

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

A. Background

The Centers for Medicare and Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) review and approve this extension without change request of the currently published OMB No. 0938-0102, Form CMS-216-94, Organ Procurement Organization (OPO) / Histocompatibility Laboratory (HCL) Cost Report. OPOs and HCLs submit these cost reports annually to report costs and statistical data used by CMS to determine reasonable costs.

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 OPO and HCL to be paid the reasonable costs for its services related to kidney transplants. 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 the healthcare industry. Changes in these practices and systems are not required 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.

CMS requires the Form CMS-216-94 to determine an OPO's or an HCL's reasonable costs incurred in procuring, perfusing, testing, or transporting deceased donor organs for transplant into Medicare beneficiaries and reimbursement due to or from the provider. The Form CMS-216-94 cost report is filed by each OPO and HCL at the end of its fiscal year and a reconciliation and settlement of costs is determined for the difference between the total

reasonable costs incurred by the OPO and HCL minus the total interim payments received or receivable from the transplant hospitals.

2. Information Users

The primary function of the Form CMS-216-94 cost report is to establish an interim rate for OPOs and HCLs based on the average cost per organ acquired. The rates billed by the OPO or HCL are paid by the transplant centers and the transplant centers are reimbursed by Medicare for Medicare's share of the costs. Contractors use the Form CMS 216-94 to reconcile and settle Medicare's share of costs to OPOs and HCLs for providing kidney acquisition services to transplant centers.

OPOs and HCLs must follow Medicare's principles of reasonable cost reimbursement, which require that OPOs and HCLs 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 staff; operational data such as the number of organs procured locally and imported, the number of pre-transplant histocompatibility 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 HCL. 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) require that each OPO or HCL submit an annual cost report to their contractor in a standard American Standard Code for Information Interchange (ASCII) electronic cost report (ECR) format. An OPO or HCL submits the ECR file to contractors on a compact disk (CD) or flash drive, or through the CMS approved Medicare Cost Report E-filing (MCREF) portal, [URL: <https://mcref.cms.gov>]. The OPO / HCL cost report, CMS Pub. 15-2, chapter 33, includes instructions on page 33-503 for cost report submission.

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 Businesses

CMS requires all OPOs and HCLs, regardless of size, to complete the cost report. CMS collects the form as infrequently as possible (annually) and requires only those data items necessary to evaluate a provider's costs.

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 or HCL submit the cost report on an annual basis with the cost reporting period based on the OPO's or HCL's accounting period, which is generally 12 consecutive calendar months. A less frequent collection would impede the annual interim rate setting process and adversely affect provider payments.

7. Special Circumstances

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

8. Federal Register/Outside Consultation

The 60-day Federal Register notice was published on 06/27/2024 (89 FR 53625). No comments were received.

The 30-day Federal Register notice was published on 09/09/2024 (89 FR 73097).

9. Payments/Gifts to Respondents

CMS makes no payments or gifts to respondents for completion of this data collection. The Form CMS-216-94 collects data to determine accurate cost reimbursements to be made to an OPO or HCL. The cost reimbursements made to an OPO or HCL from CMS are for covered pre-transplant laboratory testing and procurement services for kidney transplants provided to Medicare beneficiaries. If an OPO or HCL 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 or HCL files the report timely there is no interruption of cost reimbursements.

10. Confidentiality

Confidentiality is not assured. MCRs 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/HCLs		95
Hours burden per OPO/HCL		45
Reporting	15	
Recordkeeping	<u>30</u>	
Total hours burden (95 facilities x 45 hours per facility)		<u>4,275</u>
Average cost per OPO/HCL		<u>\$2,739.90</u>
Total annual cost estimate (\$2,739.90 x 95 OPOs & HCLs)		<u>\$260,291</u>

