AMERICAN SOCIETY OF TRANSPLANTATION

October 1, 2024

Christina Murphy
Analyst, Health Care
U.S. Government Accountability Office
441 G St NW
Washington, DC 20548

Submitted via email

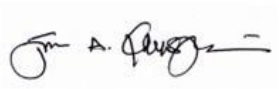
Re: AST Response to Government Accountability Office Queries on the Organ Procurement and Transplantation Network

Dear Ms. Murphy:

On behalf of 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, I am pleased to submit the attached written comments in response to your queries regarding the Organ Procurement and Transplantation Network. Further, I and other AST members appreciated the opportunity to participate in an interview with your team on July 7, 2024.

The AST thanks you for your important work on this issue. We remain available if you have follow-up questions or require additional information.

Sincerely,



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American Society of Transplantation
Written Responses to Government Accountability Office
General Questions Following Interview on July 9, 2024

Government Accountability Office Examination & Study of the Organ Procurement and Transplantation Network

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, is appreciative of the opportunity to provide information and perspectives on the Organ Procurement and Transplantation Network (OPTN) to the Government Accountability Office (GAO).

Please see AST's responses below. Please do not hesitate to reach out directly if you have questions or require additional information.

AST–GAO Interview Participants:

AST Members: Jon Kobashigawa, Dave Foley, Nicole Turgeon, Jonathan Maltzman, Luke Preczewski, and Roy Bloom. See page 7 for complete information on participant titles, affiliations, and AST roles.

AST Staff: Bill Applegate and Cindy Reilly

GAO Participants: Christina Murphy, Deirdre Brown, and Madeline Day

GAO Written Request and Response for Additional Information

1. **Please generally describe how transplant providers work with the OPTN.**

    a. **What specific services does the OPTN provide to transplant providers? Please describe.**

    b. **Do transplant providers use additional services provided by the United Network for Organ Sharing (UNOS) outside of the services UNOS provides as the OPTN contractor? If so, please list and describe them.**

Response
AST members and their employers utilize OPTN-provided services and resources, specifically transplant policies developed through committees, the Board, and the public comment periods in which AST participates. As members of the OPTN, transplant centers are guided by these policies and receive oversight by OPTN entities, such as the Membership and Professional Services and Committee (MPSC).

2. **In your opinion, what aspects of the OPTN work well and what could be improved?**

Response
AST can identify several areas where the OPTN works well. First and foremost, the volunteers from the transplant community who serve on OPTN committees demonstrate strong commitment and dedication

to improving patient care and patient outcomes. Many of the AST members who participated in this interview have served on OPTN's volunteer committees.

AST would like to acknowledge several areas where activities of the OPTN have improved, including:

- The OPTN has done strong work in engaging knowledgeable and committed transplant professionals to serve as volunteers. The engagement of these experts is essential to the important work of the OPTN.

- There has been notable improvement in the culture of the Membership and Professional Standards Committee (MPSC), which is doing good work in engaging transplant centers. Increasingly, engagements with MPSC have shifted from being perceived as punitive to being more constructive with an emphasis on providing mentorship. In addition, beginning last year, findings from program reviews by the MPSC are now being coordinated with the Policy Oversight Committee. These improvements are to be lauded, but potential opportunities for improvement are noted in the section below.

- The work of the OPTN Policy Oversight Committee, and the subsequent comment periods, have increasingly taken a more strategic and comprehensive approach. There is increased focus on policies that have an impact across the transplant community (e.g., multi-organ transplant, continuous allocation), with outreach to the OPTN Board, relevant OPTN committees, the transplant community, and other stakeholder groups when identifying priority topics. This approach has improved efficiency in the policy process. Other Policy Oversight Committee enhancements include:
    - Financial costs to the OPTN, including staff and IT, are now evaluated. However, an assessment of expected costs for transplant centers to implement proposed policy changes does not currently occur. This shortcoming is listed below as an area for improvement.
    - Policy development time has decreased significantly, although development time should decrease further to the extent possible.
    - Evaluation tools have been developed and refined to systematically and objectively evaluate the merit of policies. The introduction of these tools represents an important improvement, but the tools require further refinement.
    - Post policy implementation evaluation has also been started. Again, these efforts require additional refinement and energy.

AST cautions that these gains have the potential to be lost if the Board were to take back responsibilities from this committee as a result of its recent re-evaluation.

Areas where OPTN improvement is needed include:

- The OPTN Board structure would benefit from changes, including those expected to occur as part of the modernization effort. For example, the current model of regional representation conflicts with the goal of overall system improvement. The large size of the Board and the potential for perceived or actual conflicts of interests represent additional opportunities for improvement.

