

**SUPPORTING STATEMENT
ORGAN PROCUREMENT ORGANIZATION/
HISTOCOMPATIBILITY LABORATORY COST REPORT
(FORM CMS-216-94; OMB-0938-0102)**

A. BACKGROUND

CMS is requesting review and approval by the Office of Management and Budget (OMB) for the reinstatement without change of the OMB No. 0938-0102, Form CMS-216-94, Organ Procurement Organization (OPO) / Histocompatibility Laboratory (HL) Cost Report, which expired on January 31, 2021. OPOs and HLs submit these cost reports annually to report costs and statistical data used by CMS to determine reasonable costs.

OPOs are non-profit organizations responsible for the evaluation and procurement of organs for transplantation. They are the entities legally permitted by law to recover organs from deceased donors and also provide support to donor families, clinical management of organ donors, and professional and public education about organ donation. Other specific tasks include identifying potential organ donors, requesting consent from the families of donors, procuring organs and working with other agencies to identify potential transplant recipients, and ensuring that organs are transferred to donor hospitals.

HLs provide tissue-typing services in preparation for certain procedures, such as kidney transplants, bone marrow transplants, and blood platelet transfusions. HLs provide pre-transplant screening tests and tissue typing for transplant hospitals and OPOs, in addition to non-transplant tissue typing and clinical laboratory services.

The following is a summary of the cost reporting forms. No revisions are proposed to the worksheets listed below in order of their sequence. Further instructions for the completion of the particular worksheets are provided in the Provider Reimbursement Manual, Part 2, Chapter 33.

1. Worksheet S - Organ Procurement Organization/Histocompatibility Laboratory General Data and Certification Statement
2. Worksheet S-1 - Organ Procurement Organization Histocompatibility Laboratory Identification Data
3. Worksheet S-2 - Provider Reimbursement Questionnaire
3. Worksheet A series- Reclassification and Adjustment of Trial Balance of Expenses
4. Worksheets B and B-1- Cost Allocation-General Service Costs
5. Worksheet C & D - Computation of Medicare Cost & Calculation of Reimbursement Settlement
6. Worksheet E series - Balance Sheet and Income Statement

B. JUSTIFICATION

1. Need and Legal Basis

Under the authority of sections 1815(a) and 1833(e) of the Act, CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report. Section 1881(b)(2)(B) of the Act requires each independent Organ Procurement Organization (OPO) and Histocompatibility Laboratory (HL) to be paid the reasonable costs for its services. Regulations at 42 CFR §§ 413.20 and 413.24 require that providers submit acceptable cost reports on an annual basis and maintain sufficient financial records and statistical data, capable of verification by qualified auditors. In addition, the regulations require that providers furnish such information to the contractor, including the provider's working trial balance and audited financial statements, as may be necessary to assure proper payment by the program, receive program payments, and satisfy program overpayment determinations. In accordance with 42 CFR 413.20(a), CMS follows standardized definitions, accounting, statistics, and reporting practices that are widely accepted in healthcare and related fields. Changes in these practices and systems are not required in order to determine costs payable under the principles of reimbursement. Essentially the methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services.

These regulations inherently require that providers make available auditable records to support data reported on the cost report. Examples of auditable records to support data reported on the cost report include square footage calculations and time studies for employees' time spent in various activities. CMS estimates additional burden for the required recordkeeping and reporting when the standardized definitions, accounting, statistics and reporting practices defined in 42 CFR 413.20(a) are not already maintained by the provider on a fiscal basis.

The Form CMS-216-94 cost report is needed to determine an OPO / HL's reasonable costs incurred in procuring and transporting organs for transplant into Medicare beneficiaries and reimbursement due to or from the provider. The reasonable costs of procuring and transporting organs cannot be determined for the fiscal year until the OPO/HL files its cost report and costs are verified by the Medicare contractor. During the fiscal year, an interim rate is established based on cost report data from the previous year. The OPO/HL bills the transplant hospital for services rendered. The transplant hospital pays interim payments, approximating reasonable cost, to the OPO/HL. The Form CMS-216-94 cost report is filed by each OPO/HL at the end of its fiscal year and there is a cost report settlement to take into account increases or decreases in costs. The cost report reconciliation and settlement take into consideration the difference between the total reasonable costs minus the total interim payments received or receivable from the transplant centers.

