

**Health Resources and Services Administration
SUPPORTING STATEMENT**

Membership Forms for Organ Procurement and Transplantation Network

OMB Control No. 0915-0184

A. Justification

1. Circumstances of Information Collection

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). 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 August 31, 2023. 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. There will not be updates 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. The Department of Health and Human Services (HHS) contracted with the United Network for Organ Sharing (UNOS), a private corporation, to operate the OPTN, per 42 U.S.C. 274(a).

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. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b-8, 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. 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 a 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

The OPTN membership criteria, bylaws, and application materials are available online at <http://optn.transplant.hrsa.gov/>. Since the last submission, a web-based tool to assist members in filling out and submitting OPTN Membership Applications electronically, has been implemented. This current submission of OPTN Membership Application revisions will enhance the tool. 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. The unprocessed applications and supporting documentation submitted by members will be stored in member specific case records in the database. Finalized applications, which are packaged into one PDF file, will be stored in official OPTN records.

4. Efforts to Avoid Duplication

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. Involvement of Small Entities

The OPTN Business Membership Application will collect data from small businesses. The data collected will not have any significant impact on small business or other small entities.

6. Consequences if Information Collected 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(d)(2)

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

8. Consultation Outside the Agency

- A 60-day Federal Register Notice was published in the *Federal Register* on Thursday, August 25, 2022. 87 Fed. Reg. 52389-01. There were no public comments.
- 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 a voting OPTN member. Medical/scientific organizations, public organizations, and individuals are also able to apply to serve as OPTN voting members. 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

President, Jerry McCauley, MD, MPH, FACP
Thomas Jefferson University Hospital (Philadelphia, PA)
Email: jerry.mccauley@jefferson.edu

Membership and Professional Standards Committee

Chair, Zoe Stewart Lewis, MD PhD, MPH
NYU Langone Health (New York, NY)
Email: zoe.stewartlewis@nyumc.org

Additionally, membership staff reviewed the forms extensively. They integrated improvement suggestions and incorporated revised elements from the current OPTN bylaws into these forms.

UNOS may be contacted at the following address:

United Network for Organ Sharing (UNOS)
Contact Person: Maureen McBride
700 North 4th Street
Richmond, Virginia 23218
Phone: 804/782-4649

9. Remuneration of Respondents

There is no remuneration to respondents.

10. Assurance of Confidentiality

The information required by the OPTN to apply for membership can include personally identifiable information on individuals. 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 in accordance with National Institute of Standards in Technology Special Publication (NIST SP) 800-53, Security and Privacy Controls for Federal Information Systems Organizations, and OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a Federal Information Processing Standard (FIPS) 140-2 validated solution, as well as Information Security Continuous Monitoring (ISCM) in accordance with Federal Information Security Modernization Act (FISMA) and NIST SP 800-137. These security features include, but are not limited to:

- 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 or access any data except those for which they are authorized. When an authorized user exits the contractor's software, he/she is automatically logged off the system. Authorized individuals are only able to access the OPTN Computer System using user id and password in conjunction with Multi-Factor Authentication token.
- Limited Access
The OPTN Computer System 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 are the business owner of the physical equipment. In addition, for each co-location site, an ID badge is required to enter the main building and is issued by the operator of the co-location facility. From that point, badge, fingerprint, and optical access is required to access the operating environment floor, and the OPTN contractor's physical systems which are located in a locked cage.
- Encrypted Identifiers
The OPTN contractor employs FIPS 140-2 compliant encryption capabilities. The OPTN Computer System is a public-facing web application, and all users require appropriate credentials to remotely access the system using Transport Layer Security (TLS) 1.2 encrypted sessions. At each layer of the system including hosting, virtualization, and presentation, TLS 1.2 is used for securing data in transit and Advanced Encryption Standard (AES) 256 for securing data at rest. In addition, all system audit logs and system backups also utilize TLS and AES for encrypting data in transit and at rest, respectively.
- 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.

Destruction of information and/or data are performed in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

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. Questions of a Sensitive Nature

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 Burden

Annual burden estimates:

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Transplant administrator or designee	OPTN Membership Application for Transplant Hospitals and Programs	251	0.28	70	4	280
Transplant administrator or designee	OPTN Membership Application for Kidney Transplant Programs	234	0.56	131	8	1,048
Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Transplant administrator or designee	Primary Program Administrator Form	1,562	0.05	78	0.25	20
Transplant administrator, OPO Director, Lab Director, or designee	Primary Data Coordinator Form	1,760	0.03	53	0.13	7
Transplant administrator or designee	Additional Surgeon and Physician Request Form	1,562	0.08	125	1.17	147
Transplant administrator or designee	HOPE Act Variance Request Form ⁴	68	0	0	1.33	0
Transplant administrator or designee	Kidney Paired Donation Pilot Program (KPDPP) contact update Form	159	0.33	53	1.63	87
	Total = 22 forms	Total 8,153		Total 870		Total 5,699

1. The numbers of respondents were updated with the data as of December 31, 2021 and reflect changes in members' statuses.
2. There were no Islet applications processed in 2021, hence no responses.
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 built into the organ application data.
4. There were no HOPE Act Variance Request forms processed in 2021, hence no responses.

