

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.

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 5,557 ASCs.

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.

Additionally, CMS published revisions to certain ASC conditions for coverage related to admission and pre-surgical assessment on September 30, 2019.

B. Justification

1. Need and Legal Basis

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.

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.

2. Information Users

The CfCs are used by Federal (CMS) 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.

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

This information collection request is associated with Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (0938-AT23) which was proposed on September 20, 2018 (83 FR 47686), and finalized on September 30, 2019 (84 FR 51732).

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)

Table 1: Assumptions and Estimates Used Throughout

# of Medicare ambulatory surgical centers nationwide	5,557
# of patients per ASC (average)	1300
Hourly rate of registered nurse	\$70
Hourly rate of administrator	\$108
Hourly rate of physician	\$242
Hourly rate of office clerks, general	\$32

Salary data is based on the Bureau of Labor Statistics (BLS) May 2017 National Occupational Employment and Wage Estimates located at https://www.bls.gov/oes/current/oes_nat.htm and apply to the following personnel:

“Registered nurse” refers to the registered nurse who runs the day to day operation of an

ASC, and who, according to the 2017 BLS data has a mean annual income of \$73,550, with a mean hourly wage of approximately \$35. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the hourly wage to \$70.

“Administrator” refers to the administrator who runs the day to day operation of the ASC, and who, according to the 2017 BLS data has a mean annual income of \$111,680, with a mean hourly wage of approximately \$54. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the hourly wage to \$108.

“Physician” refers to the physician who runs the day to day operation of an ASC, and who, according to the 2017 BLS data has a mean annual income of \$251,890, with a mean hourly wage of approximately \$121. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the hourly wage to \$242.

“Office clerk” refers to the clerical staff who run the day to day operation of an ASC, and who, according to the 2017 BLS data have a mean annual income of \$33,910, with a mean hourly wage of approximately \$16. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the hourly wage to \$32.

§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 \$108 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 \$108 per hour, with a net cost of \$432 per ASC (4 hours x \$108). The total annual burden cost for all ASCs is estimated to be \$2,400,624 (\$432 x 5,557 ASCs).

Table 2: Governing Body and Management Burden Assessment

Standard	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
Disaster preparedness plan	4	22,228	\$432	\$2,400,624

§416.43(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 \$108, the total burden associated with these requirements per ASC is \$3,240 (30 hours x \$108). The total annual burden cost for the ASC industry is \$18,004,680 (\$3,240 x 5,557 ASCs)

Table 3: Quality Assessment and Performance Improvement Burden Assessment

Standard	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
Developing QAPI	12	66,684	\$1,296	\$7,201,872
Collecting/analyzing/documenting findings	18	100,026	\$1,944	\$10,802,808
Annual total	30	166,710	\$3,240	\$18,004,680

§416.47 Condition for coverage - Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. There are no collection of information requirements associated with this requirement because maintaining a medical record for each patient is a usual and customary practice in accordance with the implementing regulations of the Paperwork Reduction Act (PRA) at 5 CFR 1320.3(b)(2).

§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. We estimate that there are approximately 57 new ASCs per year that will incur this one-time burden. 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 57 (1 hours x 57 ASCs). At the average hourly rate of \$70 for a registered nurse, it will cost an ASC \$70 to meet this requirement. The total one time burden cost for the industry is \$3,990.

§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 nurse 15 minutes at a cost of \$70 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 16,671 hours (3 hours x 5,557 ASCs) at a cost of \$1,166,970 (\$70 x 16,671 hours).

§416.52(a) Standard: Admission and pre-surgical assessment.

The operating physician and ASC must determine which patients would require more extensive testing and assessment prior to surgery. The burden associated with this requirement would be the time and effort necessary to create new policies for when, and whether, to require some

form of history and physical that would require pre-operative examination and testing, and on what time schedule. We assume that creating these policies (which could leave such decisions to the surgeon’s discretion in most or all cases) would require 10 hours of physician time, 10 hours of RN time, and 10 hours of clerical time, at the preceding hourly rates, for a total of 30 hours per facility. This would be a one-time cost of \$3,440 per facility ($[10 \times \$242] + [10 \times \$70] + [10 \times \$32]$). Therefore, the total one-time burden for all 5,557 ASCs is \$19,116,080 and 166,710 hours (30 hours X 5,557 facilities). Annualized over the 3-year approval period, this comes to 55,570 hours or \$6,372,026. In subsequent years, we estimate that 57 new ASCs will incur this one-time burden annually, for a total of 1,710 hours per year (30 hours x 57 facilities), or \$196,080 ($\$3,440 \times 57$ facilities).

Table 4: Total Burden and Cost Estimates (Annualized)

Regulation Sections	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
§416.41(c)(1)	4	22,228	\$432	\$2,400,624
§416.43(d)	30	166,710	\$3,240	\$18,004,680
§416.50(a)(1)	1	57	\$70	\$3,990
§416.50(a)(3)	3	16,671	\$210	\$1,166,970
§416.52(a)	30	57,280	\$3,440	\$6,568,106
Totals	0	0	0	0

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

We have adjusted the burden estimates to reflect that the previously approved one-time burden at §416.50(a)(1) for all ASCs to develop a patient rights form will only be incurred by an estimated 57 new ASCs each year in the future. In addition, we have annualized the new one-time burden associated with 84 FR 51732 at §416.52(a) over the 3-year approval period. These changes result in a decrease of burden from 377,876 hours to 262,946 hours compared to what was proposed, or a decrease of 48,446 compared to the previous approved package (ICR Reference Number: 201704-0938-009). Refer to Table 4 for details.

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.