OPTN Response to 30-day Federal Register Notice: Process Data for Organ Procurement and Transplantation Network (ICR Reference Number: 202507-0906-001)

July 31, 2025

Introduction

Thank you for the opportunity to comment on the Information Collection Request Process Data for Organ Procurement and Transplantation Network, Office of Management and Budget (OMB) No. 0906-xxxx—New. We are responding as the Organ Procurement and Transplantation Network (OPTN) Board of Directors (BOD), the organization authorized to manage the matching of donated organs with transplant recipients nationwide and to manage the collection of federally required data reported for organ donors, transplant candidates and transplant recipients.

The OPTN BOD is advised by more than 20 OPTN committees, each of which has broad national representation and fulfills a charge to develop or advise on policies within their expertise. The following response, approved by OPTN Board leadership on behalf of the OPTN BOD, reflects the comments and recommendations from the Data Advisory Committee (DAC) with input from two cross-functional workgroups (the DAC-sponsored Pre-Waitlist Data Collection workgroup and the MPSC-sponsored OPO Performance Monitoring Enhancement workgroup) with direct stakeholder interest and involvement in the material the data directive addresses. The DAC advises the OPTN BOD regarding OPTN data collection and is charged with ensuring that data collection activities are aligned with the OPTN Data Collection Principles.

The OPTN thanks HRSA for the opportunity to collaborate on establishing a rigorous foundation nationwide collection of these new data which could have significant impact on improving processes of care and outcomes for patients with end-stage organ disease and donors. However, we are disappointed that prior feedback from the OPTN during the 60-day review period was not fully incorporated. The OPTN and HRSA share the goal of ensuring meaningful and high quality data is collected to reflect all key phases of an individual's transplantation journey, from initial referral to long term outcomes. Our 60-day response was intended to maximize the usefulness of the initially proposed forms so as to allow meaningful statistical analyses, incorporation of specific processes of care in which data could be ascertained, and balance the administrative burden upon organ procurement organizations (OPOs) and organ transplant programs that collect, verify and report the data.

Upon review of the 30-day package, the OPTN suggested changes to the pre-waitlist data collection and the ventilated patient form (VPF) do not appear to be incorporated. (See the OPTN's 60-day response in the Appendix.) We respectfully request that HRSA reconsider our 60-day response, which importantly incorporated input from a wide array of transplant stakeholders knowledgeable about the clinical, operational and policy implications of these new data collection efforts. In particular, we are concerned the data collected from the developed VPF forms will not be meaningful to guide improvement in the system, resulting in wasted time, effort, and cost. We also note that the OPTN committees charged with reviewing the proposals report that they have not had an opportunity to articulate the rationale for the 60-day FRN response, which may improve understanding, despite having offered such discussions on multiple occasions.

Background

On January 31, 2024, the DAC provided early feedback and recommendations to HRSA on three drafted directive forms, in response to a request made at the DAC November 13, 2023 meeting. Information on how DAC addressed this request, by working with two OPTN workgroups, can be found on the data directive toolkit page of the OPTN website.

Following the Directive, issued on February 5, 2024, the DAC's pre-waitlist feedback was incorporated into the 60-day federal register notice (FRN) forms issued on November 4, 2024; however, feedback related to several aspects of the ventilated patient form (VPF) went unaddressed.

On December 18, 2024, the OPTN submitted a detailed response to the 60-day FRN which appears in this document as Appendix A and can also be found on the OPTN website.

Below is the OPTN's feedback on the 30-day FRN.

Data Collection Feedback Summary

- The majority of the OPTN's 60-day feedback was not incorporated, and the OPTN's volunteer expertise, while leveraged to review and provide feedback, was not utilized. No justifications were provided, and numerous questions remain.
- We acknowledge there are internal federal processes for addressing all comments in response to the FRN but would recommend public responses to maintain transparency and engender trust among all relevant stakeholders. Adjudication in private can be conflated with lack of responsiveness. The OPTN recommends HRSA educate the OPTN Board and community on the OMB process, including ways to engage and where to find materials and responses.
- The directive process appears to be inefficient in improving OPTN data collection despite the potential to provide a more expeditious pathway for policy development.
  - HRSA's original approach in submitting a data directive to the OPTN stopped the submission of the OPTN's 2023 Data System package, containing seven board approved data collection

projects, from proceeding for OMB approval. This action by HRSA delayed the implementation of these projects for at least one year, some two years.

  - The timing and resources required to develop and implement data collection solutions remain unclear to the Board and the community.
  - The approach appears to have underleveraged stakeholder expertise and input to the VPF.

- The HRSA approach skipped critical steps that are part of the OPTN's process (e.g., documenting all the functional requirements not just data collection, identifying OPTN policy changes and developing a compliance monitoring plan, etc.).
  - The federal OMB process does not allow HRSA to have open conversations with the OPTN about data collection.
  - Public comments are submitted to HRSA, adjudicated by them, and no discussions with the OPTN leadership or subject matter experts are allowed.

