January 3, 2025

RE: Public Comment on the Information Collection Request Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx-New.

Thank you for the opportunity for LifeLink Foundation and the independent LifeLink Organ Procurement Organizations: LifeLink of Florida, LifeLink of Georgia and LifeLink of Puerto Rico to provide feedback. We appreciate the ability to work with HRSA to ensure that meaningful and consistent data is collected on deceased organ donors.

Our response is generally iterative of the MPSC sponsored OPO Performance Monitoring Enhancement workgroup, and detailed comments are included in the Table.

We agree with HRSA's goal to collect data to provide "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." Additional data fields on the proposed Ventilated Patient Data form (VPF) must be clearly defined to ensure consistent and reliable reporting. These data fields should not increase the burden of collection or reporting. These data fields should have a clear purpose to ensure the public does not have concern over the information being collected. The VPF includes intended fields to collect both process and outcomes related data. It is important for these fields to be separated as blending them complicates the ability to clearly understand process deviations.

The instructions for the VPF, "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)." The patient referral pathway potentially includes both living and deceased patients. The VPF should focus on patients who move forward into the evaluation phase.

It is imperative that "Ever-ventilated" be clearly defined with the appropriate level of detail regarding the timing of ventilation to ensure consistency in the patient population being captured.

"Pronouncement of Death" should be changed to the "Determination of Death", along with associated fields.

In regard to the data fields, we generally endorse the response of the MPSC sponsored OPO Performance Monitoring Enhancement workgroup, with modifications, as noted in the table below.

Table

Ventilated Patient Form – Field and Instructions Feedback

Field Label	**Feedback**
Home Zip Code	• 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. • Include an instruction of what to enter if patient does not live in the United States.
Race	• 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. • 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	• Recommend removal of this data element as it is
	  ○ Inconsistent with the pre-waitlist forms and other OPTN data collections.
	  ○ This information is not consistently collected by donor hospitals.
	  ○ Gender identity has no clinical relevance to organ donation and transplantation.
	• 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	• 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. • Suggest this field should only be required for patients with a Donor ID
Weight	• 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. • Suggest this field should only be required for patients with a Donor ID
Age	• 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. • Recommend inclusion of option for unknown for patients that have not been identified or age is reported as unknown or estimated by donor hospital.

HIV Status	• 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. • 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?	• 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. Collecting information on restrictions when Next of Kin authorize donation is important to capture
First Person Authorization Restrictions	• Request clarification on what should be the definitive sources for these restrictions. • 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	• 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. Over 80% of referrals are not dead at time of referral. Many are ruled out at the time of initial referral 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 and would increase the data burden as OPOs would likely have to enter the referral information and then subsequently provide an update when the date/time of death is received. • For this reason, 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. • Suggest replacing “pronouncement” with “determination” because official pronouncement of death sometimes is done much later. • Suggest inclusion of additional question to gather whether the patient experienced a neurologic death or a circulatory death

KDPI (not required field)	• Recommend removal of this field for the following reasons:
	• 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.
	  ○ 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.
	  ○ The KDPI changes as additional patient information is collected.
	• 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)	• Since this field is not required, recommend that it be removed. • This information is not captured by OPOs for ventilated patient referrals or donors. • 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. • Concern that collecting this field could impact public trust in the donation system, for example, the public could deduce that OPOs are seeking uninsured patients ("poor") for donation • For these reasons, it is likely to be reported as "Unknown" for most patients.
Date of Death Record Review	• 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. • 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?	• 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	• 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. • 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.
OPO Onsite Response	• Clarification is needed - Is this intended to be the first OPO Onsite response? • If the OPO responded on-site after accessing the EMR via Remote Access clarification is needed on how this data will be completed
Date and Time of OPO Onsite Response	• See comment above regarding OPO Onsite response
Remote EMR Access	• Clarification requested on what this field is intending to collect - did the OPO have remote access to the hospital EMR or did the OPO access the hospital EMR remotely for this patient? • Remote access to hospital EMRs is determined at the hospital level or by OPO staff user, not on a patient level. • 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	• 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	• 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 • Patients are not referred as "Brain Dead" – the diagnosis isn't determined until the terminal event and sometimes after initial donation conversation. • 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?	• 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." • 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	• Clarification of how this field should be completed when there is first person authorization and an objection from legal next of kin. • Recommend that "family" be replaced with "legal next of kin" in the field name.
Date and Time of First OPO Hierarchy Approach for Authorization	• Request for definition of "first" in the instructions. • 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	• The options provided in the instructions require clarification. • Clarify whether response to this question is dependent on documentation of authorization. • 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	• Suggest removing this field as it is not relevant to the organ donation process and not within OPTN scope.
Case Disposition	• Request definitions for each of the disposition options be included in the instructions. • 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. • Suggest adding "wardens" in addition to ME and Coroner, since the warden can decline when the patient is in custody at time of death. • 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	• 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. o 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 o 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. o 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. o 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: o Hospital approached, family declined, OPO unable to talk with family o Hospital declined to medically treat o Patient appeared brain dead but testing not completed o 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	• 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. • 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.

	• 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	• 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. • 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.

Date and Time Case Close	• 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.), or
	  ○ 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?
	• Recommend using “disposition” as opposed to “close” to ensure consistency with wording on Terminal Step Case Disposition

Date of Referral	• Update to “Date of Ventilated Referral” to match “Time of Ventilated Referral”
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) • Method of Authorization Used by OPO • Approaches

	• Modality of First Approach • Language of First Approach • Interpreter for Approach • Date and Time of Authorization Obtained

Note: Adapted from OPTN Response to HRSA (p .16-23), 2024.

Again, we appreciate the opportunity to provide this feedback and look forward to collaborating with HRSA and CMS on this initiative.

Sincerely,

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LifeLink Foundation, Inc.