The burden estimates are derived from assessment surveys completed by the OPTN members . These revised forms are streamlined and in some instances rearrangements of previously approved OMB application documents. There is no formal pretest performed. There is no requirement for prescreening respondents in order to submit these application materials.

Planned frequency of information collection:

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Transplant administrator or designee	OPTN Membership Application for Liver Transplant Programs	143	0.59	84	13	1,092
Transplant administrator or designee	OPTN Membership Application for Pancreas Transplant Programs	120	0.26	31	13	403
Transplant administrator or designee	OPTN Membership Application for Heart Transplant Programs	145	0.34	49	20.5	1,005
Transplant administrator or designee	OPTN Membership Application for Lung Transplant Programs	72	0.64	46	9	414
Transplant administrator or designee	OPTN Membership Application for Islet Transplant Programs ²	19	0	0	5	0
Transplant administrator or designee	OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	43	0.98	42	15.5	651
Transplant administrator or designee	OPTN Membership Application for Intestine Transplant Programs	21	0.19	4	11	44
OPO Director or designee	OPTN Membership Application for Organ Procurement Organizations (OPOs)	57	0.14	8	40	320
Lab Director or designee	OPTN Membership Application for Histocompatibility Laboratories	141	0.21	30	2.5	75
Organization Director or Designee	OPTN Representative Form	1,760	0.02	35	0.25	9
Organization Director or Designee	OPTN Medical/Scientific Membership Application	10	0.3	3	0.75	2
Organization Director or Designee	OPTN Public Organization Membership Application	7	0.57	4	0.5	2
Organization Director or Designee	OPTN Business Membership Application	11	0.55	6	0.88	5
Organization Director or Designee	OPTN Individual Membership Application	8	0.88	7	0.25	2
Transplant administrator or designee	OPTN Membership Application Surgeon or Physician Log ³	0	0	0	0	0

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

13. Estimates of Annualized Cost Burden to Respondents

Member application information is collected and submitted by a wide range of individuals who represent various medical occupations. The Bureau of Labor Statistics most recent report *May 2021 National Industry-Specific Occupational Employment and Wage Estimates*, http://www.bls.gov/OES/current/naics4_622100.htm#11-0000, contains hourly wage data for hospital staff positions, which are typical organ transplantation occupations designated to collect information. Examples include:

- Program primary administrator mean hourly wage \$62.22
- Medical administrative assistant mean hourly wage \$19.45
- Registered nurse mean hourly wage \$40.88

The \$40.85 hourly rate used for administrative designees seemed defensible and appropriate.

Individual applicants are mainly employed professionals. Individual applicant wages are not easily identifiable. These applicants are in positions covered by the Federal minimum wage. The \$10.00 hourly rate used for individual applicants is slightly above the Federal minimum wage.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Administrative designees	5651	\$40.85	\$230,843.35
Individuals	2	\$10.00	\$20.00
Total	5653		\$230,863.35

There are no capital or start-up costs for application to the network.

14. Estimates of Annualized Cost to the Government

HRSA Division of Transplantation is responsible for coordinating the OPTN's preparation of OMB 0915-0184, monitoring and reviewing the OPTN membership application compliance with the National Organ Transplant Act and the OPTN Final Rule, reviewing and responding to public comments, and other activities related to submitting the OPTN membership application for OMB review. Costs associated with Federal staff conducting Pre-OMB approval activities are specified in Table 14-1.

Since this is a federal cost-sharing contract, it is based on cost-reimbursement with the OPTN contractor receiving no fee and being reimbursed only for an agreed-upon portion of its allowable costs. Costs related to membership application are 100% reimbursable. As such the cost given below under “Contractor Costs” represents the estimated cost charged for membership application work. It is an aggregate amount.

Contractor tasks include developing and maintaining membership application forms, providing application forms with instruction as requested, assisting applicants in completing the forms, securing application form completion, packaging and releasing application for peer review, presenting application as required in order to achieve final decision on the application and always being available as an application subject matter expert for anyone needing assistance.

