



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Membership Forms for Organ Procurement and Transplantation Network, OMB No. 0915-0184 - Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network, OMB No. 0915-0184 – Revision

Abstract: The purpose of this ICR is to renew and revise membership application materials for the Organ Procurement and Transplantation Network (OPTN). Membership in the OPTN is determined by submission of application materials to OPTN demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, et seq., the OPTN final rule, 42 C.F.R. Part 121, OPTN Policies, and OPTN Management and Membership Policies. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b–8 requires that hospitals in which transplants are performed by members of OPTN abide by the rules and requirements of OPTN (that have been approved by the Secretary of HHS) as a condition of participation in Medicare and Medicaid.

A 60-day Federal Register notice was published in the **Federal Register** on August 20, 2025, Vol. 90, No. 159; pp. 40606-40608. HRSA received one comment from the President of the Association of Organ Procurement Organizations. The commenter expressed support for the necessity and utility of the proposed information collection, noting that it provides critical information to assess whether applicants meet OPTN membership requirements. The commenter also sought clarification on whether a written agreement is required between an Organ Procurement Organization (OPO) and its laboratory when the two entities operate under separate Centers for Medicare & Medicaid Services Certification Numbers.

HRSA Response: Laboratories are required to maintain written agreements with each OPO they serve, unless clinical urgency prevents such an agreement. These agreements delineate the respective responsibilities and expected procedures of the OPO and the laboratory to ensure compliance with OPTN membership standards and support the integrity of the organ

procurement process. This requirement is outlined in OPTN Bylaw C.2.D (OPO Affiliation), which specifies the elements that must be included in OPO-laboratory agreements.

Need and Proposed Use of the Information: The application materials are needed to ensure that all members and prospective members of OPTN submit evidence that they meet the required qualifications for membership. These materials provide OPTN with the information necessary to confirm and demonstrate that applicants meet OPTN membership application requirements and create a record of the application review process and resulting actions for consideration by the Secretary of HHS in the event an applicant subsequently appeals a membership rejection by OPTN.

Transplant hospitals, OPOs, transplant histocompatibility laboratories, medical/scientific and public organizations, business organizations, and individuals complete the appropriate application materials to meet or sustain requirements for OPTN membership. The revisions include the addition of a new data collection form for Information Security Contact Management, a required role for accessing the OPTN Computer System; additional updates to align the membership applications for histocompatibility laboratories and businesses with new requirements, as well as non-substantive changes to the existing OMB data collection forms to improve clarity and efficiency for both members and OPTN.

Likely Respondents: New and existing transplant hospitals, organ procurement organizations, histocompatibility laboratories, medical/scientific and public organizations, businesses, and individual members.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the

collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The estimated burden hours for this collection decreased by 2,062 hours from the currently approved ICR package. The decrease in burden can be attributed to members becoming more familiar with the revised 2022 application forms and from consultation with the appropriate OPTN committees to estimate the burden. Specifically, OPTN based its burden hour estimates on input from a representative sample of potential respondents. Accordingly, the estimates were developed through consultation with the Transplant Administrator, Histocompatibility, OPO, and Vascularized Composite Allograft committees. These committees reviewed the forms and instructions and determined the estimates through consensus during their meetings. In preparation for these discussions, some committee members also sought input from subject matter experts within their respective organizations.

Total Estimated Annualized Burden Hours:

Form #	Form Name	Number of Respondents ¹	Number of Responses per Respondent	Total Responses ²	Average Burden per Response (in hours)	Total Burden Hours
1	OPTN Membership Application for Transplant Hospitals and Programs	250	0.14	35	12.17	425.95
2	OPTN Membership Application for Kidney Transplant Programs	235	0.34	80	6.85	548.00
3	OPTN Membership Application for Liver Transplant Programs	144	0.46	67	5.79	387.93
4	OPTN Membership Application for Pancreas	135	0.22	30	5.79	173.70

Form #	Form Name	Number of Respondents ¹	Number of Responses per Respondent	Total Responses ²	Average Burden per Response (in hours)	Total Burden Hours
	Transplant Programs					
5	OPTN Membership Application for Heart Transplant Programs	155	0.25	39	16.82	655.98
6	OPTN Membership Application for Lung Transplant Programs	81	0.2	17	5.79	98.43
7	OPTN Membership Application for Islet Transplant Programs	22	0.09	2	8	16.00
8	OPTN Membership Application for Vascularized Composite Allograft Transplant Programs	48	0.27	13	23.79	309.27
9	OPTN Membership Application for Intestine Transplant Programs	19	0.16	4	11	44.00
10	OPTN Membership Application for Histocompatibility Laboratories	138	0.22	31	3.7	114.70
11	OPTN Membership Application for Organ Procurement Organizations	55	0.18	10	18.33	183.30
12	OPTN Medical/Scientific Membership Application	11	0.18	2	1.42	2.84

Form #	Form Name	Number of Respondents ¹	Number of Responses per Respondent	Total Responses ²	Average Burden per Response (in hours)	Total Burden Hours
13	OPTN Public Organization Membership Application	10	0.4	4	2	8.00
14	OPTN Business Membership Application	19	0.47	9	1.61	14.49
15	OPTN Individual Membership Application	16	0.625	10	1.53	15.30
16	OPTN Representative Form	499	0.27	135	0.43	58.05
17	Primary Data Coordinator Form	1,032	0.09	93	0.43	39.99
18	Primary Program Administrator Form	839	0.12	101	0.45	45.45
19	Additional Surgeon and Physician Request Form	839	0.37	311	0.84	261.24
20	HOPE Act Variance Request Form	56	0.02	2	0.5	1.00
21	Kidney Paired Donation Pilot Program contact update form	160	0.18	29	0.56	16.24
22	OPTN Membership Application Surgeon or Physician Log ³	0	0	0	0	0.00
23	Information Security Contact Management Form ⁴	462	1.46	675	0.19	128.25
	Total = 23 forms	5,225		1,699		3,548

Notes:

1. The numbers of respondents were updated with OPTN membership data as of December 2, 2024, and reflect the number of current OPTN members.

2. The numbers of total responses were calculated with data from January 1, 2023, through December 31, 2023. “Total Responses” are rounded to the nearest whole number.

3. The OPTN Membership Application Surgeon or Physician Log is an optional form. The information can also be submitted by the OPTN member using a different format. The burden of completing the application is included in the organ specific application form. Please note that if a form has 0.00 under average number of responses, this is an indicator that there were no submissions in calendar year 2023.

4. The Information Security Contact Management Form is new, added to the Membership ICR in 2025.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025-22330 Filed: 12/8/2025 8:45 am; Publication Date: 12/9/2025]