- As noted above, the impact of policy changes on transplant centers, including costs of implementation, should be considered as part of proposed policies. Currently, there is insufficient attention to logistical challenges. While the intent of these policies is good, an evaluation of what is

necessary to operationalize the change is necessary if the work is to be sustainable. This statement applies not only to the OPTN, but also to programs under the Centers for Medicare & Medicaid Services (CMS).

- The Expeditious Task Force is another area where refinement is needed. The intent of this task force is to pilot projects and to identify and address areas where existing policies prevent or prohibit improvement. The scope of the task force has now expanded to include broader issues, such as establishing a goal for the number of transplants per year. As another example, organ non-utilization is an area where the task force has engaged. However, it is unclear if the resulting variance policy will work for the entire country.

- The accuracy and reliability of OPTN data represents another opportunity for improvement. For example, data on deaths is not always accurate. The importance of reliable data is underscored by the use of data to inform policy and practice research. Additional AST comments on data as it relates across agencies are found under the response to question 5.

- Improvements to MPSC should include:
    - Timely acknowledgement and response when members submit concerns to MPSC.
    - Engagement by MPSC in issues surrounding out of sequence allocation. Further, AST encourages consideration of findings from an in-process OPTN Ethics Committee white paper on this topic when that work is complete.

a) Has AST shared this feedback with HRSA and the OPTN contractor? If so, how have they responded?

Response
AST has shared much of this feedback in our official comment letters and through regular meetings with the Health Resources and Services Administration (HRSA) Associate Administrator, the OPTN, and Congress.

3. Please describe the OPTN's oversight of transplant providers.

a) Is the OPTN's oversight and feedback to transplant providers helpful in improving their performance? Why or why not?

Response
See response to question 2 regarding notable improvement in the culture and function of MPSC.

4. What is AST's position on HRSA's OPTN Modernization Initiative?

Response:
AST is supportive of OPTN modernization and recognizes the need for change, especially with some existing OPTN systems and processes that are outdated or inefficient.
AST has encouraged HRSA staff to be as transparent as possible throughout the duration of the modernization effort. Given the complexity of the transplant system, strong and frequent communication is necessary to avoid misconceptions that occur in the absence of information. We are encouraged by HRSA's recent efforts to be more responsive to stakeholder concerns.

Areas of concern where additional information is needed include:

- What will OPTN membership look like under modernization?
- How will members' expertise be employed to support contractors?
- How might the roles and responsibilities of the OPTN Board change? AST recognizes the need to separate the Board from the contractors, but under that arrangement, how will the Board work with the contractors? By what process or mechanism will the Board be able to request that activities be completed by the contractors to support the Board's mission?
- How will oversight of committees, policy development, and other activities occur?

AST leadership has been engaging with Dr. Suma Nair, HRSA's Associate Administrator for the Health Systems Bureau on an ongoing basis. AST's goal is to build a strong relationship with HRSA. We are preparing to mobilize the expertise of our members to support work of the OPTN Board and contractors.

a) In what ways, if any, has or might the Modernization Initiative address any challenges transplant providers face?

b) In what ways, if any, has or might the Modernization Initiative hinder transplant providers' performance or cause additional challenges?

Response

An example of how HRSA's modernization efforts, combined with the work of other agencies, may hinder improvement are instances where regulations may set the performance bar too high. For example, a transplant center may experience less than favorable outcomes when it approves transplant candidates with higher unadjusted risk or accepts hard-to-place organs, resulting in the loss of their Center of Excellence status. Of note, publicly reported metrics on post-transplant survival are used by commercial payers. Thus, this scenario may create a disincentive for adopting the more assertive approach that HRSA and CMS are encouraging transplant centers to take.

5. Please describe any challenges with the organ procurement and transplantation system you think will not be addressed by HRSA's OPTN Modernization Initiative and any actions HRSA or the OPTN contractor could take to mitigate them.

Response

Data collection, integration, and use within HRSA/OPTN as well as across other federal agencies is a challenge that will not be fully addressed by the OPTN Modernization Initiative.

For example:

- There is a need for electronic medical record (EMR) integration so that policy changes requiring new data collection will not create undue burden or adversely impact center operations. Data collection should all be automated across all EMR platforms.
- Accurate data are necessary so that policy development simulations will be more representative of expected changes and, therefore, allow for appropriate decision making.
- There is a need to clarify how government contractors may use data within and outside the work contracted by the government to support quality improvement and practice evaluations.
- Data coordination among agencies is imperative. Metrics should be the same or aligned if they are different.

