Supporting Statement – Part A

Submission of Information for the Ambulatory Surgical Center Quality Reporting Program: CY 2020 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 (ASCs).

Section 109(b) of the Medicare Improvements and Extension Act of the Tax Relief and Health Care Act of 2006 (MIEA-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 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 Patient Protection and Affordable Care Act of 2010 (ACA) modified section 1890(b) of the 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.

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 year 2014 until present and has made these 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 2022 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 2021 through 2024 payment determinations and subsequent years.

In implementing this and other quality reporting programs, CMS' seeks 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. Justification

1. Need and Legal Basis

Section 109(b) of MIEA-TRCHA (Pub. L. 109-432) amended section 1833(i) of the Act by redesignating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system "in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7)." 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 authorizing legislation 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, 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 Medicare claims.

CMS 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.

ASCQR Program Measures

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), CY 2017 OPPS/ASC final rule with comment period (81 FR 79797 through 79825), CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 79475) and CY 2019 OPPS/ASC final rule with comment period (83 FR 59110 through 59138) CMS finalized quality measures, administrative processes and data submission requirements for the CYs 2014 through 2022 payment determinations. The information collection requirements for the CY 2014 through CY 2022 payment determinations are currently approved under OMB Control Number 0938-1270.

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. We note that in the CY 2019 OPPS/ASC Final Rule that we suspended data collection of these measures until further action in rulemaking with the goal of updating them.

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.

ASCQR PROGRAM MEASURES FOR THE CY 2022 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

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	Quality Data
	Procedure, Wrong Implant*	Codes via Claims
0265	ASC-4: Hospital Transfer/Admission*	Quality Data
		Codes via Claims
0658	ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-	Web-based
	Up Interval for Normal Colonoscopy in Average Risk	(CMS)
	Patients	·

NQF No.	Measure Name	Data Collection Mode
1536	ASC-11: Cataracts: Improvement in Patient's Visual	Web-based
	Function within 90 Days Following Cataract Surgery	(CMS;
		Voluntary)
2539	ASC-12: Facility Seven-Day Risk-Standardized Hospital	Claims
	Visit Rate after Outpatient Colonoscopy	
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	Survey-based
	Procedure**	
N/A	ASC-15c: OAS CAHPS – Preparation for Discharge and	Survey-based
	Recovery**	
N/A	ASC-15d: OAS CAHPS – Overall Rating of Facility**	Survey-based
N/A	ASC-15e: OAS CAHPS – Recommendation of Facility**	Survey-based
3470	ASC-17: Hospital Visits after Orthopedic Ambulatory	Claims
	Surgical Center Procedures	
3366	ASC-18: Hospital Visits after Urology Ambulatory Surgical	Claims
	Center Procedures	
3357	ASC-19: Facility-Level 7-Day Hospital Visits after General	Claims
	Surgery Procedures Performed at Ambulatory Surgical	
	Centers***	

^{*} Data collection suspended beginning with the CY 2021 payment determination (CY 2019 data collection) until further action in rulemaking

Forms Used in ASCQR Program Procedures

Two administrative forms are utilized by the ASCQR Program: Extraordinary Circumstances Exception Request form and Reconsideration Request form. Neither of these forms is completed on an annual basis; both 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

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

^{***} Finalized in the CY 2020 OPPS/ASC Final Rule, for implementation beginning with the CY 2024 payment determination and subsequent years.

accounted for in a separate PRA package, OMB Control Number 0938-1022.¹ 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.

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.

-

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.

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. Use of 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 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 Efforts

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

There are no 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 60-day Federal Register notice for this data collection was published on November 12, 2019 (84 FR 61142). The CY 2020 Outpatient Prospective Payment System and Ambulatory Surgical Center final rule with comment period is available on 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 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.

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 labor cost (wage plus fringe and overhead) of \$38.80²/hour, in accordance with the Bureau of Labor Statistics, as discussed in more detail below.

All burden hour and cost estimates have been rounded to the nearest whole number.

a. Previously Finalized Measures Burden Summaries

The following section outlines the previously estimated and finalized burdens associated with the measures.

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

² The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of \$19.40 per hour for a Medical Records and Health Information Technician professional. Occupational Employment and Wages. Available at: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm

For the four claims-based measures 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). As noted above, in the CY 2019 OPPS/ASC Final Rule we suspended data collection of these measures until further action in rulemaking with the goal of updating them. We note that this does not change our burden estimates as there is only a nominal burden associated with reporting the measures.

(2) 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 2022 payment determination and subsequent years.

In the CY 2018 OPPS/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.

b. Adjusted Burden Estimates for the CY 2021 Payment Determination & Burden Estimates for the CY 2022 Payment Determination and Subsequent Years

(1) Calculation of Wage Rate

According to the Bureau of Labor Statistics rate for 2018, the median wage for Medical Records and Health Information Technicians is \$19.40 per hour³ before inclusion of overhead and fringe benefits. This labor cost is based on the Bureau of Labor Statistics (BLS) wage for a Medical Records and Health Information Technician. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for submission for the ASCQR Program.