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

Burden hours for each OPO/HCL 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/HCLs that file Form CMS-216-94 annually. We estimate an average burden per OPO/HCL of 45 hours (30 hours for recordkeeping and 15 hours for reporting). We calculated the annual burden hours as follows: 95 OPOs/HCLs times 45 hours per OPO/HCL equals 4,275 total annual burden hours. We recognize this average varies depending on the OPO/HCL’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) data in its May, 2023 Occupation Outlook Handbook, the mean hourly wage for Category 43-3031 (bookkeeping, accounting and auditing clerks) is \$23.84¹. We added 100% of the mean hourly wage to account for fringe benefits and overhead costs, which calculates to \$47.68 (\$23.84 + \$23.84) per hour and

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

multiplied it by 30 hours, to determine the annual recordkeeping costs per OPO/HCL to be \$1,430.40 (\$47.68 x 30 hours). The mean hourly wage for Category 13-2011 (accounting and audit professionals) is \$43.65². We added 100% of the mean hourly wage to account for fringe benefits and overhead costs, which calculates to \$87.30 (\$43.65 + \$43.65) and multiplied it by 15 hours, to determine the annual reporting costs per OPO/HCL to be \$1,309.50 (\$87.30 x 15 hours). We calculated the total annual cost per OPO/HCL of \$2,739.90 by adding the recordkeeping costs of \$1,430.40 plus the reporting costs of \$1,309.50. We estimated the total annual cost for all OPOs/HCLs to be \$260,291 (\$2,739.90 times 95 OPOs/HCLs).

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

<u>Annual cost to Medicare Contractors:</u>	
Annual cost incurred is related to processing information contained on the forms, particularly associated with achieving settlements. The contractor’s costs are based on estimates provided by the CMS Office of Financial Management.	\$270,630
<u>Annual cost to CMS:</u>	
Total CMS processing cost is from the HCRIS Budget:	<u>\$44,000</u>
<u>Total Federal Cost</u>	<u>\$314,630</u>

There are 50 OPOs and 45 HCLs, for a total of 95 providers. Burden to the Federal government consists of an estimated 35 hours for the contractor to accept, review, validate, and finalize each OPO cost report. We calculated the OPO annual burden hours as follows: 50 OPOs multiplied by 35 hours per OPO equals 1,750 annual OPO burden hours. The burden to the federal government also consists of an estimated 30 hours for the contractor to accept, review, validate, and finalize each HCL cost report. We calculated the HCL annual burden hours as follows: 45 HCLs multiplied by 30 hours per HCL equals 1,350 annual HCL burden hours. In total, the contractor burden hours for both OPOs and HCLs equals 3,100 hours (1,750 total OPO hours plus 1,350 total HCL hours). These estimates of burden hours were provided by the CMS Office of Financial Management (OFM). OFM estimated the costs to the Federal government using the BLS May, 2023 mean hourly wage for Category 13-2011 www.bls.gov/oes/current/oes132011.htm (accounting and audit

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

professionals) of \$43.65. OFM added 100% of the mean hourly wage to account for fringe benefits and overhead costs, resulting in an hourly rate of \$87.30 (\$43.65 plus \$43.65). We multiplied the hourly rate of \$87.30 by the total of 3,100 hours to determine the annual costs to the Federal government of \$270,630 plus the costs to process the cost reports through HCRIS of \$44,000 for a total Federal cost of \$314,630.

15. Changes to Burden

The change in burden is due to revised hourly rates based on data from the BLS May, 2023 Occupation Outlook Handbook (for categories 43-3031, bookkeeping, accounting, and auditing clerks, and 13-2011, accounting and audit professionals) that resulted in an increased cost per OPO/HCL of \$354.00 (from \$2,385.90 in 2021 (using May 2019 BLS data) to \$2,739.90 in 2024 (using May 2023 BLS data)). There were no changes to the number of OPOs/HCLs or to the total burden hours.

16. Publication/Tabulation Dates

CMS requires that each Medicare-certified provider submit an annual cost report to its contractor. The cost report contains provider information such as facility characteristics and utilization data 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). 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

On the first page of the data collection instrument, CMS displays the expiration date in the upper right corner and in the PRA disclosure statement at the bottom. CMS includes the PRA disclosure statement with the expiration date in instructions on page 33-3.

18. Certification Statement

There are no exceptions to the certification statement.