



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Agency Information Collection Activities: Submission to OMB for Review and Approval;**

#### **Public Comment Request; Process Data for Organ Procurement and Transplantation**

#### **Network, OMB No. 0906-xxxx - New**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-9094.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx - New

*Abstract:* Section 372 of the Public Health Service Act requires that the Secretary of HHS, by awards, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under oversight of the Health Resources and Services Administration (HRSA), operates the U.S. organ procurement and transplantation system. The Secretary/HRSA may direct the collection of data in accordance with the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits data elements for collection to OMB for official federal approval.

A 60-day Notice was published in the Federal Register, 89 Fed. Reg. 87592 (November 4, 2024). The 60-day Federal Register Notice publication generated 53 public comments, with the majority submitted by transplant centers. The public comments offered input to improve the quality and clarity of the data forms, including by standardizing the definitions of the terminology used on the forms and making additions and revisions to response options and categories. The respondents also provided feedback on the perceived burden of data collection. They suggested submitting these data on a quarterly, semi-annual, or annual basis, rather than in real-time, to reduce the time and staffing required to report the data to HRSA. Nearly all respondents who commented on the use of automated collection techniques supported efforts to automate data collection in these forms, including coordinating updates with Electronic Health Record vendors and other software developers. Others recommended a phased-in approach with a pilot testing period.

HRSA conducted a thorough review of all the feedback provided by the public during the 60-day publication period. HRSA will incorporate many public comments into the new forms, including through the removal and/or revision of current fields (for example, removing HIV status and Primary Insurance from the Ventilated Patient Form) and explore options to automate the data collection process and incorporate education and training for data respondents to reduce burden and ensure data quality and accuracy. Other suggestions may be further reviewed for consideration in future OMB packages or non-substantive change memos.

*Need and Proposed Use of the Information:* HRSA and the OPTN Board of Directors use data to develop transplant, procurement, and allocation policies; to determine whether institutional members are complying with policy; to determine member-specific performance; to ensure patient safety; and to fulfill the requirements of the OPTN Final Rule. The regulatory authority in 42 CFR 121.11 of the OPTN Final Rule allows the Secretary of HHS to prescribe data collection. This regulatory authority requires the OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, and members of the public for evaluation, research, patient information, and other purposes.

This is a request to expand the current OPTN data collection, approved under OMB No. 0915-0157. HRSA is submitting this new data collection, separate from OMB No. 0915-0157, since it includes new forms developed in response to an HHS Secretarial Data Directive that are not in use by OPTN. HRSA believes that separating these data collections will minimize confusion, increase clarity among OPTN members and stakeholders, and enable more direct feedback on the new forms. Both data collections include time-sensitive, life-critical data on transplant candidates and potential organ donor patients, the organ matching process, histocompatibility results, organ labeling and packaging, as well as pre- and post-transplantation data on recipients and donors. The OPTN collects these specific data elements from transplant centers.

HRSA and the OPTN use this information to (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation, procurement, and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; and (5) perform transplantation-related public health surveillance, including the possible transmission of donor disease.

This new collection consists of three new data forms as directed by the Secretary of HHS, which were developed to improve the OPTN organ matching and allocation process and OPTN member compliance with OPTN requirements:

- One new form will collect data from the point of referral of a patient to an Organ Procurement Organization (OPO) for potential deceased organ donation. These data will provide a more objective source of information on procurement practices, the management of potential donor patients, and how these practices inform the supply of deceased donor organs available for transplant. These data may also help improve the monitoring of OPO performance, facilitating quality assurance and performance improvement efforts to reduce variation in the quality of care that OPOs provide to prospective donors and donor families.
- Two new forms will expand data collection from the point of patient registration, referral, and evaluation at transplant centers. These data will enable the collection of data from the point of referral. Pre-waitlisting data will provide insight into who is referred and by whom, who is evaluated, and who is placed on the organ transplantation waiting list. These data will also facilitate the OPTN's ability to address disparities in processes of care, improve access to organ transplantation, and assess overall system performance.

Once this collection is approved, HRSA will cease use of the Death Notification Registration and the Deceased Donor Death Referral forms that are included within the existing

OMB-approved Data System for Organ Procurement and Transplantation Network OMB No. 0915-0157. HRSA decided to decommission these forms to avoid unnecessary burden and redundancy in the data collected by this package and the existing OMB data collection instrument.

*Likely Respondents:* Transplant Centers, OPOs, and Histocompatibility Laboratories.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The total estimated burden hours for this Secretary of HHS directed data collection is 252,216.84 hours.

**Total Estimated Annualized Burden - Hours**

Form #	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
1	Pre-Waitlist Transplant Referral Form	248	1,164.68	288,840.64	0.35	101,094.22
2	Pre-Waitlist Transplant Evaluation Form	248	594.22	147,366.56	0.40	58,946.62
3	Ventilated Patient Form	56	3,292.00	184,352.00	0.47	86,645.44.00
	Total	552		620,559.20		246,686.28

The average burden estimates for both new pre-waitlist forms are based on the 2023 burden estimates of existing OMB-approved Transplant Candidate Registration forms, which were approved under OMB control number 0915-0157. The average burden estimate of the Ventilated Patient Form is based on the average burden estimate of the 2024 burden estimates of the existing OMB-approved Death Notification Registration form, with an additional 0.08 hour per collected form burden to reflect an increase in total data fields. The burden estimate for the Ventilated Patient Form has decreased since the publication of the 60-day Federal Register Notice due to the removal of measures from the form in response to public comment.

**Maria G. Button,**

*Director, Executive Secretariat.*

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