From:	Haley Lewis
To:	HRSA Paperwork
Subject:	[EXTERNAL] Public Comment on Published Document 2024-25522 Regarding Pre-Waitlist Data Collection
Date:	Thursday, January 2, 2025 2:26:14 PM

I am submitting this comment as an affected member of the public regarding the proposed document 2024-25522 (89 FR 87592), issued by HRSA on November 4, 2024, related to additional data collection by the OPTN for potential transplant candidates.

My comments focus solely on the pre-waitlist data collection, not the deceased donor referral data, which I defer to OPO colleagues. These remarks are provided by me as a transplant professional and not on behalf of any institution.

While I understand the intent behind this proposal and acknowledge its potential value, I believe it is flawed and should be reconsidered. No specific use for the collected data has been outlined, and the method of collection imposes an unnecessary burden on transplant centers, diverting resources from essential clinical work. As such, the proposal does not comply with the Paperwork Reduction Act, nor does it serve the public interest in its current form.

If this proposal moves forward despite its unclear purpose, it should be revised to reduce the burden on transplant centers. Instead of individual patient forms, a single annual spreadsheet submission per program would be more efficient, as used by the OIG for similar data. The patient-by-patient method is necessary for time-sensitive OPTN tasks like waitlist registration, but no such urgency exists here. Since the data is for study and possible policy development, a simplified spreadsheet submission would ease the burden on centers, allowing them to focus more on clinical care than on uncertain administrative tasks.

I recognize HRSA's good intentions in proposing this initiative and am eager to collaborate on future policy assessments once the results of relevant studies are published. However, the Paperwork Reduction Act requires a clear justification for the burden imposed by new data collection, and it mandates that efforts be made to minimize that burden through technology and efficient processes. Unfortunately, this proposal fails to meet both criteria, and it should either be withdrawn by HRSA or rejected by OMB. Instead, the existing OIG research effort (and any additional research deemed necessary) should be concluded and published, with any subsequent data collection only proposed after these results are thoroughly reviewed. If additional data collection is required, it must adhere to the minimum burden standards, which could be achieved through periodic report submissions rather than the cumbersome patient-by-patient data entry.

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