Supporting Statement – Part A

Submission of Information for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

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

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

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

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

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

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

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

The CMS program established under these amendments is referred to as the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

Section 3014 of the Affordable Care Act of 2010 (ACA) modified section 1890(b) of the Social Security Act to require CMS to develop quality and efficiency measures through a "consensus-based entity". To fulfill this requirement, the Measure Applications Partnership (MAP) was formed to review measures consistent with these requirements. MAP is convened by the National Quality Forum (NQF), a national consensus organization, with current organizational members including the American Association of Retired Persons (AARP), America's Health Insurance Plans, the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), the American Hospital Association, the American Medical Association, the American Nurses Association, the Federation of American Hospitals, and the Pacific Business Group on Health. Nationally recognized subject matter experts are also voting members of the MAP. CMS consulted with the MAP and received its formal recommendations before identifying ASCQR measures to be included in the CY 2015 OPPS/ASC proposed rule. This proposed rule also includes proposed measures for the CY 2017 and subsequent years' payment determinations as well as a listing of previous adopted measures.

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

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

B. ASCQR Quality Measures and Forms

1. Introduction

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

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

2. CYs 2014, 2015, and 2016 Payment Determinations

The CY 2012 OPPS/ASC and CY 2014 OPPS/ASC final rules with comment periods finalized quality measures, administrative processes, data submission, and validation requirements for the CYs 2014, 2015, and 2016 payment determinations.

ASCQR PROGRAM MEASURES FOR THE CYs 2014, 2015, and 2016 PAYMENT DETERMINATIONS

NQF No.	Measure Name	Data Collection Mode
0263	ASC-1: Patient Burn	Quality Data Codes via Claims
0266	ASC-2: Patient Fall	Quality Data Codes via Claims
0267	ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	Quality Data Codes via Claims
0265	ASC-4: Hospital Transfer/Admission	Quality Data Codes via Claims
0264	ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing	Quality Data Codes via Claims
N/A	ASC-6: Safe Surgery Checklist Use	Web-based (CMS)
N/A	ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures	Web-based (CMS)
0431	ASC-8: Influenza Vaccination Coverage among Healthcare Personnel	Web-based (NHSN)
0658	ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Web-based (CMS)
0659	ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use	Web-based (CMS)
1536	ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (CMS; Voluntary)

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

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

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

3. CY 2017 Payment Determination

In the CY 2015 OPPS/ASC proposed rule, CMS plans to propose to add one additional claims-based measure, which will be calculated by CMS using standard Medicare claims. CMS is also proposing to make one measure voluntary (ASC-11), meaning that it will not impact payment determinations.

Therefore, the entire measure set proposed for the CY 2017 payment determination is outlined in the below table:

ASCQR PROGRAM MEASURES FOR THE CY 2017 PAYMENT DETERMINATION

NQF No.	Measure Name	Data Collection Mode
0263	ASC-1: Patient Burn	Quality Data Codes via Claims
0266	ASC-2: Patient Fall	Quality Data Codes via Claims
0267	ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	Quality Data Codes via Claims
0265	ASC-4: Hospital Transfer/Admission	Quality Data Codes via Claims
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)

NQF No.	Measure Name	Data Collection Mode
1536	ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (CMS; Voluntary)
Pending	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

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

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

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

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

4. Forms Used in ASCQR Program Procedures

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

In the event of extraordinary circumstances not within the control of an ASC, such as a natural disaster, an ASC can request a waiver or extension for meeting program requirements. For the ASC to receive consideration for an extension or waiver, an Extraordinary Circumstances Extensions or Exemption Request must be submitted. CMS provides this form to ASCs on-line and facilities may submit the form electronically, by mail, or fax.

When an ASC is determined by CMS to not have met program requirements and has had a 2 percentage point reduction in their APU, the ASC may submit a request for reconsideration to CMS. This request must be submitted by the first business day in February in the year the payment reduction has occurred. CMS provides this form to ASCs on-line and facilities may submit the form by mail or by fax.

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

2. Information Users

This information is used by CMS to direct its contractors, including Quality Improvement Organizations (QIOs), to focus on particular areas of improvement, and to develop quality improvement initiatives. The information is made available to ASCs for their use in internal quality improvement initiatives. 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.

3. Improved Information Technology

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

One of the measures, ASC-8, is submitted through the CDC’s National Healthcare Safety Network.

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

4. Duplication of Similar Information

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

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

5. Small Business

There are 5,260 ASCs eligible to participate in the program; these facilities have an average of twenty-eight employees. All of the program information collection requirements are designed to allow maximum flexibility to facilities possible to encourage participation in the program. We have designed the collection of quality of care data to be the minimum necessary for the calculation of summary figures that are reliable estimates of ASCs performance. We have also incorporated measures that use data collected on Medicare claims whenever possible to ease burden. This program will assist all ASCs, especially those of smaller size in gathering information for their own quality improvement efforts.

6. Less Frequent Collection

We have designed the collection of quality of care data to be the minimum necessary for data validation and calculation of summary figures to be reliable estimates of ASCs performance. To collect the information less frequently would compromise the timeliness of any calculated estimates.

