Supporting Statement for Paperwork Reduction Act Submissions

<u>CMS-370</u> -- Health Insurance Benefits Agreement <u>CMS-377</u> -- Ambulatory Surgical Center (ASC) Request for Certification or Update of Certification Information

OMB 0938-0266

A. <u>Background</u>

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 (the "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 ASC Request for Certification or Update of Certification Information in the Medicare Program

This form is utilized to collect facility-specific characteristics that facilitate CMS' oversight of ASCs, for example, through the ability to track and trend survey results broken down by various facility characteristics. The data also enables CMS to respond to inquiries from the Congress, GAO, OIG concerning the characteristics of Medicare-participating ASCs.

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 that meet health, safety, and other standards specified by the Secretary to participate in Medicare. Section 934 amended various sections of the Act, including sections 1832 and 1863 which instruct the Secretary to consult with appropriate State Agencies and recognized national accreditation bodies in developing the conditions (health and safety requirements) as well as section 1864, which authorized the Secretary to use States in determining compliance with the conditions, referred to in regulations as conditions for coverage (CfCs).

The Health Insurance Benefits Agreement (CMS-370) is used for the purpose of establishing eligibility for payment under Title XVIII of the Act.

The Form CMS-377 is submitted by ASCs when they request initial certification of compliance with the ASC CfCs or to update an ASC's existing certification information.

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

The Request for Certification or Update of Certification Information in the Medicare Program Form (CMS-377) is used by State agencies who conduct certification surveys on CMS' behalf to maintain information on the facility's characteristics that facilitate conducting surveys, e.g., determining the size and the composition of the survey team on the basis of the number of ORs/procedure rooms and the types of surgical procedures performed in the ASC. CMS also intends to make increasing use of aggregated data to analyze trends in facility compliance to determine whether there are correlations based on key facility characteristics, and, if so, to use such information in better targeting scarce survey resources to ASCs more likely to be noncompliant with the CfCs. In addition, CMS receives inquiries periodically from members of Congress, the GAO, or OIG concerning the characteristics of participating providers and suppliers, in order to facilitate policy review and development. Collection of this data will allow CMS to be responsive to such inquiries.

3. <u>Improved Information Technology</u>

The CMS-370 and CMS 377 do not lend themselves to electronic collection at this time.

4. <u>Duplication of Similar Information</u>

Neither form CMS-370 or form CMS-377 duplicates any information collection. Each form addresses specific requirements for either eligibility for payment or certification or update of certification in the Medicare program.

5. Small Businesses

Many ASCs affected by this requirement are small businesses; however, the information collection is necessary for the business to participate in the Medicare program. These paperwork requirements are minimal and are necessary to meet the participation requirements of the law.

6. Less Frequent Collection

The Form CMS 370 is collected one time only over the course of the duration of the agreement between CMS and the ASC applicant. It is necessary to prevent fraud and abuse in the Medicare program and to assure that ASCs understand they must comply with all applicable Federal requirements and make a binding commitment to compliance throughout their participation in theMedicare program. If the information were collected less frequently, CMS would not have a binding commitment on the part of

ASCs to comply with all applicable Medicare requirements. The presence of unsafe, fraudulent, or abusive entities in the Medicare program puts patients/residents at risk of harm and diverts resources from the Medicare Trust Funds that are needed to reimburse legitimate claims for medical care provided to Medicare beneficiaries.

The Form CMS 377 is collected at most once every three years. Less frequent collection would result in CMS potentially having significantly outdated information on the ASC's characteristics, which could adversely impact oversight activities.

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

The 60-day Federal Register notice published on April 2, 2014. No comments were received.

9. Payment/Gift To Respondent

There are no payments or gifts associated 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 approximately 5,449 ASCs plus an approximate gain of 166 new suppliers per year totalling 5,947 within 3 years. Combined, the CMS-370 and CMS-377 estimated burden is 633 hours (28 + 605) at a cost of \$42,385.40 (\$1,362.86 + \$41,022.54).

