

**Organ Procurement and Transplantation Network**  
(42 CFR Part 121.3(b)(4) and 121.9(d))

SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

This is a request for OMB approval for the extension of information collection requirements to comply with any burden associated with filing appeals to the Secretary under the Final Rule of the Organ Procurement and Transplantation Network (OPTN). The operation of the OPTN necessitates certain record keeping and reporting requirements in order to perform the functions related to organ transplantation under contract to the Department of Health and Human Services (HHS). OMB requires review and approval of record keeping and reporting requirements associated with the Final Rule related to Secretarial review and appeals. Specifically, OMB noted that not all requirements related to the rulemaking requirements covered under OMB No. 0915-0184 were included in the docket and requested that Health Resources and Services Administration (HRSA) identify and submit these requirements for PRA review and public comment. The currently approved OMB collection (OMB No. 0915-0286) will expire on June 30, 2007.

All other requirements related to record keeping and reporting contained in the Final Rule are approved under OMB No. 0915-0184. The worksheets associated with this collection are approved under OMB No. 0915-0157.

The National Organ Transplant Act of 1984, as amended, requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN) (42 USC 274). The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour system to facilitate matching organs with individuals included on the list.

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 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). In effect, section 1138 has made 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. Organizations must apply for membership in the OPTN, and applicants rejected for membership may appeal to the Secretary. To be a designated transplant program, transplant programs must apply to the OPTN, and those applicants rejected for designation may appeal to the Secretary. The burden for the application requirements for OPTN membership and for application for designation is approved under OMB 0915-0184.

This request is for approval of record keeping and reporting requirements associated with the processes for filing appeals in the case where applicants are rejected for membership or designation.

**42 CFR 121.3(b)(4)** requires that applicants rejected for membership in the OPTN may appeal to the Secretary of HHS.

**42 CFR 121.9(d)** requires that applicants rejected for designation may appeal to the Secretary.

## 2. Purpose and Use of Information

**42 CFR 121.3(b)(4)** provides applicants that apply for membership in the OPTN and are rejected 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.

The requirements for applying for OPTN membership are minimal. All OPOs and transplant hospitals participating in the Medicare and Medicaid programs are to be admitted as members to the OPTN. For organizations, institutions, and individuals which are neither an OPO nor a transplant center, an interest in the field of organ donation or transplantation must be demonstrated. Upon receiving a rejection notice from the OPTN for membership, the applicant would need to forward a written appeal to the Secretary stating the reasons the applicant is seeking a review by the Secretary on the membership decision, along with any relevant documentation that was before the OPTN at the time of the OPTN's rejection.

**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.

Upon receiving a rejection notice from the OPTN for designation, the applicant would need to forward a written appeal to the Secretary stating the reasons the applicant is seeking a review by the Secretary on the designation decision, along with any relevant documentation that was before the OPTN at the time of the OPTN's rejection.

## 3. Use of Improved Information Technology

To expedite the appeals process, an appeal can be made to the Secretary electronically via e-mail transmission. However, the applicant also must submit to the Secretary a signed copy of the appeal with the required accompanying supporting documentation.

## 4. Efforts to Identify Duplication

This activity is unique to the OPTN requirements as stated in the Final Rule and does not duplicate other data collection activities.

5. Involvement of Small Entities

This project 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

Data must be provided to the OPTN on a case-by-case basis, i.e., as each applicant applies and is rejected for membership with the OPTN or applies and is rejected to be a designated transplant program.

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 March 12, 2007, (72 FR 11029-11030). No comments were received.

Sources of Consultation Outside of the Agency

HHS Office of General Counsel  
Emily Marcus Levine, Attorney  
301/443-6659

United Network for Organ Sharing (UNOS)  
Contact Person: Sally Aungier  
700 North 4<sup>th</sup> Street  
Richmond, Virginia 23218  
804/782-4812

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurances of Confidentiality

No personal identifiers will be collected. This request is for record keeping and reporting requirements associates with processes for filing appeals when applicants are rejected for membership or designation.

11. Questions of a Sensitive Nature

There are no sensitive questions for this activity. This request is for record keeping and reporting requirements associated with processes for filing appeals when applicants are rejected for membership or designation.

12. Estimates of Annualized Hour Burden

To date, no appeals have been filed; and any forthcoming burden requirements for this process will be minimal.

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

Section	Number of Respondents	Responses per Respondent	Total Responses	Hours per response	Total hour burden	Wage rate	Total hour cost
121.3(b)(4) Appeal for OPTN membership	2	1	2	3	6	\$23.00	\$138.00
121.9(d) Appeal for designation	2	1	2	6	12	\$23.00	\$276.00
Total	4		4		18		\$414.00

Basis for Burden Estimates:

**42 CFR 121.3(b)(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 hours.

**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.

Basis for Hour Costs:

Total hour costs are estimated at \$414.00 (18 hours x \$23.00/hour).

### 13. Estimates of Annualized Cost Burden to Respondents

#### Capital costs and start-up costs:

The OPTN system has been in place for many years; there are no capital or start-up costs for the basic network. The UNet<sup>SM</sup> system is internet-based and, therefore, does not carry capital or start-up costs. Additionally, most facilities are equipped with PCs and Internet connections and should incur no costs.

#### Operation and maintenance costs:

There are no operation and maintenance costs for this activity.

### 14. Estimates of Annualized Cost to the Government

There are no costs to the Government.

### 15. Changes in Burden

The estimated burden requirements for the extension remain unchanged.

### 16. Time Schedule, Publication and Analysis Plans

Publication of information and data is not planned. If there are any requests for appeals, the information will be reviewed for internal administrative purposes.

### 17. Exemption for Display of Expiration Date

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.