7. Special Circumstances

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

8. Federal Register Notice/Outside Consultation

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

9. Payment/Gift to Respondent

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

10. Confidentiality

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

11. Sensitive Questions

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

12. Burden Estimate (Total Hours & Wages)

Section 109(b) of the Tax Relief and Health Care Act of 2006 (TRCHA) (Pub. L. 109-432) gives the Secretary the authority to establish requirements that affect the payment rate update applicable to ASC Payment System payments for services furnished by ACSs. Section 1833(i)(7) of the Act, which applies to ASCs, states that ASCs that fail to report data required for quality measures selected by the Secretary in the form and manner required by the Secretary under section 1833(i)(7) of the Act may incur a reduction in their annual payment update factor to the ASC fee schedule by 2.0 percentage points. Section 1833(i)(7)(B) incorporates language from Sections 1833(t)(17)(C)(i) and (ii) of the Act that authorizes the Secretary to develop measures appropriate for the measurement of the quality of care furnished by ASCs. The program established under these amendments is referred to as the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

CY 2016 and CY 2017 Burden Estimates

For the CY 2016 and CY 2017 payment determinations, the burden associated with program requirements is the time and effort associated with completing the collecting and submitting the

data on the required measures, and submitting documentation for validation purposes. We estimated that there will be approximately 5,260 respondents per year.

For the five claims- based measures included in the CY 2016 and CY 2017 payment determination that require ASCs to use quality data codes (QDCs) on Medicare claims (ASC-1, ASC-2, ASC-3, ASC-4, and ASC-5), we believe that the reporting burden will be nominal for CY 2016 and CY 2017. 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 2016 and CY 2017 payment determinations. Similarly we estimate the burden associated with submitting QDCs for ASC-5 to be nominal as well for the CY 2016 and CY 2017 payment determinations.

For the ASC-12 measure, which is calculated by CMS based on Medicare claims and does not require ASCs to use QDCs, we estimate that any burden would be nominal for the CY 2017 payment determination.

ASCs will incur a financial burden associated with the web-based ASC-6 and ASC-7 measures for the CY 2016 and CY 2017 payment determinations. We estimated that each participating ASC will spend 10 minutes per year to collect and submit the required data for each of these measures, making the estimated annual burden associated for each measure 878 hours (5,260 ASCs × 1 measures × 0.167 hours per ASC) and $26,353 annually (878 hours x $30.00 per hour) for each measure.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-6	5,260	0.1670	1	5,260	878.42	$30	$26,353
ASC-7	5,260	0.1670	1	5,260	878.42	$30	$26,353

ASCs will also incur a burden to collect and submit the information on the NHSN HAI measure, ASC-8, for the CY 2016 and CY 2017 payment determinations. We estimated that the total annual burden associated with this measure for ASCs, including NHSN registration (5,260 ASCs × 0.083 hour per facility = 437 hours) and data submission (5,260 ASCs × 0.167 hour per response for 20 workers per facility = 17,568) would be 18,005 hours or $540,149 (18,005 hours x $30.00 per hour) for the CY 2016 and CY 2017 payment determinations. 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.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-8	5,260	3.4230	1	5,260	18,004.98	$30	$540,149

ASCs will incur a financial burden associated with the chart-abstracted web-based measures, ASC-9 and ASC-10. For the chart-abstracted measures, we estimated that each participating ASC would spend 35 minutes per case to collect and submit the data, making the total estimated burden for ASCs with a single case per ASC of 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC), and 193,195 hours for each measure across all ASCs based on an average sample of 63 cases. We estimate that the reporting burden for ASCs with a single case per ASC for ASC-9 and ASC-10 would be 3,067 hours and $92,010 (3,067 x $30.00 per hour) and $5,795,836 for each measure across all ASCs based on an average sample of 63 cases for the CY 2017 payment determination.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-9	5,260	0.583	63	331,380	193,195	$30	$5,795,836
ASC-10	5,260	0.583	63	331,380	193,195	$30	$5,795,836

Some ASCs will incur a financial burden associated with reporting the chart-abstracted web-based ASC-11 measure, which we plan to propose as a voluntary measure, which would not impact any ASCs payment determination. We estimated that each participating ASC would spend 35 minutes per case to collect and submit the data for this measure. We expect that ASCs would vary greatly as to the number of cases per ASC due to ASC specialization. We estimated that approximately 20 percent of ASCs would elect to report this measure on a voluntary basis, and so we estimate the total estimated burden for ASCs with a single case per ASC to be 613 hours (1,052 ASCs x 0.583 hours per case per ASC) and $18,390 (613 hours x $30.00 per hour), and a total estimated burden of 38,639 hours and $1,159,167 across all ASCs based on an average sample of 63 cases for the CY 2017 payment determination.

Measure	Respondents	Hours per Case	Sample	Cases (Responses)	Hours	Hourly Rate	Burden
ASC-11	1,052	0.583	63	66,276	38,639	$30	$1,159,167

The following table summarizes the burden for ASC-6, ASC-7, ASC-8, ASC-9, ASC-10, and ASC-11 (note that the burden for all other measures is estimated to be nominal):

Measure	Burden
ASC-6	$ 26,353
ASC-7	$ 26,353
ASC-8	$ 540,149
ASC-9	$ 5,795,836
ASC-10	$ 5,795,836
ASC-11	$ 1,159,167
Total	**$ 13,343,694**

Reconsideration and Appeals Procedures

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.

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

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

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

15. Program or Burden Changes

This is a new information collection.

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

We request a 10/31/2017 expiration date as ASCQR Program requirements and activities outlined are included to this date in this request.