Health Resources and Services Administration (HRSA)

SUPPORTING STATEMENT

Data System for Organ Procurement and

Transplantation Network (OPTN)

OMB Control No. 0906-xxxx - New

Terms of Clearance: None

A. Justification

1. Circumstances of Information Collection of Information Necessary

This is a request under the Paperwork Reduction Act (PRA) 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 a Department of Health and Human Services (HHS) Secretarial Data Directive. 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. For proposed OPTN policy changes, there is a public comment separate from the PRA process (see https://optn.transplant.hrsa.gov/policies-bylaws/public-comment). However, these new forms developed in response to an HHS Secretarial Data Directive are not policy-related, so the separate OPTN public comment period does not apply.

Section 372 of the Public Health Service (PHS) Act (42 USC § 274) requires that the Secretary, by grants, contracts, or cooperative agreements, provide for the establishment and operation of an OPTN, which on behalf of the Health Resources and Services Administration (HRSA), oversees the U.S. donation and transplantation system. The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants. It also maintains a computerized system, available 24 hours a day, for matching donor organs with transplant candidates on the waiting list. In accordance with Section 372(b)(2)(I) of the PHS Act (42 U.S.C. § 274 (b)(2)(I)), the OPTN must also collect, analyze, and publish data concerning organ donation and transplants.

The regulatory authority in 42 CFR 121.11 of the OPTN Final Rule allows the HHS Secretary 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.

2. Purpose and Use of the Information

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 HHS Secretary, 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 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 donors and their 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 the 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. This decision was made to avoid unnecessary burden and redundancy in the data collected by this package and the existing OMB data collection instrument.

The practical utility of the data collection is further enhanced by requirements that the OPTN database must be made available, consistent with applicable laws, for use by the OPTN members, the Scientific Registry of Transplant Recipients (SRTR), HHS, and, in many circumstances, others for evaluation, research, patient information, and other important purposes.

This disclosure is governed by the OPTN Final Rule (42 C.F.R. §121.11). HRSA has also published a Privacy Act System of Records Notice #09-15-0055 (Notification of an altered system of records was published in the Federal Register on August 1, 2022 (87 Fed. Reg. 46967), describing routine uses of the data. OPTN must report a variety of data to the Secretary of HHS, including data on performance by organ and status category, program-specific data, OPO-specific data, data by program size, and data aggregated by organ procurement area, OPTN region, States, the Nation as a whole, and other geographic areas (42 CFR § 121.8(c)(3)). Much of this data is made available to OPTN members and the general public.

3. Use of Improved Information Technology and Burden Reduction

Since October 25, 1999, the OPTN contractor has provided an electronic data collection system to reduce the paperwork burden on the respondents (transplant programs, OPOs, and histocompatibility labs) and to minimize any intrusion into the immediate processes of organ procurement and transplantation. For example, transplant candidates can be registered, and critical data regarding candidates can be updated through direct electronic access by transplant programs and OPOs using the central OPTN contractor's computer software, which maintains the national waiting list.

The contract requires the OPTN contractor to develop direct electronic data submission. All major reports issued under the OPTN contract are required to be available in electronic format.

Weekly and monthly, the OPTN provides data to the Centers for Medicare & Medicaid Services (CMS) to support policy development and data analysis.

4. Efforts to Avoid Duplication and Use of Similar Information

The OPTN data system is the only data collection effort in the U.S. encompassing living and deceased organ donors, transplant candidates, and transplant recipients for all organ transplants (i.e., kidney, heart, heart-lung, lung, liver, pancreas, kidney-pancreas, intestines, vascularized composite allografts). CMS, as a condition of approval for Medicare reimbursement for a heart transplant, requires that heart transplant programs seeking to receive approval submit specified data on all their heart transplant recipients (not just those paid for by Medicare) to CMS. The data required by CMS is included in the OPTN data requirements.

OPTN data also contributes to the United States Renal Data System (USRDS). Thus, two major additional data collection requirements are satisfied by using this data system.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The frequency of collection varies by form and data submission requirements, as specified in OPTN Policy 18. Timeliness in organ transplantation is critical because organ function will begin to deteriorate once cardiac and respiratory functions cease. For example, suppose donor organs are not listed within the OPTN Donor Data and Matching System as soon as they become

available. In that case, organ function will be compromised, and patient and graft survival rates will be lower. The timeliness of post-transplant data collection is essential for advancing organ transplantation policy and science.

7. Consistency With the Guidelines in 5 CFR § 1320.5

The current method of collecting race and ethnicity data does not align with SPD-15 guidelines. Efforts to update the OPTN systems to support the revised categories have been limited by time constraints related to the expiration of the OPTN contract at the end of the year, budgetary constraints, and challenges with budgeting and workload. Implementation of these changes is anticipated during the next contract cycle.

The OPTN data collection has various expectations of timely submission as detailed in OPTN Policy 18. The Form Documentation, associated with each form, includes Section 3 Frequency of reporting on the form. The frequency is based on the burden. The pertinent OPTN Policy is available at: URL.https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

A 60-day Federal Register Notice, "**Process Data for Organ Procurement and Transplantation Network,**" was published in the *Federal Register* on Monday, November 4, 2024. 89 Fed. Reg. 87592. HRSA received 53 distinct comments.

