Supporting Statement for Ambulatory Surgical Center (ASC) Health Insurance Benefits Agreement (CMS-370); ASC Request for Certification (CMS-377); ASC Survey Report Form (CMS-378) and Supporting Regulations Contained in 42 CFR 416.41, 416.43, 416.47 and 416.48

A. Background

The information collections that are included with this request are:

CMS-370 Health Insurance Benefits Agreement
This form is utilized for the purpose of establishing eligibility for payment under Title XVIII of the Social Security Act. This agreement, upon submission by the ASC and upon acceptance for filing by the Secretary of Health & Human Services, shall be binding on the ASC and the Secretary. The agreement may be terminated by either party in accordance with regulations. In the event of termination, payment will not be available for ASC services furnished on or after the effective date of termination.

CMS-377 Ambulatory Surgical Center (ASC) Request for Certification in the Medicare Program

This form is utilized as an application for facilities wishing to participate in the Medicare program as ASCs. This form initiates the process of obtaining a decision as to whether the conditions of coverage are met. It also promotes data retrieval from the Online Data Input Edit (ODIE system, a subsystem of the Online Survey Certification and Report (OSCAR) system by the Centers for Medicare and Medicaid Services (CMS) Regional Offices (ROs)). Should any questions arise regarding the structure of the organization, this information is readily available without going through the process of completing this form again.

CMS-378 - Ambulatory Surgical Center Survey Report Form.

The form CMS-378 is an instrument used by the State survey agency to record data collection in order to determine supplier compliance with individual conditions of coverage and to report it to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction and retrieval into the ODIE/OSCAR system at the CMS ROs. This form includes basic information on compliance (i.e., met, not met and explanatory statements) and does not require any descriptive information regarding the survey activity itself. CMS has the responsibilily and authority for certification decisions which are based on supplier compliance with the conditions of coverage. The information needed to make these decisions is available to CMS only through use of information abstracted from the survey checklists.

Ambulatory Surgical Center Conditions of Coverage (CoC) – Sections 42 CFR 416.41, 416.43, 416.47, and 416.48

Section 416.41 – Condition for coverage – Governing body and management.

The ASC must have a written transfer agreement with a local, Medicare participating hospital for immediate transfer of patients requiring emergency medical care (or all physicians of the ASC must have admitting priveleges at such a hospital).

Section 416.43 - Condition for coverage -- Evaluation of quality.

The ASC, with the active participation of the medical staff must conduct and ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

Section 416.47 - Condition for coverage - Medical Records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) Standard: Organization. The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) Standard; Form and content of record. The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records include at least the following:

(1) Patient identification

(2) Significant medical history and results of physical examination.

(3) Pre-operative diagnostic studies (entered before surgery), if performed.

(4) Findings and techniques of the operation, including the pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

(5) Any allergies and abnormal drug reactions.

(6) Entries related to anesthesia administration.

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis

Section 416.48 Condition for coverage-Pharmaceutical services.

Adverse reactions must be reported to the physician responsible for the patient.

These information collections requirements are commonly accepted as good medical practice. They do not impose any additional burden since they would be performed in the absence of this Federal regulation. Therefore, the burden associated with them is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

**B.** Justification

1. Need and Legal Basis

This activity is authorized by Section 934 of the Omnibus Budget Reconciliation Act of 1980, which is implemented under 42 CFR 416, which allows ASCs meeting health, safety, and other standards specified by the Secretary to participate in Medicare. Scction 934 amended various sections of the Social Security Act, including sections 1832 and 1863 which instruct thc 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 authorized the Secretary to use States in determining compliance with the conditions, refcrred to in regulations as conditions of covcrage.

The conditions of coverage are based on criteria described in law. The standards 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.

CMS uses the conditions of coverage to certify health care facilities wishing to paticipate in the Mcdicare program.

To determine compliance with conditions of coverage, the Secretary has authorized States, through contracts, to conduct surveys of health care providers. For Medicare purposes, cerfication is based on the State survey agency's recording of a providers or supplier's compliance or noncompliance with health and safety requirements published in regulations. The certification form (CMS-377) is the form used in the initial stages of the process for allowing a supplier to participate in the Medicare program. It establishes ncccssary identification data for the supplier for interaction with ODIE/OSCAR system and screens for supplier capacity to meet specifications which must be met before a supplier can be considered to participate in the Medicare program as an ASC. In order for the State agency to report its generic findings on supplier compliance with the individual standards on which CMS determines certification, the agency completes the ASC Survey Report Form (CMS-378). This form is a listing of the regulatory conditions we rcquire to be met for participation in the Medicare program.

