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LifeShareNetwork.org

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

LifeShare Network appreciates the opportunity to provide feedback on the proposed Information Collection Request (ICR) for the Process Data for Organ Procurement and Transplantation Network (OPTN). As the organ procurement organization (OPO) serving the state of Oklahoma, we believe the effort to collect more granular data to enhance the organ transplant system is commendable. Improved data collection has the potential to address critical issues, such as disparities in access and variations in system performance, ultimately advancing equity and outcomes in organ transplantation.

Though we support the goal of improving the system through enhanced data collection, we are compelled to note that the additional burden placed on stakeholders (OPOs and donor hospitals) is significant and must therefore be weighed against the accuracy and ultimate usefulness of the data collected. We are particularly concerned that, at the point of organ donor referral, the proposed new requirements will require considerable resources and effort to collect. For these additional efforts to be of value and the associated cost justified, data collected must provide clear, actionable insights that directly contribute to meaningful improvements in organ donation and transplantation. Without this value-added assurance, there is a risk the increased burden could significantly outweigh the intended benefit.

As an OPO, our extensive experience is that some data elements proposed to be collected at the time of referral from the donor hospital are frequently not available to the OPO. Further, that data which is available at the time of referral is often not accurate or is not accurately relayed by the hospital. These issues could lead to challenges in meeting the data requirements and simultaneously provide an inaccurate conclusion as to opportunities for desirable system improvements. Providing flexibility or clear guidance on managing incomplete data could mitigate these challenges and enhance though not assure more reliable reporting.

Corrective actions to improve system performance are desirable and we strongly support planning and implementing such actions. However, we also strongly support holding donor hospitals accountable for improving their own performance in timely, accurate, and appropriate referral of potential donors, and in collaborating with their OPO to create an environment supportive of organ donation. As written, the proposed language places responsibility for submitting a corrective action plan on the OPO, rather than on the donor hospital. This approach misplaces accountability, as OPOs lack the authority or resources







to unilaterally address systemic or process deficiencies within donor hospitals and donor hospital systems, and there is no requirement that the donor hospital either accept such a plan or actively participate in implementing it. Simply, the responsibility and accountability for corrective actions addressing hospital performance should reside with the donor hospital, where such issues originate and can be effectively addressed, with the OPO providing a supportive and collaborative role in making necessary process improvements.

We value HRSA's commitment to improving the organ procurement and transplantation system and urge careful consideration of these concerns. By ensuring that the proposed data collection provides actionable value, addresses practical implementation challenges, and correctly aligns accountability, this initiative can achieve its intended impact of enhancing the organ transplant system.

Sincerely,

Jeffrey P. Orlowski, MS, CPTC, FAST President and Chief Executive Officer