

## Supporting Statement – Part A

### Submission of Information for the Ambulatory Surgical Center Quality Reporting Program: CY 2019 OPPTS/ASC Proposed 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 (ASCs).

The Medicare Improvements and Extension Act of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109-432) Section 109(b) 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 Ambulatory Surgical Center (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 Outpatient Quality Reporting (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, 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 OQR 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 Ambulatory Surgical Center Quality Reporting (ASCQR) Program available to the public. Such procedures include providing facilities 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. In the CY 2019 OPPI/ASC proposed rule, CMS is not proposing to add any new measures for the ASCQR Program. The CY 2019 proposed rule includes proposed measure removals 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 14 quality of care measures for the ASC setting; data has been collected for calendar years (CYs) 2014 through 2017 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 2019 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 2020, 2021 and 2022 payment determinations.

In implementing this and other quality reporting programs, CMS’ overarching goal is to reduce regulatory burden on the healthcare industry, lower health costs, and enhance patient care through the Meaningful Measures initiative launched in October 2017. CMS is implementing broad efforts to reduce administrative burden on providers so they can spend more time with patients and provide high quality care. The Meaningful Measures initiative has identified core quality of care issues that advance CMS’ work to improve patient outcomes while reducing paperwork and reporting burden associated with quality measurement for clinicians and other providers: address high-impact measure areas that safeguard public health; patient-centered and meaningful to patients; outcome-based where possible; fulfill each program’s statutory requirements; minimize the level of burden for providers; significant opportunity for improvement; address measure needs for population-based payment through alternative payment models; and align across programs and/or with other payers.

The ASCQR Program supports these goals by making collected clinical quality of care information publicly available and by fostering quality improvement. Considering the need to balance breadth with minimizing burden, program measures address as fully as possible, the Meaningful Measures cross-cutting measure criteria of eliminating disparities, tracking measurable outcomes and impact, safeguarding public health, achieving cost savings, improving access for rural communities, and reducing burden.

**B. ASCQR Program Quality Measures and Forms**

**1. Introduction**

ASCQR Program payment determinations are made based on ASCQR Program 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 2019 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 2019 payment determinations. The information collection requirements for the CY 2014 through CY 2019 payment determinations are currently approved under OMB Control Number 0938-1270.

**ASCQR PROGRAM MEASURES FOR THE CY 2014 THROUGH CY 2019  
PAYMENT DETERMINATIONS**

<b>NQF No.</b>	<b>Measure Name</b>	<b>Data Collection Mode</b>
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

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 2020 Payment Determination**

In the CY 2019 OPPI/ASC proposed rule, CMS is proposing to remove one measure from the ASCQR Program measure set beginning with the CY 2020 payment determination and

for subsequent years: ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel, a non-CMS web-based measure.

If this proposed removal is finalized, the entire measure set finalized for the CY 2020 payment determination would be:

**ASCQR PROGRAM MEASURES FOR THE CY 2020 PAYMENT DETERMINATION**

<b>NQF No.</b>	<b>Measure Name</b>	<b>Data Collection Mode</b>
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
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: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	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

\* Measure delayed for reporting 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.

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 mode of “Survey-based” have information derived through analysis of data submitted via the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey and do not require additional effort or burden from ASCs beyond administering the survey and submitting survey data to CMS. Additionally, the OAS CAHPS Survey is delayed for reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. These survey administration burdens are captured under a previously finalized PRA Package, OMB Control Number 0938-1240.

**4. CY 2021 Payment Determination**

In the CY 2019 OP/ASC proposed rule, CMS is proposing to remove seven measures from the ASCQR Program measure set beginning with the CY 2021 payment determination and for subsequent years: ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC-4: All-Cause Hospital Transfer/Admission; ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use; and ASC-11: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

Therefore, if the measures proposed for removal beginning with the CY 2020 payment determination (described in section B.3. above) and the removal of the seven measures for the CY 2021 payment determination are finalized, the entire measure set finalized for the CY 2021 payment determination would be:

**ASCQR PROGRAM MEASURES FOR THE CY 2021  
PAYMENT DETERMINATION**

NQF No.	Measure Name	Data Collection Mode
2539	ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	Claims

<b>NQF No.</b>	<b>Measure Name</b>	<b>Data Collection Mode</b>
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

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

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.

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 mode 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. Additionally, the OAS CAHPS Survey is delayed for reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. These survey administration burdens are captured under a previously finalized PRA Package, OMB Control Number 0938-1240.

