

Organ Procurement and Transplantation Network
(42 CFR Part 121)
SUPPORTING STATEMENT

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 of the Organ Procurement and Transplantation Network. This Information Collection Request (ICR) contains the membership application and associated requirements for the OPTN, approved under OMB No. 0915-0184, with an expiration date of December 31, 2007. The OPTN patient level forms associated with the registration, transplantation, and follow-up of transplant recipients are approved as a **completely separate activity** under OMB No. 0915-0157.

The National Organ Transplant Act of 1984 required the establishment of a unified transplant network to be operated by a private, non-profit organization under federal contract. Following task force recommendations and extensive public comment, a Final Rule (42 U.S.C. 274) was published establishing a regulatory framework for the structure and operation of the Organ Procurement and Transplantation Network (OPTN). Policies of the OPTN are developed by professionals in the transplant community in an open environment that includes the public, particularly 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. 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, including those relating to data collection, mandatory for all transplant programs and OPOs.

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 application attached to this request provides the OPTN with information required to make determinations regarding membership and compliance with OPTN policies and bylaws.

Under the regulations, the OPTN has responsibility for developing policies, subject to the approval of the Secretary, governing the allocation of organs and other major aspects of the OPTN, and for developing procedures and issuances governing the day-to-day operation of the OPTN that do not require approval by the Secretary for implementation. The 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.

HRSA did not develop the application materials; applicants do not apply to HRSA for membership; and HRSA does not make membership determinations for the OPTN.

The OPTN/UNOS Membership and Professional Standards Committee considers, under confidential medical peer review, each application for membership, designation as a transplant program, and changes in key personnel. Recommendations regarding such applications for membership and designated transplant program status are forwarded to the Board of Directors for final action.

HRSA is requesting OMB approval for the revisions to the OPTN membership application requirements contained in the final rule for the CFR citations listed below. There are no major substantive changes to the applications for the current transplant programs; however, there have been several changes to the bylaws with which programs certify compliance and submission of a coverage plan. A separate attachment lists the revisions to the application requirements. Programs now must certify the following:

- 1) Development of protocols regarding the recovery of organs from donation after death;
- 2) Submission of a Program Coverage Plan documenting 100% medical and surgical coverage by individuals certified by the institution to provide transplant service for the program; and,
- 2) Certification of peer review of all physicians and surgeons for compliance with OPTN/UNOS bylaws.

Disclosure:

42 CFR 121.6(c) requires that transplant programs provide criteria for organ acceptance to their OPOs.

Reporting:

42 CFR 121.3(c) specifies application requirements for OPOs, hospitals, and other organizations, institutions or individuals with an ongoing interest in the field of organ transplantation.

42 CFR 121.3(c)(4) provides applicants that apply for membership in the OPTN and are rejected the opportunity to appeal to the Secretary of HHS. Appeals should be submitted in writing within 30 days of rejection of the application. The Secretary may deny the appeal or direct the OPTN to take action consistent with the Secretary's response to the appeal.

42 CFR 121.6(c) requires that transplant programs provide criteria for organ acceptance to the OPTN.

42 CFR 121.7(b)(4) requires that transplant programs that refuse an organ, provide the reason for refusal to the OPTN and the OPO.

42 CFR 121.7(e) requires that if a transplant program transplants an organ into a medically suitable candidate to prevent wastage of the organ, it must notify the OPTN and the OPO of the circumstances justifying such action.

42 CFR 121.9(b) specifies application requirements for transplant programs applying to be designated as eligible to receive organs for transplantation.

42 CFR 121.9(d) provides applicants that apply to be a designated transplant program and are rejected for designation the opportunity to appeal to the Secretary of HHS. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may deny the appeal or direct the OPTN to take action consistent with the Secretary's response to the appeal.

2. Purpose and Use of Information

The application materials are needed to ensure that all members of the OPTN meet the required qualifications and agree and certify compliance with OPTN bylaws and policies. These materials provide the OPTN with information used for the following purposes:

- \$ Application requirements are needed to ensure that all qualified entities are accepted for membership in the OPTN, and that only qualified entities are accepted for membership.
- \$ Requirements for documenting reasons for refusing an organ and for reporting instances in which an organ is transplanted to prevent wastage are needed to ensure proper control of the distribution of organs.
- \$ Information maintained by and collected from the OPOs and transplant programs is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to prepare a legislatively-mandated report each year on information on the comparative costs and patient outcomes at each transplant center affiliated with the OPTN. These data also will be used by HRSA and other departmental agencies in developing policies relating to transplantation, and by HRSA to assess the effectiveness of the Nation's organ donation, procurement, and transplantation system, and to analyze variances for all organs and present results to the Department.
- \$ Reports, based in part on the information obtained from the OPOs and transplant programs, are provided by the OPTN to HRSA. These reports are used by HRSA in preparing the annual report on the scientific and clinical status of organ transplantation

required by Section 376 of the Public Health Service Act. Additionally, these data are used by HRSA's Division of Transplantation to monitor the contracts for the OPTN and to carry out other statutory responsibilities. Information from these reports is made available to the public and is routinely used for public information purposes. The public may obtain these data, including transplant center- and OPO-specific performance data, on the web at www.ustransplant.org.

