

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

A. Background

We are seeking reinstatement of a revised version of the CMS-576 form. We are also seeking reinstatement for the CMS-576A form. The CMS-576 and CMS-576A forms have been updated to a fillable .pdf format. In addition, multiple changes were made to the CMS-576 and CMS-576A forms. See the change crosswalks for each form for a detailed description of these changes.

Organizations seeking designation from CMS as a qualified and approved Organ Procurement Organization (OPO), as per §§ 371(a) and 1138 of the Social Security Act (“the Act”) must complete and submit the CMS-576 form, titled **“Organ Procurement Organization (OPO) Request for Designation As An OPO Under § 1138 Of The Social Security Act.”**

After designation as an OPO, the organization must sign a **“Health Insurance Benefits Agreement” (CMS-576A form)** in order to be reimbursed by Medicare for their services. The CMS-576A form requires the OPO “to maintain compliance with the requirements of titles XVIII and XIX of the Act, §1138 of the Act, applicable regulations including the conditions set forth in Part 486, subpart G, title 42 of the Code of Federal Regulations, those conditions of the Organ Procurement and Transplantation Network established under §372 of the Public Health Service Act that have been approved by the Secretary, and to report promptly to CMS. The information provided on this form serves as a basis for continuing the CMS and OPO agreements for participation in the Medicare and Medicaid programs and will allow CMS to continue to reimburse the 58 OPOs for their services.

The CMS-576A form requires OPOs to agree to comply with current CMS regulation. This includes an agreement to:

- Maintain compliance with the requirements of titles XVIII and XIX of the Act, §1138 of the Act, applicable regulations including the conditions set forth in Part 486, subpart G, title 42 of the Code of Federal Regulations, those conditions of the Organ Procurement and Transplantation Network established under §372 of the Public Health Service Act that have been approved by the Secretary, and to report promptly to CMS.
- File a cost report in accordance with 42 CFR 413.24(f) within 5 months after the end of each fiscal year;
- Permit CMS to designate an intermediary to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPO and to make a determination of reasonable cost based upon the cost report filed by the OPOs;
- Provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

- To pay to CMS amounts that have been paid by CMS to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the OPO; and,
- Not to charge any individual for items or services for which that individual is entitled to have payment made under §1881 of the Act.

B. Justification

1. Need and Legal Basis

Under section 1138(b) of the Act, effective April 1, 1988, Medicare payment for organ procurement costs may be made only if an organ procurement agency has been designated by the Secretary as the OPO for its service area. Consequently, all organizations wishing to receive Medicare and Medicaid reimbursement for organ procurement costs must have a signed agreement with CMS. 42 CFR 486.301-486.360 sets forth the Health and Safety Conditions of Participation that all OPOs must meet to participate in Medicare.

2. Information Users

The information from these forms will be used by CMS to continue to reimburse Medicare payment for organ procurement costs.

3. Improved Information Technology

The form contains statutory and regulatory criteria that must be met in order for an OPO to participate in the Medicare/Medicaid program and for inputting minimal information into the Online Survey Certification Reporting (OSCAR) System. The standardized format method provides for consistent reporting by State survey agencies. Recording this information would be no easier for surveyors using direct access equipment.

4. Duplication of Similar Information

This agreement form does not duplicate any other information collection system. The form addresses specific requirements of a new agreement based on a recertification survey. This form will be a basic deliverable and is the only one of its kind collected by CMS for OPOs.

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

5. Small Business

These information collection requirements do not affect small businesses.

6. Less Frequent Collection

Submission of the certification form is based on the publication date, May 31, 2006 of the OPO Conditions for Coverage requiring that CMS and the 56 OPOs have agreements to continue reimbursement for Medicare services performed.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register and Outside Consultation.

The 60-day Federal Register notice was published on June 13, 2023 (88 FR 38513). Two public comments were received. The comments were not related to the information collection. The response to the comments is in the response to comments document,

The 30-day Federal Register notice published on October 17, 2023 (88 FR 71570).

9. Payments or Gifts.

There are no payments or gifts associated with this collection.

10. Confidentiality

We do not pledge confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature associated with either the CMS-576 or CMS-576A forms.

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

12. Estimate of Burden (Total Hrs. & Wages)

A. Time and Cost Burden Associated With the CMS-576 Form

The CMS-576 form must be submitted in 2 circumstances. First, the CMS-576 form is completed by organizations seeking new designations as an OPO. However, at this time, CMS has placed a moratorium on the designation of new OPOs. This moratorium will continue for the foreseeable future.

Second, OPOs must submit the CMS-576 form when there is a CHOW or merger or consolidation on OPOs. We anticipate that 1 OPO merger/consolidation will occur each year.

We estimate that the time required to complete *each* CMS-576 form is approximately three eight-hour days or **24 hours**. We say this because the CMS-576 form requires the organization to provide detailed written responses to 12 questions. These written responses will require the respondent to perform research and obtain specific information and documentation in order complete their responses.