Closing

Pre-waitlist data collection

In closing, the OPTN supports the pre-waitlist data collection requirements as proposed in the 30-day FRN. Additional comments and recommendations were included in the 60-day FRN response to assist HRSA in finalizing the specific data elements and planning for implementation. Recommendations previously detailed in the 60-day response but not yet addressed include:

- Explanation for removal of two data fields the DAC Pre-waitlist Workgroup recommended for collection: Initial Evaluation Appointment Completion Date and Evaluation Status/Evaluation Cancelation Reason.
- Using a pre-implementation pilot to identify any unforeseen challenges with data collection.
- Consider batched data extraction from centers to reduce center resource utilization.
- Provide centers with center specific data reports to help improve processes of care and outcomes.
- Utilize additional data sources to adjudicate outcomes of patients in pre-listing phases needed to accurately assess care processes.
- Engage EMR vendors proactively to facilitate identification of common data elements and maximize efficiency of data abstraction.

Ventilated Patient data collection

The OPTN believes the VPF data collection requirements need substantial work prior to their implementation. The DAC and the MPSC workgroup chair shared recommendations to improve the VPF

on January 31, 2024, and offered to assist HRSA in making the necessary adjustments to the VPF. The following concerns with the VPF data collection form persist:

- Data elements require further specificity to ensure mutually exclusive choices, fixed choice options for categorical variables where relevant, and a logical data flow to collect consistent and complete data.
- The OPTN notes that the VPF contains many data fields insufficiently defined, thereby creating the risk of subjective interpretation that could inadvertently increase rather than decrease variability in reporting across OPOs.

  Specific examples include:

  - Medical and neurological data at the time of patient referral, which is critical to understand decision making in referral eligibility.
  - Lack of clear definitions or a hierarchical deterministic algorithm in the VPF to select a single case disposition from the options provided will result in inaccurate data collection.

The OPTN strongly recommends HRSA partner with the MPSC workgroup to develop a comprehensive approach to data collection so it can be standardized in the EDR systems to ultimately provide accurate and complete data downstream to the OPTN Computer System.

As a partner in managing the OPTN data registry, the OPTN wants to partner with HRSA to efficiently address remaining questions and ambiguities related to the new data collection so that it can proceed to the next step in the approval process without further delay. If a pilot implementation is considered the best strategy for identifying and addressing these challenges, the OPTN would welcome the opportunity to advise HRSA on the appropriate scale and selection for a pilot program. The OPTN welcomes the earliest opportunity to discuss this feedback with HRSA and identify the next steps.

Appendix A: OPTN Response to 60-day FRN (pages 5-25)

Introduction

Thank you for the opportunity to comment on the Information Collection Request Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New. We are responding as the Organ Procurement and Transplantation Network (OPTN) Board of Directors (BOD), the organization authorized to manage the matching of donated organs with transplant recipients nationwide and to manage the collection of federally required data reported for organ donors, transplant candidates and transplant recipients.

The OPTN thanks HRSA for the opportunity to work with them establishing appropriate data collection principles for this new data collection. We share the common goal of ensuring that meaningful and consistent data is collected regarding the key phases of someone's transplantation journey, from initial referral to registration of individuals either as deceased organ donors or organ transplant candidates. Our response is intended to improve upon the initially proposed forms and processes to maximize their usefulness for meaningful analysis, while also minimizing to the greatest degree possible the additional burden upon organ procurement organizations (OPOs) and organ transplant programs to collect, verify and report the data.

The OPTN BOD is advised by more than 20 OPTN committees, each of which has broad national representation and fulfills a charge to develop or advise on policies within their expertise. The following response, approved by the Executive Committee on the behalf of the OPTN BOD, reflects the comments and recommendations from the Data Advisory Committee (DAC) with input from two cross-functional workgroups (the DAC-sponsored Pre-Waitlist Data Collection workgroup and the MPSC-sponsored OPO Performance Monitoring Enhancement workgroup) with direct stakeholder interest and involvement in the material the data directive addresses. DAC advises the OPTN BOD regarding OPTN data collection and is charged with ensuring that data collection activities are aligned with the OPTN Data Collection Principles.

In general, the response addresses the following themes:

- The data fields should be sufficiently detailed to support careful, reliable and reproducible interpretation based on clearly articulated study design. This will enhance the ability to use these data for describing system performance and opportunities for improvement and the impact of systemic changes on various issues including access to care and variations in care.
- While additional data collection is welcome to increase understanding of key trends, the fields and mechanism of data collection/reporting should first utilize discrete data elements already available to OPOs and transplant hospitals to the greatest extent possible. This will allow for the earlier development and implementation of the new data collection forms while reducing the additional data burden on OPTN member institutions and decreasing the time frame needed to develop and implement methods to collect and verify any additional data.

- Some of the comments address data that may be unknown under certain circumstances or present substantial challenges for members to collect. In these cases, we have provided feedback or recommendations for modification.

Data Collection Feedback Summary

As background, on January 31, 2024, the DAC provided early feedback and recommendations to HRSA on the three drafted directive forms. HRSA made this request to the DAC at their November 13, 2023 meeting. Information on how DAC addressed this request, by working with two OPTN workgroups, can be found on the data directive toolkit page of the OPTN website.

The drafted forms released with the Directive, issued on February 5, 2024, did not incorporate the DAC and workgroup recommendations. DAC's pre-waitlist feedback was incorporated into the 60-day federal register notice (FRN) forms issued on November 4, 2024 , however only a small amount of the feedback on the ventilated patient form (VPF) was addressed.

Below is the OPTN's summarized feedback on the proposed data collection. The summary references detailed sections in this document where field level comments and recommendations are provided.

