From: Luke Preczewski
To: HRSA Paperwork
Subject: [EXTERNAL] Public Comment on Published Document: 2024-25522 (89 FR 87592), proposed by HRSA on 4 November 2024
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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.

While I have no doubt this submission is well-intended and that the data provided have the potential to prove interesting, it is also critically flawed and should be withdrawn. First, while the proposed data collection has the potential to ultimately prove useful, no actual specific use of the new data to be collected is proposed here. Further, the method of collection is tremendously and unnecessarily burdensome on transplant centers, which will redirect effort from useful activities to this data collection of undefined purpose. As such, this proposal is not compliant with the Paperwork Reduction Act nor is it in the public interest to proceed as proposed.

The proposed data collection is one only of potentially interesting information in developing future policy. It is not currently clear it will serve any actual purpose in executing the OPTN's authorized function. This sort of collection is best undertaken first as a research project, and only after the publication of those results, considered for permanent public burden based on the demonstrated likely usefulness of the information. This would best be done by funding an academic study, for which HHS has multiple mechanisms. Moreover, in this case, there is already an effort underway. The OIG already required transplant centers to submit similar information less than one year ago. Before anything is put forward as a proposal, the results of that should be shared. From that, further study could be undertaken, discussion could occur, and ultimately policy could be proposed that might be able to justify the considerable public burden being suggested here.

If this proposal does move forward despite its undefined purpose -- which it should not -- it should at least seek to minimize the burden it places on centers. This could be accomplished easily by removing the request to submit hundreds of thousands of individual forms and replacing it with an annual submission of a single spreadsheet per transplant program. This method was used by the OIG in its recent request to look at similar data. The single patient form methodology is required for other OPTN data collection such as waitlist registration because of the time-sensitive need to place patients on the waiting list to match them with offered organs. No such need exists here. As these data are being collected at this point only for study and possibly later for policy development and monitoring, no such urgency exists nor is it ever likely to. An annual submission of a spreadsheet would create considerably less burden for transplant centers, diverting less effort from useful clinical work to this only potentially useful data collection.

I appreciate the good intentions of HRSA in putting this forward, and look forward to working with the Agency on appropriate efforts to assess future policy in this area following the results of study. But the Paperwork Reduction Act contains explicit requirements for the government both to justify the specific purpose of proposed new burden, and to take steps (including the use of technology) to minimize that burden where possible. This submission fails on both

counts, and as such must be withdrawn by HRSA or denied by OMB. 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 rather than patient-by-patient form-filling.

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