



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

Information Collection Request Title: 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 requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or by mail to the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443-9094.

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 the 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 the OPTN abide by the rules and requirements of, the OPTN (that have been approved by the Secretary of HHS) as a condition of participation in Medicare and Medicaid.

Need and Proposed Use of the Information: The application materials are needed to ensure that all members and prospective members of the OPTN submit evidence that they meet the required qualifications for membership. These materials provide the 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 the OPTN.

Transplant hospitals, organ procurement organizations, 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 organizations, 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 2,091 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, Organ Procurement Organization, 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 ³
1	OPTN Membership Application for Transplant Hospitals and Programs	250	0.14	35	12.17	426
2	OPTN Membership Application for Kidney Transplant Programs	235	0.34	80	6.85	548
3	OPTN Membership Application for Liver Transplant Programs	144	0.46	66	5.79	382
4	OPTN Membership Application for Pancreas Transplant Programs	135	0.22	30	5.79	174
5	OPTN Membership Application for Heart Transplant Programs	155	0.25	39	16.82	656
6	OPTN Membership Application for Lung Transplant Programs	81	0.20	16	5.79	93
7	OPTN Membership Application for Islet Transplant Programs	22	0.09	2	8	16
8	OPTN Membership Application for Vascularized Composite Allograft Transplant Programs	48	0.27	13	23.79	309
9	OPTN Membership Application for Intestine Transplant Programs	19	0.16	3	11	33
10	OPTN Membership Application for Histocompatibility Laboratories	138	0.22	30	3.7	111
11	OPTN Membership Application for Organ Procurement Organizations	55	0.18	10	18.33	183

Form	Form Name	Number of Respondents ¹	Number of Responses per Respondent	Total Responses ²	Average Burden per Response (in hours)	Total Burden Hours ³
12	OPTN Medical/Scientific Membership Application	11	0.18	2	1.42	3
13	OPTN Public Organization Membership Application	10	0.40	4	2	8
14	OPTN Business Membership Application	19	0.47	9	1.61	14
15	OPTN Individual Membership Application	16	0.625	10	1.53	15
16	OPTN Representative Form	499	0.27	135	0.43	58
17	Primary Data Coordinator Form	1,032	0.09	93	0.43	40
18	Primary Program Administrator Form	839	0.12	101	0.45	45
19	Additional Surgeon and Physician Request Form	839	0.37	310	0.84	260
20	HOPE Act Variance Request Form	56	0.02	1	0.50	1
21	Kidney Paired Donation Pilot Program contact update form	160	0.18	29	0.56	16
22	OPTN Membership Application Surgeon or Physician Log ⁴	0	0	0	0	0
23	Information Security Contact Management Form ⁵	462	1.46	675	0.19	128
		5,225		1,693		3,519

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 December 1, 2023, through December 31, 2023. "Total Responses" are rounded to the nearest whole number.
3. "Total Burden Hours" are rounded to the nearest whole number.
4. 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.

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

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director,

Executive Secretariat.

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