SUPPORTING STATEMENT FOR FORM CMS-216-94
ORGAN PROCUREMENT ORGANIZATION/
HISTOCOMPATIBILITY LABORATORY COST REPORT

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 OPOs and Histocompatibility Laboratory providers participating in the Medicare program, to determine the reasonable costs incurred to furnish kidneys to 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 Form CMS-216-94 cost report is needed to determine a provider's reasonable costs incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or due from a 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 primary function of the cost report is to implement the principles of cost reimbursement which require all OPOs and Histocompatability Laboratories maintain sufficient financial records and statistical data for proper determination of costs. 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 Laboratories are required to submit Medicare cost reports electronically.

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 has been designed with a view toward minimizing the reporting burden for small OPOs and Histocompatibility Laboratories. 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 Notice

   The 60 day Federal Register notice published on July 19, 2017 (82FR33134) with no comments received. The 30-day Federal Register notice published on September 29, 2017(82FR45589) with no comments received.

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. Estimate of Burden (Hours & Wages)

Number of OPOs and Histocompatibility Laboratories required to file the form CMS-216-94 (as of 2/6/17)	102
Number of hours of reporting	30
Number of hours of record keeping	15
Hours burden per facility to complete the cost report (30 hours + 15 hours)	45
Total hours burden (102 facilities x 45 hours)	4590
Standard rate per hour	$54.92
Total respondent cost estimate	$252,128.70

The estimate burden for each OPO/Histocompatability Laboratory is primarily affected by the collection of the data needed to complete the Form CMS-216-94. The standard rate per hour is a weighted average derived from the most recent salary reported by the Bureau of Labor Statistics (BLS) in its 2015 Occupation Outlook Handbook for data entry, clerical, accounting and audit professionals (https://www.bls.gov/oes/current/oes_nat.htm#13-0000). Specifically, the hourly rates for accounting/auditor professionals and data entry/clerical professionals were weighted to determine the average rate of $27.46 per hour. An additional 100% is added to cover the cost of overhead and fringe benefits resulting in a total value of $54.92 per hour ($27.46 x 2).

The rate per hour reflects the significant use of data entry/clerical professionals for ongoing data gathering and record keeping tasks. And, a moderate use of accounting/financial professionals for information verification and review, and cost report preparation and submission to the applicable Medicare Administrative Contractor (MAC).

Burden hours per facility are an estimate of the time required (number of hours) to complete the information collection (cost report) for each OPO/Histocompatability Lab, including time to review the cost report instructions, search existing resources, gather the data needed,

and complete and review the information collection.

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).	$397,800
Annual cost to CMS: Total CMS processing cost is from the HCRIS Budget:	$0
Total Federal Cost	$397,800

15. Changes To Burden

The change in burden is due to two factors:

1) the number of respondents decreased from 107 in 2014 to 102 in 2017; and

2) the standard rate increased from $20 per hour in 2014 to $54.92 per hour in 2017 to account for the increase administrative/overhead costs associated with completing the information collection.

16. Publication and Tabulation Dates

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

17. Expiration Date

CMS will display the expiration date on the first page of the data collection instrument forms, in the upper right hand corner. The PRA disclosure statement with expiration date included in the instructions appears on page 33-3.

18. Certification Statement

There are no exceptions to the certification statement.

C. STATISTICAL METHODS

There are no statistical methods employed in this collection.