From:	Karen Kennedy
To:	HRSA Paperwork
Subject:	[EXTERNAL] Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx-New - Comment
Date:	Friday, January 3, 2025 6:27:01 PM

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

Good afternoon,

Infinite Legacy ("IL"), the organ procurement organization ("OPO") serving Maryland, Washington, D.C., and Northern Virginia, appreciates the opportunity to provide comments on the Health Resources and Services Administration ("HRSA") Information Collection Request ("ICR") referenced above.

As a general matter, IL supports efforts to obtain more objective information on organ procurement practices in order to better assess OPO performance and provide more meaningful comparisons across OPO practices. However, as outlined in comments provided by the Organ Procurement and Transplantation Network ("OPTN") Board of Directors and by the Association of Organ Procurement Organizations ("AOPO"), the proposed ICR contains a number of problematic aspects that are counterproductive to its purpose, including data requests that require subjective interpretation, as well as data fields that an OPO would not have access to. IL generally agrees with the comments provided by the OPTN and AOPO and takes this opportunity to reiterate some specific concerns as follows.

It is unclear when in the process this data is to be collected, especially because several of the fields on the new ventilated patient form will not be known to the OPO at the time of referral but will instead appear in the later summary report. Any additional data collection should request information already available to or otherwise readily obtainable by OPOs. This would balance the need for consistent and reliable data without adding a significant burden on OPOs by requiring them to pull information that is not routinely pulled. As proposed, IL estimates an additional FTE position would be needed. Relatedly, some of the requested data is not within the purview of the OPO, such as the potential donor's insurance information.

Moreover, many of the data elements would not be available to an OPO depending on how far the patient progressed in the donor evaluation process. Depending on the nature of the referral and outcome, not all information will be gathered and it would be burdensome and add no value if an OPO was required to collect this information. in certain situations where a patient has been ruled out early as having no donation potential, such as by having metastatic cancer.

Similarly, it would be burdensome and provide no value to require an OPO to complete the

ventilated patient form, including the date and time of death, for referred patients who never had a potential for donation. Completion of the form could instead be triggered when a patient dies within a specified time frame after extubation where there was a potential for donation. By limiting form completion to donors and those patients who expired within a set time frame, the data burden would not be as overwhelming.

It is also unclear why certain data is being requested, such as patient HIV status. HIV status is not an absolute rule out for donation, so it is not obvious what metrics or other performance information would be gleaned from its collection. Moreover, collecting this sensitive information for all patient referrals would be inappropriate. Accordingly, this collection field should be removed.

Next, several terms could be interpreted differently across OPOs, meaning the data collected would not provide an objective picture of OPO practices. Many data fields do not provide sufficient guidance or explanation, thereby reducing uniformity and increasing variability. The instructions to the ventilated patient form should be specific and all terms should be well defined to ensure that all OPOs understand the requests and answering questions the same way. Having some type of exhaustive legend or glossary that describes critical terms, as well as definition tabs tied to each disposition option, could help ameliorate potentially wide variation in interpretation. Only by providing succinct, easy-to-interpret definitions will it be possible to compare processes and outcomes in an "apples-to-apples" context.

For example, the term 'ever-ventilated' could be interpreted differently across OPOs. At the very least, the term should be defined to only cover patients ventilated during the present hospitalization who are expected to progress in the donation process. As another example, what constitutes "Hospital Interference" as a case disposition is vague and open to interpretation. It could be interpreted to mean a hospital's inadvertent untimely referral, or it could mean a hospital's deliberate failure to cooperate with the OPO's donor assessment protocols. Although IL agrees that capturing instances of a hospital's lack of cooperation that impede the donation process is important in assessing OPO performance, clearer definitions and explanations describing what constitutes Hospital Interference is needed. Additionally, it may be beneficial to use a less negatively charged term.

Finally, the ICR assumes that OPOs have similar practices, such as in their death record reviews. However, OPO death record review practices differ across the board. In order for consistent data and meaningful objective comparisons between OPO practices and processes, consideration should be given to standardization of death record reviews.

Thank you again for this opportunity to offer our comments.

Regards,
Karen Kennedy

Infinite Legacy
Giving Life. Restoring Hope.

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