January 3, 2025

HRSA Information Collection Clearance Officer
Room 14NWH04
5600 Fishers Lane, Rockville, Maryland, 20857
(submitted via *paperwork@hrsa.gov*)

Re: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx-New

I am writing on behalf of the Association of Organ Procurement Organizations (AOPO), and we appreciate the opportunity to provide our comments in response to the *Information Collection Request Title: Data System for Organ Procurement and Transplantation Network (OPTN)*.

AOPO collectively represents 47 federally designated, non-profit Organ Procurement Organizations (OPOs) in the United States, which together serve millions of Americans. As an organization, AOPO is dedicated to providing education, information sharing, research, technical assistance, and collaboration with OPOs, other stakeholders, and federal agencies to continue this nation's transplantation success while consistently improving towards the singular goal of saving as many lives as possible.

AOPO endorses the recommendations contained in the OPTN Executive Committee's comments submitted to the docket. Their letter was built on the recommendations of the OPTN's Member and Professional Standards Committee (MPSC) paper entitled *Concepts for OPOs Referral and Evaluation Data Collection Process* ("MPSC Paper"). It was developed by people with expertise who work in the field and with the relevant data. A significant amount of time and effort went into preparing the paper, and it should be seriously reviewed and considered as HRSA looks to measure and improve the operations of the donation and transplantation system.

Data Collection Related to Process Components

AOPO endorses the effort to collect performance data from OPOs and other stakeholders with the goal of developing performance measures that accurately assess member performance, drive system improvement and increase donation and transplantation. Data on specific process components will facilitate identification of both effective practices and areas for improvement. Accurately measuring specific performance points in the donation process will assist OPO professionals in identifying and implementing effective practices employed by high performing OPOs.

AOPO also supports the increased collection of process points, especially data that provides insight into the timeliness or tardiness of donor referrals from hospitals to OPOs, to optimize the donor referral processes and increase the number of lives saved through transplantation.

Importantly, broadening the capture of data to all ventilated referrals from a donor hospital will provide a wider lens on the number and disposition of potential donors. The increased data obtained will improve

the understanding of the scope of work provided by the OPO in the donation process, as well as enhance the ability to assess individual OPOs within this wider pool of donors, potentially identifying areas for system improvement. The donation process includes work by the OPO on referrals that ultimately do not become donors. Currently, the ventilated referrals reported through the OPTN comprise approximately 5-10% of all ventilated referrals. It is important to capture that work to help identify process points that present barriers to donation.

Clarification and Standardization of Data Elements and Definitions

The proposed data collection tools include 52 data points with limited definitions provided approximately 12 (23%) of the data points are not currently collected by all OPOs. An additional 7 (13%) could be collected with additional clarification and potentially some data translation. Five (10%) of the 52 are available but are not currently part of an existing form. The remaining 28 (54%) are currently being collected on existing forms. AOPO has identified barriers for OPOs to collect some of the data proposed for collection.

Many of the proposed data elements lack definitions and risk inconsistent interpretations of the data being requested. This subjectivity will lead reporters to use their subjective interpretation of the data to be collected. Standardized definitions are critical to ensure data collected is consistent to support performance improvement efforts. AOPO strongly encourages HRSA to adopt the data definition recommendations set forth in the MPSC Paper and devised with input from OPOs and Transplant centers. One of the points made in the MPSC response is that there is a lack of granularity in some of the questions and proposed responses. As an example, during the Terminal Step, the Case Disposition proposed responses are not mutually exclusive. Several of the choices can be true at the same time. This could imply that HRSA only wants to collect hospital interference or FPA objections on cases that do not move forward.

Addressing Challenges to Data Collection

Data is not currently uniformly collected by OPOs and the data elements in this HRSA directive lack definitions to provide uniform collection. Implementation of standardized data collection, including some new data elements, will require collaboration with OPO software vendors to create fields for the OPOs to be able to capture the required data. AOPO estimates it would take 6-14 months to incorporate this full dataset in the existing Electronic Records, with the final thorough specification process, development, testing and implementation. Once the additions to the Electronic Donor Record (EDR) are developed, OPOs must adopt the changes and develop training for staff. AOPO strongly recommends HRSA proactively consult with software vendors to identify and address any software revisions that might be necessary to capture the additional data required.

Further, due to the volume of ventilated referrals, it is strongly recommended to allow the software vendors to develop a way to electronically import data from the EDR to the OPTN system. This development time is included in the 6-14 month timeline stated above.

AOPO estimates approximately 60-90 minutes for OPOs to complete each form if entered manually.