We estimate that the total annual time burden for the completion of all CMS-576 forms *across* OPOs with CHOWs or mergers or consolidations each year would be **24 hours**.

- 1 OPO per year x 24 hours per each form = 24 hours

We believe that the person at the OPO who would complete the CMS-576 form would have a management position equivalent to the U.S. Bureau of Labor Statistics job classification of Medical and Health Services Manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical and Health Services Manager is \$57.61.¹ This hourly wage, adjusted for the employers overhead and fringe benefits would be **\$115.22**.

We estimate that the cost burden for the completion of each CMS-576 form would be **\$2,765**.

- 24 hours x \$115.22 per hour = \$2,765.28

¹ See <https://www.bls.gov/oes/current/oes119111.htm>

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

We further estimate that the total annual cost burden for the completion of the CMS-576 form across all OPOs with CHOWs or mergers/consolidations each year would be **\$2,765**.

- 24 hours x \$115.22 per hour = \$2,765.28

B. Time and Cost Burden Associated with the CMS-576A Form

The CMS-576A form is completed by new OPOs that are entering the Medicare program for the first time. However, at this time, CMS has placed a moratorium on designation of new OPOs. This moratorium will continue for the foreseeable future.

The CMS-576A form must also be submitted by currently designated OPOs upon renewal of their OPO designation. An organization must renew their OPO designations every 4 years.

Currently there are 56 CMS-designated OPOs. The designation of these OPOs is renewed every 4 years. This would equate to approximately **14 OPOs** renewing their CMS OPO designation each year. Also, as stated above, we anticipate that 1 OPO merger/consolidation will occur each year. This would equate to approximately 15 CMS-576A forms being submitted per year.

- 56 OPOs divided by 4 years = 14 OPOs re-designations per year
- 14 re-designations + 1 merger/consolidation = 15 CMS-576A forms/year

There are a total of 16 responses (15 for CMS-576A and 1 for CMS-576).

We estimate that it would take each OPO approximately **30 minutes** to complete *each* CMS-576A form. We further estimate that the total annual time burden for the completion of *all* CMS-576A forms *across all* OPOs having their CMS-designation renewed each year would be **7.5 hours**.

- 15 CMS-576A forms/year x 0.5 hour per CMS-576A form = 7.5 hours

We believe that the person at the OPO who would complete the CMS-576A form would have a management position equivalent to the U.S. Bureau of Labor Statistics job classification of Medical and Health Services Manager. As stated above, the adjusted hourly wage for a Medical and Health Services Manager is **\$115.22**.

We estimate that the cost burden associated with the completion of *each* CMS-576A

Supporting Statement A

**CMS-576 – Organ Procurement Organization Request for Designation as
an OPO Under §1138 of the Social Security Act; *and*
CMS-576A - Health Insurance Benefits Agreement**

form would be \$58.

- 0.5 hours x \$115.22 = \$57.61

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

We further estimate that the total annual cost for completion of *all* CMS-576A forms *across all* OPOs having their CMS-designation renewed or a CHOW or merger/consolidation each year would be **\$864**.

C. Summary of Time and Costs Burdens

Time Burden Per Each Form:

Time burden per each CMS-576 form	24.0 hours
<u>Time burden per each CMS-576A form</u>	<u>0.5 hours</u>
TOTAL:	24.5 hours

Annual Time Burden Across all OPOs:

Annual time burden across all CMS-576 forms	24.0 hours
<u>Annual time burden across all CMS-576A forms</u>	<u>7.5 hours</u>
TOTAL:	31.5 hours

Cost Burden Per Each Form:

Cost burden per each CMS-576 form	\$2,765
<u>Cost burden per each CMS-576A form</u>	<u>\$ 58</u>
TOTAL:	\$2,823

Annual Cost Burden Across all OPOs:

Annual cost burden across all CMS-576 forms per year	\$2,765
<u>Annual cost burden across all CMS-576A forms per year</u>	<u>\$ 864</u>
TOTAL:	\$3,629

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

CMS is responsible for accepting the CMS-576 or CMS-576A forms (as applicable) submitted. Following a review of the file, an authorized CMS staff person will approve and sign the form.

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

We estimate that it would take a CMS reviewer **30 minutes** to review and file each CMS-576/CMS-576A form. We further estimate that the total annual time expended by CMS reviewers for this task would be **8 hours**.

- 30 min. x 1 CMS-576 form per year = 30 min.
- 30 min. x 15 CMS-576A forms per year = 450 min.
- 450 min. ÷ 60 min per hr. = 7.5 hours

- 0.5 hours + 7.5 hours = **8 hours**

We believe that the person at CMS who would perform this task would have the job title of “Reviewer.” We further believe that this person would be a GS-13, step 5. Such a person in the Pennsylvania region would have an annual salary of \$116,459, and which equates to an average hourly pay of \$55.99.²

We estimate that the cost associated with the receipt, review and filing of **each** CMS-576/CMS-576A form by CMS would be **\$27.99**

- \$55.99 divided by 60 min. per hour = \$0.933 per min
- \$0.933 per min. x 30 min. = \$27.99

We further estimate that the cost for the review of all CMS-576/CMS-576A forms submitted per year would be **\$447.92**.

