

# Supporting Statement A

## OPTN Application Form

### OMB Control No. 0915-0184 - Revision

**Terms of Clearance: None**

#### **A. Justification**

##### **1. Circumstances Making the 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 April 30, 2014. 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 with an expiration date of March 31, 2015, 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. The United Network for Organ Sharing (UNOS), a private corporation, operates the OPTN under contract with the Department of Health and Human Services (HHS).

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 (as approved by the Secretary of the HHS) of the OPTN as a condition of participation in Medicare and Medicaid for the hospital.

Section 1138 contains a similar provision for the organ procurement organizations (OPOs) and makes membership in the OPTN and compliance with its operating rules and requirements (that have been approved by the Secretary), including those relating to data collection, mandatory for all transplant hospitals and OPOs. 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: independent 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.

Under the regulations and the OPTN Contract, the OPTN has responsibility for developing policies and procedures. The OPTN final rule establishes a mechanism for the Secretary to approve or modify OPTN policies, if needed. The OPTN final rule did not alter the role of the OPTN in using its judgment regarding appropriate medical criteria for organ allocation or in the development of policies recommended for members; however, the final rule creates an enforceable standard that OPTN member transplant programs must meet to qualify to receive organs for transplantation.

## **2. Purpose and Use of Information Collection**

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, bylaws, and application materials are available online at <http://optn.transplant.hrsa.gov/>. An executable electronic form of each application is available for completion and printing, but the application submission considered as final and

retained in the database as the final product is on paper, as is much of the supporting documentation, letters of commitment, contracts, and required signatures. All final product records are saved and available in electronic format.

An electronic web based application system is in development. These applications are purposely designed to easily adapt for electronic execution and submission.

**4. Efforts to Identify 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 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 business 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. Special Circumstances Relating to the Guidelines of 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**

- Federal Register, Volume 78 Issue 224 (Wednesday, November 20, 2013)

Pages 69695-69696

A 60-day Federal Register Notice was published in the *Federal Register* on November 20, 2013, vol. 78, No. 224; pp.69695-96 (refer to hyperlink). There were no public comments.

The OPTN Charter and Bylaws were developed by the Executive and Membership and Professional Standards Committees, with input from other OPTN Committees, OPTN members, and the general public through the contractor's public comment process. The OPTN Charter and Bylaws became effective May 1, 2004 and 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 transplant programs are approved by the OPTN, 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, 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, [Kenneth Andreoni, MD](#)  
Shands Hospital/University of Florida  
Email: [Kenneth.Andreoni@surgery.ufl.edu](mailto:Kenneth.Andreoni@surgery.ufl.edu)

Membership and Professional Standards Committee

Chairman, Carl Berg, MD  
Duke University Hospital  
Email: [carl.berg@duke.edu](mailto:carl.berg@duke.edu)

Additionally, membership staff employed by the OPTN contractor reviewed the forms extensively. They integrated received comments and improvement suggestions along with incorporated revised elements from the current bylaws into these forms.

The current contractor, UNOS, may be contacted at the following address:

United Network for Organ Sharing (UNOS)  
Contact Person: Sally Aungier  
700 North 4<sup>th</sup> Street  
Richmond, Virginia 23218  
Phone: 804/782-4800  
Fax: 804/782-4896

Specific UNOS staff that provided considerable input on the development of the application forms and/or Charter and Bylaws includes the following:

David Kappus, Membership Director  
Jacqueline O’Keefe, Assistant Membership Director  
Sally Aungier, Senior Membership Standards Advisor

**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. 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 permanently stored electronically. Processes and protocols to maintain documents confidentiality are imposed and adhered to by the OPTN contractor.

Data collected under the OPTN contract is well protected by a number of the contractor's 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.
- Limited Access  
There is extremely limited physical access to the contractor's computer system. The UNOS' premises are personally monitored 24 hours a day, 7 days a week. No one can enter the computer area without authorization. There is an electronic pass-card-activated system in place. Card readers have been placed at the main building entrances, elevators, data center and all telecommunication access panels. In addition, for the data center and telecommunications panels, a pin code must be provided in addition to the pass card.
- Encrypted Identifiers  
All data are encrypted in motion. All tapes sent offsite are encrypted.
- Disaster Recovery  
The contractor maintains an up-to-date Continuity of Operations Plan (COOP), which contains emergency operations, backup operations, and recovery plans to ensure continuous operation of the system's facility. Testing of this system occurs every other week. The contractor uses a third-party co-location site for its COOP.