Pre-waitlist Data Collection

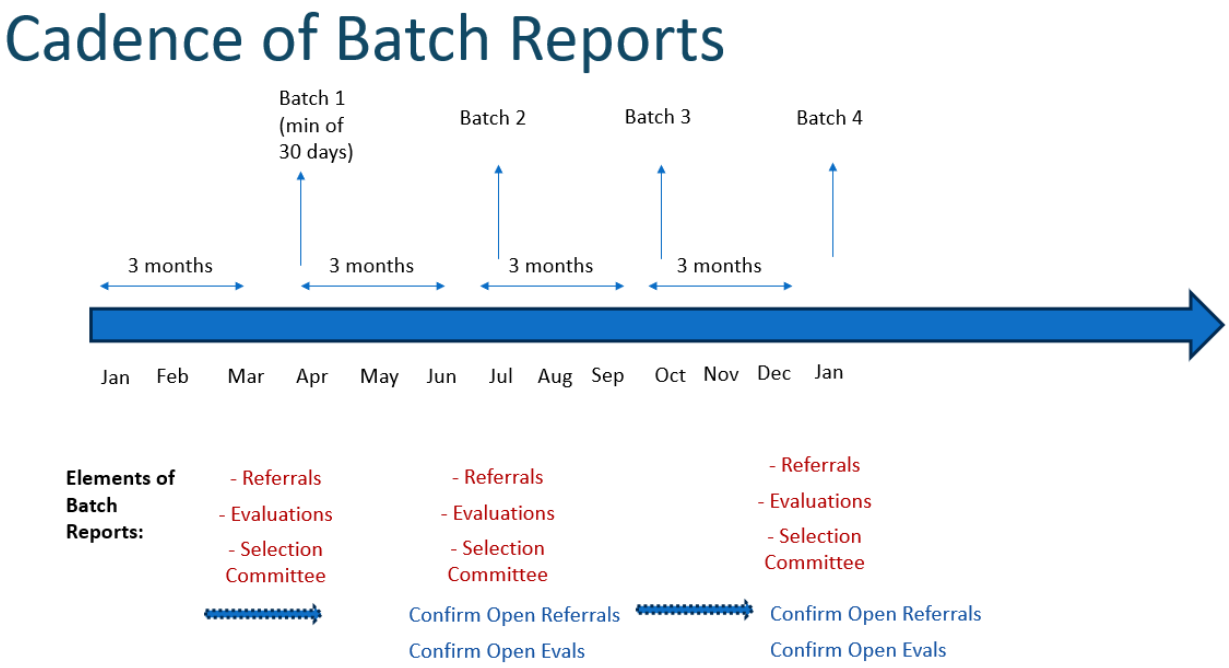
The OPTN largely supports the proposed Pre-waitlist Referral and Pre-waitlist Evaluation forms while respectfully requesting additional information and/or context from HRSA. The proposed forms reflect the vast majority of recommendations DAC provided to HRSA on January 31st, 2024, and the OPTN appreciates their acceptance by HRSA. However, there were DAC-recommended data fields removed from the forms, and it would be helpful to understand the concerns that lead to their removal. This question is included in the pre-waitlist field section of this document.

The OPTN also supports the following recommendations DAC provided to HRSA on January 31, 2024, regarding the pre-waitlist data collection cadence and methods:

- Each event (referral and evaluation) has a start and end trigger that mandates sequential data gathering (1st referral event > 2nd evaluation event > 3rd Waitlist registration event).
- Data collection will start at a point in time (TBD by HRSA) for new referrals.
- Do not allow transplant programs the ability to edit the data after event closure.
- Target a quarterly data collection cycle with the option to submit the data in bulk or manually at predefined intervals.

1) A batch reporting cadence is recommended, as reflected in the below graphic, because real-time referral and evaluation data is not currently needed for immediate operational purposes of the OPTN. This cadence of data reporting will still facilitate all use cases under consideration while significantly reducing data burden associated with individual patient level real-time forms.

Importantly, this cadence is also more likely to yield higher quality data as information is aggregated over time rather than strictly available on the date of the event (e.g. referral).



As the pre-waitlist data collection is implemented, the OPTN will want to know the number of patients 'at-risk' of progressing past referral to evaluation or waitlisting. To fully capture the outcomes of patients who do not return after referral or evaluation, the OPTN will need to supplement information about patient mortality. Implementing this practice is consistent with the current processes for waiting list candidates and post-transplant recipients. The OPTN recommends partnering with HRSA to prioritize and fund an initiative to augment the OPTN data registry with pre-waitlist patient mortality information. This will also facilitate understanding patient outcomes in this context as centers may be unlikely to acquire mortality data for all patients outside of their healthcare system. Failure to supplement these data will significantly bias estimation of key potential metrics deriving from these data (e.g. time from referral to evaluation) as these estimates will be dependent on understanding the number of patients eligible to progress to a subsequent phase of care.

Ventilated Patient Data Collection

The OPTN strongly supports the stated goal for this data collection of providing "a more objective source of information on procurement practices, the management of donor patients, and how these practices inform the supply of deceased organ donors available for transplant." There is a need for accurate, reproducible data available in a timely manner that can be used to reliably assess OPO performance and for use by OPOs in their own quality assurance and performance improvement efforts. However, the OPTN has significant concerns that the proposed VPF, if implemented without significant improvement

on data definitions, logical construct and more granular medical data will not fulfill this stated goal or fulfill the need for accurate, timely assessment of OPO performance.

