American Society of Transplant Surgeons®

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Submitted via email to Ninazawa@hrsa.gov

May 9, 2022

Carole Johnson
Director
Health Resources and Services Administration
HHS/HRSA/OAMP
5600 Fishers Lane
Rockville, MD 20857

Notice number: 541611
Title: HHS/HRSA/OAMP Request for Information (RFI) on the Organ Procurement and Transplantation Network (OPTN)
Date of issuance: Friday, April 8, 2022
Name: American Society of Transplant Surgeons
Address: 1401 S. Clark Street, Suite 1120, Arlington, VA 22202

Dear Ms. Johnson:

The ASTS is pleased to have the opportunity to respond to the Request for Information (RFI) issued by the Health Resources and Services Administration (HRSA) soliciting comments on potential improvements in the contract arrangement between HRSA and the entity selected to function as the Organ Procurement and Transplantation Network (OPTN). ASTS is a medical specialty society representing approximately 1,900 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.

ASTS appreciates HRSA's taking prompt action to address the issues related to the organization and operation of the OPTN that were raised in the National Academy of Sciences, Engineering, and Medicine (NASEM) recent report entitled, *Realizing the Promise of Equity in the Organ Transplantation System (2022)* (the NASEM Report*).* We believe that, in light

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of the substantial changes in the field that have taken place over the many years since the first OPTN contract was awarded, the time is ripe to assess how the system is functioning for the benefit of our patients and what improvements can and should be made. At the same time, it is equally important to recognize the accomplishment of the current system. The number of transplants performed in the United States has increased annually with **more than 41,000 organ transplants performed in the U.S. in 2021**. Transplant outcomes have improved substantially: In fact, at this stage, the average one-year patient and graft survival for kidney transplantation is about 96%, and only a handful of transplant centers have one-year graft and patient survival of less than 90%. While we most certainly agree that improvement—especially in the areas of access and equity—are critical, care should be taken to preserve the gains that have been made over the past decades.

While the NASEM Report may include some recommendations with which we disagree, this Report provides a reasonable blueprint for addressing important gaps in the current system. The NASEM Report clearly states—and we agree—that reform efforts must start with a clear statement of system goals and priorities and with improved coordination among the various components of the system, including regulatory bodies. As the NASEM Report observes:

> The current organ transplantation system is unduly fragmented and inefficient. The system's component parts—physicians caring for patients with organ failure, donor hospitals, OPOs, the OPTN, transplant centers, the Scientific Registry of Transplant Recipients, CMS, and other payers, among others—do not operate as a fully integrated system. Likewise, each of the entities with oversight responsibilities oversee particular components, but none monitors the performance of the system as a whole in producing predictable, consistent, and equitable results.
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> The organ transplantation system could save additional lives and be more equitable if its component parts functioned in a more cohesive fashion and were overseen by a single entity, or by several entities operating in a coordinated fashion with common goals and unified policies and processes. Such alignment of all components and oversight responsibilities would allow the public and Congress to ascertain whether the system is fairly and efficiently maximizing the benefits provided by organ donation and transplantation.

NASEM Report at S-10. Any re-thinking of HRSA's contractual arrangements with the OPTN therefore should begin with a re-examination of the respective roles of the OPTN, the SRTR, CMS, the FDA, NIH and other components of HHS with authority over transplantation, with a view toward the avoidance of duplication and the coordination of potentially overlapping areas of jurisdiction.

Without this broader re-examination of the roles of each agency (or government contractor), any effort to reconfigure the OPTN contract is likely to perpetuate existing inefficiencies and inhibit system improvements.[1] We believe that this re-examination and the elimination of overlapping

[1] Beginning in 2018, ASTS put forth a proposal to HRSA and CMS for the elimination of duplicative and overlapping oversight of Transplant Centers, which, among other things,

or duplicative areas of responsibility (especially as between the OPTN and CMS) should be undertaken before the next OPTN contract is awarded, potentially as part of the Development of National Transplantation Goals (NASEM Recommendation 1). Narrowing the focus of the OPTN's oversight functions to specific areas not already overseen by CMS or other agencies would focus the OPTN's efforts on core areas delegated to it under NOTA and the Final Rule. We also believe that, to the extent that overlapping or duplicative areas of responsibility cannot be avoided, HRSA evaluate the OPTN's coordination with CMS and other agencies as one component of its evaluation of OPTN performance.

The RFI solicits feedback on a number of aspects of HRSA's contractual relationship with the OPTN, including OPTN Technology/IT; Data Collection Activities; OPTN Finances; OPTN Governance; Increasing Organ Donation and Improving Procurement; Organ Usage; OPTN Operations and Policy Improvement; and Stakeholder Engagement (especially in connection with transparency of organ acceptance decisions). We offer the following comments and observations with respect to these areas:

A. OPTN Technology – IT System

While the IT specifications that should be included in the OPTN contract are beyond ASTS' expertise, we do believe that, to the extent practicable, IT (as well as other) contract specifications should be drafted in a manner that does not restrict potential applicants to UNOS. A competitive process will help ensure that the OPTN contractor is incentivized to continually improve its performance. We also believe that, to the extent that implementation of significant IT modifications from the current system are included in the next OPTN RFP, the RFP also should include contractor requirements designed to ensure a smooth transition, so that critical OPTN functions, including for example, organ matching and transportation, are not disrupted.

