Health Resources and Services Administration (HRSA)
SUPPORTING STATEMENT

Organ Procurement and Transplantation Network (OPTN) Ventilated Patient Form (VPF)

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 through two new OMB control numbers. This is the first of the two information collections, all of which were developed in response to a Department of Health and Human Services (HHS) Secretarial Data Directive. This collection consists of the Ventilated Patient Form (VPF). The second consists of two Pre-waitlist forms. Originally these forms were to be approved under one OMB control number, but due to comments received during the 60-day and 30-day comment periods, HRSA wanted to take more time to revise the two pre-waitlist forms and will now submit them under a new OMB control number. This collection only covers the VPF forms. HRSA believes that separating these data collections will minimize confusion, increase clarity among OPTN members and stakeholders, and enable more direct feedback on the newly developed forms.

Both OMB No. 0915-0157 and these new collections (OMB No. 0906-New) 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 donors and recipients.

While proposed OPTN policy changes undergo a public comment separate from the PRA process (see https://optn.transplant.hrsa.gov/policies-bylaws/public-comment), these three new forms developed under the HHS Secretarial Data Directive are not policy-related. Therefore, the separate OPTN public comment period process does not apply. This ICR includes only one of the three forms—the Ventilated Patient Form (VPF). The remaining two pre-waitlist forms will be submitted under a separate ICR.

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 which were directed by the HHS Secretary and developed to improve the OPTN organ matching and allocation process, as well as member compliance with OPTN requirements. This Supporting Statement includes only the Ventilated Patient Form (VPF); the remaining Pre-waitlist forms will be addressed separately.

The VPF 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.

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, followed by a 30-day Federal Register Notice published in the Federal Register on Tuesday, July 1, 2025, 90 FR 28754. HRSA received, received a total of 89 comments, 31of which applied to the VPF. HRSA conducted a comprehensive review of all feedback provided by the public during the 60- and 30-day comment windows.

Respondents provided a wide range of general feedback on the proposed VPF. Overall, commenters expressed strong support for the initiative, emphasizing that the VPF will improve national consistency in data collection, enhance understanding of OPO processes, support identification of missed referral cases, and strengthen accountability across hospitals and OPOs. Some commenters additionally underscored the importance of ensuring public availability of OPTN-related data. HRSA concurred that the VPF supports its broader modernization goals, including improved oversight, transparency, and alignment with the authority under 42 CFR § 486.348.

Several commenters noted that the VPF does not introduce new reporting obligations because OPOs are already required under CMS regulations (42 CFR § 486.328 and § 486.330) to collect and maintain these data elements. HRSA agreed, highlighting that the VPF serves as a standardized mechanism to consolidate and compare data already required for quality-assessment and regulatory purposes. HRSA also reiterated that a substantial portion of the VPF content is drawn directly from existing, OMB-approved forms (DNR and DDDR), thereby limiting additional burden.

Commenters raised concerns regarding potential manual data-entry burden and encouraged HRSA to pursue electronic automation. HRSA responded that it is already coordinating with major EMR vendors to support API-based automation and will discontinue duplicative forms from the legacy OPTN data system to streamline reporting.

Many commenters also requested clear and standardized definitions to ensure consistency across OPOs. In response, HRSA committed to developing and publishing a data dictionary in collaboration with OPOs and stakeholders, during the implementation phase.

Comments also sought clarification regarding the scope of cases included in the VPF—specifically recommending that the form focus only on particular referral pathways or limit cases based on timing after extubation. HRSA clarified that the VPF is intended to capture data on all ever-ventilated, deceased patients with a formal death pronouncement who were referred to or identified by the OPO during Death Record Review, consistent with regulatory requirements. Limiting the scope would risk excluding cases relevant to assessing referral timeliness and missed donation opportunities.

Several commenters highlighted that not all data elements are available at the time of referral. HRSA agreed, noting that OPOs will be allowed to save incomplete records locally and submit them within the reporting window, consistent with current practice. HRSA further described built-in cascading skip logic to ensure only applicable fields are required for each case.
A small number of commenters expressed concerns regarding data elements that appeared to place responsibility for hospital remediation plans on OPOs. HRSA acknowledged this concern and removed those fields from the VPF, reiterating that the form is intended to document communication between OPOs and hospitals—not shift responsibility for hospital obligations. Other comments recommended removal or modification of specific fields, including HIV status, which HRSA confirmed has already been removed. HRSA also acknowledged comments requesting standardized national DRR protocols but noted that such standard-setting is outside the scope of this particular data-collection instrument; still, the VPF captures the necessary death classification elements to support consistent national reporting.

HRSA also received public comments on a wide range of fields within the proposed Ventilated Patient Form (VPF). The feedback primarily addressed clarity of field definitions, reporting burden, data element redundancy, alignment with OPTN and federal standards, and variation in clinical and operational practices across Organ Procurement Organizations (OPOs). In response, HRSA carefully reviewed all recommendations and revised the VPF to reduce redundancy, improve usability, clarify instructions, and ensure that final data elements remain meaningful for oversight, audit integrity, and national analyses.