We estimate the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, as is currently done in other CMS quality reporting programs. This is necessarily a rough adjustment, because fringe benefits and overhead costs vary significantly from employer to

³ Occupational Employment and Wages. Available at: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm

employer. Nonetheless, we believe that doubling the hourly wage rate ($$19.40 \times 2 = 38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will use an hourly labor cost estimate of \$38.80 (\$19.40 salary plus \$19.40 fringe and overhead) for calculation of burden forthwith.

(2) Estimated Burden for Measures Submitted Via a Web-based Tool

We note that we previously have not accounted for the web-based portion of the burden associated with submission of ASC-9, ASC-11, ASC-13 and ASC-14. To be conservative in our comprehensive burden estimates, and also to better align with the Hospital OQR Program, we note that beginning with the PRA materials for the CY 2020 OPPS/ASC proposed and final rules, we will include this portion of burden in our overall program estimates. We also note that we are including adjusted burden estimates for the CY 2021 payment determination (reflected in Table 5 below) to account for this change in burden calculation methodology. Lastly, because we are finalizing a proposal in the CY 2020 OPPS/ASC final rule that will not go into effect until the CY 2024 payment determination, the burden estimates for the CY 2022 payment determination will remain as they were from the previous payment determination. In addition, as explained below in section B.12.c., because we are finalizing the adoption of a claims-based measure, this finalized proposal does not pose any increase in burden for the CY 2024 payment determination (reflected in Table 6 below).

(a) Web-Based Submission of ASC-9, ASC-13, and ASC-14

ASCs will incur a financial burden associated with ASC-9, ASC-13, and ASC-14 for their chart abstraction and for submitting the measures to the web-based tool. For the web-based submission, we estimate that each participating ASC would spend 10 minutes per measure to submit the data. We therefore estimate the reporting burden for each measure to be 0.167 hours (10 minutes/60 minutes) and \$6.48 (0.167 hours x \$38.80/hour). We further estimate a total burden of 657 hours (3,937 ASCs x 0.167 hours) and \$25,510 (3,937 ASCs x 0.167 hours x \$38.80/hour) each for ASC-9, ASC-13, and ASC-14.

Table 1. Summary of Web-based Burden Estimates for ASC-9, ASC-13 & ASC-14

		Hours per	Total	Hourly	Total
Measure	Respondents	Facility	Hours	Rate	Burden
ASC-9	3937	0.167	657	\$38.80	\$25,510
ASC-13	3937	0.167	657	\$38.80	\$25,510
ASC-14	3937	0.167	657	\$38.80	\$25,510

(b) Web-Based Submission of ASC-11

Some ASCs will incur a financial burden associated with submitting the ASC-11 measure to the web-based tool (a voluntary measure), which would not impact any ASC's payment determination. We estimate that each participating ASC would spend 10 minutes per measure to submit the data for this measure. We estimate that approximately 20 percent of ASCs, or 787 ASCs $(3,937 \text{ ASCs} \times 0.20)$ will elect to report this measure on a voluntary basis, therefore we

calculated a total estimated burden for a single ASC to be \$6.48 (0.167 hours x \$38.80/hour). We further estimate a total burden of 131 hours (3,937 ASCs x 0.20 x 0.167 hours) and \$5,102 (3,937 ASCs x 0.20 x 0.167 hours x \$38.80/hour) across all ASCs.

Table 2. Summary of Web-based Burden Estimate for ASC-11

Measure	Respondents	Hours per Facility	Total Hours	Hourly Rate	Total Burden
	3,937 ASCs				
ASC-11	x 0.20	0.167	131	\$38.80	\$5,102

(3) Estimated Burden for Chart Abstracted Measures

(a) Chart-Abstraction for ASC-9, ASC-13, and ASC-14

ASCs will incur a financial burden associated with ASC-9, ASC-13, and ASC-14 for their chart abstraction in addition to submitting the measures to the web-based tool. For the chartabstracted aspect of the measures, we estimate 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, estimate 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 \$611 (15.75 hours x \$38.80/hour). We further estimate a total burden of 62,008 hours (3,937 ASCs x 15.75 hours) and \$2,405,901 (3,937 ASCs x 15.75 hours x \$38.80/hour) each for ASC-9, ASC-13, and ASC-14.

