Supporting Statement For Paperwork Reduction Act Submissions

A. Background

This information collection package is a request for new information collection requirements related only to those new requirements contained in the final rule. The burden associated with the current ASC information collection is currently approved under OMB No. 0938-0266, with an expiration date of June 30, 2011. With this submission, we are creating a supplemental PRA package for ambulatory surgical centers (ASCs).

The requirements in the regulation 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.

The ambulatory surgical center conditions for coverage (CfCs) were originally published on August 5, 1982, and, for the most part, these regulations have remained unchanged since that time. To take advantage of the continuing advances in the health care delivery field, be more in alignment with today's ASC health care industry standards, and incorporate recommendations made by various government agencies, we've revised the CfCs.

CMS published the ASC conditions for coverage final regulation on November 18, 2008. The ASC CfCs focus on a patient-centered, outcome-oriented, and transparent process that promotes quality patient care. The final rule contained both new provisions and provisions that were carried over from the previous version of the ASCs.

This submission captures information necessary to support the implementation of the CfCs for 5,100 ASCs. Salary data is based on the salary website at http://www.hrsalarycenter.salary.com 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 http://hrsalarycenter.salary.com, has a median annual income of $101,920. Thus, the hourly rate used in this report is $49.00 (i.e., $101,920 divided by 52 weeks per year divided by 40 hours per week).

"Registered nurse" refers to the registered nurse who runs the day to day operation of an ASC, and who, according to http://hrsalarycenter.salary.com, has a national median salary of $81,120. Thus, the hourly rate used in this report is $39.00 (i.e., $81, 120 divided by 52 weeks per year divided by 40 hours per week).

This document represents the ASC CfCs that are effective in the final rule published on November 18, 2008.

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 facility has properly trained staff to provide the appropriate type and level of care for that facility and provide a safe physical environment for patients.

2. Information Users

The CfCs are used by Federal or State surveyors as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare**.** CMS and the healthcare industry believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability.

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.

7. Special Circumstances

Absent a legislative amendment, we are unable to anticipate any circumstances that would change the requirements of this package.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on March 20, 2009.

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.

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	5,100
# of patients per ASC (average)	1240
Hourly rate of registered nurse	$39

Hourly rate of administrator	$49

Note: All salary information is from the salary.com website at http://hrsalarycenter.salary.com.

§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 $49.00 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 $49.00 per hour, with a net cost of $196.00 per ASC (4 hours x $49.00). The total annual burden cost for all ASCs is estimated to be $999,600 ($196.00 x 5100 ASCs).

GOVERNING BODY AND MANAGEMENT BURDEN ASSESSMENT

Standard	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
Disaster preparedness plan	4	20,400	$196.00	$999,600

§416.43 Quality assessment and performance improvement.

(a. Standard: Program scope. 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 $49.00, the total burden associated with these requirements per ASC is $1,470 (30 hours x $49.00). The total annual burden cost for the ASC industry is $7,497,000 ($1,470 x 5100 ASCs)

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN ASSESSMENT

Standard	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
Developing QAPI	12	61,200	$588	$2,998,800
Collecting/analyzing/documenting findings	18	91,800	$882	$4,498,200
Annual total	30	153,000	$1,470	$7,497,000

§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 in advance of the date of the 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 and furnished to the patient in advance of the date of the procedure. 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 5,100 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 5,100 (1 hours x 5,100 ASCs). At the average hourly rate of $39 for a registered nurse, it will cost an ASC $39 to meet this requirement. The total one time burden cost for the industry is $198,900.

§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 15 minutes at a cost of $39.00 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 15,300 hours (3 hours x 5100 ASCs) at a cost of $596,700 ($39.00 x 15,300 hours).

PATIENT RIGHTS BURDEN ASSESSMENT

Standard	Time per hospice (hours)	Total time (hours)	Cost per average hospice	Total cost
Develop form	1	5,100	$39	$198,900
Documentation of grievances	3	15,300	$117	$596,700
Totals	4	20,400	$156	$795,600

13. Capital Costs

There are no additional 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

This is a new information collection.

16. Publication/Tabulation Dates

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

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

This section does not apply because statistical methods were not used in developing this collection.