First, the VPF provides these instructions "*The purpose of the Ventilated Patient Form (VPF) is to collect demographic information and OPO process data on ever-ventilated patients with a documented Pronouncement of Death who were referred to the OPO by a hospital or found by the OPO upon death record review as required at 42 CFR 486.348(b).*" Understanding the patient population for the VPF and following standardized practices is critical to ensuring consistent and quality data collection. The OPTN requests consideration of the following feedback and recommendation on the form instructions:

1. The term 'ever-ventilated' could be interpreted differently across OPOs as currently described, so we request this term be clearly defined, with the appropriate level of detail including reference to timing of ventilation, to ensure consistency in the patient population being captured for reporting.
2. Since non-donor deaths may not be pronounced in a timely fashion, we recommend relabeling the instructions and the corresponding data field (Date and Time of Pronouncement of Death) to 'Determination of Death'.
3. Currently, death record review practices differ across OPOs. In light of this, we request a standard protocol be developed and criteria be defined and implemented for death record reviews. In absence of a standardized process, the data collected from death record reviews will be inconsistent and unlikely to yield objective comparisons between OPOs.
4. Today, most OPOs have broad clinical triggers for referrals, and over 80% of the patients referred are not dead at the time of referral. A significant portion of these patients are ruled out for both organ and tissue donation at the time of referral. The OPTN recognizes the criteria for 'ruling out' are not standardized across OPOs and supports working with HRSA to establish a list of absolute contraindications to donation that can be implemented with the VPF data collection to ensure that there is consistent data capture across the system. Additionally, more granular medical and neurological data regarding the patient referral is needed to understand decision making in ruling in or out referrals.
5. To achieve the data directive goals, the OPTN recommends HRSA reconsider the scope of the VPF population. The VPF population can include all patient referrals for both living and deceased patients. For those 'ruled out' based upon the absolute contraindications list, OPOs can provide limited data while also being adequate to facilitate an understanding of OPO practices/performance. For those patients who proceed in the donation evaluation process or go on to become a donor, a full VPF can be completed. The standard death record review process would identify any VPFs to submit that were not referred by the hospital.

Secondly, the OPTN notes that the VPF contains many data fields that do not provide sufficient guidance or granularity, thereby creating the risk of subjective interpretation that could inadvertently increase rather than decrease variability in reporting across OPOs. While choice list values are provided within the instructions (e.g., case disposition field), those values do not include definitions to help inform selection of the appropriate choice. The limited guidance and granularity will adversely impact the

ability to use the data for comparison of OPO performance and for OPO quality assurance and performance improvement efforts. Importantly, the listed choices are not mutually exclusive outcomes/process and with little guidance a user could select different outcomes for the same fact pattern of a patient's outcome.

As an example, the medical rule-out data element illustrates this concern with the lack of guidance or granularity. Increasing the number of organs procured and transplanted from medically complex donors is one key strategy to make more organs available for transplant. Current OPTN definitions for eligible and imminent neurological death support this strategy through the inclusion of both donor and organ-specific medical exclusionary criteria designed to ensure that patients are not medically ruled out even if only one organ is suitable for transplant. No such exclusionary criteria are provided in the VPF instructions, nor is any additional objective verifiable data requested to support or substantiate a medical rule-out case disposition. The OPTN recommends adding objective, verifiable medical suitability data so that conclusions can be drawn regarding the suitability of specific organs for transplant, making it possible to evaluate and compare OPO performance in maximizing organ utilization.

Thirdly, the OPTN is concerned that the lack of clear definitions or a hierarchical deterministic algorithm in the VPF to select a single case disposition from the options provided will result in widespread variability in reporting. The following two scenarios exemplify how different case dispositions could be selected depending on how an OPO interprets the options provided in the VPF:

Scenario 1: A 36-year-old male with gunshot wound referred to the OPO cardiac arrests prior to onsite response or approach.

Potential dispositions an OPO could select in this case include:

- OPO Decline to Pursue Donation (the OPO did not offer the hospital suggestions to support the patient hemodynamically, did not respond on site, did not coordinate uncontrolled DCD)
- Medical Rule Out (since patient had a cardiac arrest, the OPO considers this a medical rule out)
- Cardiac Arrest prior to OR (there is no clear guidance that would indicate that this is an inappropriate choice for outcome)
- Hospital Interference (patient was not called with sufficient time for OPO to get on site and coordinate a different outcome so could be considered a referral made to OPO outside of timely requirement)

Scenario 2: A 36-year-old brain-dead potential organ donor referred to the OPO has a living will opposing donation.

There is no case outcome explicitly available for this scenario, so the OPO could choose:

- OPO Decline to Pursue Donation

- Cardiac Arrest Prior to OR
- Medical Rule Out

These two scenarios are not meant to encompass all possible points of variation, but rather to demonstrate the need for a clear algorithm that precludes variation in reporting. Additional comments on case disposition options are provided in the VPF field section of this document.

The OPTN has studied this situation and in 2023, the Membership and Professional Standards Committee (MPSC) developed a concept paper titled *Concepts for OPOs Referral Evaluation Data Collection Process.* The concept paper acknowledged that OPOs collect a large amount of data on referrals, but there is inconsistency in their processes and in how the data points are defined. The paper proposes a new approach to OPTN data collection by focusing on developing a module that can be incorporated into Electronic Donor Records (EDRs) that includes standardized documentation of referral findings and logic to drive responses by frontline staff to questions during the referral evaluation process. The module would include algorithms that would define outcomes. The standardized data captured through this EDR module would then electronically transfer this data to the OPTN Computer System. This proposed approach also aligns with the OPTN's recommendation on reconsidering the patient population for the VPF. The OPTN requests HRSA evaluate the MPSC's work product, attached, alongside this VPF feedback.