2. Information Users

The primary function of the cost report is to establish an interim rate based on the average cost per organ acquired. The rates billed by the OPO or HL are reimbursed by the transplant centers and the transplant centers are reimbursed by Medicare for Medicare's share of the costs. Each OPO and HL submits the cost report to its contractor for reimbursement determination. The functions of the contractor are described in § 1874A of the Act.

OPOs and HL must follow the principles of cost reimbursement, which require that OPOs and HLs maintain sufficient financial records and statistical data for proper determination of costs. The S series of worksheets collects provider information such as the provider's location, date of Medicare certification, number of full time equivalent employees; statistical data such as the number of organs procured locally and imported, the number of tissue typing and pre-transplant tests completed, and the amount of payment received for procuring organs for transplant, and furnishing pre-transplant and clinical laboratory testing. The A series of worksheets collects the provider's trial balance of expenses for overhead costs, and revenue and non-revenue generating cost centers, amounts paid to donor hospitals for procuring organs, and costs from related organizations or home offices. The B series of worksheets allocates the overhead costs attributable to organ procurement, and pre-transplant and clinical laboratory testing to revenue and non-revenue generating cost centers using functional statistical bases. The C series of worksheets computes Medicare's share of costs for pre-transplant testing and procuring kidneys for transplantation. The D series of worksheets calculates the reimbursement settlement for the OPO and histocompatibility laboratory. The E series of worksheets collects financial data from the provider's balance sheet and income statement.

3. Use of Information Technology

CMS regulations at 42 CFR § 413.24(f)(4)(ii) require that each OPOs and HLs submit an annual cost report to their contractor in a standard American Standard Code for Information Interchange (ASCII) electronic cost report (ECR) format. OPOs and HLs submit their ECR file to their contractor using a compact disk (CD), flash drive, or the CMS approved Medicare Cost Report E-filing (MCREF) portal, [URL: <https://mcref.cms.gov>]. The instructions for submission are included in the OPO and HLs cost report instructions on page 33-503.

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

All OPOs and HLs regardless of size, are required to complete these cost reporting forms. The forms are collected as infrequently as possible (annually) and only those data items necessary to determine the appropriate reimbursement rates, are required.

6. Less Frequent Collection

Under the authority of 1861(v)(1)(F) of the Act, as defined in regulations at 42 CFR 413.20 and 413.24, CMS requires that each OPO/HL submit the cost report on an annual basis with the reporting period based on the OPO/HL's accounting period, which is generally 12 consecutive calendar months. 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. There is no opportunity for a less frequent collection than the annual cost report as this would impede the annual rate setting and adversely affect the OPO/HL's payments.

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 notice published in the Federal Register on April 9, 2021 (86 FR 18534). No comments were received in response to the 60-day notice.

The 30-day notice published in the Federal Register on October 15, 2021 (86 FR 57431).

9. Payment/Gift to Respondent

CMS makes no payments or gifts to respondents for completion of this data collection. The Form CMS-216-94 collects data to determine accurate payments made to an OPO/HL. The payments made to an OPO/Histocompatibility Laboratory from CMS are for covered services provided to Medicare beneficiaries. If an OPO/HL fails to submit the Form CMS-216-94 the contractor imposes a penalty by suspending payments until the report is submitted. Once the cost report is submitted, the contractor releases the suspended payments. If the OPO/HL files the report timely there is no interruption of the payments.

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 OPO/HL facilities Form CMS 216-94		95
Hours burden per OPO/HL		
Reporting	15	
Recordkeeping	30	
Total hours burden per facility		45
Total hours burden (95 facilities x 45 hours)		4,275
Average cost per OPO/HL		<u>\$2,385.90</u>
Total annual cost estimate (\$2,385.90 x 95 OPO/HLs)		<u><u>\$226,661</u></u>

Only when the standardized definitions, accounting, statistics and reporting practices defined in 42 CFR 413.20(a) are not already maintained by the provider on a fiscal basis does CMS estimate additional burden for the required recordkeeping and reporting.