HRSA has conducted a thorough review of all the feedback provided by the public during the 60-day publication period. The information collection instruments include a redline version showing the changes between the draft forms associated with the 60-Day FRN and the version submitted to OMB for final review. This comprehensive review, which underscores our commitment to considering all suggestions, ensured that every input was given the attention it deserved.

The majority of form field recommendations pertained to the proposed **Ventilated Patient Form (VPF).** Suggested changes included the removal of "HIV status" and "Primary Insurance" as fields due to patient privacy concerns and difficulties implementing the collection of that information. HRSA concurs with those comments and has removed those fields from the VPF. HRSA will also remove the "Gender" field from the VPF to avoid conflict with Executive Order 14168 and OMB guidance on implementation.

Regarding the **Pre-Waitlist Referral and Evaluation forms**, some commenters expressed concern that they would be penalized for incomplete follow-ups on patient referrals who do not proceed to evaluation or listing. HRSA understands that there will be more referrals than evaluations and will work with transplant centers to ensure accurate data collection and reporting.

Additionally, HRSA received a number of suggested revisions to the "Referral Status/Referral Closure Reason" and "Selection Committee Decision" fields, including additional answer options and the ability to select more than one answer option. HRSA will work with the OPTN Committees and the Board of Directors to review these and other suggested revisions and will

consider them in future OMB packages and non-substantive change memos. During the implementation phase of this Data Directive, HRSA will work with the OPTN to provide training and technical assistance to OPTN members who will report these data to HRSA.

Themes across all three forms included:

1) **The need for standardization and clarification of form field definitions and instructions,** since certain terms (for example, "cause of death") could be interpreted differently across OPOs and Transplant Centers. During the implementation phase of this Data Directive, HRSA will work with the OPTN to provide training and technical assistance to OPTN members who will report these data to HRSA
2) Several commenters expressed concern over the **administrative burden** entailed in completing these forms and offered valuable feedback on how to reduce the burden, including by submitting these data on a quarterly, semi-annual, or annual basis, versus in real time, and coordinating with Electronic Health Records vendors and other software developers prior to implementing the data collection. Still others recommended that HRSA pursue a phased implementation approach with a pilot testing period. HRSA appreciates this feedback and will explore options to further automate the data collection process. HRSA also notes that OPOs and Transplant Centers already collect many of these fields to fulfill other data reporting requirements, and to enact facility-level quality assurance and quality improvement efforts.
3) Some commenters recommended the **addition of data fields** (for example, the CMS Certification Number for the dialysis facility or hospital system that referred the patient) and answer options (for example, additional reasons for "Referral Closure") to the forms. HRSA appreciates these suggestions and will consider them for inclusion in future OMB packages and non-substantive change memos.
4) Finally, while the majority of commenters expressed neutral or positive sentiments regarding the "necessity and utility" of the forms, some commenters questioned the rationale behind collecting these data. For example, one respondent expressed concern over the "lack of specifics surrounding how the proposed data collection will be utilized or accessed." HRSA notes that collecting data about the processes OPOs use to interact with patients who may donate organs, as well as the processes transplant centers use for listing an end-stage organ disease patient for transplant, will yield information that increases transparency into the effectiveness, safety, and efficiency of the national procurement and transplant system. As with other OPTN data, these data will be made available under appropriate research and use agreements to facilities, researchers, patients, and the public.

Section 8B:

The design and development of the OPTN computer system have involved consultation not only with the providers of the data, but also with OPTN expert Committees, the OPTN Board of Directors (BOD), the SRTR contractor, and federal government entities, as well as members of the transplant community. The most significant collaborative efforts to date have been with other HHS agencies, including CMS, NIH, CDC, and the Office of the Secretary.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

Data collected under the OPTN contract is well protected by a number of security features. HRSA certifies that OPTN contractor' 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 compliant 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 OPOs, 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 their user ID and password in conjunction with a 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 is the business owner of the physical equipment. Additionally, for each co-location site, an ID badge is required to enter the main building, which is issued by the operator of the co-location facility. From that point, a badge, fingerprint, and optical access are required to access the operating environment floor and the OPTN contractor's physical systems, which are located in a locked cage with limited access.

- 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 to secure data in transit, and Advanced Encryption Standard (AES) 256 is used to secure data at rest. Additionally, all system audit logs and system backups 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 utilizes multi-regional co-location facilities in a resilient hybrid cloud configuration, featuring load balancing, redundancy, and automated site-to-site failover of system workloads.

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

- Paper Documents
  No paper data collection instruments are maintained.

- Confidentiality Agreements
  All of the contractor's personnel have signed confidentiality agreements stating they will not reveal sensitive data to unauthorized individuals. The contractor has agreed to comply with the requirements of the Privacy Act as it pertains to the data in this system. A Privacy Act System of Records has been established for this project (09-15-0055). Notification of a modified system of records was published in the Federal Register on August 1, 2022 (87 FR 46967).