Finally, the VPF is intended to collect data on OPO processes. The OPTN believes that the blending together of process and outcome data fields in one data collection form undermines the ability to accurately measure the incidence and prevalence of process deviations from evidence-based best practices. Process deviations do not necessarily result in failed donation outcomes but preventing the documentation of process deviations for organ donors, or when other case disposition is selected, will result in the underreporting of process deviations and undermine the ability to have meaningful comparisons of OPO performance in managing process deviations. The inclusion of Hospital Interference as a case disposition option is the most notable example of the problematic blending of process and outcome measures in the VPF. Clearer definitions describing what constitutes Hospital Interference in addition to specific guidance related to OPO provision of process deviation reports or remediation plans to hospitals or hospital acceptance of process deviation reports or remediation plans provided by the OPO is needed.

The proposed VPF is too subjective to be meaningful and too limited in its specificity to be useful for purposes of OPO performance assessment and OPO quality assurance and performance improvement efforts. Major changes are required as described above and further documented in the VPF field level section to meet the stated goals.

Additional Comments

In addition to the data collection feedback, the OPTN is providing additional comments for HRSA's consideration:

- Communicate OPTN policy changes as the result of the Directive

  As the steward of OPTN Policy 18: Data Submission Requirements, the DAC and the OPTN BOD need to understand the impacts of the directive on this OPTN policy. Based on the proposed data collection, policy changes are expected. Since these changes are not following the normal OPTN policy development process, the OPTN requests HRSA communicate these policy changes prior to submitting this data collection package to the Office of Management and Budget (OMB) for final approval. For members to adequately prepare for this change in data collection, it is imperative they understand the submission timelines and start dates for this new data collection.

- Set implementation plans and timelines in collaboration with vendor stakeholders

  The implementation of the directive has dependencies on member systems, third-party systems development efforts and testing. The VPF form implementation is expected to bring significant change to OPO processes and systems. Since the member systems are where the data originates, proactive coordination and collaboration is essential for the OPTN to manage its limited financial and human resources. To support a successful roll-out, the DAC members have offered to be part of a pre-waitlist pilot roll-out. The OPO community also supports a pilot approach to rolling out the new data collection.

- Provide resources needed to support benchmark reporting

  Assist members in improving their practices by developing benchmark reporting for the new data collection. Making such benchmarks publicly available can also improve system transparency for patients, donor families, and other patient-centric entities.

- Support the OPTN further improving this data collection

  HRSA shared their goal with this directive is to have the OPTN start collecting the appropriate data required to understand referral and evaluation activity. The OPTN Board encourages HRSA to communicate broadly their support for future committee projects that will further enrich this data. For example, the OPTN should take up projects to add social determinants of health factors so leadership can gain a deeper understanding of the population of potential donors and patients being referred and evaluated.

Closing

<u>Pre-waitlist data collection</u>

In closing, DAC generally endorses and the OPTN Executive Committee supports the pre-waitlist data collection requirements as proposed in the 60-day FRN. Additional comments and recommendations are

included in this response to assist HRSA in finalizing the specific data requirements and planning for the development and implementation phases.

Ventilated Patient data collection

In closing, DAC advised the OPTN Executive Committee that the VPF data collection requirements need additional work prior to their endorsement. To support improving the VPF, this response contains comments and recommendations for HRSA's consideration. DAC and the MPSC workgroup chair shared much of this feedback on January 31, 2024, and offer again to assist HRSA in making the necessary adjustments to the VPF. In summary, the DAC has the following concerns: The VPF data collection in its current form

1. is unlikely to meet HRSA's stated goals, as some of the data collection lacks the granularity needed for its intended use, for example medical rule-out reasons.
2. requires further definition of terms, choice list values and a logical data flow to collect consistent and complete data.
3. is likely to have fields reported as "Unknown" for patients that are ruled out early in the donor evaluation process prior to OPO going on-site or accessing medical record.
4. does not have a clear target population; several items require clarification and standardization to achieve the goals.
    1. The OPTN strongly recommends HRSA partner with the MPSC workgroup to layout a holistic approach for this data collection so it can be standardized in the EDR systems to ultimately source the appropriate data fields downstream to the OPTN Computer System.
5. blends together two types of data collection on one form
    1. Combining patient demographic, clinical and terminal step data alongside process data and hospital interference is problematic.
    2. Hospital interference data fields require further information to achieve a higher level of data quality and consistency in the responses.
    3. Data submission timelines are unclear however it is unlikely all this data would be available in the same timeframe for timely submission. HRSA should consider this data being captured on separate forms.

As a partner in managing the OPTN data registry, the OPTN wants to partner with HRSA to improve this new data collection quickly so that it can proceed to the next step in the approval process. The OPTN welcomes the earliest opportunity to discuss this feedback with HRSA and identify next steps.

