Supporting Statement
Medicare and Medicaid Programs: Conditions for Coverage for Ambulatory Surgical Centers
(CMS-10279)

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of the collection of information requirements for the conditions for coverage (CfCs) that ambulatory surgical centers (ASCs) must meet to participate in the Medicare program.

ASCs that wish to obtain Medicare certification must meet the Medicare Conditions for Coverage (CfCs) for Ambulatory Surgical Centers. States have their own health and safety office which is referred to as a State Agency. Each State has their own individual State ASC laws in addition to Federal laws. The State surveyors (employed by State survey agencies) work for the State and survey the ASCs for compliance with State and Federal regulations. If they meet the standards by observation/correct documentation, etc., then the ASC is approved/reapproved for Medicare certification. If not, it's denied, given citations for violating Medicare Conditions for Coverage and usually re-surveyed at a set interval.

The ASC CfCs focus on a patient-centered, outcome-oriented, and transparent process that promotes quality patient care. This submission captures information necessary to support the implementation of the CfCs for 5,500 ASCs across the United States.

The CfCs are based on criteria in 42 CFR 416 and are standards designed to ensure that each ASC has a properly trained staff to provide the appropriate type and level of care for that environment of patients. CMS needs the CfCs to certify ambulatory surgical centers wishing to participate in the Medicare and Medicaid programs.

The requirements in the ASC regulations, located at 42 CFR Part 416, establish the development of the disaster preparedness plan, quality assessment and performance improvement plan development and collection, analysis, documentation of the findings, and the development of a patient rights informational sheet and related documentation requirements of alleged violations or complaints and the disclosure statements to the appropriate personnel.

To determine compliance with the CfCs, the Secretary has authorized States, through contracts, to conduct surveys of ASCs. For Medicare purposes, certification is based on the State survey agency's recording of a provider or supplier's compliance or noncompliance with the health and safety requirements published in the regulations.

B. Justification

1. Need and Legal Basis

The CfCs are designed to ensure that each ASC has properly trained staff to provide the appropriate type and level of care for that ASC and provide a safe physical environment for patients.

Section 934 of the Omnibus Budget Reconciliation Act of 1980, which is implemented under 42 CFR 416, allows ASCs meeting health, safety, and other standards specified by the Secretary to participate in Medicare. Section 934 amended various sections of the Social Security Act, including sections 1832 and 1863 which instruct the Secretary to consult with appropriate State Agencies and recognize national listing or accreditation bodies in developing the conditions (health and safety requirements), and section 1864, which authorizes the Secretary to use States in determining compliance with the requirements, referred to in regulations as CfCs.

2. Information Users

The CfCs are used by Federal (CMS surveyors) or State surveyors (employed by State survey agencies) as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare**.** Surveyors make an in-person visit to ASCs to perform the complete survey. The information gleaned by surveyors on whether or not the ASC facility is meeting the Conditions for Coverage is then used to accept/continue their medicare certification or discontinue it.

The CfCs don't require the ASCs to send specific information or data to CMS. The information we glean is from Federal (CMS) or State surveyors (employed by State survey agencies) performing a survey to obtain evidence they are meeting the Conditions for Coverage requirements

3. Use of Information Technology

ASCs may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation in no way prescribes how the facility should prepare or maintain these records. Facilities are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Efforts

These requirements are specified in ways that do not require an ASC to duplicate efforts. If an ASC already maintains these general records, regardless of format, they are in compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records from one ASC to another acceptable.

5. Small Businesses

These requirements will not have a significant impact on ASCs and other suppliers that are small entities. Further, most of the requirements in this rule are part of ASCs' standard practices. We understand that there are different sizes of ASCs and that the burden for ASCs of different sizes will vary.

6. Less Frequent Collection

CMS does not collect information directly from ASCs. In most cases, the rule does not prescribe the manner, timing, or frequency of the records or information that must be available. ASC records are reviewed at the time of a survey for initial or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare CfCs, which in turn, would jeopardize the health and safety of ASC patients and provision of quality healthcare.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on February 17, 2017 (82 FR 11040). There were no public comments.

The 30-day Federal Register notice published on April 28, 2017 (82 FR 19734). There were no public comments.

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

Confidentiality will be maintained to the extent provided by law. We pledge confidentiality of

patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

Assumptions and Estimates Used Throughout the Impact Analysis Section

# of Medicare ambulatory surgical centers nationwide	5,500
# of patients per ASC (average)	1300
Hourly rate of registered nurse	$68.00
Hourly rate of administrator	$102.00

Salary data is based on the BLS 2016 National average salary located at www.bls.gov and apply to the following personnel:

"Administrator" refers to the administrator who runs the day to day operation of the ASC, and who, according to the 2016 www.bls.gov website has a median annual income of $106,070, with a median hourly salary of $51.00. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the median hourly salary wage to $102.00.

"Registered nurse" refers to the registered nurse who runs the day to day operation of an ASC, and who, according to the 2016 www.bls.gov website has a median annual income of $71,000, with a median hourly salary of $34.00. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the median hourly salary wage to $68.00.

§416.41(c)(1) Standard: Disaster preparedness plan.

