$ 2,268,243.50
ASC-10	62,008	$ 2,268,243.50
ASC-11	16,569	$ 606,094.02
ASC-13	62,008	$ 2,268,243.50
ASC-14	62,008	$ 2,268,243.50
ASC-16	984	$36,004.87
Total	**278,077**	**$ 10,172,032.94**

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs being placed on the ASCs. In fact, successful submission will result in an ASC receiving the full payment update, while having to expend no capital costs for participation. CMS is providing a data collection tool and method for submission of data to the participants. There are no additional data submission requirements placing additional cost burdens on ASCs.

14. Cost to Federal Government

The cost to the Federal Government is approximately $9,500,000 on an annual basis. CMS must maintain and update existing information technology infrastructure on My QualityNet. CMS must also provide ongoing technical assistance to ASCs and data vendors to participate in the program. CMS also will calculate one additional claims-based measure for ASCs, and provides ASCs with feedback reports about all of the measures.

ASCs will be reporting outpatient quality data directly to CMS through My QualityNet. An abstraction tool is under development that is based upon the current tool for collecting ASC data. The tools will be revised as needed and updates will be incorporated.

15. Program or Burden Changes

In the CY 2018 OPPS/ASC final rule, CMS is removing three measures from the ASCQR Program beginning with the CY 2019 payment determination; suspending the five survey-based measures beginning with the CY 2020 payment determination; and adopting two new measures beginning with the CY 2022 payment determination. We anticipate that the removal of ASC-6 and ASC-7 will reduce burden. Additionally, we have reduced the estimated number of eligible ASCs from 5,360 to 3,937. As a result, policy changes and estimate changes both contribute to our estimated burden changes. The following table shows the burden for ASC measures estimated in the previously approved PRA package:

Measure	Hour Burden	Calculation
ASC-6	878	5,260 ASCs x 0.167 hours per case
ASC-7	878	5,260 ASCs x 0.167 hours per case
ASC-8	18,005	5,260 ASCs x 3.423 hours per case
ASC-9	82,845	5,260 ASCs x 0.25 hours per case x sample of 63
ASC-10	82,845	5,260 ASCs x 0.25 hours per case x sample of 63
ASC-11	16,569	1,052 ASCs x 0.25 hours per case x sample of 63
ASC-13	82,845	5,260 ASCs x 0.25 hours per case x sample of 63
ASC-14	82,845	5,260 ASCs x 0.25 hours per case x sample of 63
Total	**367,711**	

The following table shows our newly estimated burden based on policy changes and changes to the estimated number of eligible ASCs (as described in detail above).

Measure	Hour Burden	Calculation
ASC-6	657	Measure for removal
ASC-7	657	Measure for removal
ASC-8	13,476	3,937 ASCs x 3.423 hours per case
ASC-9	62,008	3,937 ASCs x 0.25 hours per case x sample of 63
ASC-10	62,008	3,937 ASCs x 0.25 hours per case x sample of 63
ASC-11	16,569	1,052 ASCs x 0.25 hours per case x sample of 63
ASC-13	62,008	3,937 ASCs x 0.25 hours per case x sample of 63
ASC-14	62,008	3,937 ASCs x 0.25 hours per case x sample of 63
Total	**278,077**	

We estimate a burden reduction of 1,314 (657 + 657) due to our removal of ASC-6 and ASC-7. We also estimate a burden reduction of 88,319 due to the reduction in our estimated number of ASCs, as shown below.

Measure	Previously finalized burden (5,260 ASCs)	Newly estimated burden (3,937 ASCs)	Burden change due to estimate changes
ASC-6	878	657	-221
ASC-7	878	657	-221
ASC-8	18,005	13,476	-4,529
ASC-9	82,845	62,008	-20,837
ASC-10	82,845	62,008	-20,837
ASC-11	16,569	16,569	0
ASC-13	82,845	62,008	-20,837
ASC-14	82,845	62,008	-20,837
Total	**278,077**	**278,077**	**-88,319**

Therefore, we estimate a total reduction in burden of 89,633 hours and total program burden hours of 278,077 (367,711 hours currently approved -89,633 hours).

16. Publication/Tabulation Dates

The goal of the data collection is to tabulate and publish ASC-specific data. We will continue to display information on the quality of care provided in the ASC setting for public viewing as by the Tax Relief and Health Care Act (TRHCA). Data from this initiative is currently used to populate the Hospital Compare Web site, www.hospitalcompare.hhs.gov.

17. Expiration Date

CMS will display the expiration date on the manual.

18. Certification Statement

There are no exceptions to the certification statement.

19. Collections of Information Employing Statistical Methods

This information collection does not employ the use of statistical methods.