Pre-waitlist Referral Form – Field and Instructions Feedback

The OPTN recommends including the definition of referral, including guidance on the beginning and end points of the referral in a short paragraph at the beginning of the form and form instructions. This would mirror current forms that define the timing of the data collection for said form in an instruction paragraph located at the top of the form. Proposed Referral definition: The organ transplant referral phase begins with the first medical record notification to the transplant team of the following: Minimum of three patient identifiers (name, birth date, birth sex) and patient contact information. The organ transplant referral phase ends with the medical record notification to the transplant team of any of the following: Initial visit with the patient (in-person or virtual encounter) or Tx team orders tests. At this time, the referral closure and reasons are documented.

Field Label	Feedback
Organ	Recommend clarifying how to report multi-organ patients or patients referred for single organ but become multi-organ candidates.
Source of payment/secondary	Options are TBD, could utilize options in primary insurance
Referring provider NPI	1. Recommend including an option for self-referral. 2. Recommend including how to report referrals from dialysis center social workers in instructions.
Referral status	Recommend adding more information to the definition/instructions to include information about the process to report a patient that moved to the Evaluation Phase.

Category	Feedback
Missing Fields	• Consider adding - Evaluated and declined by another center for transplant: yes/no
Additional Feedback	○ Patients referred but not seen would not be able to complete all the required fields. ○ DAC's Pre-waitlist Workgroup can support reviewing the final choice list values for code fields during the solutioning of this data collection.
Functionality/ Solutioning	○ Cascade patient demographic data from Referral to Evaluation form to reduce burden. ○ Data collection must be a periodic upload or API due to volume.
Fields without feedback	○ Transplant center

Category	Feedback
	○ Transplant center code ○ Patient MRN ○ First name ○ Middle name ○ Last name ○ DOB ○ Birth sex ○ SSN ○ Race ○ Ethnicity ○ Primary phone number ○ Permanent street address ○ City of permanent residence ○ State of permanent residence ○ Zip code of permanent residence ○ Country of permanent residence ○ Referral date ○ Death date ○ Referral status/Referral closure reason

Pre-waitlist Evaluation Form – Field and Instructions Feedback

The OPTN recommends including the definition of evaluation, including guidance on the beginning and end points of the evaluation in a short paragraph at the beginning of the form and form instructions. This would mirror current forms that define the timing of the data collection for said form in an instruction paragraph located at the top of the form. Proposed Evaluation definition: In the evaluation phase, medical and non-medical information is gathered about the patient so that the multidisciplinary selection committee can determine whether the patient is suitable to be registered to the national waitlist for an organ. The evaluation phase begins at the initial visit with the patient's agreement to complete the review process. The evaluation phase ends when the patient's case is presented during the committee review meeting.

Field Label	**Feedback**
Initial Evaluation Appointment Completion Date	This field was removed from DAC's original submission. What was the intent to remove this data field? The OPTN recommends this field be retained.
Evaluation Status/Evaluation Cancelation Reason	This field was removed from DAC's original submission. What was the intent to remove this data field? The OPTN would like to understand how a canceled evaluation (reported in error by the member) would be managed.
Organ	OPTN suggests multi-select functionality to account for more than one organ transplant
Source of Payment/Secondary	Recommend choice list options match the new source of payment options DAC recently approved
Working for Income	Clarify the definition of part-time to include "casual employment"
Height	1. Add a "not available" option (if patient drops out or is declined prior to measurements being collected) 2. Include better clarification on what height to use, such as the most recent or at initial evaluation time
Weight	1. Add a "not available" option (if patient drops out or is declined prior to measurements being collected) 2. Include better clarification on what weight to use, such as the most recent or at initial evaluation time
Primary Diagnosis	Recommend choice list options match diagnosis options used in other OPTN Computer System

Category	Feedback
Additional Feedback	DAC's Pre-waitlist Workgroup can support reviewing the final choice list values for code fields during the solutioning of this data collection.
Fields without feedback	1. Transplant Center 2. Transplant Center Code 3. Patient MRN 4. First Name 5. Last Name 6. DOB 7. Birth Sex 8. SSN 9. Race 10. Ethnicity 11. City of Permanent Residence 12. State of Permanent Residence 13. Zip Code of Permanent Residence 14. Country of Permanent Residence 15. BMI (Read only) 16. Evaluation Status 17. Selection Committee Decision 18. Selection Committee Date 19. Selection Committee Decision/Death Date 20. Selection Committee Decision/Declined Reason

Ventilated Patient Form – Field and Instructions Feedback

Many of the data elements on the VPF would not be available for all patient referrals due to how far the patient progressed in the donor evaluation process resulting in submission of 'unknown' values. Limited data is gathered when there is a clear reason to rule out a patient early in the process versus a more complete VPF submission for a patient where the OPO goes on-site or accesses the patient's medical record remotely.

Field Label	Feedback
Home Zip Code	1. Recommend that the instructions include a note to not report the hospital zip code in this field and choose "Unknown" if the patient's home zip code is not known. 2. Include an instruction of what to enter if patient does not live in the United States. 3. Likely that the data will be reported as "Unknown" for patients that are ruled out early in the donor evaluation process prior to OPO going on-site or accessing medical record.
Race	1. Recommend assessing the priority of updating race data collection to the recently issued OMB standard. Concerns about current data collection not addressing bi-racial and multi-racial categories. 2. Likely that the data will be reported as "Race Not Reported" for patients that are ruled out early in the donor evaluation process prior to OPO going on-site or accessing medical record.
Gender Identity	1. Recommend removal of this data element as it is 1. Inconsistent with the pre-waitlist forms and other OPTN data collections. 2. This information is not consistently collected by donor hospitals. 3. Gender identity has no clinical relevance to organ donation and transplantation. 2. Likely that the data will be reported as "Unknown" for patients that are ruled out early in the donor evaluation process prior to OPO gathering information from legal next of kin.
Height	1. Likely that the data for majority of patients will be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO going on-site.
Weight	1. Likely that the data for majority of patients will be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO going on-site. 2. Requiring gathering of weight for these patients will pose significant time and financial cost burden.
Age	1. Recommend consistency with other OPTN data collection that includes date of birth, if available, that will calculate age and age be collected only if date of birth is unknown.

