

**Supporting Statement for the Organ Procurement Organization/
Histocompatibility Laboratory Cost Report
FORM CMS-216-94**

A. Background

CMS is requesting the Office of Management and Budget (OMB) review and approve this extension request for the Form CMS 216-94, Organ Procurement Organization (OPO)/ Histocompatibility Laboratory Cost Report. These cost reports are filed annually by freestanding OPO and Histocompatibility Lab providers participating in the Medicare program to determine the reasonable costs incurred to furnish treatment for renal transplant patients.

B. Justification

1. Need and Legal Basis

Providers of services participating in the Medicare program are required under sections 1815(a) 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. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis.

The CMS-216-94 cost report is needed to determine the provider's reasonable costs incurred in furnishing treatment for Medicare transplant beneficiaries and reimbursement due to or due from the provider.

2. Information Users

The cost reports are required to be filed with the provider's Medicare Administrative Contractor (MAC). The functions of the MAC are described in section 1816 of the Social Security Act.

The collection of data is a secondary function of the cost report. The data is used by CMS to support program operations, payment refinement activities, and to make Medicare Trust Fund projections.

3. Use of Information Technology

OPOs and Histocompatibility Labs are required to submit Medicare cost reports electronically for cost reporting periods ending on or after March 31, 2005.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Business

These cost reporting forms have been designed with a view towards minimizing the reporting burden for small OPOs and Histocompatibility Labs. 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. A provider who fails to file a cost report by the statutory due date is notified that interim payments will be reduced, suspended or deemed overpayments.

7. Special Circumstances

This information collection complies with all general information collection guidelines in 5 CFR 1320.6, without the existence of special circumstances.

8. Federal Register/Outside Consultation

The 60 day Federal Register notice was published on March 24, 2014.

9. Payment/Gift to Respondent

There is no payment or gift to respondents.

10. Confidentiality

Confidentiality is not assured. 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. Burden Estimates (Hours & Wages)

Number of OPOs/Histocompatibility Laboratories facilities required to file the form CMS 216-94 (as of 3/1/2014)	107
Hours burden per facility to complete the cost report	45
Total hours burden (107 facilities x 45 hours)	4,815
Standard rate per hour	\$20.00
Total respondent cost estimate	<u>\$96,300</u>

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Annual cost to Medicare Contractors:

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

\$ 411,280

Total Federal Cost

\$ 411,280

15. Changes to Burden

The increase in burden is due to two factors: 1) the number of respondents decreased from 115 in 2010 to 107 in 2014; and 2) the standard rate increased from \$15 per hour in 2010 to \$20 per hour in 2014.

16. Publication and Tabulation Dates

The data submitted on the cost report is not published or tabulated.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis and change infrequently.

18. Certification Statement

There are no exceptions to the certification statement.

C. Statistical Methods

There are no statistical methods employed in this collection.