CMS-370 Health Insurance Benefits Agreement

We estimate that it will take approximately 5 minutes for each new supplier to complete the form. We also estimate that it will take approximately 5 minutes to file the form. We estimate that there will be approximately 166 new suppliers a year that will have to fill out this form.

The cost to each facility for reviewing and signing this agreement has been calculated at the average national executive salary of \$85.02 per hour. A Chief Executive Officer of a facility would be responsible for reviewing and signing this agreement. Based on a timeframe of 5 minutes to complete this document, the cost per facility would be \$7.09. For the approximately 166 new suppliers, the national cost to review and sign the agreement would be \$1,176.94.

The cost to each facility for filing the document has been calculated assuming the national average salary of \$13.48 per hour, since office administrative staff would be expected to file the agreement. Based on a timeframe of 5 minutes needed to file the agreement, the cost per facility would be \$1.12. For the approximately 166 new suppliers, the national cost to file the agreement would be \$185.92.

The total hour burden is estimated to be 28 (14 + 14).

The total burden cost is estimated to be \$ 1,362.86 (1,176.94 + 185.92)

CMS-377 Request for Certification or Update of Certification Information

Based on past usage of this form and the general nature of the questions, we estimate that it will take a facility appropriately 15 minutes to review and sign the form and an additional 5 minutes to file the form. We estimate that there will be approximately 166 ASCs seeking initial certifications yearly and 1667 ASCs requested yearly to update their information that will have to complete and file the form.

The cost to each facility for reviewing and signing this form has been calculated at the average national executive salary of \$85.02 per hour. A Chief Executive Officer of a facility would be responsible for reviewing and signing this form. Based on a timeframe of 15 minutes to complete this document, the cost per facility would be \$21.26. For the approximately 166 ASCs seeking initial certifications and the approximately 1667 ASCs requested yearly to update their information (based on each ASC being asked every 4 years to provide an update), the national cost to review and sign the agreement would be \$38,969.58. The cost for filing the agreement has been calculated at the national average of \$13.48 per hour. Based on a timeframe of 5 minutes needed to file the agreement, the cost per facility would be \$1.12 . For the approximately 166 ASCs seeking initial certifications yearly and the approximately 1667 ASCs requested yearly to update their information (based on each ASC being asked every 4 years to provide an update), the national cost to file the agreement would be \$2.052.96.

The total hour burden is estimated to be 605 (147 + 458).

The total burden cost is estimated to be \$41,022.54 (2,052.96 + 38,969.58)

The CMS-370 and CMS-377 forms combined burden cost is estimated to be \$42,385.40.

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

The CMS Regional Offices are responsible for approving the CMS Form 370 while the State Survey Agencies code information from the CMS Form 377.

Counter-signing the Form 370 follows a review of the file for a new Medicare ASC applicant. The amount for review of the form was calculated using an average salary of \$44.65 /hour for a Regional Office reviewer, and assuming it would take 30 minutes to review the file; the Federal cost is \$22.33 /agreement times the average number of annual new ASC supplier agreements (166), or \$3,706.78.

State Survey Agencies are responsible for reviewing the Form 377, entering data from it into the survey and certification data base, and filing the hard copy. The amount for accomplishing this was calculated using an average salary of \$25.00 for a State Survey Agency reviewer, and assuming it would take 30 minutes to perform the required tasks; the Federal cost is \$17.00 /agreement times the 1666 forms submitted yearly, or \$28,322.00

Printing and Distribution costs

CMS-370 \$ 690.00 CMS-377 \$ 570.00

TOTAL COSTS \$33,288.73 (3,706.78+28,322.00+690.00+570.00)

15. Program/Burden Changes

The burden is adjusted to account for a reduction in annual growth in the number of ASCs and wage changes per the Bureau of Labor Statistics.

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.