Burden hours for each OPO/HL estimate the time required (number of hours) to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the Form CMS-216-94. The most recent data from the System for Tracking Audit and Reimbursement, an internal CMS data system maintained by the Office of Financial Management (OFM), tracks the current number of 95 Medicare certified OPOs/HLs that file Form CMS-216-94 annually. We estimate an average burden per OPO/HL of 45 hours (30 hours for recordkeeping and 15 hours for reporting). We calculated the annual burden hours as follows: 95 OPOs/HLs times 45 hours per OPO/HL equals 4,275 total annual burden hours. We recognize this average varies depending on the OPO/HL's size and complexity. We invite public comment on the hours estimate as well as the staffing requirements utilized to compile and complete the Medicare cost report.

The 30 hours for recordkeeping include hours for bookkeeping, accounting and auditing clerks; the 15 hours for reporting include accounting and audit professionals' activities. Based on the most recent Bureau of Labor Statistics (BLS) in its 2019 Occupation Outlook Handbook, the mean hourly wage for Category 43-3031 (bookkeeping, accounting and auditing clerks) is \$20.65¹. We added 100% of the mean hourly wage to account for fringe benefits and overhead costs, which calculates to \$41.30 (\$20.65 + \$20.65) and multiplied it by 30 hours, to determine the annual recordkeeping costs per OPO/Histocompatibility Laboratory to be \$1,239.00 (\$41.30 x 30 hours). The mean

hourly wage for Category 13-2011 (accounting and audit professionals) is \$38.23². We added 100% of the mean hourly wage to account for fringe benefits and overhead costs, which calculates to \$76.46 (\$38.23 + \$38.23) and multiplied it by 15 hours, to determine the annual reporting costs per OPO/Histocompatibility Laboratory to be \$1,146.90 (\$76.46 x 15 hours). We calculated the total annual cost per OPO/Histocompatibility Laboratory of \$2,385.90, by adding the recordkeeping costs of \$1,239.00 plus the reporting costs of \$1,146.90. We estimated the total annual cost to be \$226,661 (\$2,385.90 times 95 OPO/Histocompatibility Laboratories).

¹ <https://www.bls.gov/oes/current/oes433031.htm>

² <https://www.bls.gov/oes/current/oes132011.htm>

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

<u>Annual cost to Medicare Contractors:</u>	
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).	\$370,500
<u>Annual cost to CMS:</u>	
Total CMS processing cost is from the HCRIS Budget:	\$44,000
<u>Total Federal Cost</u>	<u>\$414,500</u>

15. Changes To Burden

The change in burden is due to two factors:

1) the number of respondents decreased from 102 in 2017, to 95 in 2021. The decrease reflects the termination of 6 HLs and 1 OPO; and

2) the average cost per OPO/HL decreased from \$2,471.85 in 2017, to \$2,385.90 in 2021. The decrease was due to the estimated cost calculation in 2017, that used a mean hourly wage derived from BLS's 2015 Occupation Outlook Handbook, Category 13-2011 (accounting and audit professionals) with a mean hourly rate of \$27.46 versus 2021 that uses a mean hourly wage derived from BLS's 2019 Occupation Outlook Handbook, Category 13-2011 (accounting and audit professionals) with a mean hourly rate of \$38.23 and Category 43-3031 (bookkeeping, accounting and auditing clerks) with a mean hourly rate of \$20.65.

16. Publication and Tabulation Dates

CMS requires that each Medicare-certified provider submit an annual cost report to their contractor. The cost report contains provider information such as facility characteristics; utilization data; cost and charges by cost center, in total and for Medicare; Medicare settlement data; and financial statement data. The provider must submit the cost report in a standard (ASCII) ECR format. CMS maintains the cost report data in the Healthcare Cost Reporting Information System (HCRIS). Currently OMB No. 0938-0102, Form CMS-216-94 is not collected in HCRIS; however, effective April 1, 2021, this will change and this data will also be compiled in HCRIS. The HCRIS data supports CMS's reimbursement policymaking, congressional studies, legislative health care reimbursement initiatives, Medicare profit margin analysis, market basket weight updates, and public data requirements. CMS publishes the HCRIS dataset for public access and use at

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/>.

17. Expiration Date

CMS displays 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 is included in the instructions 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.