

Health Resources and Services Administration

Supporting Statement A

Membership Forms for Organ Procurement and Transplantation Network

OMB Control No. 0915-0184

Terms of Clearance: None.

A. Justification

1. Circumstances of Information Collection of Information Necessary

This is a request for OMB approval for a revision to the information collection activities for the application and membership requirements contained in the Final Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN), (Final Rule). This packet contains the membership application documents used to collect information required for membership in and designation of transplant programs by the OPTN. These documents are approved under OMB No. 0915-0184, and currently have an expiration date of December 31, 2025. The OPTN patient level forms associated with the registration, transplantation, and follow-up of transplant recipients are approved as a separate activity under OMB No. 0915-0157 and will not be updated at this time in this statement.

The National Organ Transplant Act of 1984, as amended, required the establishment of a unified transplant network to be operated by a private, non-profit organization under federal contract. 42 U.S.C. 273, et seq. Following task force recommendations and extensive public comment, a Final Rule (42 CFR Part 121) was published establishing a regulatory framework for the structure and operation of the OPTN. Policies of the OPTN are developed by professionals in the transplant community in an open environment that includes the public, including transplant patients and donor families.

Membership in the OPTN is determined by submission of application materials to the OPTN (not to HRSA) 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. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b-8 (section 1138) requires that hospitals in which transplants are performed be members of, and abide by, the rules and requirements of the OPTN as a condition of participation in Medicare and Medicaid for the hospital. Section 1138 contains a similar provision requiring organ procurement organizations (OPOs) to be members of, and abide by the rules and requirements of, the OPTN. In addition, hospitals wishing to obtain designation for specific (e.g., organ specific) transplant programs must submit applications to the OPTN.

Under Federal law, all U.S. transplant centers and organ procurement organizations must be members of the OPTN to receive any funds through Medicare. Other members of the OPTN include: histocompatibility laboratories involved in organ transplantation; relevant medical, scientific, and professional organizations; relevant voluntary health and patient advocacy organizations; and members of the general public with a particular interest in donation and/or transplantation.

The applications associated with this request provide the OPTN with information required to make determinations regarding compliance with membership and designated transplant program requirements established in OPTN policies and bylaws.

2. Purpose and Use of the Information

The application materials are needed to ensure that all members and prospective members of the OPTN submit, in an organized manner, verifiable evidence that they meet the required qualifications, and the OPTN provides written confirmation of their rights and obligations as members. These materials provide the OPTN with information used for the following purposes:

- Application requirements are met and the OPTN demonstrates that all qualified entities are accepted for membership in the OPTN and designation of transplant programs, and that only qualified entities are accepted for membership or designation.
- Evidence of non-qualification can be documented and specific remedial or alternative action can be requested from the member.
- Evidence of non-qualification is collected and documented so a record exists of the application review process and resulting actions for consideration by the Secretary of HHS if an applicant subsequently appeals the rejection.

3. Use of Improved Information Technology and Burden Reduction

The OPTN membership criteria, policies, and application materials are available online at <http://optn.transplant.hrsa.gov/>.

This current cycle of OPTN Membership Application revisions will coincide with the use of a web-based tool that assists users in filling out applications and submitting them

electronically. Approval signatures required for application submission are also captured electronically using the web-based application tool.

A static version of the OPTN Membership Application will still be available to users to print out and complete if they choose.

The final application, whether submitted via the web-based tool or the printed application, as well as supporting documentation, will be retained in the database and available in electronic format.

4. Efforts to Avoid Duplication and Use of Similar Information

The information and supporting documentation provided for application for membership (and transplant program designation) in the OPTN does not exist in any current database or system. There is no other source available that could be used to determine whether applicants meet the required membership and designation criteria or compliance with current OPTN policies and bylaws.

5. Impact on Small Businesses or Other Small Entities

This activity will not be collecting any data from small businesses. The data collected will not have any significant impact on small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

Organizations and institutions required by the Final Rule to be members of the OPTN and organizations interested in membership (and transplant program designation) in the OPTN must submit the application materials. Without this information, the OPTN cannot determine if the required criteria for membership and designation have been met or if members are compliant with OPTN bylaws and policies.

7. Consistency With the Guidelines in 5 CFR § 1320.5

This data collection is consistent with the guidelines under 5 CFR 1320.5(d)(2). It fully complies with this regulation.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

A 60-day Federal Register Notice was published in the *Federal Register* on August 20, 2025, Vol. 90, No. 234; pp. 40606-40608. A 30-day Federal Register Notice was published in the *Federal Register* on December 9, 2025, Vol. 90, No. 159; pp. 57077-57079.

HRSA received a comment from the President of the Association of Organ Procurement Organizations (AOPO). 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 Organ Procurement and Transplantation Network (OPTN) membership requirements.