- 8 hours x \$55.99 hours = \$447.92

² https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/PHL_h.pdf

Supporting Statement A

**CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and
CMS-576A - Health Insurance Benefits Agreement**

15. Changes in Burden/Program Changes

Task	Total Requested	Due to Adjustment in OPDIV/Office Estimate	Currently Approved
a. Annual number of responses for the CMS-576 form	1 response	+1 response	0 responses
b. Annual number of responses for CMS-576A form	15 responses	-14 responses	29 responses
c. Burden hours to complete each form CMS-576 form	24 hours	+24 hours	0 hours
d. Total annual burden hours across all CMS-576 forms	24 hours	+24 hours	0 hours
e. Burden hours to complete each form CMS-576A form	0.5 hours	+/-0 hours	0.5 hours
f. Total annual burden hours across all CMS-576A forms	7.5 hours	-21.5 hours	29 hours
g. Annual cost burden per each CMS-576 form	\$2,765	+\$2,765	\$0
h. Total annual cost burden across all CMS-576 forms	\$2,765	+\$2,765	\$0
i. Annual cost burden per each CMS- 576A form	\$58	+\$58	\$0
j. Total annual cost burden across all CMS-576A forms	\$864	+\$864	\$0
Total Annual Responses for Both Forms	16 Responses	-42 Responses	58 Responses
Total Annual Hour Burden for Both Forms	32 hours	3 hours	29 hours
Total Cost Burden for Both Forms	\$3,629	+\$3,629	\$0

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

As the above table shows, the time burden for the CMS-576A form has been reduced. The previous PRA package estimated the number of respondents for the CMS-576A form to be 58. It was further estimated that it would take 30 minutes to complete the CMS- 576A form and the total annual time burden across all respondents was estimated to be 29 hours.

In the current PRA package, we estimate that for the CMS-576A form, there are 56 respondents every 4 years or 15 respondents annually. We have further estimated that it would take 30 minutes to complete each CMS-576A form and 7.5 hours annually to complete all CMS-576A forms across all 15 respondents. We also estimate that the cost burden for completion of each CMS-576A form would be \$58 and the total annual cost burden across all respondents would be \$864.

Also, in the current PRA package, we estimate that for the CMS-576 form, there would be 1 respondent annually for OPOs that are undergoing a CHOW, merger or consolidation. We estimate that it would take approximately 24 hours to complete the CMS-576 form and that the total annual time burden across all respondents would also be 24 hours. We estimate that the cost burden for each CMS-576 form would be \$2,765 and the total annual cost burden across all respondents would also be \$2,765.

We believe that the burden stated in the previous PRA package was incorrectly calculated for the following reasons:

First, in the previous PRA package, the writer used the number of respondents for a 4- year period to calculate the time burden for the CMS-576A form. This made the time burden estimate in the previous PRA package too high.

We believe that the time burden should have been calculated using an annual number of respondents instead of the 4-year number of respondent. In calculating the time burden for the CMS-576A form, we estimated that there would be 56 respondents over a 4-year period.² To calculate the annual number of respondents, we divided the number of 56 respondents over 4 years by 4 to get a total of 14 respondents per year.

Second, the previous PRA package did not address any time and cost burdens related to the CMS-576 form. OPOs that are new and entering the Medicare program for the first time or undergoing a CHOW, merger or consolidation must submit a CMS-576 form. As there is currently a moratorium on new OPOs, we have estimated that there will be approximately one CHOW or merger/consolidation per year. This would equate to one CMS-576 form being submitted annually. We estimate that the cost burden for each CMS-576 form would

Supporting Statement A

CMS-576 – Organ Procurement Organization Request for Designation as an OPO Under §1138 of the Social Security Act; and CMS-576A - Health Insurance Benefits Agreement

be \$2,765 and the total annual cost burden per 1 respondent per year would be \$2,765. The addition of the time and cost burdens for the CMS-576 form has increased the total annual time burden by 24 hours and the total annual cost burden by \$2,765.

Third, the writer of the previous PRA package did not address the cost burden for the CMS-576A form. The addition of the cost burden for both the CMS-576 and CMS-576A forms has added a total annual cost burden of \$864.

The addition of the cost burdens for both the CMS-576 and CMS-576A forms have added an *existing* total annual cost burden of \$3,629 (\$2,765 +\$865). *It is important to note that this is not an increased cost burden but instead the first time that the cost burden has not previously been calculated for this ICR.*

16. Publication/Tabulation Date

There are no publication dates.

17. OMB Expiration Date

CMS will display expiration date on the form.

18. Certification Statement

There are no exceptions to the agreement statement.

C. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods associated with this collection.