Since the number of ventilated referrals in the US is not reported anywhere, AOPO used a surrogate to estimate this number. The number of Imminent and Eligible referrals from the DonorNet Monthly Donation Data Report was obtained, as reported by each OPO. Based on a survey of a subset of

OPOs, the total number of Imminent and Eligible referrals comprise approximately 7% of total ventilated referrals. Extrapolating this over 55 OPOs, AOPO believes the estimated time burden would equate to:

- 55 Number of respondents
- 6195 Number of responses per respondent
- 340,731 Total responses
- 1.0 h – Average burden per response
- 340,731 Total burden hours

Finally, the ventilated patient form with our comments and recommendations on specific, individual data fields for your consideration is attached below and available here.

Sincerely,

Dorrie Dils
AOPO President
President & CEO
Gift of Life Michigan

Field Label	Availability	Feedback
Status	-	no feedback
DonorNet Donor ID	Available, currently in DNR	no feedback
OPO Record ID	Available, currently in DNR	no feedback
OPO	Cascades from database unless no DonorNet Donor ID	no feedback
Patient Hospital	Cascades from database unless no DonorNet Donor ID	no feedback
Case detail/How did the OPO learn of this patient?	Available, currently in DNR	no feedback
Last Name	Cascades from database unless no DonorNet Donor ID	no feedback
First Name	Cascades from database unless no DonorNet Donor ID	no feedback
Middle Initial	Cascades from database unless no DonorNet Donor ID	no feedback
Home Zip Code	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Ethnicity	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Race	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Birth Sex	Cascades from database unless no DonorNet Donor ID	no feedback
Gender Identity	May be available from some OPOs; unlikely to have for all referrals.	This information is not collected routinely by hospitals and therefore will be unavailable on most patients who do not become donors. It is unclear to AOPO what clinical relevance this question has to donation.
Height	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Weight	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Age	Cascades from database unless no DonorNet Donor ID	AOPO recommends this field be calculated using date of birth. If the patient is unidentified, there should be an "unknown" option.
HIV Status	Cascades from database unless no DonorNet Donor ID	no feedback
Cause of Death	Cascades from database unless no DonorNet Donor ID	no feedback
Mechanism of Death	Cascades from database unless no DonorNet Donor ID	no feedback
Circumstance of Death	Cascades from database unless no DonorNet Donor ID	no feedback
Did patient legally document their decision to be an organ donor?	Cascades from database unless no DonorNet Donor ID	no feedback
First Person Authorization Restrictions	Available, currently in DNR	no feedback
Date and Time of Pronouncement of Death	Cascades from database unless no DonorNet Donor ID	AOPO recommends that this field not be required or add clarification to require for donors only. The majority of ventilated patient referrals are not dead at the time of referral. In many cases, these patients do not die. Further, many are ruled out prior to their determination of death. Due to a non-specific CMS regulation for death record review, there is wide variation in this process, which is where one might find the date of death. For many OPOs, it is not feasible to go back to all of the ruled out referrals to determine a date and time of death. To require OPOs to do so, would add substantial time burden.
KDPI	Available on donors only, but should cascade from DonorNet	This field is part of the DonorNet record for those for whom it is calculated. Recommend cascading this information from DonorNet.
Primary Insurance	Not available or captured by OPOs	AOPO recommends this field be removed.This information is not collected by OPOs. Gaining access to this information for all referrals would be additional time burden for hospital personnel as well as OPOs. Asking for this information would potentially harm the relationship between the OPO and the hospital due to the sensitive nature of this information.