The commenter also sought clarification on whether a written agreement is required between an OPO and its laboratory when the two entities operate under separate Centers for Medicare & Medicaid Services (CMS) 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.

HRSA appreciates all feedback and will continue to review and evaluate all data collection efforts forward in consultation with the OPTN members and the public.

Section 8B:

- The OPTN Charter became effective May 1, 2004. OPTN policies and bylaws are approved by the OPTN Board of Directors after being developed by OPTN Committees, OPTN members, and the general public through the OPTN public comment process. The OPTN policies and bylaws are amended periodically. The membership application forms incorporate applicable provisions of the OPTN bylaws and Charter.
- Currently, every transplant hospital program, organ procurement organization, and histocompatibility laboratory in the United States is an OPTN member. Membership means that their organizations are approved by the OPTN, that they abide by OPTN Obligations, and that they play an active role in forming the policies that govern the transplant community. Individuals from member organizations participate in the

decision making process through representation on committees and on the Board of Directors. Designation by transplant programs (e.g., kidney transplant programs) within transplant hospitals means that such programs can receive particular organs for transplantation.

- The following committees, comprised of transplant surgeons, transplant physicians, other transplant professionals, patients, organ procurement representatives, health policy analysts, and computer science specialists, have provided significant input to this process.

Board of Directors and Executive Committee

Membership and Professional Standards Committee

Additionally, membership staff reviewed the forms extensively. They integrated improvement suggestions along with incorporated revised elements from the current OPTN Management and Membership Policies into these forms.

9. Explanation of any Payment/Gift to Respondents

There is no remuneration to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information required by the OPTN to apply for membership can include personally identifiable information on individuals. All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). The application materials collect information on interested individuals seeking membership, organ procurement organizations, transplant hospitals, histocompatibility laboratories, and other organizations and institutions. All application materials received are stored electronically. Processes and protocols to maintain confidentiality are imposed and adhered to by the OPTN contractor.

Data collected under the OPTN contract is well protected by a number of security features. HRSA certifies that UNOS' security systems meet or exceed the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Department's Automated Information Systems Security Program Handbook. These security features include:

- Captured Accounts

All accounts utilized by organ procurement organizations, transplant centers, or histocompatibility laboratories are captured accounts. This means that, once an authorized individual gains access to the contractor's computer system, he/she cannot execute any commands except those for which they are authorized.

When he/she exits the contractor's software, he/she is automatically logged off the system. In addition to captured accounts, the user can gain access by an account/password combination. Individuals are only able to access the OPTN Computer System using credentials in conjunction with Multi-Factor Authentication.

- Limited Access

The operating environment is hosted in multi-regional co-location facilities in a hybrid cloud configuration. All personnel entering the co-located facilities must be explicitly approved for access by the OPTN contractor, who is the business owner of the physical equipment. For each co-location site, an ID badge is required to enter the main building. From that point, badge, fingerprint, and optical access are required to access the computing environment floor and the contractor's physical systems located in a locked cage.

- Encrypted Identifiers

All data are encrypted in motion. All tapes sent offsite are encrypted.

- Disaster Recovery

The contractor maintains an up-to-date Contingency Plan, which contains emergency operations, backup operations, recovery plans, and identifies roles and responsibilities of the recovery team to ensure continuous operations of the OPTN Computer System. Testing of the system occurs twice per year. As mentioned earlier, the contractor uses multi-regional co-location facilities in a resilient hybrid cloud configuration with load balancing, redundancy, and automated site-to-site failover of system workloads.

Application materials are also reviewed by OPTN Membership and Professional Standards Committee (MPSC) members, who are volunteer transplant professionals from the transplant community. The MPSC members sign confidentiality agreements, and the applications are reviewed under peer review and are subject to applicable peer review protections and laws.

11. Justification for Sensitive Questions

Questions of a sensitive nature that may exist involving membership application materials are generally related to personnel moving between transplant programs or concern regarding potential competition for transplant business within regions. All membership information is handled with care and attention is given to the need for confidentiality. All staff and reviewing parties exposed to application related information sign confidentiality agreements and will receive training on keeping privileged information confidential.

12. Estimates of Annualized Hour and Cost Burden

Estimates are based on the number of OPTN members in each membership category (i.e., transplant center, OPO, histocompatibility laboratory) as of December 2, 2024, form submission volumes from January 1, 2023, to December 31, 2023, and average burden per response estimated by either a survey of OPTN members or consultation with OPTN committees. This is the most current and reliable dataset available at this time for estimating burden. The number of members in each category will vary as new members are approved and/or members relinquish their OPTN membership when a member ceases activity related to organ transplantation.

