

Supporting Statement for the Organ Procurement Organization's
"Health Insurance Benefits Agreement" CMS-576A
and Supporting Regulations CFR Part 486.301-486.348

A. Background

The form CMS-576A was previously approved for emergency clearance on June 23, 2006 and is now being resubmitted for a 3-year extension. The Medicare and Medicaid Programs; Final Conditions for Coverage for Organ Procurement Organizations (CMS-3064-F), which were published in the Federal Register (Vol. 71, No. 104) on May 31, 2006, require OPOs to sign agreements with the Centers for Medicare & Medicaid services (CMS) by August 1, 2006. The OPOs must have signed agreements with CMS to continue to be reimbursed and perform their services.

The form is an agreement with the facility, "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 agreement form requires OPOs to agree to comply with current CMS regulation. This includes:

- 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.
- To file a cost report in accordance with 42 CFR 413.24(f) within 5 months after the end of each fiscal year;
- To 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;
- To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;
- 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 486.301-486.348 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 new regulation and current period. The new agreement will be valid from August 1, 2006 and will end January 31, 2011. This form will be a basic deliverable and is the only one of its kind collected by CMS for OPOs.

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 42 CFR 486.301-486.348 requiring that CMS and the 58 OPOs have agreements to continue reimbursement for Medicare services performed.

7. Special Circumstances

There are no special circumstances associated with this collection. These requirements comply with all general information collection guidelines in 5 CFR 1320.6.

8. Federal Register and Outside Consultation

A 60-day Federal Register notice was published on 12/18/2009.

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 this form.

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

This form is completed by the OPO upon the renewal period of the CMS agreement for payment of services provided. The next time this form will need to be completed will be prior to the end of this agreement on January 31, 2011 and then respectively every 4 years. The time required to complete this form is approximately 2 hours.

Public Cost

The financial cost to the public rests solely with the time/salary element of OPO employees that complete the request for certification.

58	OPOs surveyed annually
<u>2</u>	hours per form
116	hours of respondent burden

116 hours x \$40.00 (professional annual wage for Federal calculations)= \$4640.

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

All costs associated with this form are incurred by the Federal Government in the normal course of business; therefore, there are no additional costs to the Federal Government.

15. Changes in Burden/Program Changes

There are no burden or program changes.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. OMB Expiration Date
CMS would like to display expiration date.

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.