Field Label	Availability	Feedback
Date of Death Record Review	Available, currently in DNR	As stated above, there are no clear standards outlined in CMS regulations for this process. While this information is currently being collected for the DNR, as stated in the letter, the referrals included in the DNR capture represent only approximately 7% of total ventilated patient referrals. Death record review regulations states "an assessment of the medical chart of a deceased patient to evaluate potential for organ donation." If a patient has been ruled out early in the donation evaluation process, there may not be a full death record review. This would add significant time burden for the OPO, not only for this form completion. AOPO recommends better definition and standards for death record review process.
Was the patient referred by the hospital to the OPO?	Available, currently in DNR	AOPO recommends removal of this field as it is duplicate information to the question of how did the OPO learn of the patient.
Date and Time of Hospital Referral	Available, currently in DNR	no feedback
OPO Onsite Response	Available, may need data configuration or transformation	no feedback
Date and Time OPO Onsite Response	May be available at some OPOs, others would need to build process and database for collection of discrete information.	no feedback
Remote EMR Access	Not collected on individual referrals	AOPO recommends removal of this field. OPOs do not collect this on a referral basis.
Advance Directive	Available, but may need data transformation	AOPO seeks clarification on the purpose of this question - Is this solely for first person authorization, or other purposes?
Patient Record Type	Available for donors, should cascade from DonorNet	AOPO seeks clarification on this question. This information may be available at some OPOs, but will only be available once intent is organ recovery. This information could be provided as the 'donation pathway', again at the point where intent to recover organs is detemined. This would only be able to be determined at the terminal step.
Was the patient medically ruled out by the OPO prior to approach?	May be available, but needs more clarification.	AOPO seeks clarification for the language "medically ruled out". OPOs rule out patients for neurologic reasons as well as medical suitability reasons. Additionally, from a data collection standpoint, it would also be important to clarify what type of medical suitability rule-out was made (i.e. infectious disease, cancer, organ function). Lastly, cases are sometimes ruled out after an approach. Clarification is needed if those cases are included in this question.
Method of Authorization Used by OPO	Cascades from database unless no DonorNet Donor ID	no feedback
Family Objection	May be available, may need data transformation and development of process points in database to capture this question.	Need clarification as to whether this field can be completed if donation moves forward as there are objections that are successfully navigated, as well as those that are not. "Family" should be replaced with "Legal next of kin".
Approaches	Available	no feedback
Date and Time of First Approach	May be available at some OPOs, others would need to build process and database for collection of discrete information.	no feedback
Modality of First Approach	May be available at some OPOs, others would need to build process and database for collection of discrete information.	no feedback
Language of First Approach	May be available	no feedback
Interpreter for Approach	May be available	no feedback
Authorization	Available	no feedback
Date and Time Authorization Obtained	Cascades from database unless no DonorNet Donor ID exists; "Date and Time Consent Obtained for Organ Donation"	no feedback
Date and Time of First OPO Hierarchy Approach for Authorization	Sub-question of Authorization	The instructions need revision for this question. Replace "time of OPO onsite response" to "time of approach".
Tissue Authorization	Available at some OPOs, but need clarification on research versus transplant.	no feedback

Field Label	Availability	Feedback
Case Disposition	Data could be available but would need transformation of data.	AOPO recommends revisiting this question, potentially breaking it into several questions to obtain information requested. Several of the choices are not mutually exclusive in a case setting. For example, there could be Hospital Interference for a case that proceeds to donation. Having this as part of the terminal step implies that this form is only looking for Hospital Interference when a case does not proceed to donation. Further, there could be a registry objection but proceed to donation. If the question is not changed, AOPO recommends clear definitions be outlined for each choice, and the determination as to whether this is a multi-select or single select.
Describe Hospital Interference	Not always available on individual referrals and needs significant work to define and develop a system for submitting this information.	AOPO seeks clarification as to whether the "interference" is only required to be reported when donation doesn't occur due to that interference. There is also a concern that reporting the interference would damage the relationship between the hospital and the OPO. "Timely" is defined differently across OPOs. Clarification needed for a single definition, or data will not be comparable. "Ventilated patient not referred" is obtained via death record review, and therefore since asked how OPO learned of the patient, this information is already captured. "Hospital blocked approach" - Is this only if donation doesn't proceed?
Report Provided to Hospital	Not always available on individual referrals and needs significant work to define and develop a system for submitting this information.	There is currently no standardized method to collect this information on the referral record level. Currently, OPOs have different methods of conducting follow-up, which may or may not be documented in their electronic donor record. Further, the follow-up with hospitals may not be on a case basis, but rather in aggregate of a particular issue (i.e. patients not referred, timeliness, approach interference). This aggregate follow-up may be conducted over a period of time (monthly, quarterly). AOPO believes that the inclusion of these questions should be revisited and a process for following up with the hospital regarding interference be outlined and standards set, prior to a requirement to report this information to the OPTN/CMS. Without such clarification, the value of the reported data will be lost.
Report to Hospital Accepted	Not always available on individual referrals and needs significant work to define and develop a system for submitting this information.	
Remediation Plan Provided to Hospital	Not always available on individual referrals and needs significant work to define and develop a system for submitting this information.	
Remediation Plan for Hospital Accepted	Not available on individual referrals and needs significant work to define and develop a system for submitting this information.	
Date and Time Case Close	Available in some form	Need clarification as to the definition of "close". For each OPO this may be defined differently (exit OR, end of allocation, end of documentation).