ASTS
American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

January 14, 2021

Thomas J. Engels, Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906-0034—Extension (SRTR Data Collection Request)

Dear Administrator Engels:

The American Society of Transplant Surgeons (ASTS) is pleased to have the opportunity to comment on the Scientific Registry of Transplant Recipients Information (SRTR) Data Collection Request. ASTS is a medical specialty society representing over 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

The SRTR Data Collection Request solicits comments on a number of issues, each of which is addressed separately below.

(1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions

We stand for the protection of living donors and recognize the importance of data collection on long-term living donor outcomes. However, we support these efforts with the caveat that the transplant community does a great job evaluating, consenting, and caring for living donors. Stewardship of this heroic patient population and the precious gifts of life they provide means working to maximize the number of transplants performed in a safe way. While we understand and support the need for long-term follow up data on living donors, it should also be recognized that overarching and ever-expanding data submission requirements consume precious resources and risk compromising those overriding missions.

ASTS understands that the Department of Health and Human Services (HHS) is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living organ donation (42 U.S.C. 273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. 273b). While we recognize that the collection of data on living donors from Transplant Centers through the SRTR data collection efforts may be consistent with

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the Department's statutory responsibilities and may be useful in the preparation of the required report, it is less clear to us that the collection of data through SRTR reports is, a priori, the sole data collection mechanism available for HHS to fulfill its legal responsibilities or to produce this report. We encourage HRSA to explore other data collection methodologies that may prove at least as accurate and effective in obtaining long-term follow up data and that can be utilized in conjunction with or to supplement SRTR data collection efforts.

(2) The accuracy of the estimated burden

The measured data submission burden (based on data in the table in the linked *Federal Register*) seems implausibly optimistic. The time for completion and submission of the data elements likely dramatically underestimates the burden for transplant programs. It does not take into account the time and expense of training staff to fill out the forms or to transition between tasks, to explain to donors why data collection is important, or do service recovery with donors concerned about center or donor-self reported data submissions.

The estimated burden also does not account for the significant time spent on developing data submission compliance programs and monitoring and tracking the efficacy of meeting this requirement. Regulatory and compliance burdens have real, typically underestimated, costs for patients and all other stakeholders. The administrative burden in question brings significant opportunity costs by consuming scarce resources that otherwise would be spent on direct patient care and education. For this reason, the fact that the administrative burden of the SRTR Data Collection appears to be dramatically underestimated, raises our concern.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected

While collecting data from Transplant Centers may be an effective data collection approach for data related to living donors at the time of donation, it is not clear to us that Transplant Centers are likely to be the most accurate or cost-effective source of information on the long-term health effects of living donation. For example, living donors may reside some distance from the Transplant Center where the recipient procedure is performed, and the Transplant Center may have no ongoing clinical relationship with the living donor. We encourage HHS to explore alternative means of tracking the long-term impact of donation on living donors, including the use of Medicare, Medicaid, and private payer claims-based data bases, which may provide a more accurate picture of the health status of living donors over time.

(*4) The use of automated collection techniques or other forms of information technology to minimize the information collection burden.*

As we look towards the future of transplantation, we at ASTS remain committed to working with the SRTR, the Organ Procurement and Transplantation Network (OPTN), and others to explore and investigate new technology solutions that continue to improve data quality and minimize the information collection burden placed on Transplant Centers. Both UNOS and the SRTR continue to implement and release new programming interfaces to improve the connection between multiple platforms, thus streamlining crucial living donor data exchange and monitoring while minimizing the burden placed on individuals for manual data tracking. We applaud their innovation, while simultaneously recognizing that technical solutions take time and money to implement and often consume more resources than originally intended—sometimes resources that turn out to be comparable to those involved in current data collection methods. These solutions in the short-term also require extensive education, training, and explanation of documentation.

Despite these caveats, when we consider the long-term benefits, ASTS believes that the successful implementation of technologically sound solutions ultimately will decrease the labor burden of manual data entry, decrease expenditures overall, and allow our medical professionals to remain true to our mission of continuing to provide excellent patient care with the utmost level of quality. Therefore, we continue to remain diligent in our efforts to move towards finding technological solutions as a transplant community to reduce labor burdens as well as reduce the risk of errors inherent to human abstraction. We stand ready to help in any pilot trials of such systems to test for feasibility.

If you have any questions, or if we can be of further assistance, please contact ASTS Executive Director Maggie Kebler-Bullock at Maggie.Kebler@asts.org or on (703) 414-7870.

Sincerely,

Marwan Abouljoud, MD, FACS, CPE, MMM
President
American Society of Transplant Surgeons