The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event that fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances are likely to threaten the health and safety of those in the ASC. We estimate the burden associated is the time and effort necessary to draft and maintain the written disaster preparedness plan. In addition, there is burden associated with drafting and maintaining the reports on the effectiveness of the plan. We estimate that an administrator, earning $102.00 per hour, would be largely responsible for developing the plan and for managing the yearly drills and evaluations. We estimate that the yearly cost for one ASC to develop, implement and maintain a disaster preparedness plan will be approximately 4 hours at $102.00 per hour, with a net cost of $408.00 per ASC (4 hours x $102.00). The total annual burden cost for all ASCs is estimated to be $2,244,000

($408.00 x 5500 ASCs).

Governing Body and Management Burden Assessment

Standard	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
Disaster preparedness plan	4	22,000	$408.00	$2,244,000

§416.43 Quality assessment and performance improvement. (d. Standard: Performance improvement projects.)

An ASC must develop, implement, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. In addition, the ASC must maintain documentary evidence of its quality assessment and performance improvement program. The QAPI program must be able to demonstrate measurable improvement in indicators related to improved health outcomes and by the identification and reduction of medical errors. An ASC must use all relevant quality indicator data to design its QAPI program, monitor the effectiveness and safety of services and quality of care, identify, and prioritize improvement opportunities. An ASC must track adverse patient events, analyze their causes, and implement preventative actions and mechanisms that include feedback and learning throughout the ASC. An ASC must measure its success and track performance in its performance improvement initiatives to ensure that the improvements are continuous**.** The burden associated with the requirements contained in §416.43 is the time and effort necessary to develop, draft, and implement a QAPI program. As part of implementing the QAPI program, an ASC must record quality data for performance improvement initiatives. We estimate that it will take 12 hours for each ASC to develop its own quality assessment performance improvement program. We also estimate that each ASC would spend 18 hours a year collecting, analyzing and documenting the projects that are being conducted. The ASC must document, at a minimum, the reason for implementing the project, and a description of the project's results. Both the program development and the improvement projects would most likely be managed by the ASC's administrator. Based on an hourly rate of $102.00, the total burden associated with these requirements per ASC is $3,060 (30 hours x $102.00). The total annual burden cost for the ASC industry is $16,830,000 ($3,060 x 5500 ASCs)

Quality Assessment and Performance Improvement Burden Assessment

Standard	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
Developing QAPI	12	66,000	$1,224	$6,732,000
Collecting/analyzing/documenting findings	18	99,000	$1,836	$10,098,000

Annual total	30	165,000	$3,060	$16,830,000

§416.50(a)(1) Standard: Notice of rights and responsibilities

An ASC must provide the patient or the patient's representative with written and verbal notice of the patient's rights prior to the start of the surgical procedure and, in a language and manner that the patient or the patient's representative understands. The ASC must post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representative, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the website for the Office of the Medicare Beneficiary Ombudsman. The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing. The burden associated with this notification requirement is the time and effort necessary for an ASC to develop the notification form, to provide both verbally and in writing the patient or the patient's representative a notice of patient's rights where applicable, disclosure of physician financial interests or ownership in the ASC facility and distribute information pertaining to its policies on patient rights.. There are 5,500 ASCs that must comply with the aforementioned requirements. We estimate that an ASC will utilize a registered nurse to develop the patient right form. We estimate that it will take one hour on a one-time basis for an ASC to develop the form. The total one time burden hours for the industry are 5,500 (1 hours x 5,500 ASCs). At the average hourly rate of $68.00 for a registered nurse, it will cost an ASC $68.00 to meet this requirement. The total one time burden cost for the industry is $374,000.

§416.50 (a)(3) Standard: Submission and investigation of grievances.

An ASC is required to establish a grievance procedure for documenting the existence, submission, investigation and disposition of a patient's written or verbal grievance. The ASC must document all alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse. All allegations must be immediately reported to a person in authority in the ASC and only substantiated allegations must be reported to the State authority or the local authority, or both. The ASC must also take action to correct problems once they are identified. The burden associated with the recordkeeping and reporting requirements described in §416.50(a)(3) is the time and effort necessary to fully document the alleged violation or complaint, disclose the written notice to each patient who filed a grievance, and report the alleged violations to the aforementioned entities. We estimate that in a one year period an ASC would need to conduct investigational sessions for alleged violations involving about 1% (12) of its patients. On average we estimate that, it will take each ASC registered nurse15 minutes at a cost of $68.00 an hour to develop and disseminate 12 notices on an annual basis (15 minutes x 12 patients = 3 hours per ASC), for a total annual ASC burden of 16,500 hours (3 hours x 5500 ASCs) at a cost of $1,122,000 ($68.00 x 16,500 hours).

Patient Rights Burden Assessment

Standard	Time per ASC (hours)	Total time (hours)	Cost per average ASC	Total cost
Develop form	1	5,500	$68.00	$374,000
Documentation of grievances	3	16,500	$204	$1,122,000
Totals	4	22,000	$272	$1,496,000

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

There are minimal costs associated with these requirements that are accrued at the Federal level and especially at the regional office (RO) levels. For example, RO staff is responsible for acting on the information collections requirements discussed in this package as it relates to ASC compliance. Once state survey agencies have completed their surveys and if a final decision to terminate an ASC for noncompliance is to be made, such decisions are made by the Central Office and the RO.

15. Changes to Burden

Changes to the burden are a reflection of the increase in number of Medicare certified ASCs at this time compared to the previous collection. The number of ASCs increased from 5,300 to 5,500 therefore the burden hours increased from 206,700 to 214,500. There were also changes in current average hourly rate for medical professionals used in the calculations. In addition, the figures include a 100% benefits and overhead package figured as part of their salary.

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.