As of December 2, 2024, there were 250 transplant centers, 55 OPOs, 138 histocompatibility laboratories, 155 transplant centers with heart program, 81 transplant centers with lung program, 235 transplant centers with kidney program, 144 transplant centers with liver program, 19 transplant centers with intestine program, 135 transplant centers with pancreas program, 22 transplant centers with pancreas islet program, 48 transplant centers with vascularized composite allograft (VCA) program, and 160 transplant centers participating in the Kidney Paired Donation Pilot program.

12A. 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	0.47	67	5.79	387.93
4	OPTN Membership Application for Pancreas Transplant	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
	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	0.21	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 (VCA) Transplant Programs	48	0.27	13	23.79	309.27
9	OPTN Membership Application for Intestine Transplant Programs	19	0.19	4	11	44.00
10	OPTN Membership Application for Histocompatibility Laboratories	138	0.22	31	3.7	114.70
11	OPTN Membership Application for OPOs	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	0.03	2	0.5	1.00
21	Kidney Paired Donation Pilot Program (KPDPP) 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			1,699		3,548.11 ⁵

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.
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 to complete is included into the organ specific application form. If a form has 0.00 under the 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 a new form, added to the Membership OMB package this year.
5. Total burden hours shows up as 3546 in ROCIS due to rounding.

The burden estimates are derived from consultation with the appropriate OPTN Committees, including the Transplant Administrators Committee (TAC), Histocompatibility Committee, OPO Committee, and the Vascularized Composite Allograft (VCA) Committee. These revised forms are streamlined, and in some instances, updated versions of previously approved OMB application documents. . There is no requirement for prescreening respondents in order to submit these application materials.

Planned frequency of information collection:

Respondents submit these forms on an as-needed basis. The frequency of information collection will be occasional.

12B.

Data collection and reporting is carried out at transplant programs, OPOs, and histocompatibility laboratories by a variety of personnel including transplant coordinators, nurses, laboratory technicians, medical record specialists, etc. The individual(s) responsible for filling out the data collection forms will vary among the respondents. Therefore, for purposes of estimating the cost to the respondents, the average hourly wage reflects the mean hourly wage of a Registered Nurses by the U.S. Department of Labor - Bureau of Labor Statistics.¹ The median hourly wage as of May 2023, for this position is \$ 45.00. Doubling the median hourly wage to account for overhead costs (e.g., benefits) brings the total hourly cost to \$90.00. The total estimated annualized burden costs are \$319,329.90 (see 12B).

¹ [Bureau](https://data.bls.gov/oesprofile/) of Labor Statistics. Occupational Employment and Wage Statistics Profiles – 29-1141 Registered Nurses. May 2024. <https://data.bls.gov/oesprofile/>.

12B. Estimated Annualized Burden Costs

Form #	Form Name	Total Burden Hours	Hourly Wage Rate (x2)	Total Cost
1	OPTN Membership Application for Transplant Hospitals and Programs	425.95	90.00	\$38,335.50
2	OPTN Membership Application for Kidney Transplant Programs	548	90.00	\$49,320.00
3	OPTN Membership Application for Liver Transplant Programs	387.93	90.00	\$34,913.70
4	OPTN Membership Application for Pancreas Transplant Programs	173.7	90.00	\$15,633.00
5	OPTN Membership Application for Heart Transplant Programs	655.98	90.00	\$59,038.20
6	OPTN Membership Application for Lung Transplant Programs	98.43	90.00	\$8,858.70
7	OPTN Membership Application for Islet Transplant Programs	16	90.00	\$1,440.00
8	OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	309.27	90.00	\$27,834.30
9	OPTN Membership Application for Intestine Transplant Programs	44	90.00	\$3,960.00
10	OPTN Membership Application for Histocompatibility Laboratories	114.7	90.00	\$10,323.00
11	OPTN Membership Application for OPOs	183.3	90.00	\$16,497.00
12	OPTN Medical/Scientific Membership Application	2.84	90.00	\$255.60
13	OPTN Public Organization Membership Application	8	90.00	\$720.00
14	OPTN Business Membership Application	14.49	90.00	\$1,304.10
15	OPTN Individual Membership Application	15.3	90.00	\$1,377.00
16	OPTN Representative Form	58.05	90.00	\$5,224.50
17	Primary Data Coordinator Form	39.99	90.00	\$3,599.10
18	Primary Program Administrator Form	45.45	90.00	\$4,090.50
19	Additional Surgeon and Physician Request Form	261.24	90.00	\$23,511.60

Form #	Form Name	Total Burden Hours	Hourly Wage Rate (x2)	Total Cost
20	HOPE Act Variance Request Form	1	90.00	\$90.00
21	Kidney Paired Donation Pilot Program (KPDPP) contact update form	16.24	90.00	\$1,461.60
22	OPTN Membership Application Surgeon or Physician Log	0	90.00	\$0.00
23	Information Security Contact Management Form	128.25	90.00	\$11,542.50
	Total = 23 forms	3,548.11		\$319,329.90

Planned frequency of information collection:

Frequency of information collection varies by form and data submission requirements are specified in [OPTN Policy 18](#) and [OPTN Management and Membership Policies](#).

