

August 11, 2025

Ms. Nancy Lee
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Rockville, MD, 20857

Delivered Electronically

RE: RFI on the Scientific Registry of Transplant Recipients (SRTR)

Dear Ms. Lee:

The American Society of Transplant Surgeons (ASTS) welcomes the opportunity to respond to the recent Request for Information in preparation for a formal RFP for a contractor to serve as the Scientific Registry of Transplant Recipients (SRTR). ASTS is a medical specialty society representing approximately 2,400 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 ASTS strongly feels that the SRTR fulfills a critical role in serving multiple stakeholders within the transplant ecosystem, including the general public, patients, transplant candidates, hospitals, transplant and donation professionals and researchers to provide an independent source of the data and analysis and necessary to allow the success of an evidence-based national transplant system. While we have not always agreed with the architecture of some SRTR data reports, we have found SRTR to be outstanding in the skill and integrity with which they approach data collection and analysis. Furthermore, public confidence in SRTR's fulfillment of its role is enhanced by meeting quarterly with an advisory SRTR Review Committee (SRC) comprised of a range of transplant community stakeholder representatives.

QUESTION 1: What METRICS should the government use to measure the success and impact of the SRTR in meeting its users' needs:

1A: INDEPENDENT SRTR Data Analysis & Reporting

We unambiguously assert that an independent contractor that has a reporting obligation to the transplant community is critical. Both independence and the reporting requirements are vital for the continued success of the nation's transplant system and the protection of the patients we all serve. Maintenance of the SRTR contract as outlined by the National Organ Transplant Act (NOTA) to be fulfilled by an independent non-profit entity is absolutely necessary to maintain a high performing, efficient and fair transplant ecosystem. We recommend that SRTR data analysis and reporting continue to be performed by an independent contractor that operates separately from HHS agencies and individual transplant centers.



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It appears that HRSA intends to engage a “data analysis” contractor separate from the SRTR. If so, it is conceivable, even likely, that that contractor will report directly to HRSA rather than to the critical transplant stakeholders supporting the transplant ecosystem. Transparency, and potentially accuracy, would fall victim to this approach if implemented. Therefore, if HRSA engages a “data analysis” contractor, we recommend that HRSA require the data analysis contractor(s) to maintain a public site detailing the data, computational assumptions, methodologies, and other tools necessary for third parties to replicate critical analyses and simulations.

1B: TRANSPARENCY of SRTR Research Dissemination

We note the critical importance for safety, quality, and preservation of the public trust that transparency of data collection and analysis play. The notion that data collection and analysis are transparent has been a crucial component, and guiding principle, of the SRTR. We recommend that all SRTR derived research whether conducted by SRTR employees, OPTN committee members or transplant community stakeholders be freely disseminated to the public in a timely fashion. Further, all SRTR derived patient centric tools that have been vetted through the SRTR review committee be released for use to the public in a timely fashion.

We again express our grave concern that HRSA sanctioned and approved SRTR derived research resulting in peer-reviewed abstracts and presentations have been censored and the analyses and tools that can greatly aid the transplant community and patient stakeholders have been withheld by HRSA. This understandably leads to a perception that HRSA has prevented the dissemination of data and analyses that contradicts favored narratives regarding the state of transplantation in the United States. We again encourage HRSA to allow, as it has for decades prior, frank and open public discourse and careful review of the available evidence. These are critical components of the scientific peer review process that inform and drive changes in policy and the monitoring of those policies.

Unfortunately, during the past several years, there has been an erosion of public trust and confidence in the transplant endeavor by multiple stakeholders in the transplant ecosystem and by the general public on which transplantation relies. We recommend that HRSA immediately implement the SRTR-derived, patient-friendly and patient-centric website developed in response to the transplant community recommendations that arose from the SRTR Task Five “People Driven Transplant Metrics” initiative. This action would be both symbolically and pragmatically helpful in signaling a commitment to transparency and accountability to patients.

QUESTION 7: Describe suggestions for incorporation of contract requirements to increase SRTR’s technical ability to use existing regulatory standards and ensure appropriate alignment with other federal agencies, including the Centers for Medicare & Medicaid Services.



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For the SRTR and the OPTN to function efficiently, obstructions in flow of data from the different agencies of the Department of Health and Human Services (DHHS) need to be minimized to the extent feasible. For many years, there has been a lack of unimpeded data flow, for example data from CMS to HRSA and its contractors. This limits collaboration, data analysis, policy development and strategic planning, and creates a perception that one arm of HHS does not effectively communicate with another. We recommend that HHS agencies collaborate to remove barriers to data flow, which is critical to the efficient functioning of the contractors and the transplant system they are intended to serve.

QUESTION 10. *Make recommendations for re-structuring SRTR contract requirements to eliminate redundancies with other OPTN contract activities.*

We recommend that any re-structuring of the SRTR contract a) does not impair the independence of the SRTR contractor data analysis and reporting to the transplant community and b) that the scope of data analysis and reporting continues to encompass all OPTN data.

QUESTION 11: *What specific prior experience should a vendor be able to demonstrate to be considered qualified to meet and excel at SRTR contract requirements?*

We recommend that the SRTR contractor have demonstrable understanding of the organ donation and transplantation system that includes documented engagement with the transplant community, peer-reviewed publications with SRTR data, a track record of data use integrity and responsiveness to data users' needs and concerns and a commitment to consistently include transplant stakeholders' perspectives in review of SRTR approach, methodology, algorithms, policy outcomes and patient centric tool development.

We offer these recommendations respectfully in the hope that HRSA will give serious consideration to this constructive feedback as they prepare the RFP for the SRTR contract. If you have further questions, please do not hesitate to contact ASTS Associate Director, Advocacy & Professional Practices, Emily Besser, at Emily.Besser@asts.org.

Sincerely,

James F. Markmann, MD, PhD
President, American Society of Transplant Surgeons