A significant number of comments focused on duplicative referral questions, specifically the overlap between “How did the OPO learn of this patient?” and “Was the patient referred by the hospital to the OPO?” HRSA concurred with these concerns and updated the form logic so that the hospital referral question appears only once, preventing respondents from encountering the same data element multiple times. A similar concern was raised between “Advance Directive” and “Did patient legally document their decision to be an organ donor?” HRSA removed the “Advance Directive” field since it was largely redundant. HRSA also concurred with comments on field sequencing and made modifications around several referral-related fields, including Date and Time of Hospital Referral, Date of Death Record Review, and Onsite Response, ensuring that the form flow better aligns with OPOs’ operational processes.

Several commenters noted that certain information is frequently unknown at the time of referral, such as cause of death, mechanism of death, or whether documentation of first-person authorization is available. HRSA acknowledged these challenges and confirmed that OPOs may update such fields after referral, consistent with the existing submission timeframe under HRSA reporting policy. HRSA similarly clarified reporting expectations for fields relating to pronouncement of death, emphasizing that the VPF applies only to patients with a documented pronouncement of death and that existing donor records will populate corresponding fields where applicable.

Commenters also requested updates to race and ethnicity categories to align with the revised OMB Statistical Policy Directive No. 15 (SPD-15). HRSA agrees that these updates are needed; however, system limitations, timing constraints related to the conclusion of the current OPTN contract, and competing data modernization priorities prevent immediate implementation. HRSA plans to incorporate updated demographic standards in a future contract cycle.

To reduce burden while improving clarity and data utility, HRSA made several targeted modifications. HRSA allowed multiple selections for case disposition, added "wardens" to the Medical Examiner/Coroner option to account for incarcerated patients, and moved Hospital Interference to a standalone field to allow clearer reporting and reduce confusion around case outcomes. HRSA also added or clarified fields related to EMR access, patient donation pathways, and operational case closure to ensure consistent national reporting. HRSA removed several fields entirely in response to public comment. These removals reflect commenters' concerns about burden. And lack of consistent availability of information, and redundancies. The following fields were removed from the proposed form:

- HIV
- Primary Insurance
- Advance Directive
- Was the Patient Referred by the Hospital to the OPO
- Report to Hospital Accepted
- Remediation Plan Provided to Hospital
- Remediation Plan for Hospital Accepted

These fields were removed because commenters highlighted that such information is not consistently collected at the patient level, is often documented in aggregate rather than at the referral level and could introduce substantial administrative burden.

Overall, the final updates to the VPF reflect HRSA's careful consideration of public feedback and balance the need for accurate, comprehensive oversight data with the imperative to minimize burden and ensure clarity for respondents. HRSA incorporated technical, editorial, and structural changes throughout the form, strengthened instructions for multiple fields, repositioned several items to improve usability, and removed elements that did not clearly support program goals. The result is a revised VPF that is clearer, less duplicative, more operationally aligned, and better able to support national monitoring of OPO activities and outcomes.

For detailed information on the HRSA responses, please see Attachment: *VPF Field Adjudication* and *VPF General Comment Adjudication*.

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

The CMS conditions for Coverage for OPOs (42 CFR §§486.301-348) include a requirement that the OPO must "Determine whether there are conditions that may influence donor acceptance," and "If possible, obtain the potential donor's medical and social history." This information is included in this data collection. 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 estimate for the Ventilated Patient Form is based on the average burden estimate for the 2024 burden estimates of the existing OMB-approved Death Notification Registration form, with an additional 0.08 hour per collected form to reflect an increase in total data fields.

To more accurately estimate the total number of responses and the number of responses per respondent, HRSA used the CMS CALC (Cause, Location, and Circumstances of Death) count —CMS's measure of inpatient deaths that meet clinical criteria for potential organ donation and serve as an upper-bound estimate of current DNR activity—in the updated formula. We calculated this estimate by averaging CMS CALC values over the most recent four years of available data (2020–2023).

After addressing stakeholder comments, HRSA is reducing the average burden per response in the VPF to 0.37 hours. This reduction reflects the removal of seven additional fields and modifications to several others to simplify completion of the form.

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	Ventilated Patient Form	56	1,876.70	105,095	0.37	38,885

‡ 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.

As noted earlier, 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	Ventilated Patient Form	38,885.15	$90.00	$3,499,663.50

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 form 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 $45.00. Doubling the median hourly wage to account for overhead costs (e.g., benefits) brings the total hourly cost to $90.00. The total estimated burden hours is $3,499,663.50 (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 this form 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.

The estimated annualized burden hours and costs per respondent, Organ Procurement Organizations (OPOs), associated with the Ventilated Patient Form (VPF) are shown in the table below. These estimates include both re-occurring and non-reoccurring activities required for implementation of the VPF and ongoing reporting. Costs are calculated using average wage rates for OPO clinical and administrative staff involved in form completion and associated recordkeeping.

Category	Totals
Re-occurring ($)	**$997,114** ($17,805 per OPO)
Re-occurring (hours)	**12,963 hours** (231 hours per OPO)
Non-Reoccurring ($)	**$279,989** ($5,000 per OPO)
Non-Reoccurring (hours)	**3,640 hours** (65 hours per OPO)
Total ($)	**$1,277,103** ($22,805 per OPO)
Total (hours)	**16,603 hours** (296 hours per OPO)

These totals reflect the combined burden for all 56 OPOs.

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.