Field Label	Feedback
	2. Recommend inclusion of option for unknown for patients that have not been identified.
HIV Status	1. Requests clarification for why HIV status is being collected and no other relevant serologies, especially when HIV positive status is no longer an absolute rule out. 2. Suggest removal of this field and only collect for donors given the sensitivity of this information and that HIV is not an absolute rule out for donation.
Did patient legally document their decision to be an organ donor?	1. Request clarifying the instructions regarding cascade to the Date and Time of Pronouncement of Death in the event of a No response to this question. 2. Most responses will likely be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO accessing registries or DMV records.
First Person Authorization Restrictions	1. Request clarification on what should be the definitive sources for these restrictions. 2. Suggest removing tissue as an option as tissue authorization is not relevant to the organ donation process and not within OPTN scope.
Date and Time of Pronouncement of Death	1. As noted in feedback for population definition, suggest completion of form and collection of this data element only when patient died within a set time after extubation where there was a potential for donation. Over 80% of referrals are not dead at time of referral and a large portion of those are ruled out for both organ and tissue donation. These patients may not die for days, weeks or even months later or potentially not die. Requiring date and time of death for all these patients is a significant cost burden that provides little value for improvement of the donation process. 2. Date and time for death of a referred patient that was ruled out for both organ and tissue donation early in patient evaluation will be unknown. 3. Suggest replacing "pronouncement" with "determination" because official pronouncement of death sometimes is done much later. 4. Suggest inclusion of additional question to gather whether the patient experienced a neurologic death or a circulatory death
KDPI (not required field)	1. Recommend removal of this field for the following reasons: 1. Optional data collection

Field Label	Feedback
	2. The raw data needed to calculate the KDPI would not be available for non-donors since much of the data needed to accurately calculate KDPI comes from a medical/social history collected from the legal next of kin and testing which is conducted on a small fraction of patients. 1. The calculation of KDPI is done by the OPTN Computer System and not by OPOs for donors. The KDPI for registered donors can be provided by the OPTN. 2. The KDPI changes as additional patient information is collected. 3. If this field is retained, recommend changing it to KDRI rather than KDPI given that the KDPI is calculated based on a reference to all recovered donors from the prior year.
Primary Insurance (not required)	1. Since this field is not required, recommend that it be removed. 2. This information is not captured by OPOs for ventilated patient referrals or donors. 3. Concern that collecting this information from the donor hospital could impact the relationship between hospital personnel and OPOs as it is highly sensitive information and it has no effect on the donation process or OPO performance. 4. For these reasons, it is likely to be reported as "Unknown" for most patients.
Date of Death Record Review	1. Suggest moving the "Date of Death Record Review" and the "Date and Time of Hospital Referral" fields to follow the "How did the OPO learn of this patient" field for better flow of the form. 2. Recommend that the scope of death record review be defined and standardized to produce consistent, quality data as there is variability in how death record reviews are performed.
Was the patient referred by the hospital to the OPO?	1. Recommend removal of this field as it is duplicate of the "How did the OPO learn of this patient?" field.
Date and Time of Hospital Referral	2. Suggest moving the "Date of Death Record Review" and the "Date and Time of Hospital Referral" fields to follow the "How did the OPO learn of this patient" field for better flow of the form. 3. Recommend clarifying instructions to provide guidance on how to document patients referred by one hospital and transferred to another, including patients that were referred and closed and then referred again by the same hospital or a different hospital.
Remote EMR Access	1. Clarification requested on what this field is intending to collect - did the OPO have remote access to the hospital EMR or did the OPO accessed the hospital EMR remotely for this patient? 2. Remote access to hospital EMRs is determined at the hospital level or by OPO staff user, not on a patient level.

Field Label	Feedback
	3. There are also varying levels of remote EMR access granted by hospitals. 4. Clarification of the instructions is requested as to whether this is a child question when the OPO responds "No" to the "Did the OPO respond onsite at the hospital to the patient referral" or is to be entered for all referred patients.
Advance Directive	1. Clarification is requested as to whether this would be collected only as the source of first-person authorization or objection to donation, used in determining the appropriate LNOK decisionmaker, or if an advanced directive on end-of-life care such as withdrawal of care exists.
Patient Record Type	2. Clarification is requested in the instructions to provide guidance on at what point in the evaluation this should be determined – at time of referral or at time of case disposition since eligibility changes as more patient information becomes known about the patient or the patient's condition changes 3. Suggestion that the field label be changed to "Donation pathway" or "Pathways being considered for donation"
Was the patient medically ruled out by the OPO prior to approach?	1. Recommend a standardized definition of the criteria for a medical rule out and more granular data be collected on the reason a patient is medically ruled out for use here and for the case disposition of "Medical Rule Out." 2. Clarification requested of the meaning of the term "prior to approach" and what is expected if the patient is ruled out after the legal next of kin is approached, either before or after legal donation authorization is obtained.
Family Objection	1. Clarification of how this field should be completed when there is first person authorization and an objection from legal next of kin. 2. Recommend that "family" be replaced with "legal next of kin" in the field name.
Date and Time of First OPO Hierarchy Approach for Authorization	1. Request for definition of "first" in the instructions. 2. Request that instructions be revised to request "time of approach" rather than "time of OPO onsite response" which could be via telephone or onsite.
Authorization	3. The options provided in the instructions require clarification. Regardless of whether the hospital discusses donation with the legal next of kin, the OPO will discuss with legal next of kin and get legal authorization. 4. Clarify whether response to this question is dependent on documentation of authorization.