11. Justification for Sensitive Questions

Social security numbers (SSNs) are requested as needed. The SSN is a unique identifier that facilitates data categorization and analysis. Without the SSN, data on commonly named recipients could be erroneously attributed and, therefore, could adversely affect analyses and conclusions about organ disposition and transplant outcomes. The SSN is requested once a candidate or living donor is added to the OPTN Computer System database and then displayed on all forms except the Deceased Donor Registration form.

It is also essential to ask questions regarding race and ethnicity to compare the scientific and clinical outcomes among various minority populations, to evaluate access to transplantation, and to understand donation rates among various ethnic and racial populations.

12. Estimates of Annualized Hour and Cost Burden

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.

12A. 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 (in hours) ‡
1	Pre-Waitlist Transplant	248	1,164.68	288,841	0.35	101,094

Form #	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses‡	Average Burden per Response (in hours)	Total Burden (in hours) ‡
	Referral Form					
2	Pre-Waitlist Transplant Evaluation Form	248	594.22	147,367	0.4	58,947
3	Ventilated Patient Form	56	3,292.00	184,352	0.47	86,645
	Total	552		620,560		246,686

‡ Total responses and total burden hours are rounded up to the nearest whole number to ensure the Total Responses match what is sent to OMB for review in ROCIS.

Once this collection is approved, HRSA will cease the 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. This decision was made to avoid unnecessary burden and redundancy in the data collected by this package and the existing OMB data collection instrument.

12B. Estimated Annualized Burden Costs:

Form #	Form Name	Total Burden (in hours)	Wage Rate	Total Hour Cost
1	Pre-Waitlist Transplant Referral Form	101,094.22	$82.76	$8,366,557.65
2	Pre-Waitlist Transplant Evaluation Form	58,946.62	$82.76	$4,878,422.27
3	Ventilated Patient Form	86,645.44	$82.76	$7,170,776.61
	Total	246,686.28		$20,167,476.53

Data collection and reporting are carried out at transplant programs and OPOs by a variety of personnel, including transplant coordinators, nurses, laboratory technicians, and medical record specialists. The individual(s) responsible for completing the data collection forms will vary among respondents. Therefore, to estimate the cost to the respondents, the average hourly wage reflects the mean hourly wage of a Registered Nurse, as reported on the United States Department of Labor - Bureau of Labor Statistics website. The mean hourly wage as of May 2023, for this position is $41.38. Doubling the median hourly wage to account for overhead costs

(e.g., benefits) brings the total hourly cost to $82.76. The total estimated burden hours across forms is $20,167,476.53 (see 12B).

Planned frequency of information collection:
The frequency of information collection varies by form, and data submission requirements are specified in OPTN Policy 18.

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

(a) Total Capital costs and start-up costs component:
The OPTN Computer System has been in place for many years, with no capital or start-up costs associated with the basic network. The system is internet-based and, therefore, does not carry capital or start-up costs. Additionally, facilities are equipped with PCs and Internet connections and should incur no costs.

(b) Total Operation and maintenance and purchase of services component:
Users have computers for their normal business activities and, therefore, will not need to change maintenance practices for this purpose. Some users have internal import/export systems that facilitate the completion of these forms through their electronic medical record systems. These systems may require some cost to develop and/or modify, resulting in costs to respondents. Transplant centers and OPOs are responsible for all proposed data collection modifications and typically account for the majority of the data collection volume. Most of the cost is attributable to respondents' staff time.

14. Annualized Cost to Federal Government

The annual cost to the Federal Government consists of those costs allocated to the data system under the HRSA contract for the OPTN. There is also the cost to the government of monitoring the data system.

Listed below are costs from the OPTN Task #5, "Collect official OPTN data to support the operations of the OPTN," and OPTN Task #9, "The Contractor shall maintain and improve the OPTN website for dissemination of transplant information to the public and the transplant community". These tasks do not include costs for the development and maintenance of OPTN systems or the maintenance of OPTN security requirements.

A. OPTN contract (HRSA 250-2019-00001C)

Direct Cost	
1. Direct Salaries and Wages	$4,639,200
2. Fringe Benefits	$2,291,764
3. Travel	0
4. Other Direct Costs	$2,887,213

Total Direct Costs	$9,818,177
5. Indirect Costs	$1,327,355
TOTAL ESTIMATED COST	$ 11,145,532*

* The OPTN is a cost-share contract with the contractor contributing 92.23 percent of this cost from patient registration fees. Thus, the estimated net cost to the Federal government for performing the contract tasks related to data collection and dissemination in fiscal year 2024 is $519,606.

15. Explanation for Program Changes or Adjustments

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. 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.

16. Plans for Tabulation, Publication, and Project Time Schedule

The OPTN data is used to produce annual and biannual reports to Congress.

HRSA provides selected OPTN data to the public through the HRSA Health Data Warehouse at www.data.hrsa.gov and HRSA's OPTN website at https://optn.transplant.hrsa.gov/.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB number and Expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.