3. Use of Improved Information Technology

The OPTN membership criteria, bylaws, and application materials are available online at www.optn.org. The application submission is on paper, as much of the supporting documentation, letters of commitment, contracts, required signatures and records are not all available in electronic format.

4. Efforts to Identify Duplication

The information and supporting documentation provided for application for membership 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 criteria or compliance with current policies and bylaws.

5. Involvement of 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 if Information Collected Less Frequently

Organizations and institutions required by the Final Rule to be members of the OPTN and organizations interested in membership in the OPTN must submit the application materials. Without this information, the OPTN cannot determine if the required criteria for membership 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).

8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8(d) was published in the Federal Register on May 18, 2007 (72 FR 28060). No comments were received from the public.

The OPTN Charter and By-Laws 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 By-Laws became effective May 1, 2004. The membership application forms incorporate

applicable provisions of the OPTN By-Laws 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 certified by UNOS, 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.

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, Timothy L. Pruett, M.D.
University of Virginia Health Sciences Center
Email: tp2w@virginia.edu

Membership and Professional Standards Committee
Chairman, Robert S. D. Higgins, M.D., MSHA
Rush University Medical Center
Email: robert_higgins@rush.edu

Membership Services staff employed by the OPTN contractor reviewed the forms extensively. They integrated comments from the Membership and Professional Standards Committee members and incorporated 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 4th 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 By-Laws include the following:

Karl McCleary, Director of Policy, Membership, and Regional Administration
David Kappus, Assistant Director, Membership and Policy
Douglas Heiney, Director of Administration and Management

HHS Office of General Counsel

Emily Marcus Levine, Attorney
301/443-6659

9. Remuneration of Respondents

There is no remuneration to respondents.

10. Assurances of Confidentiality

The information required by the OPTN to apply for membership does not include personally identifiable information on individuals. The application materials collect information on organ procurement organizations, transplant hospitals, histocompatibility laboratories, and other organizations and institutions.

All transplant registration and follow-up data collected on individuals under the separate OMB control number 0915-0157 are subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected under the OPTN contract also are 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. Questions of a Sensitive Nature

There are no questions of a sensitive nature in the application materials for membership in the OPTN.

12. Estimates of Annualized Hour Burden

The following is an estimate of the annual reporting and record keeping burden.

Section	Activity	Number of Respondents	Responses per Respondent	Total Responses	Hours per response	Total hour burden	Wage rate	Total hour cost
121.3(c)	OPTN membership and application requirements for OPOs, hospitals, histocompatibility labs	40	1	40	45	1,800	\$23.00	\$41,400
121.3	Application for Non-Institutional Members	20	1	20	10	200	\$23.00	4,600
121.3(c)(4)	Appeal for OPTN membership	2	1	2	3	6	\$23.00	138
121.6(c) (Reporting)	Submitting criteria for organ acceptance	900	1	900	0.5	450	\$23.00	10,350
121.6(c) Disclosure	Sending criteria to OPOs	900	1	900	0.5	450	\$23.00	10,350
121.7(b)(4)	Reasons for Refusal	900	38	34,200	0.5	17,100	\$23.00	393,300
121.7(e)	Transplant to prevent organ wastage	260	1.5	390	0.5	195	\$23.00	4,485
121.9(b)	Designated transplant program requirements	10	1	10	5	50	\$23.00	1,150
121.3	Personnel Change Application	324	1	324	10	3,240	\$23.00	74,520
121.9(d)	Appeal for designation	2	1	2	6	12	\$23.00	276
	Total	974		39,704		23,503		\$461,449

The final rule has reporting and disclosure requirements as follows.

Basis for Burden Estimates:

42 CFR 121.3(c) specifies application requirements for OPOs, hospitals, and other organizations, institutions or individuals with an ongoing interest in the field of organ

transplantation. Applications will be submitted only once. It is expected that the number of new applications annually for OPOs, histocompatibility laboratories, and hospitals will average 45. Each program will complete (1) application that is estimated to take 40 hours, based on information from programs that reviewed the forms, for a total of 1,800 burden hours annually.

42 CFR 121.3 specifies application requirements for non-institutional members, such as organizations that are not OPOs or transplant hospitals, to apply for membership in the OPTN. Medical/scientific organizations, businesses, and individuals with an interest in the field of organ donation and transplantation may apply for public membership in the OPTN. Approximately 20 applications are submitted annually, with an estimated burden of 10 hours per response, for a total of 200 burden hours annually.

42 CFR 121.3(c)(4): It is estimated the preparation in drafting and finalizing the response letter would take 2.0 hours. Copying and mailing of supporting documentation of the individual's or institution's interest in organ donation or transplantation would take an additional 1.0 hour, for a total of 6 burden hours.

42 CFR 121.6(c) (Reporting) Submitting criteria for organ acceptance requires that transplant programs provide their criteria for organ acceptance to the OPTN. There are 900 transplant programs, each of which submit criteria to the OPTN. Programs are expected to report once a year which will require 30 minutes (0.5 hours). The total burden hours for the 900 programs is expected to be 450 hours.

