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Comments Received :

As a transplant professional with 20 years of experience in managing operations, quality, and regulatory compliance across adult, pediatric, abdominal and thoracic transplant programs, I offer the following comments. I also conferred with the abdominal and thoracic transplant surgical and medical directors as well as transplant quality and data professionals at my center to consolidate this feedback on this important initiative.

The prospect of additional metrics to benchmark performance, such as elapsed time from referral to evaluation; time from evaluation to listing; and referral-to-listing yield; is encouraging. We plan to incorporate the benchmarks into our QAPI structures and analysis, aiming for quicker response times to patients who are in need of an organ transplant. Some of the clinicians are also enthusiastic about the ability to publish research related to the new data. While we support sharing this data with HRSA and the downstream benefits, we have concerns about the current design and offer the following feedback:

- (1) **Data Quality:** A clear definition of "referral" is crucial for data accuracy. This is particularly true in heart transplantation, where pre-evaluation interventions by transplant teams are common. Often a heart patient is referred for 'advanced medical therapies' and it is not until the evaluation, that a patient's intervention is determined, sometimes this includes heart transplant.
- (2) **Patient Consent and Privacy for Referred Patients:** We have concerns regarding patient privacy and consent. Patients referred to a transplant program may not be aware (or can feasibly consent) to their information being shared with an external registry. The referral stage is often too early for patients to fully understand the implications.
- (3) **Minimizing Burden Through Technology:** We urge HRSA to allow batch submission of referral (and potentially evaluation data), rather than relying on the current UNet forms. This would significantly reduce the manual data entry burden and a preferable method for the highest volume programs, such as a kidney transplant program.
- (4) **Accuracy of Estimated Burden:** The estimated burden to complete a form on each new referral may be underestimated. Furthermore, accurate data capture at the time of referral is challenging and we would not want any significant data burden at the time of referral to cause a delay in processing the important referral.
- (5) **Challenges with Collecting Ethnicity at Referral:** Capturing ethnicity data at the referral stage may be problematic. Patients may be hesitant to disclose this information without understanding its purpose and how it will be used. In our program, sensitive information is gathered by a transplant social worker who can build trust and explain its relevance, a process not feasible during the referral steps.