Table 14-1 Cost to Federal Government

Tasks/Personnel	Annual Salary	% of Time	Cost
Pre-OMB Approval			
Government Personnel Costs:			
Public Health Analyst-GS13, Step 4 ¹	\$89,337	2%	\$1,786.74
Government Non-Personnel Costs:			
	NA	NA	
Contractor Costs:			
Estimated Membership Application Work Effort			\$347,361

15. Change in Burden

The burden estimates, reported in Section 12, are derived from Burden Surveys sent out by the OPTN Contractor to the OPTN members who have participated in this data collection activity. The survey is sent to 5-9 members per form. The survey includes the form and instructions and asks respondents to estimate the time and effort expended for (A) reviewing instructions, (B) searching and gathering information, (C) preparing required documentation and (D) completing the necessary fields of the application. The survey results are collected from the respondents and the Average Burden is calculated. Using annual data from the prior year, each form’s Total Burden Hours are calculated as follows; Number of Respondents multiplied by the Number of Responses per Respondent multiplied by the Average Burden per Response (in hours).

¹ Based on 2022 OPM Pay Schedule for Washington D.C. Metro area, <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/GS.pdf>.

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

Changes to the forms are proposed to make application requirements even clearer and organized, and thus less cumbersome for applicants to complete. Proposed revisions include changes to wording to make questions more consistent with the language of the OPTN bylaws. In addition, the applications have been revised so that the sequence of questions is parallel to that of the bylaws. Using the bylaws as a baseline, the revamped applications have been constructed in parallel order of the bylaws so that an applicant can have the application and bylaws side-by-side for easy reference. Additional proposed changes to the application include the following:

- The addition of 5 new forms – The Primary Program Administrator Form, the Primary Data Coordinator Form, the Additional Surgeon and Physician Request Form, the HOPE Act Variance Request Form, and the Kidney Paired Donation Pilot Program (KPDPP) contact update form.
 - The Primary Program Administrator and Primary Data Coordinator forms were data previously collected within the organ-specific program applications. However, the need to change the individuals designated in these roles is typically independent of and more frequent than a key personnel change or new program application, so separate forms were created to add more flexibility for applicants. Separating the forms from the organ-specific program applications allows for completion of one form to update the role across multiple programs, making the process less cumbersome. No form existed for collection of Primary Data Coordinator information from histocompatibility labs and OPOs; the new form is inclusive of these members.
 - The Additional Surgeon and Physician Request Form is a dedicated form for designation of transplant program surgeons and physicians credentialed by the transplant hospital to independently manage patient care, as outlined in the OPTN bylaws. This information was previously collected on the Certificate of Assessment form, however the frequency of the request warranted creation of the dedicated form. The new form allows for completion of one form to designate additional surgeons and physicians across multiple programs, making the process less cumbersome.
 - The HOPE Act Variance Request and Kidney Paired Donation Pilot Program (KPDPP) contact update forms already existed but were not OMB-approved. Since the Membership Team processes these forms as well as all of the membership applications, these two forms have been added to the Membership package.
- One form has been removed from the package – the Certificate of Assessment and Program Coverage Plan.
 - The Certificate of Assessment and Program Coverage Plan were placed back in the organ-specific applications. Since this information is needed for every key personnel change request, it was more helpful to applicants to include this information right in the form. The specific information requested is tailored to

each organ program's requirements, where applicable. Instructions on how to complete these portions of the applications have been included within the forms. New questions were added to the Program Coverage Plan to ensure all bylaw requirements are addressed by the form.

- The Membership Application Surgeon or Physician Log was modified to better reflect the format of information required by the OPTN bylaws, organized in a way that makes more sense for both the member and the Membership Team's process in preparing and reviewing applications.
- The previous membership applications had several places for those named or otherwise involved in the application to sign. The new application requests only one signature (the "OPTN Representative") who must verify all of the information contained in the application is accurate. Any document requiring a signature outside of the form itself is indicated in the instructions within the form.
- The pediatric component portion of the Kidney, Liver, Heart, Lung, and Pancreas program applications has been modified to remove duplicative information. The pediatric portion now only includes the pediatric-specific requirements and refers back to the main program sections for demonstration of a proposed primary meeting main program requirements. Instructions have been included within the pediatric component sections to direct users on what to complete based on their need.
- The living donor component portion of the Liver application was reformatted to align with the living donor component portion of the Kidney application, and to be inclusive of all bylaw requirements and pathways for living donor liver components. The living donor component portion of the Kidney application now includes bylaw requirements for Kidney Paired Donation.
- The Histocompatibility Laboratories Application was reformatted to align with the formatting of other Membership applications. Part 5: Laboratory Coverage Plan was updated to include bylaw requirements for coverage plans.
- The Vascularized Composite Allograft (VCA) Transplant program application now includes information collection that reflects approved requirements for VCA Uterus programs and living donor components.
- Changes have been made to the Islet Transplant program application to clearly distinguish current OPTN bylaw requirements from not yet implemented requirements.
- Across several applications, questions that do not require supporting documentation or specific information were changed to a "Check to attest to the following" format.

16. Plans for Analysis and Timetable of Key Activities

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

17. Exemption for Display of Expiration Date

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

18. Certifications

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