The surveyor reports on each condition by checking a box alongside the condition or standard indicating whether or not the Statc found that the supplicr meets the rcquirement. Space is also provided for appropriate explanatory statements regarding negative findings.

2. Information Users

The Health Insurance Benefits Agreement, CMS-370, is used for the purpose of establishing eligibility for payment under Title XVIII of the Social Security Act. Upon

acceptance by the Secretary of Health & Human Services, shall be binding on the supplier of services and the Secretary.

The request for certification (CMS-377) and the survey form (CMS-378) are used by CMS in making ccrtification decisions. When a supplier initially expresses an interest in participating in the Medicare program as an ASC, contact is made with the State agency which forwards the Request for Ccrtificaiton to the supplier. The information on the completed form serves as a screen for the State agency to determine whether the supplier has the basic capabilities to participate in the Medicare program and whether the survey is appropriate. The basic identifying information from this form and the individual compliance codes from the survey form are entered into the ODIE/OSCAR system and serve as the information base for the creation of a record for the future Federal certification and monitoring activity.

3. Improved Information Technology

The certification form lists minimum criteria that must be met in order to be approved for Medicare participation. The standardized format and simple check box method provide for consistent reporting by State survey agencies. Recording this information would be no easier for State surveyors using direct access equipment.

4. Duplication of Similar Information

This certification form does not duplicate any information collection. The form addresses specific requirements for certification. State survey agencies conduct these reviews with Federal funds under contract with CMS. This form is a basic deliverable under these contracts and is the only one of its kind collected by CMS for ASCs. This form is the only standardized mechanism available for reporting the basic preliminary requirement for ASCs wishing to participate in the Medicare program.

5. Small Businesses

These information collection requirements do not have a significant impact on small businesses.

6. Less Frequent Collection

It is a basic contract requirement that State surveyors transmit their compliance findings for each survey they conduct. If this information were collected less frequently, facilities out of compliance with the law could be out of compliance for longer periods of time.

7. Special Circumstances

There are no special circumstances associated with this collection. This information collection complies with the general guidelines in 5 CFR 1230.6.

8. Federal Register Notice/ Outside Consultation

A 60-day Federal Register notice was published on 9/7/2007, attached. No other outside consultation was performed.

9. Payment/Gift To Rcspondent

There are no payments or gifts associatcd with this collection.

10. Confidentiality

We do not pledge confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature on these forms.

12. Burden Estimate (Total Hours & Wages)

Reporting burden is based on 4823 ASCs plus an approximate gain of 300 new suppliers per year for a total of 5123.

CMS-370 Health Insurance Benefits Agreement

We estimate that it will take approximately 30 minutes for each new provider to ensure that he/she meets the conditions set forth in Part 416 and to complete the form. We estimate that there will be 300 new providers a year that will have to fill out the form, or 150 burden hours.

CMS-377 Certification Form

Based on past usage of this form and the general nature of the questions, we estimate that is takes appropriately 15 minutes to complete the form. We estimate that there will be 300 new providers a year that will have to fill out the form, or 75 burden hours.

CMS-378 Survey Form

It takes approximately 30 minutes for experienced CMS agents to complete the survey form. Total burden for the survey report is 2562 hours.
(5123 suppliers x ½ hour per form = 2562)

The total aggregate burden for these ICRs is 2787 annual hours.

The non-Federal cost for the CMS-377 is $ 1,500 ($20.00 X 75 hours) and for the CMS-378 we estimate the cost to be $20,810 ($10.00 X 2,081)

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs associated with this collection.

14. Cost to Federal Government

All costs associated wilh the CMS-378 are incurred by the Federal government.

Number of facilities surveyed annually, average 5123

Average annual contracting costs to complete form based on
$37.00 per hour x [(1/2 hour x 4832) + (300 x ¼ )] = $92,498

Printing and Distribution costs

| | |
|---|---|
| CMS-377 | $54.00 |
| CMS-378 | $223.00 (average) |
| CMS-370 | $50 |
| TOTAL COSTS | $ 98,825 |

15. Program/Burden Changes

There are no program. The slight increase in burden is based on estimated new suppliers.

16. Publication and Tabulation Dates

There are no publication and tabulation dates associated with collection.

17. Expiration Date

CMS does not want to display the OMB expiration date, as it would involve the destruction of too many forms every three years; these forms are used on a continuing basis.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.