Field Label	Feedback
	5. Suggest adding an option of "Undecided" as authorization may have been requested at time of case disposition but the legal next of kin may not have decided whether to authorize.
Tissue Authorization	1. Suggest removing this field as it is not relevant to the organ donation process and not within OPTN scope. 2. If the field is retained, an additional option for ruled out for tissue donation should be added and clarification on what would be included in tissue, for example eye dispositions, and categories of tissue since may get authorization for some types of tissue and not others.
Case Disposition	1. Request definitions for each of the disposition options be included in the instructions. 2. Clarification if the disposition options are mutually exclusive and if so, define when each option should be used to the exclusion of others. For example, hospital interference can occur at same time as other dispositions on the option list. 3. Suggest adding "wardens" in addition to ME and Coroner, since the warden can decline when the patient is in custody at time of death. 4. Request clarification for appropriate case dispositions to use for ventilated patients found on death record review. The only disposition that appears to apply is Hospital Interference so should this be the default?

Describe Hospital Interference	• Suggest replacing the term "interference" with a less harsh term as use of interference could damage relationship with donor hospitals
	• Concern that reporting hospital interference to OPTN and CMS could damage OPO relationship with donor hospitals.
	• Clarification requested as to when a response to this question is needed – only when the interference is an outcome that was the cause for no donation or anytime there is hospital interference reflecting opportunities for improvement in hospital process.
	• Request specific definitions and clarifications of the options.
	  ○ Referral made outside timely requirement – Should this be completed for every non-timely referral or only those that result in inhibition of donation. OPO definitions of timely referral vary so will limit the use of the data for comparison purposes
	  ○ Ventilated Patient Not Referred to the OPO – there is no medical or age criteria defined for use by OPOs to identify ventilated patients with donation potential on death record review.

Field Label	Feedback
	○ Unplanned Extubation After Referral Made to OPO – hospital may have planned extubation but not communicated it to the OPO or hospital may not have planned the extubation and not communicated it to the OPO. ○ Hospital Blocked OPO Approach for Authorization – clear definition is needed here. • Suggest Ventilated Patient Not Referred to the OPO autofill for ventilated patients identified on death record review. • Suggest additional options: ○ Hospital approached, family declined, OPO unable to talk with family ○ Hospital declined to medically treat ○ Patient appeared brain dead but testing not completed ○ Patient Transitioned to Comfort Care Before Referral Made to OPO – family may transition to comfort care only but not extubated
Report Provided to Hospital and Report to Hospital Accepted	1. Concern these fields carry a significant burden by individual case and require a change in process since OPOs generally formally document reports on a monthly or longer cadence and not by individual case. 2. Clarification requested for if reports are required only for those cases where it inhibited donation; what constitutes a report, verbal or written; who at hospital specifically should receive report for it to be considered provided to the hospital; what constitutes acceptance by the hospital; how the hospital will demonstrate or document acceptance or rejection of the report. 3. Clarification is needed for the expected time frame for reporting of these fields as may not be available in the same time frame as other data requested on the form.
Remediation Plan Provided to Hospital and Remediation Plan for Hospital Accepted	4. Concern these fields carry a significant burden by individual case and require a change in process since OPOs generally formally document improvement plans on a monthly or longer cadence. • Suggest replacing “remediation” with less harsh term such as “Improvement Plan” • Clarification requested of definition of "remediation plan;" if plan is required only for those cases where it inhibited donation; what constitutes a remediation plan, verbal or written; who at hospital specifically should receive report for it to be considered provided to the hospital; what constitutes acceptance by the hospital; how the hospital will demonstrate or document acceptance or rejection of the remediation plan.

Field Label	Feedback
Date and Time Case Close	1. Clarification required of the definition of "case close." A case has many end points depending on the disposition and the regulatory requirements governing it. For example, would the case close date and time be when the OPO has ceased external contact in the case (hospital partners, legal next of kin, etc.), when the last necessary field is completed in the OPO EMR, or when the case is required to be reported to the OPTN. How is this determined for patients identified on death record reviews?
Fields for which no field-specific feedback is provided	• Status • DonorNet Donor ID • OPO Record ID • Case detail/How did the OPO learn of this patient? (remove "Case detail/" from field name • OPO • Patient Hospital • Last Name • First Name • Middle Initial • Birth Sex • Ethnicity (comment in Additional Feedback) • Cause of Death (comment in Additional Feedback) • Mechanism of Death (comment in Additional Feedback) • Circumstance of Death (comment in Additional Feedback) • OPO Onsite Response • Date and Time of OPO Onsite Response • Method of Authorization Used by OPO • Approaches • Modality of First Approach • Language of First Approach • Interpreter for Approach

Field Label	Feedback
	• Date and Time of Authorization Obtained