## **5. CY 2022 Payment Determination**

In the 2018 OPPS/ASC final rule with comment period, we finalized the adoption of two measures where data is collected via Part A and Part B Medicare administrative claims and Medicare enrollment data to the ASCQR Program measure set beginning with the CY 2022 payment determination and for subsequent years: (1) ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.

If the measures proposed for removal beginning with the CY 2020 and CY 2021 payment determinations (discussed in section B.3. and B.4. above, respectively) in the CY 2019 OPPS/ASC proposed rule are finalized, the entire measure set finalized for the CY 2022 payment determination would be:

**ASCQR PROGRAM MEASURES FOR THE CY 2022  
PAYMENT DETERMINATION**

NQF No.	Measure Name	Data Collection Mode
2539	ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	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

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

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.

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 mode 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. Additionally, the OAS CAHPS Survey is delayed for reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. These survey administration burdens are captured under a previously finalized PRA Package, OMB Control Number 0938-1240.

**6. Forms Used in ASCQR Program Procedures**

Two administrative forms are utilized by the ASCQR Program: the Extraordinary Circumstances Exception Request 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 either 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 Exception Request form must be submitted. CMS provides this form to ASCs online and facilities may submit the form electronically, by mail, or fax. We note that the burden associated with completing and submitting an Extraordinary Circumstances Exception request is already accounted for in a separate PRA package, OMB Control Number 0938-1022.<sup>1</sup> Therefore, the burden associated with completing and submitting and Extraordinary Circumstances Exception Request is not addressed in this PRA Package.

When an ASC is determined by CMS to not have met program requirements and has had a 2.0 percentage point reduction in their APU, the ASC may submit a Reconsideration Request to CMS. An ASC must submit a Reconsideration Request to CMS by no later than the first business day on or after March 17 of the affected payment year. CMS provides this form to ASCs online 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,

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<sup>1</sup> 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.

consensual 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 ASCQR 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 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 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.

This section is not applicable to claims-based measures as they are calculated from data 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 requires ASCs to submit quality measure data for services provided.

Once an ASC submits quality measure data to the ASCQR Program, it is considered to be participating in the program. 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; these facilities have an average of twenty employees and many would be considered to be small businesses. All 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 in a 2.0 percentage point reduction in the APU.

## **8. Federal Register Notice/Outside Consultation**

The 60-day Federal Register notice for this data collection will be published on July 31, 2018 (83 FR 37046). The CY 2019 Outpatient Prospective Payment System and Ambulatory Surgical Center proposed rule with comment period is available on the Federal Register and CMS Web sites. Comments will be accepted for 60 days from the date of this proposed rule's publication, and CMS will respond to those comments accordingly following the end of the comment period.

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 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: the Extraordinary Circumstances Exception Request and Reconsideration Request forms. 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 Exception 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 required to participate in the ASCQR Program.
- 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.

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. Therefore, we believe it is most appropriate to estimate that 3,937 ASCs are submitting data as mandated by the Secretary. 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); 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 2020, CY 2021, and CY 2022 Payment Determinations and Subsequent Years: Previously Finalized Measures**

For the CY 2020 payment determination and subsequent years, we previously adopted 12 measures. The following section outlines the previously estimated and finalized burdens associated with measures.

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

For the four claims-based measures included in the CY 2020 payment determination that require ASCs to use quality data codes (QDCs) on Medicare claims (ASC-1, ASC-2, ASC-3, and ASC-4), 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, and ASC-4 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 2020 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 2020 payment determination and subsequent years.

### Estimated Burden for Measures Submitted Via a Web-based Tool

ASCs will incur a burden to collect and submit the information on the non-CMS web-based tool measure, ASC-8. We note, however, that the burden associated with ASC-8, a NHSN measure, is accounted for under a separate PRA Package, OMB Control Number 0920-0666. Thus, regardless of whether the proposed removal of ASC-8 is finalized, our burden estimates for the CY 2020 payment determination exclude the burden associated with collecting and reporting this NHSN measure. We note that to be as conservative as possible in our burden estimates, we previously included the burden associated with ASC-8 as part of our total burden estimates in prior PRA Packages for earlier calendar year payment determinations. Accordingly, removing the NHSN measure from the ASCQR Program is shown as a burden reduction in this PRA package, in order to account for the fact that our previous totals included NHSN measure burden.

The burden associated with successful reporting of ASC-8 data includes registering with the National Healthcare Safety Network (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 previously 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.<sup>2</sup> 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 data submission (3,937

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<sup>2</sup> 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.

