

January 3, 2025

Joella Roland  
Health Resources and Services Administration (HRSA) Information Collection Clearance Officer  
Room 14NWH04  
5600 Fishers Lane  
Rockville, MD 20857

*Submitted electronically at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov)*

**Re: Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New**

Dear Ms. Roland:

The American Society of Transplantation (AST), which represents more than 5,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care, appreciates the opportunity to provide comment to the Health Resources and Services Administration (HRSA) prior to the agency's submission of the Information Collection Request (ICR) entitled "Process Data for Organ Procurement and Transplantation Network" to the Office of Management and Budget (OMB). The United States operates the most successful transplant system in the world because of the successful partnership among government, organ procurement organizations (OPOs), and transplant centers.

AST strongly supports HRSA's commitment to increase the number of deceased donor organs transplanted. Further, we support HRSA's effort to expand data collection early in the potential donor patient assessment, consent, and conversion process, beginning at the point of referral of a donor-candidate to an OPO. Similarly, we strongly support data collection early in the potential transplant patient referral and evaluation process. As HRSA notes in its proposal, this information is essential in understanding variations in practice that may be contributing to healthcare disparities. Collecting these additional data is another positive step in continuing efforts to maximize the gift of life for patients enduring end-stage organ failure.

**Despite our unmitigated support for the goals of increasing organ transplants and improving patient outcomes, AST believes the proposed methodology must be modified to minimize unnecessary burden on already resource-limited transplant centers and OPOs.** After consulting with our members (including some who have attempted to estimate the

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#### GOVERNMENT RELATIONS

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time needed to complete the processes outlined in the proposal), AST believes that the burden is likely underestimated. Even if the agency's calculation of more than 252,000 hours was not underestimated, it would still divert the efforts of 120 transplant professionals (based on a standard work year of 2,080 hours) from their critical work, thereby unnecessarily increasing the cost of organ transplantation.

Fortunately, a more efficient option exists that does not compromise the proposal's goals. AST recommends that a periodic bulk submission of these data would effectively accomplish the important and necessary data collection while being far less burdensome on transplant centers and OPOs. Annual submission of these data would likely be sufficient, but AST would have no objection to biannually or quarterly submission. AST offers this alternative based on experience with the Department of Health and Human Services Office of the Inspector General's project to understand similar data in transplant referral and evaluation. That methodology required transplant centers to affect a one-time upload of one year's worth of data in kidney transplantation. The burden of this request was limited because most transplant centers had existing reports that allowed the output of the required information. If that data collection were to be a recurring requirement, we believe that virtually all transplant centers would simply automate such report collection.

Applying that experience to the proposed data collection, many transplant centers would require little effort to create the initial report. For others, some moderate programming would be required. Subsequent periodic reporting for all programs would require only a few hours per transplant center or OPO. Transplant centers preferring to manually assemble the data could do so using a CSV file. However, we suspect few, if any, would elect to follow this manual process.

AST acknowledges that transplant centers and OPOs currently use data collection forms akin to the ones that are proposed. However, those existing forms are used to collect data needed immediately to support organ allocation, whereas the proposed data collection is necessary only for periodic analysis. Importantly, most transplant candidates and donor patients for whom the proposed data would be collected will never have additional data submitted on individual forms. Therefore, even if the information could be moved forward in the system, it would be of no use nor would it reduce the burden. Ultimately, all the data collected under both this proposal and existing data collection should be collected by electronic interface from electronic medical records. Unfortunately, that is currently not realistic for most transplant centers and OPOs. AST supports efforts to move in that direction as technology permits, and that whenever it can be reasonably accomplished, it should be permitted as an optional alternative method to periodic data uploads.

AST notes that the Paperwork Reduction Act requires government agencies proposing data collection to minimize burden on non-government submitters of data, including the use of information technology to affect this goal<sup>1</sup>. As such, we do not believe the current proposal is compliant with federal law. A revised proposal that leverages periodic bulk upload as described above would much more likely achieve a minimum necessary standard for public burden.

**An additional concern that AST must highlight is that the use of collected data must be carefully considered prior to implementation.** Historically, data gathered from the transplant system have been used by government agencies, contractors, and private payors in a manner that has had unintended consequences in reducing access to transplant care without improving

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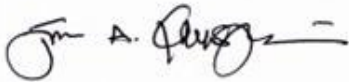
<sup>1</sup> 44 USC Sec. 3501: Purposes. From Title 44, Public Printing and Documents. Chapter 35, Coordination of Federal Information Public Policy; Subchapter I, Federal Information Policy.

desired outcomes.<sup>2</sup> This proposal does not describe how the data will be ultimately used, but it does indicate that it “may also help to improve monitoring of OPO performance and would facilitate quality assurance and performance improvement efforts to reduce the variation in the quality-of-care OPOs provide to donors and donor families.” To avoid unintended consequences, AST urges HRSA to avoid developing reports and regulations using the data without engagement of the transplant community. AST stands ready to work closely with HRSA in those efforts when the time comes.

In summary, while we strongly support the intent of the data collection proposed here, AST does not support this proposal as constructed given the unnecessary and excessive financial and human resource burden on the transplant community. Fortunately, we believe it can be easily modified to dramatically decrease burden with no adverse impact to the goal of collecting these important data. We urge HRSA to adopt the modified approach described here, which would allow us to fully support this important effort.

Again, thank you for the opportunity to comment on “Process Data for Organ Procurement and Transplantation Network” prior to HRSA submitting the ICR to the OMB. Please do not hesitate to reach out to myself or the AST Director of Government Relations, William Applegate ([bappegate@polsinelli.com](mailto:bappegate@polsinelli.com)) should you have any questions or require additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Jon A. Kobashigawa". The signature is fluid and cursive, with a horizontal line extending to the right.

Dr. Jon Kobashigawa  
President  
American Society of Transplantation

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<sup>2</sup> Buccini LD, Segev DL, Fung J, et al. Association Between Liver Transplant Center Performance Evaluations and Transplant Volume. *Am J Transplant*. 2014;14(9): 2097-105.