

From: [McNatt, Gwen E](#)
To: [HRSA Paperwork](#)
Subject: [EXTERNAL] Comment
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This E-mail is my comment as an affected member of the public on Published Document: 2024-25522 (89 FR 87592), proposed by HRSA on 4 November 2024 regarding additional data collection by the OPTN.

This comment is regarding the data collection for pre-waitlist information on potential transplant candidates, not the collection of deceased donor referral data, which I defer to colleagues from the OPO community. This comment is submitted on behalf of myself as a career transplant professional, and not on behalf of any institution or organization.

Although I do not question the good intentions of those making the proposal, I do not support it. The proposed data may prove to be interesting or useful, no actual use of the data has been specified in the proposal. The data collection will also add a considerable burden on transplant centers, diverting resources from more useful activities. Both the resource burden and lack of specific purpose render the proposal non-compliant with the Paperwork Reduction Act and not in the public interest.

The proposed data collection could provide interesting data to develop future policy, but it is not clear that it will serve any purpose in the OPTN's authorized functions. This sort of data collection search for a purpose would best be accomplished as a research project, the results of which could be used to justify a permanent public burden. This, in fact, has already been started by OIG less than a year ago. The OIG required transplant centers to submit data similar to data in this proposal. The results of that submission should be shared and discussed.

I am also concerned about the data collection methodology. What is proposed involves submitting thousands of forms with manually abstracted data. In the very least, OPTN should work with the major electronic health record vendors to develop APIs and discrete fields for this data. However, this process would still involve tremendous effort by transplant centers. A preferable alternative would be to use the methodology employed by the OIG. Instead of thousands of individual forms, transplant centers could annually submit data on a single spreadsheet. The data is certainly not time sensitive. This would considerably decrease the effort required.

I appreciate the opportunity to provide comment on this proposal. I believe that the proposal fails to meet the requirements of the Paperwork Reduction Act as no explicit purpose for use of the data is specified and there is no effort to minimize the tremendous effort required. I recommend that the proposal be withdrawn. The HHS OIG research effort initiated already (and any other needed research efforts) should be conducted, published, and discussed, and only then should further data collection be proposed. If and when it is, it should adhere to minimum necessary burden requirements, which would in this case be achieved by periodic report submission and use of technology rather than manually abstracted data on individual forms.

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