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 <sup>3</sup>	Sample	Cases (Responses)	Hours	Hourly Rate	Total 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, ASC-10, 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 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 15 hours and 45 minutes (0.25 hours x 63 cases, 15.75 hours) and \$576.14 (15.75 hours x \$36.58/hour). We further estimated a total burden of 62,008 hours (3,937 ASCs x 15.75 hours) and \$2,268,243.50 (62,008 hours x \$36.58/hour) each for ASC-9, ASC-10, ASC-13, and ASC-14.

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
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

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 15 hours and 45 minutes (0.25 hours x 63 cases, 15.75 hours) and \$576.14 (15.75 hours x \$36.58/hour). We further estimated a total burden of 16,569 hours (1,052 ASCs x 15.75 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
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<sup>3</sup> 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.

ASC-11	1,052	0.25	63	66,276	16,569	\$36.58	\$606,094.0 2
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In the CY 2017 OPPTS/ASC final rule, CMS finalized five survey-based measures; 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, and ASC-15e: OAS CAHPS – Recommendation of Facility in the ASCQR Program.<sup>4</sup> In the CY 2018 OPPTS/ASC final rule with comment period, CMS delayed implementation of the five OAS CAHPS survey-based measures until further action in rulemaking. The information collection requirements associated with measures ASC-15a –e 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.

In the CY 2018 OPPTS/ASC final rule with comment period, CMS added two measures collected via Part A and Part B Medicare administrative claims and Medicare enrollment data to the ASCQR Program measure set beginning with the CY 2022 payment determination: (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 claims data for the purposes of payment and do not require any additional data collection. Therefore, we estimate that any burden resulting from the data collection for ASC-17 and ASC-18 would be nominal for the CY 2022 payment determination and subsequent years.

The following table summarizes the previously finalized burden estimates for the CY 2020, CY 2021, and CY 2022 payment determinations and subsequent years (note that the burden for all other measures; ASC-1, ASC-2, ASC-3, ASC-4, ASC-17, and ASC-18, is estimated to be nominal and do not influence burden estimates as described above):

<b>Previously Finalized Burden for CYs 2020, 2021, and 2022</b>		
<b>Measure</b>	<b>Hour Burden</b>	<b>Cost</b>
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
<b>Total</b>	<b>278,077</b>	<b>\$ 10,172,032.94</b>

**b. CY 2020, CY 2021, and CY 2022 Payment Determinations and Subsequent Years: Measure Proposals**

<sup>4</sup> We note that these proposed measures were finalized in the CY 2017 OPPTS/ASC final rule with comment period. In the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59433), CMS finalized the delayed implementation of the five OAS CAHPS Survey-based measures until further action. CMS is not proposing any additional changes to the CY 2020 payment determination.



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

**i. CY 2020 Payment Determination**

In the CY 2019 OPPTS/ASC proposed rule, CMS is proposing to remove one previously finalized measure from the ASCQR Program beginning with the CY 2020 payment determination. This measure is:

- ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel

ASC-8 is submitted via a non-CMS, NHSN web-based tool. As detailed in section C.12.a above, the burden associated with ASC-8 is accounted for under a separate PRA package, OMB Control Number 0920-0666. Thus, regardless of whether the proposed removal of ASC-8 is finalized, our burden estimates for the CY 2020 payment determination exclude the burden associated with collecting and reporting this NHSN measure. We previously estimated that each ASC will experience a reduction in burden of 3.423 hours and \$125.21 based on this proposal, for a total annual burden reduction of 13,476 hours (3,937 ASCs × 1 measures × 3.423 hours per ASC) and \$492,965 annually (13,476 hours x \$36.58 per hour).

<b>CY 2020: Non-CMS Web-based Tool Measure Proposed for Removal</b>					
	Annual Dollars Per Facility	Annual Hours Per Facility	Annual Burden Nationally	Annual Number of Responses	Annual Hour Burden Nationally
ASC-8	\$125.21	3.423	\$492,964.92	3,937	13,476.35
<b>Total Burden</b>	<b>\$125.21</b>	<b>3.423</b>	<b>\$492,964.92</b>	<b>3,937</b>	<b>13,476.35</b>

We estimate a total burden reduction of 13,476 hours and \$492,965 for the CY 2020 payment determination. The following table summarizes the revised total burden estimates for the CY 2020 payment determination (note that the burden for all other measures is estimated to be nominal):

<b>Estimated Burden, CY 2020 Payment Determination</b>		
<b>Measure</b>	<b>Hour Burden</b>	<b>Cost</b>
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
<b>Total</b>	<b>264,601</b>	<b>\$ 9,679,068.02</b>

**ii. CY 2021 Payment Determination**

Beginning with the CY 2021 payment determination, in the CY 2019 OPPS/ASC proposed rule we are proposing to remove seven measures from the ASCQR Program measure set; ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC-4: All-Cause Hospital Transfer/Admission; ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use; and ASC-11: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

As discussed in section C.12.a above, because ASC-1, ASC-2, ASC-3, and ASC-4 are claims-based measures that require ASCs to use quality data codes (QDCs) on Medicare claims, we believe that the reporting burden is nominal. 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). Subsequently, we do not anticipate a burden reduction from the removal of ASC-1, ASC-2, ASC-3, and ASC4 from the ASCQR Program measure set.

