Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

General Comment Analysis

Comment	Comment Numbers	HRSA Response
Commenters expressed support for the Ventilated Patient Form (VPF), stating that improved data collection will enhance understanding of OPO processes, help identify missed referral rates, and increase accountability across hospitals and OPOs. One expressed that the OPTN data must be publicly available.	9, 10, 16, 19, 20, 21, 22, 50, 60, 64, 66, 69	We appreciate the commenters' support for the implementation of the Ventilated Patient Form (VPF). These enhancements directly support the quality-assessment and performance-improvement requirements in 42 CFR § 486.348, and align with HRSA's ongoing efforts to improve organ donation outcomes and equity through consistent, data-driven oversight and improved data transparency and access.
Several commenters stated that the Ventilated Patient Form (VPF) does not create additional reporting burden, since CMS regulations already require OPOs to collect and maintain these data elements under 42 CFR § 486.328 and § 486.330.	16, 60	HRSA appreciates the commenters' support and agree that the data elements included in the Ventilated Patient Form (VPF) align with existing CMS requirements for OPOs to collect and maintain hospital-specific organ donation and transplantation data. Specifically, 42 CFR § 486.328(a) requires OPOs to provide individually identifiable, hospital-specific data and other information to the OPTN, SRTR, and HHS, and § 486.330 requires OPOs to maintain detailed records of each donor case for a minimum of seven years. Therefore, the VPF does not establish new data collection obligations but rather provides a standardized mechanism for HRSA to receive, analyze, and compare these data elements across OPOs in support of oversight and quality-improvement functions.
Several commenters stated that the Ventilated Patient Form (VPF) would be burdensome to complete manually and recommended that data entry be automated where possible.	23, 48, 56, 57, 73, 86	HRSA has been in contact with the electronic medical record (EMR) vendors used by the vast majority of OPOs regarding APIs to automate this data flow. This approach will reduce manual data entry, improve accuracy, and streamline reporting processes. To further minimize redundancy, HRSA will discontinue use of the Death Notification Registration and the Deceased Donor Death Referral forms currently included within the OMB-approved Data System for Organ Procurement and Transplantation Network (OMB No. 0915-0157). This change eliminates duplicative data collection and consolidates reporting within the VPF. Finally, it should be noted that the majority of fields in the VPF are existing fields carried over from these legacy forms, ensuring continuity and minimizing additional workload for OPOs.

Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

Comment	Comment Numbers	HRSA Response
Several commenters recommended that HRSA be clear on definitions used in the Ventilated Patient Form (VPF) and develop them with input from OPOs to ensure that the data collected are consistent, interpretable, and useful for oversight and performance improvement. One commenter mentioned the GLDP Donor Tracking Tool as an example of data entry consistency that eliminated subjectivity in this space.	48, 53, 54, 62, 73, 75, 89	HRSA will develop and publish a data dictionary in collaboration with OPOs and other stakeholders prior to full deployment of the VPF.
A commenter stated that the patient referral pathway may include both living and deceased patients and recommended that the Ventilated Patient Form (VPF) focus only on patients who move forward into the evaluation phase for organ donation.	53	HRSA appreciates the comment and the opportunity to clarify the intent and scope of the Ventilated Patient Form (VPF). The purpose of the VPF is to collect demographic information and OPO process data on ever-ventilated patients with a documented pronouncement of death who were either referred to the OPO by a hospital or identified by the OPO through the death record review (DRR) process, as required under 42 CFR § 486.348(b). The VPF does not capture data on living patients or on all hospital referrals. Rather, it is limited to cases where death has been formally pronounced and where OPOs are required to review hospital records to assess donor potential and compliance with timely referral requirements. Within that defined population, the form already includes fields to indicate which cases progressed into the evaluation, authorization, and donation phases. These data elements allow OPOs and HRSA to analyze performance while maintaining a complete DRR record set, consistent with regulatory expectations.
Several commenters provided specific feedback on several of the VPF fields.	53, 56, 58, 87, 88, 89	HRSA has responded to specific feedback on the VFP fields in the VFP Field Adjudication HRSA will develop and publish a data dictionary in collaboration with OPOs and other stakeholders prior to full deployment of the VPF.

Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

Comment	Comment Numbers	HRSA Response
A commenter stated that the Ventilated Patient Form (VPF) misplaces responsibility for corrective or remediation plans on OPOs, when accountability for addressing deficiencies or improving compliance with referral requirements should rest with hospitals.	57	We appreciate this comment and agree that donor hospitals bear responsibility for meeting requirements for timely referral and collaboration with the OPO, as outlined in 42 CFR § 486.322(a) and § 486.348(b). The intent of the Ventilated Patient Form (VPF) is not to shift responsibility for corrective action from hospitals to OPOs, but rather to document the OPO's communication when issues such as hospital interference are identified. These fields were not to assign corrective ownership to OPOs; rather, to ensure that both OPOs and hospitals are jointly accountable for addressing systemic barriers to donation. However, the two fields on hospital remediation plans have been removed from the VPF form.
Many commenters noted that data may be incomplete at the time of referral. They recommended allowing "Not Available" or similar options for required data fields to avoid reporting errors or delays in form submission.	57, 58, 62, 87	We agree with commenters that certain data elements may be incomplete at the time of referral for many records. To accommodate this, OPOs will have the option to save data in their local systems, and not submit to HRSA until up to 30 days after the end of the month in which a death occurred, consistent with the current Death Notification Registration (DNR) process.
Multiple commenters stated that the VPF's scope is too broad and recommended limiting the collection to patients who expire within a specific time frame after extubation, or to define ever-ventilated regarding the timing of ventilation to ensure consistency.	53, 62	We appreciate the comment and the perspective regarding the scope of cases included in the Ventilated Patient Form (VPF). The purpose of the VPF is to collect demographic and process data on ever-ventilated patients with a documented pronouncement of death who were either referred to the OPO or identified by the OPO during death record review (DRR), as required under 42 CFR § 486.348(b). Limiting data collection to patients who expire within a specific time frame after extubation would exclude cases that are critical for understanding hospital referral timeliness, donor potential, and compliance with referral requirements. Some patients who do not expire within the suggested time window may still represent missed donation opportunities or important process failures. The current scope (covering all ever-ventilated, deceased patients) ensures comprehensive death record review and comparability across OPOs, consistent with CMS Conditions for Coverage and HRSA's quality-assurance objectives. However, researchers may consider stratifying analyses to consider this.

Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

Comment	Comment Numbers	HRSA Response
		Finally, in the instructions, HRSA has clarified the patient must have been ventilated during their terminal hospitalization.
A commenter noted that many elements of the Ventilated Patient Form (VPF) may not be available for all cases, depending on how far a patient progressed through the donation process (for example, whether the case advanced to evaluation, authorization, or recovery).	62	We agree that data availability varies depending on how far a case progresses in the donation process. The Ventilated Patient Form (VPF) was intentionally designed with cascading (skip) logic to ensure that OPOs are only prompted to enter data elements that apply to each specific case. This built-in skip pattern ensures that users are not prompted to enter unavailable data, minimizes burden, and maintains data integrity across varying case pathways.
A commenter recommended that the HIV status field be removed from the Ventilated Patient Form (VPF).	62	We appreciate the comment and clarifies that the Ventilated Patient Form (VPF) no longer includes HIV status. Therefore, no changes are needed to address this concern.
A commenter recommended that HRSA standardize protocols for Death Record Reviews (DRRs) across OPOs to ensure data comparability. The commenter further stated that distinctions between brain death (BD) and donation after circulatory death (DCD) should be explicitly established and recorded as part of each DRR.	75	We agree that consistent death record review (DRR) methodology is important for ensuring data comparability across OPOs. However, the development and enforcement of standardized DRR protocols are outside the scope of the Ventilated Patient Form (VPF), which is designed solely as a data-collection instrument. The VPF captures the death classification fields necessary for DRR reporting, including identification of brain death (DBD) and donation after circulatory death (DCD) cases. While HRSA acknowledges that specific DRR procedures and definitions may vary among OPOs, consistent submission of these fields using the standardized VPF format will still allow HRSA to aggregate and compare data nationally. Future HRSA guidance may address DRR protocol standardization separately to promote greater consistency in how OPOs define and document these cases.

Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

Comment Analysis by Ventilated Patient Form Data Field

Field Name	Summary Comments	Summary Adjudication
DonorNet Donor ID	No comments received	No comments received
OPO Record ID	No comments received	No comments received
OPO	No comments received	No comments received
Patient Hospital	No comments received	No comments received
Case detail/How did the OPO learn of this patient?	Multiple commenters stated that this question regarding referral by the hospital to the OPO is asked twice: once in this question as one of the responses is "Hospital Notification: A hospital referred the patient to the OPO," and again in a question under OPO Process Data: "Was the patient referred by the hospital by the OPO?"	HRSA concurs with the commenters that this question was duplicative in the draft version of the Ventilated Patient Form. The form logic has been updated so that the referral question appears only once, thereby reducing redundancy and potential confusion for respondents.
Last Name	No comments received	No comments received
First Name	No comments received	No comments received
Middle Initial	No comments received	No comments received
Home Zip Code	Multiple commenters stated that the home zip code is often unknown and that referring hospital zip code is often included as a proxy. Some further stated that if HRSA does not want the referring hospital zip code, to include that note on the form.	HRSA concurs with the commenters that clarification is warranted. The instructions for the Home Zip Code field have been revised to explicitly state that the referring hospital zip code should not be used as a proxy when the home zip code is unknown.
Ethnicity	Commenters state that there should be more inclusive demographic data options for data integrity, such as allowing multiple selections for individuals of mixed race and ethnicity.	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, budget, as well as by budgetary and workload challenges. Implementation of these changes is anticipated during the next contract cycle.
Race	Multiple commenters requested the race categories be updated to the latest OMB standards to address multi-racial categories.	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

Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

Field Name	Summary Comments	Summary Adjudication
		constraints related to the expiration of the OPTN contract at the end of the year, budget, as well as by budgetary and workload challenges. Implementation of these changes is anticipated during the next contract cycle.
Birth Sex	No comments received	No comments received
Height	Commenters pointed out this will be unknown for the majority of patients. One commenter suggested this field only be required for patients with a Donor ID.	HRSA appreciates these comments and agrees that height data may not be available for every case. To minimize burden, OPOs may select “Not Done,” “Missing,” or “Unknown” when height is unavailable. HRSA will retain this field for all patients to support comprehensive quality assessment while allowing flexibility when the information cannot be obtained.
Weight	Commenters pointed out this will be unknown for the majority of patients. One commenter suggested this field only be required for patients with a Donor ID.	HRSA appreciates these comments and agrees that weight data may not be available for every case. To minimize burden, OPOs may select “Not Done,” “Missing,” or “Unknown” when weight is unavailable. HRSA will retain this field for all patients to support comprehensive quality assessment while allowing flexibility when the information cannot be obtained.
Age	Commenters stated that the Age field should be consistent with other OPTN data collections by using date of birth to calculate age when available, collecting age only when date of birth is unknown, and including an “Unknown” option for cases where the patient’s age cannot be determined or is estimated.	HRSA will align the Age field with OPTN standards by allowing entry of date of birth or an age in years and month. HRSA will not add an “Unknown” option for the Age field to promote data completeness and consistency, as age can typically be determined or estimated from existing records and is needed for accurate national analyses.
Cause of Death	Commenters stated that this field may be unknown at the time of referral or when the OPO closes the case later in the process.	HRSA acknowledges that this information may not always be available at the time of referral. OPOs may update or batch-submit this information within 30 days after the end of the month in which the death occurred, consistent with HRSA reporting policy.

Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

Field Name	Summary Comments	Summary Adjudication
Specify	No comments received	No comments received
Mechanism of Death	Commenters stated that this field may be unknown at the time of referral or when the OPO closes the case later in the process.	HRSA acknowledges that this information may not always be available at the time of referral. OPOs may update or batch-submit this information within 30 days after the end of the month in which the death occurred, consistent with HRSA reporting policy.
Circumstance of Death	Commenters stated that this field may be unknown at the time of referral or when the OPO closes the case later in the process.	HRSA acknowledges that this information may not always be available at the time of referral. OPOs may update or batch-submit this information within 30 days after the end of the month in which the death occurred, consistent with HRSA reporting policy.
Did patient legally document their decision to be an organ donor?	Commenters stated that documentation of a patient's legal decision to be an organ donor may not always be available at the time of referral and recommended clarifying how OPOs should report when the status is unknown.	HRSA agrees that this information may not always be known at referral. The field will be retained, and OPOs may select "Unknown" when documentation cannot be confirmed. Records may be updated or batch-submitted within 30 days after the end of the month in which the death occurred, consistent with HRSA reporting timelines.
First Person Authorization Restrictions	Commenters requested clarification on the definitive sources OPOs should use to determine First Person Authorization Restrictions. Commenters also recommended removing "Tissue" as an option, noting that tissue donation is outside the scope of OPTN oversight and not relevant to the organ donation process. Commenters also requested clarity on if tissue includes ocular tissue.	HRSA appreciates commenters' feedback. OPOs should reference any document the OPO would consider applicable under their state laws. The instructions have been updated with this clarification. This approach accommodates variation in state processes while ensuring that the information recorded in the VPF reflects the legally valid authorization sources applicable to each jurisdiction. HRSA will retain the "Tissue" option to capture donor intent and will clarify in the instructions that tissue includes ocular tissue.

Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

Field Name	Summary Comments	Summary Adjudication
Date and Time of Pronouncement of Death	Commenters stated that the *Date and Time of Pronouncement of Death* field should not be required for all referrals, noting that many ventilated patients referred to OPOs are not deceased at the time of referral and that obtaining this information later would create significant burden. They also suggested replacing "pronouncement" with "determination" of death and including an indicator for neurologic or circulatory death.	HRSA clarifies that the Ventilated Patient Form (VPF) applies only to ever-ventilated patients with a documented pronouncement of death, as required under 42 CFR § 486.348(b). Therefore, all patients reported through the VPF will already have a documented date and time of death. If this is a patient with a Donor ID, "Date and Time of Pronouncement of Death" will populate from the donor record. HRSA uses pronouncement of death because it captures the officially documented time of death needed for verification, inclusion, and audit purposes. Finally, existing fields (e.g., Patient Record Type) already capture whether the patient experienced a neurologic (brain) or circulatory death.
Date of Death Record Review	Commenters suggested moving the Date of Death Record Review field to follow the How did the OPO learn of this patient? field for improved form flow and usability. Commenters also recommended that HRSA define and standardize the scope of death record review to ensure consistent, high-quality data across OPOs, noting that DRR practices currently vary and that CMS regulations do not clearly outline the process.	HRSA appreciates these comments. Date of Death Record Review has been moved to follow "How did the OPO learn of this patient" for OPOs who select "Death record review" for improved flow and usability. HRSA agrees that consistent death record review methodology is important to ensure data comparability across OPOs. However, the development and implementation of standardized death record review protocols are outside the scope of the Ventilated Patient Form.
Date and Time of Hospital Referral	Commenters suggested moving the Date and Time of Hospital Referral field to follow the How did the OPO learn of this patient? field to improve the logical flow of the form. Commenters also requested clearer instructions on how to document referrals involving hospital transfers, closed and reopened cases, and multiple referrals of the same patient. Several commenters noted that the term "referral" can vary among hospitals and transplant centers and recommended that HRSA provide a clear definition and guidance to promote consistency in data reporting.	HRSA appreciates these comments. To improve form usability, HRSA has moved "Date and time of hospital referral" to follow "How did the OPO learn of this patient" if the OPO selects "Hospital referral." This field captures the date and time the OPO was first notified of the patient's potential for donation during a terminal admission, not earlier living-patient referrals or multiple referral events. HRSA has clarified the field name with additional detail.

Appendix A: HRSA Analysis of Public Comments for OPTN Process Data Collection – Ventilated Patient Form (VPF) (0906-New)

Field Name	Summary Comments	Summary Adjudication
Method of Authorization Used by OPO	No comments received	No comments received
Authorization	No comments received	No comments received
Date and Time of Authorization for Procurement	No comments received	No comments received
Case Disposition	Commenters stated that case disposition decisions are rarely unifactorial and recommended allowing multiple selections when more than one circumstance applies (for example, hospital interference may occur in a case that still proceeds to donation). Commenters requested that definitions be provided for each disposition option and clarification on whether the list is single- or multi-select. Additional suggestions included adding “warden” to the Procurement Denied by Medical Examiner/Coroner option to reflect cases involving incarcerated individuals.	Based on public comment, HRSA modified this field to allow selection of more than one case disposition when multiple factors apply. HRSA also added “wardens” to the Procurement Denied by Medical Examiner/Coroner option to reflect custody-related cases and moved “Hospital Interference” to a separate field to ensure clearer and more consistent reporting. Finally, definitions of each of these options will be provided to a working group of OPOs for feedback and then circulated more broadly for OPO feedback prior to the full VPF roll out.