Although not discussed during the original GAO–AST interview, below are concepts to consider that were developed by AST and American Society of Transplant Surgeons representatives to the Organ Transplantation Affinity Group (OTAG) who were tasked with identifying activities beyond modernization that may produce positive results.

- Establish an Intra-Agency Coordinating Council to include CMS, HRSA, the OPTN, and the Scientific Registry of Transplant Recipients (SRTR)—and as needed participation by other agencies, such as the National Institutes for Health and the Food and Drug Administration—to engage with the community on an ongoing basis regarding issues of concern and reports to the Secretary.
- Establish non-overlapping spheres of regulation of transplant programs. Eliminate duplicative surveys, parallel appeals and program review.
- Eliminate the SRTR five-star ratings and OPTN Transplant Performance Metrics that disincentivize acceptance of hard-to-place organs and candidates who are higher risk.
- Conduct a comprehensive study that analyzes why and which organs are being declined.
- Establish unified regulatory policy that appropriately balances the need to minimize out of sequence organ placement (equity) and the need to increase use of hard-to-place organs (efficiency).
- Establish unified regulatory policy that appropriately balances the need to institute effective screens on organ offers (OPTN) and pressure on transplant programs to keep screens wide open to increase the number of transplants performed (Center for Medicare and Medicaid Innovation [CMMI] demo).
- Establish a single, comprehensive, well-publicized, user-friendly public facing website that provides patients with the information required under the Final Rule as well as information identified by the patient community during the Task 5 HRSA Initiative, including a tool that allows patients to determine their likely wait times at various centers, waitlist criteria, and other data necessary to guide decision-making.
- Establish a unified process acceptable to all federal agencies and patients for transplant programs to take into consideration patient preferences with respect to organ acceptance and periodic reporting of a transplant program's organ acceptance practices.
- Conduct a baseline study to establish the factors that result in disparities in waitlist access to help determine whether, and to what extent, disparities arise at each stage of the process (e.g., referral for transplant evaluation, patient follow up on referrals, meeting transplant program eligibility criteria, and maintaining "active" waitlist status), including a qualitative component to determine patient perspectives.
- In determining whether and to what extent additional data is necessary to address disparities in access, consider all data sources (including data that may be available from referral sources); collect any necessary data in a manner acceptable to both agencies; and streamline data collection burden.
- Require Medicare Advantage and Medicaid Advantage plans (including special needs plans serving end stage renal disease patients) to report on transplant access, including participating transplant programs, access to transplant evaluation, and network adequacy.

6. It's our understanding that the OPTN Modernization Initiative could take years to implement. Are there steps HRSA or the OPTN could take to improve the organ procurement and transplantation system in the interim?

Response:
See answer to question 5.

7. From your perspective, please describe HRSA's/OPTN's role in transplant provider oversight versus CMS's role.

a) Are the agencies' oversight roles well-coordinated?

Response:
AST believes that there are some redundancies and inefficiencies in the roles of HRSA and CMS. Overall, there is a need for better coordination among federal agencies with oversight of organ transplantation. For example, the lack of coordination has resulted in organ procurement organizations (OPOs) attempting to meet CMS metrics in a manner that conflicts with other metrics that apply to transplant centers. These OPO metrics have resulted in match runs not being conducted for some organs. AST recommends the development of one set of inter-related metrics to guide stakeholder efforts.

Proposals from HRSA and CMS (e.g., OPTN modernization, the Expeditious Task Force, CMMI's Increasing Organ Transplant Access model, and CMS metrics for organ procurement organizations) are being issued at a rapid pace. It is unclear to the transplant community whether there has been any coordination in these efforts. AST recommends narrowing the focus and/or improving coordination of these efforts.

As noted in the response to question 5, AST participates in the OTAG, which is intended to provide better coordination of CMS and HRSA efforts. AST representatives in this effort have seen a willingness of agency staff to engage and learn from stakeholders. However, as of now, we have not seen the goal of improved coordination come to fruition. AST remains hopeful that the expected benefit of this combined effort of HRSA and CMS will be realized over time.

b) Are there any ways in which their oversight could be better coordinated? For example, do any of HRSA's and CMS's oversight activities overlap, conflict, and/or require transplant providers to duplicate efforts?

Response
AST recommends that the agencies collaborate to develop an overarching strategy—with input and involvement of the transplant community—that would then guide the development and implementation of coordinated programs that build to achieving that overarching strategy.

8. In addition to requesting comments on proposed rules and requests for information, do HRSA and CMS seek AST's input on oversight activities and/or ways to improve the organ procurement and transplantation system? If so, please describe this outreach.

Response
Yes, AST meets regularly with HRSA, CMS and Congress.

AST Participant Information

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