## 11. Justification for Sensitive Questions

Questions of a sensitive nature which 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 application related information sign confidentiality agreements and will receive training on keeping privileged information confidential.

## 12. Estimates of Annualized Hour and Cost Burden

### 12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondents	Avg Hour Burden per Response	Total Burden Hours
Transplant Administrator or designee	A New Transplant Member / Program Application-General	8	1	8	64
Transplant Administrator or designee	B Kidney (KI) Designated Program Application	94	2	4	752
Transplant Administrator or designee	B Liver (LI) Designated Program Application	73	2	4	584
Transplant Administrator or designee	B Pancreas (PA) Designated Program Application	56	2	4	448
Transplant Administrator or designee	B Heart (HR) Designated Program Application	43	2	4	344
Transplant Administrator or designee	B Lung (LU) Designated Program Application	50	2	4	400
Transplant Administrator or designee	B Islet (PI) Designated Program Application	4	2	3	24
Transplant Administrator or designee	B Living Donor (LD) Recovery Program Application	46	2	3	276
OPO Director or designee	C OPO New Program Application Application	0	1	4	0
Lab Director or designee	D Histocompatibility Lab Application	2	2	4	16
Transplant Administrator or designee	E Change in Transplant Program Key Personnel	377	2	4	3,016
Lab Director or designee	F Change in Histocompatibility Lab Director	8	1	2	16
OPO Director or designee	G Change in OPO Key Personnel	10	1	1	10
Organizational Director or designee	H Medical Scientific Org Application	16	1	2	32
Organizational Director or designee	I Public Org Application	6	1	2	12

Business administrator or designee	J Business Member Application	3	1	2	6
Individual	K Individual Member Application	6	1	1	6
<b>Totals</b>	<b>17 forms</b>	<b>802</b>			<b>6,046</b>

The burden estimates are derived from prior experience reported by applicants. 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.

**12B. Annualized cost to respondents for the hour burdens for collections of information**

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 2013 National Industry-Specific Occupational Employment and Wage Estimates*, [http://www.bls.gov/OES/current/naics4\\_622100.htm#11-0000](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 \$52.02
- Medical administrative assistant      mean hourly wage \$14.74
- Registered nurse                      mean hourly wage \$30.70

The \$32.50 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
13.	Administrative designees	6,040	\$32.50	\$196,300.00
	Individuals	6	\$10.00	\$ 60.00
	Total	6,046		\$196,360.00

**Estimates of other Total Annual Cost Burden to Respondents or Record keepers/Capital Costs**

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

**14. Annualized Cost to Federal Government**

HRSA Division of Transplantation is responsible for coordinating the OPTN contractor’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.

The United Network for Organ Sharing (UNOS) is the contractor selected to operate the Organ OPTN. Since this is a cost-sharing contract it is based on cost-reimbursement with the 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 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 <sup>1</sup>	\$98,916	2%	\$1978.00
Government Non-Personnel Costs:			
	NA	NA	
Contractor Costs:			
Estimated Membership Application Work Effort			\$345,000

**15. Explanation for Program Changes or Adjustments**

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

The paperwork burden is decreasing. The application forms were revised to make them more respondent friendly. Specifically, the revised application is rewritten in plain language and

<sup>1</sup> Based on 2014 OPM Pay Schedule for Washington D.C. Metro area, <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/DCB.pdf>.



asks only for information relevant to current membership requirements.

It is estimated that the number of respondents will increase significantly. First, there will be more individual forms to fill out. However, each individual form will be shorter and easier to complete – therefore, the burden will not be increased. In addition, some membership application activities are being formalized with the development of two new data collection forms:

- F Change in Histocompatibility Lab Director; and
- G Change in OPO Key Personnel

Although two new data forms have been developed, membership obligations have always required that this information be formally reported to the OPTN; as such, the new forms referenced above will not create a new burden for OPTN members.

**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.

**17. Reason(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.