42 CFR 121.6(c) (Disclosure) Sending criteria to OPOs requires that transplant programs send their criteria for organ acceptance to their OPOs. There are 900 transplant programs, each of which will submit criteria to their OPO. Programs will send criteria to their OPOs once a year which is estimated to take 30 minutes (0.5 hours). The total burden hours for the 900 programs is expected to be 450 hours.

42 CFR 121.7(b)(4) Reasons for Refusal requires transplant programs that refuse an organ to document the reason for refusal. The 900 transplant programs will, on average, report this information 38 times a year. Reporting will take 30 minutes (0.5 hours) for a total of 17,100 hours annually.

42 CFR 121.7(e) Transplant to prevent organ wastage requires that an OPTN member which transplants an organ into a medically-suitable candidate to prevent wastage of the organ must notify the OPTN of the circumstances justifying such action. If there is a positive crossmatch or a medical reason an organ is used for someone other than the person for whom it was intended, the transplant center writes a letter to the OPTN explaining the circumstances. The average number of transplants conducted from 2000-2002 at the same center where the expected recipient differed from the actual was 414 per year or an average of the 260 centers of 1.5 times a year. The estimated time to prepare the letter and add the appropriate codes where appropriate is 30 minutes (0.5 hours) so the total burden for transplant to prevent organ wastage would be 195 hours.

42 CFR 121.9(b) specifies application requirements for transplant programs applying to be designated as eligible to receive organs for transplantation. They apply by providing evidence that they meet one of the following three criteria: (a) they are Medicare and Medicaid-approved transplant programs, (b) they are an organ transplant program which meets several standards specified in the regulation, or (c) they are a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital. Application under (a) or (c) requires only that they provide copies of relevant approvals or agreements. An application under (b) requires that transplant programs provide more extensive evidence that they meet the specified standards; this is expected to take 5 hours. It is expected that there will be an average of 10 new transplant programs applying each year, for a total annual burden of 50 hours.

42 CFR 121.3 The Personnel Change Application provides documentation to the OPTN for changes in personnel. Approximately 324 current members use this form to submit information

on changes in transplant personnel, with a burden of 10 hours per response, for a total of 3,240 burden hours annually.

42 CFR 121.9(d): It is estimated the preparation of drafting and finalizing the response letter would take 4.0 hours. Copying and mailing of supporting documentation of the individual's or institution's interest in organ donation or transplantation would take an additional 2.0 hours, for a total of 12 burden hours.

Basis for Hour Costs:

The individual(s) responsible for completing the application materials will vary by type of organization. Therefore, for purposes of estimating the cost to the respondents, an average hourly wage for a data coordinator has been used.

121.3(b)(2)	1,800 hours x \$23.00/hour = \$ 41,400
121.3	200 hours x \$23.00/hour = \$ 4,600
121.3(b)(4)	6 hours x \$23.00/hour = \$ 138
121.6(c) (Reporting)	450 hours x \$23.00/hour = \$ 10,350
121.6(c) (Disclosure)	450 hours x \$23.00/hour = \$ 10,350
121.7(b)(4)	17,100 hours x \$23.00/hour = \$393,300
121.7(e)	195 hours x \$23.00/hour = \$ 4,485
121.9(b)	50 hours x \$23.00/hour = \$ 1,150
121.3	3,240 hours x \$23.00/hour = \$ 74,520
121.9(d)	12 hours x \$23.00/hour = \$ 276

13. Estimates of Annualized Cost Burden to Respondents

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

14. Estimates of Annualized Cost to the Government

There are no costs to the Government for this activity.

15. Changes in Burden

Currently, there are 19,459 total burden hours in the OMB inventory. HRSA is requesting an increase of 4,044 burden hours for a total estimate of 23,503 burden hours. This change in burden is the result a **program adjustment** due to an increase in the estimate from 30 to 40 respondents applying for membership and a slight increase in the hours per response from 40 to 45. UNOS has determined that the previous burden estimates for these sections were too low, and has provided an increased adjustment in the time to more accurately reflect the burden for these sections.

There is also an increase in the number of total responses, from 36,457 total responses to 39,704 responses. This increase of 3,247 responses is because this ICR separated two activities from the overall application. Previously, the Personnel Change Application and Application for Non-

Institutional Members were included in the overall application process. With the ICRAS submission system it was possible to pull these out and report on them as separate activities. These forms were included and approved in the previous clearance, but were not identified as separate from the general application.

Finally, the appeal for OPTN membership (section 121.3(b)(4)) and appeal for designation (section 121.9(d)) are included for the first time in the total estimate of burden hours. HRSA currently has a separate OMB control number that serves as a placeholder for burden for this process, should it ever be required. The Final Rule required a process for appealing decisions denying membership in the OPTN, and HRSA has a small burden approved for this process. To date, no entities have appealed the membership decisions and no burden has actually been utilized, but the burden is on the OMB inventory. Following approval of this request, the small separate burden for this process under OMB control number 0915-0286 will be discontinued.

16. Time Schedule, Publication and Analysis Plans

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.