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital

Costs

(a) Total Capital costs and start-up costs component:

The OPTN Computer System has been in place for many years; there is no capital or start-up costs for the basic network. The system is internet-based and, therefore, does not carry capital or start-up costs. Additionally, facilities are equipped with personal computers and Internet connections and should incur no costs.

(b) Total Operation and maintenance and purchase of services component:

Users have computers for their normal business activities and, therefore, will not need to change maintenance practices for this purpose. Some users have internal import/export systems that assist in the completion of these forms via their electronic medical record systems. These systems may require some cost to be developed, resulting in cost to respondents. Transplant centers are responsible for all proposed data collection modifications and are routinely responsible for most of the data collection volume. Most of the costs are attributable to respondents' staff time.

14. Annualized Cost to Federal Government

The annual cost to the Federal Government consists of those costs allocated to the data system under the HRSA contract for the OPTN. There also is the cost to the government to monitor the data system.

Listed below are costs from the OPTN Task #5 “Collect official OPTN data to support the operations of the OPTN” and OPTN Task #9 “The Contractor shall maintain and improve the OPTN website for dissemination of transplant information to the public and the transplant community”. These tasks do not include costs for development and maintenance of OPTN systems and maintaining OPTN security requirements.

A. OPTN contract (HRSA 250-2019-00001C)

Direct Cost

1. Direct Salaries and Wages	\$3,886,200
2. Fringe Benefits	\$1,921,300
3. Travel	0
4. Other Direct Costs	\$1,735,100
Total Direct Costs	\$7,542,600
5. Indirect Costs	\$1,018,300
TOTAL ESTIMATED COST	\$ 8,560,900*

* The OPTN is a cost-share contract with the contractor contributing 92.99 percent of this cost from patient registration fees. Thus, the estimated net cost to the Federal government for the performance of the contract tasks for data collection and dissemination in fiscal year 2024 is \$600,530.

15. Explanation for Program Changes or Adjustments

This renewal request is made with revisions to the expiring documents.

Changes to the forms are proposed to improve clarity and efficiency for both members and the OPTN. The redline versions of the forms include updates recently approved in the December 2024 Change Memo to remove outdated references to “bylaws” and to update OPTN business membership requirements. Additional redlines have been made to remove references to the OPTN contractor and to make requirements and instructions easier to understand. Revisions include the addition of a new data collection form for Information Security Contact Management, which is now a required role for access to the OPTN Computer System. Updates to membership applications for Histocompatibility Laboratories have been made to align with new OPTN membership requirements approved by the OPTN Board of Directors in December 2024. Updates to the Hope Act Variance Request Form have been made to align with the Revisions to

Human Immunodeficiency Virus (HIV) Policies approved by the OPTN Board of Directors in June 2025.

Proposed changes to the applications include the following:

- All forms have been updated to remove data collection fields for fax numbers and to remove reference to OPTN contractor staff contact information. Non-substantial changes have been made to language and formatting throughout the applications to improve clarity and efficiency.
- The addition of 1 new form – The Information Security Contact Management form.
 - o Members with access to the OPTN Computer System must now identify an information security contact, in accordance with OPTN Policy 3.1.D. There was not an existing form to designate individuals in the role and to collect information security contact information.
- The membership application for Histocompatibility Laboratories has been updated to align with new OPTN Histocompatibility Laboratory membership and key personnel requirements. The membership applications for transplant hospitals and organ procurement organizations have also been updated to account for laboratory testing services requirement changes.
- The Hope Act Variance Request Form has been updated to align with the new OPTN policies regarding HIV. Outdated hyperlinks have been updated and unnecessary data collection has been removed.

16. Plans for Tabulation, Publication, and Project Time Schedule

The OPTN accepts applications for membership throughout the year. There are no plans for analysis or publication of the OPTN application materials.

The OPTN membership application materials submitted by transplant hospitals, OPOs, and independent laboratories contain detailed organizational, operational, and compliance information, including personnel qualifications, facility capabilities, clinical protocols, and other sensitive data. Releasing these materials would risk disclosure of proprietary business information and confidential institutional practices.

17. Reasons(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested. The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This information collection fully complies with the guidelines set forth in 5 CFR 1320.9. The certifications are included in the package.