From: Flores, Colleen O
To: HRSA Paperwork
Cc: Flores, Colleen O
Subject: [EXTERNAL] Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx-New
Date: Friday, January 3, 2025 3:32:07 PM

Hello HRSA – This is in response to the request for public comment. If possible, I would greatly appreciate, if you could share the proposed forms and also process my public comment below? Thank you, in advance.

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 on the proposed data collection initiative and not from my institution. My experience includes service on several OPTN committees and regular use of UNet to advise my programs on compliance with OPTN data standards, SRTR outcomes, transplant Centers of Excellence eligibility, and other reporting requirements.

As far as I am aware, nearly all transplant programs routinely track and review referral data. The prospect of additional metrics to benchmark performance, such as time from referral to evaluation, time from evaluation to listing, and referral-to-listing yield, is encouraging. While I support sharing this data with HRSA, I have concerns about the current proposal and offer the following responses to the questions posed:

(1) Necessity and Utility: While programs already capture referral and evaluation information, its utility could be significantly enhanced if HRSA linked referral data with disease prevalence by service area. This would allow programs to identify potential outreach opportunities by organ. If we know that black or female patients are underrepresented on waiting lists, for example, it's not enough to benchmark against the nation, we would benefit from information on what should it be or what is the expected based on disease prevalence.

(2) Accuracy of Estimated Burden: The estimated burden is inaccurate. A high volume of UNet forms can be cumbersome and contribute to a significant administrative load. Furthermore, accurate data capture at the time of referral is challenging and I fear that any significant data burden at the time of referral could cause a delay in processing the important referral.

(3) Enhancing Data Quality, Utility, and Clarity: A clear definition of "referral" is crucial for ensuring quality data. In heart transplantation, for example, pre-evaluation interventions by transplant teams are common and the defining the referral date/time is crucial for standardization. This distinction will ensure consistent data collection.

(4) Minimizing Burden Through Technology: I 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. Furthermore, an assessment of current UNet form automation levels across programs should be reviewed, as data submission evidence suggests low automation and high manual effort.

Finally, I have serious concerns regarding patient privacy and consent, prior to meeting with the transplant team. Patients referred to a transplant program may not be aware or permissive to their information being shared with the federal government. The referral stage is often too early for patients to fully understand the implications and provide informed consent.

Similarly, capturing ethnicity data at the referral stage could be problematic. Vulnerable patients may be hesitant to disclose this information without understanding its purpose and how it will be used. In our program, this sensitive information is gathered by a transplant social worker who can build trust and explain its relevance, a process not feasible during the initial referral.

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