Table 3. Summary of Chart-Abstracted Burden Estimates for ASC-9, ASC-13 & ASC-14

Measure	Respondents	Hours per Case	Sampl e	Total Cases (Responses)	Total Hours	Hourly Rate	Total Burden
ASC-9	3,937	0.25	63	248,031	62,008	\$38.80	\$2,405,901
ASC-13	3,937	0.25	63	248,031	62,008	\$38.80	\$2,405,901
ASC-14	3,937	0.25	63	248,031	62,008	\$38.80	\$2,405,901

(b) Chart-Abstraction for ASC-11

Some ASCs will incur a financial burden associated with reporting the chart-abstracted, webbased ASC-11 measure, which is a voluntary measure, which would not impact any ASC's payment determination. We estimate that each participating ASC would spend 15 minutes per

case to collect 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 estimate that approximately 20 percent of ASCs (3,937 ASCs nationwide \times 0.20) will elect to report this measure on a voluntary basis, and so we estimate the total burden for a single ASC with an average of 63 cases to be 15 hours and 45 minutes (0.25 hours \times 63 cases = 15.75 hours) and \$610.10 (15.75 hours \times \$38.80/hour). We further estimated a total burden of 12,402 hours (3,937 ASCs nationwide \times 0.20 \times 15.75 hours) and \$481,180 (3,937 ASCs nationwide \times 0.20 \times 15.75 hours \times \$38.80/hour) across all ASCs.

Table 4. Summary of Chart-Abstracted Burden Estimate for ASC-11

		Hours		Cases			
		per		(Responses	Total	Hourly	
Measure	Respondents	Case	Sample)	Hours	Rate	Total Burden
ASC-11	3937 X 0.20	0.25	63	49,606	12,402	\$38.80	\$481,180

(4) Estimated Burden for Survey-Based Measures

In the CY 2017 OPPS/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. In the CY 2018 OPPS/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.

Summary

The following table summarizes the adjusted burden estimates for the 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 does not influence burden estimates as described above):

Table 5. Summary of Adjusted Burden Estimates for CYs 2021 and 2022 Payment Determinations

	Adjusted Burden for CYs 2021 and 2022					
Measure	Hour Burden	Total Cost				
ASC-9	62,665	\$2,431,411				

⁴ We note that these measures were finalized in the CY 2017 OPPS/ASC final rule with comment period. In the CY 2018 OPPS/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 2022 payment determination.

Total	200,528	\$7,780,515
ASC-14	62,665	\$2, 431,411
ASC-13	62,665	\$2, 431,411
ASC-11	12,533	\$486,282

c. Burden Estimates for the CY 2024 Payment Determinations and Subsequent Years

In the 2020 OPPS/ASC final rule, we are finalizing the adoption of one claims-based measure, ASC:19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers into the ASCQR Program for the CY 2024 payment determination and subsequent years. Because ASC-19 is a claims-based measure that is calculated by CMS, we estimate no change in burden due to our finalized proposal for the ASCQR Program for the CY 2024 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 2024 payment determination (note that the burden for all other measures is estimated to be nominal):

Table 6. Summary of Finalized Burden Estimates for CY 2024 Payment Determination

Finalized Burden, CY 2024 Payment Determination						
Measure	Hour Burden	Dollar Burden				
ASC-9	62,665	\$2,431,411				
ASC-11	12,533	\$486,282				
ASC-13	62,665	\$2, 431,411				
ASC-14	62,665	\$2, 431,411				
Total	200,528	\$7,780,515				

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 2020 OPPS/ASC Final Rule, CMS is finalizing the addition of one measure for which the burden is nominal to the ASCQR Program beginning with the CY 2024 payment determination. Therefore, we estimate no change in burden due to our finalized policies for the ASCQR Program.

As stated above in section B.12.b.(2), in this PRA package we have adjusted our burden calculations to account for the inclusion of the web-based portion of burden associated with the submission of ASC-9, ASC-11, ASC-13 and ASC-14. Based on these adjustments to burden for both the CY 2021 and CY 2022 payment determinations, we estimate a decrease in burden of 2,064 hours (202, 592 - 200,528 = 2,064) and an increase of \$369,690. Table 7 and Table 8 below provide more detail.

Table 7. Summary of Finalized Burden, CY 2019 PRA Package

Previously Finalized Burden for the CY 2021 Payment Determination per the CY 2019 PRA Package						
Measur	Hour Burden Cost					
е						
ASC-9	62,007.75*	\$ 2,268,243.50				
ASC-11	16,569.00*	\$ 606,094.02				
ASC-13	62,007.75*	\$ 2,268,243.50				
ASC-14	62,007.75*	\$ 2,268,243.50				
Total	202,592	\$ 7,410,825				

^{*}These figures have been previously finalized, so for continuity of what is currently approved, we did not round these figures when including them here.

Table 8. Summary of Finalized Burden, CY 2020 PRA Package

_	Adjusted Finalized Burden for the CY 2021 & CY 2022 Payment Determinations per the CY 2020 PRA Package					
Measur	Hour Burden	Dollar Burden				
e						
ASC-9	62,665*	\$2,431,411				

Total	200,528	\$7,780,515***
ASC-14	62,665*	\$2, 431,411
ASC-13	62,665*	\$2, 431,411
ASC-11	12,533**	\$486,282

^{*}Estimated burden hours increase due to update in methodology to include web-based portion of burden for ASC-9, ASC-13, and ASC-14

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.

^{**}Estimated burden hours decrease due to adjustments to ASC-11 to reflect that only 20% of ASCs will report due to measure being voluntary

^{***}Overall cost increases due to increase in estimated wage rate to \$38.80/hour