

**SUPPORTING STATEMENT FOR FORM CMS-216-94
ORGAN PROCUREMENT ORGANIZATION/HISTOCOMPATIBILITY
LABORATORY STATEMENT COST REPORT AND SUPPORTING REGULATIONS
IN 42 CFR SECTIONS 413.20 AND 413.24**

A. BACKGROUND

CMS is requesting the Office of Management and Budget (OMB) extend the approval of Form CMS-216-94 (OMB No. 0938-0102), the Organ Procurement Organization (OPO)/Histocompatibility Laboratory Cost Report and Supporting Regulations. The current form implements various provisions of the Social Security Act including Section 1881(a) which provides Medicare coverage for end stage renal disease patients, who meet certain entitlement requirements, and kidney donors. It also implements Sections 1881 (b)(2)(B) and 1861(v)(1)(A) of the Social Security Act to determine the reasonable costs incurred to furnish treatment for renal patients and transplant patients.

B. JUSTIFICATION

1. Need and Legal Basis

Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries.

The Form CMS-216-94 cost report is needed to determine the amount of reasonable cost due to the providers for furnishing medical services to Medicare beneficiaries.

2. Information Users

In accordance with sections 1815(a), 1833(e) and 1861(v)(A)(ii) of the Social Security Act, providers of service in the Medicare program are required to submit annual information to achieve reimbursement for health care services rendered to Medicare beneficiaries. In addition, 42 CFR 413.20(b) sets forth that cost reports will be required from providers on an annual basis. Such cost reports are required to be filed with the provider's contractor. The functions of the contractor are described in section 1816 of the Social Security Act.

The contractor uses the cost report not only to make settlement with the provider for the fiscal year covered by the cost report, but also in deciding whether to audit the records of the provider. 42 CFR 413.24(a) requires providers receiving payment on the basis of reimbursable cost to provide adequate cost data based on their financial and statistical records which must be capable of verification by qualified auditors. Besides determining program reimbursement, the data submitted on the cost reports supports management of the Federal programs. These data are extracted from the cost report, by the contractors, for transmission to CMS, and used in making projections of Medicare Trust Fund requirements. In addition, the data is available to Congress, researchers, universities, and other interested parties. However, collection of data is a secondary

function of the cost report, whose primary function is the reimbursement of providers for services rendered to beneficiaries.

3. Improved Information Technology

Consideration has been given to the reduction of burden by the use of improved information technology to report required cost data. For cost reporting periods ending on or after March 31, 2005, OPO's are required to submit a cost report via an electronic medium.

4. Duplication and Similar Information

The cost report is a unique form that does not duplicate any other information collection. This form specifically provides for the reimbursement methodology that is unique to OPO's. No other existing form can be modified for this purpose.

5. Small Business

This form has been designed with a view toward minimizing the reporting burden for small businesses. The form is collected as infrequently as possible (annually) and only those data items necessary to determine the appropriate reimbursement rates are required.

6. Less Frequent Collection

If the annual cost report is not filed, CMS will be unable to determine whether proper payments are being made under Medicare. If a cost report is not filed, the intermediary has the authority to reduce or suspend interim payments. In addition, if a provider fails to file a cost report, all interim payments made since the beginning of the cost reporting period may be deemed overpayment, and recovery action may be initiated.

7. Special Circumstances

This information collection complies with all general information collection guidelines as described in 5 CFR 1320.6.

8. Federal Register Notice

The 60 day Federal Register notice published on January 21, 2011 (76 FR 3909). No outside consultation was conducted; however, the public comment period gave the public opportunity to respond, at which time, we received no comments.

9. Payment/Gift to Respondent

There is no payment or gift to respondents.

10. Confidentiality

Confidentiality is not pledged. Medicare cost reports are subject to disclosure under the Freedom of Information Act.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Estimate of Burden (Hours & Wages)

- a. There are approximately 115 OPOs/ Histocompatibility Laboratories certified for the Medicare program which will be required to use the Form CMS-216-94 for Medicare end-of-year cost reporting. Using this number, we estimate the reporting and record keeping burden associated with the Form CMS-216-94 as follows:
- b. The respondent cost is calculated at the standard rate of \$15.00 per hour. The standard rate increased from \$12.00 to \$15.00 per hour due to a cost of living increase.
- c. As of 12/01/10, 115 OPOs/ Histocompatibility Laboratories file this cost report. Based on an average time of 45 hours to complete the cost report (30 hours for reporting plus 15 hours for recordkeeping), the total national reporting burden is 5,175 hours annually.
- d. Respondent cost is calculated as the number of hours of paperwork burden (5,175) times the standard rate of \$15.00 per hour. Thus the estimated respondent cost is \$77,625.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Cost associated with distribution of forms and instructions:

We no longer print and distribute paper copies of Form CMS-216-94. Forms and instructions are issued as a part of the Provider Reimbursement Manual. This manual is transmitted via the internet.

\$0

Annual cost to Medicare Contractors:

Annual cost incurred is related to processing information contained on the forms, particularly associated with achieving settlements. Medicare contractors' handling costs are based on estimates provided by the Office of Financial Management.

\$ 12,951

<u>Annual cost to CMS:</u>	
Total CMS processing cost is from the HCRIS Budget:	\$0
<u>Total Federal Cost</u>	<u>\$ 12,951</u>

15. Changes to Burden

An increase in burden occurred due to an increase in Organ Procurement Organization/Histocompatibility Laboratories from 108 facilities in 2008 to 115 in 2010.

16. Publication and Tabulation Dates

There are no publication plans for the data.

17. Expiration Date

Approval to not display the expiration date for OMB approval is being sought. Since this form is changed so infrequently and our internal change process is so extensive, it is not efficient to go through the entire process simply to revise the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. STATISTICAL METHOD

There are no statistical methods employed in this collection.