ASCs will experience a financial burden reduction associated with the proposed removal of chart-abstracted web-based measures, ASC-9, ASC-10, and ASC-11, a voluntary measure. 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. Therefore, we estimated the reporting burden for an ASC with 63 cases would be 15 hours and 45 minutes (0.25 hours x 63 cases, 15.75 hours) and \$576.14 (15.75 hours x \$36.58/hour). For ASC-9 and ASC-10, we further estimated a total burden of 62,008 hours (3,937 ASCs x 15.75 hours) and \$2,268,243.50 (62,008 hours x \$36.58/hour) each for ASC-9 and ASC-10. For ASC-11, a voluntary measure, we estimated that 20% of ASCs would report this measure, or 1,052 ASCs (5,260 X 0.20). Thus, the total reporting burden for ASC-11 is 16,569 hours (1,052 X 15.75 hours) and \$606,094.02 (16,569 X \$36.58/hour). As a result of our proposals to remove ASC-9, ASC-10, and ASC-11, we estimate a total reduction in burden of 140,585 hours and \$5,142,581.02.

<b>CY 2021: Web-based Tool Measures Proposed for Removal</b>							
<b>Measure</b>	<b>Respondents</b>	<b>Hours per Case</b>	<b>Sample</b>	<b>Cases (Responses)</b>	<b>Hours</b>	<b>Hourly Rate</b>	<b>Burden</b>
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
ASC-11	1,052	0.25	63	66,276	16,569	\$36.58	\$606,094.02
<b>Total</b>					<b>140,585</b>		<b>\$5,142,581.02</b>

The following table summarizes the estimated total burden for measure data collection and submission for the ASCQR Program for the CY 2021 payment determination (note that the burden for all other measures is estimated to be nominal or captured in a separate PRA Package):

<b>Estimated Burden, CY 2021 Payment Determination</b>		
<b>Measure</b>	<b>Hour Burden</b>	<b>Cost</b>

ASC-13	62,008	\$ 2,268,243.50
ASC-14	62,008	\$ 2,268,243.50
<b>Total</b>	<b>124,016</b>	<b>\$4,536,487.00</b>

### iii. CY 2022 Payment Determination

In the 2018 OPPS/ASC final rule with comment period, we finalized two measures beginning with the CY 2022 payment determination: (1) ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures. Because ASC-17 and ASC-18 are claims-based measures that are calculated by CMS and do not require ASCs to use QDCs, we estimated 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):

<b>Estimated Burden, CY 2022 Payment Determination</b>		
<b>Measure</b>	<b>Hour Burden</b>	<b>Cost</b>
ASC-13	62,008	\$ 2,268,243.50
ASC-14	62,008	\$ 2,268,243.50
<b>Total</b>	<b>124,016</b>	<b>\$4,536,487.00</b>

### 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 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 2019 OPPS/ASC proposed rule, CMS is proposing to remove one measure from the ASCQR Program beginning with the CY 2020 payment determination and remove seven measures beginning with the CY 2021 payment determination.

Therefore, if the CY 2019 OPPS/ASC proposed rule is finalized as proposed, we estimate a total ASCQR Program reduction in burden of 154,061 (13,476 + 62,008 + 62,008 + 16,569 hours) and \$5,635,546 (\$492,965 + 2,268,243 + \$2,268,243 +\$606,094).

Measure	Respondents	Hours Per Case	Sample	Burden Reduction, in Hours	Hourly Rate	Burden Reduction, in Dollars
ASC-8	3,937	3.423	1	13,476	\$36.58	\$
ASC-9	3,937	0.25	63	62,008	\$36.58	\$
ASC-10	3,937	0.25	63	62,008	\$36.58	\$
ASC-11	3,937	0.25	63	16,569	\$36.58	606,094.02 \$
<b>Total</b>						<b>\$5,635,545.94</b>

Therefore, we estimate a total reduction in burden of 154,061 hours and a total program burden of 124,016 hours (278,077 currently approved – 154,061 reduction in hours) as a result of our proposals.

#### 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](http://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.