B. Data Collection Activities

The RFI solicits input on how a prospective contractor would implement a "metrics dashboard" to track performance and evaluate results and would modernize the data collection for deceased donor organ procurement, allocation, distribution, and transplantation. We believe that the mechanics related to data collection and dashboard implementation are secondary: The critical questions are "What data should be collected?" and "For what purposes?" We believe that new and continued data collection activities included in the OPTN scope of work moving forward should comply with the following principles, and that OPTN performance in this area should be measured against these benchmarks:

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includes one option that would accord CMS primary responsibility for overseeing transplant center performance from admission through discharge of the transplant recipient and would accord the OPTN primary responsibility for oversight of Transplant Center waitlist practices, waitlist management, compliance with allocation rules, and post-transplant follow up (including data submission).

- Data collection should be clearly tied to, and necessary for the achievement of, a clearly stated goal or objective that is one of the National Transplantation Goals.
- New data collection should be authorized only if the data is unavailable from any existing data source.
- The appropriate audience for the data should be clearly identified and consulted about the utility of the proposed data collection before date collection is instituted.
- The potential inadvertent repercussions of data dissemination should be thoroughly considered in advance.
- The data collection administrative burden on transplant centers should not be increased: If additional data elements are to be collected, an effort should be made to reduce or eliminate other data collection requirements.

These principles raise multi-faceted questions, which impact numerous stakeholders, including, but not limited to, transplant centers, transplant surgeons and physicians, patients, payers, and researchers. To the extent that the OPTN contract solicitation for 2023 anticipates substantial changes either in the type of data to be collected or in data collection processes and procedures, we urge HRSA to require the OPTN contractor to engage in a public decision-making process that involves all affected parties and to measure OPTN performance with respect to data collection based on its adherence to these principles.

We are aware that the current SRTR contractor has been tasked with exploring and rethinking the type of data that should be collected, with special attention to patients' perspectives with respect to the types of data that would be most useful to them. We are also aware that the OPTN has only recently substantially revised the transplant center performance metrics to measure waitlist mortality and organ offer acceptance. We believe that any data collection necessary to effectuate these metrics-related activities should be analyzed based on the principles described above before being incorporated into the OPTN scope of work for 2023.

F. Organ Usage

In responds to a recent CMS RFI, ASTS has submitted extensive comments on the issue of organ usage. These comments may be accessed here. Among other things, these comments include our recommendations regarding improvements in OPTN matching and organ allocation policies that should be made in order to increase utilization of hard to place organs suitable for transplantation.

G. OPTN Operations and Policy Development Improvements

ASTS supports increasing the diversity of the OPTN Board and Committees, within any constraints imposed by applicable law and subject to the Board composition requirements in the Final Rule. Generally, we believe that OPTN policy development processes can and should be streamlined.

More specifically, we believe that the OPTN should establish a mechanism to take into account the views of professional associations such as ASTS, as well as other organizations representing stakeholder, during the policymaking process. While the OPTN does include individual surgeons, physicians, patients, and others with special expertise in various aspects of transplantation in many of its policy committees, these individuals do not have the authority to speak for the stakeholder community. We believe that earlier involvement of transplant-related associations and other groups would result in greater consensus and overall support for OPTN policies during the public comment period.

In addition, logistical challenges have become much more substantial under new policies that have resulted in broader organ allocation. We believe that the process could be improved if the OPTN were to consult with independent organizations with special expertise with logistical issues, especially in areas such as organ transport and tracking.

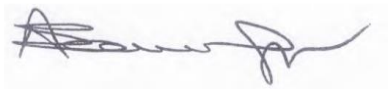
We believe that OPTN operations could be improved significantly if the OPTN were to conduct an assessment of the operational issues that the transplant community will face to implement each policy change. Such an assessment should take into account the views of the stakeholders whose own operations are likely to be impacted by the policy change, and should include an analysis of the resources likely to be required for the policy change to be implemented efficiently and effectively, with a view to minimizing or eliminating the potential impact of the policy change on patient care.

At the other end of the process, the OPTN—again with the input of affected stakeholders—should conduct an in-depth and objective post-implementation assessment of major new policies, in order to ensure that obstacles to efficient and effective implementation are identified and addressed. Post-implementation assessment that takes into account the actual experience of stakeholders has the potential to smooth implementation of future new policies.

H. Stakeholder Engagement. The RFI solicits public feedback on how the OPTN can and should encourage members to increase stakeholder involvement in organ acceptance decision making and stakeholder engagement strategies that advance equity, access, and transparency. ASTS believes that a number of steps can be taken to improve transparency and to facilitate shared decision making by waitlisted patients, and we would be delighted to work in cooperation with the OPTN, patient groups, and others to formulate processes to achieve these objectives. We strongly believe that any process that calls for notification or consultation with a patient at the time of an organ offer would be entirely unworkable and counterproductive, since any such process would substantially slow organ matching and increase organ discards overall. However, the patient voice most certainly can and should be heard at the time the patient is waitlisted and information should be provided to the patient periodically during waitlist period. We believe that the OPTN is the appropriate entity to bring all stakeholders together to design an information-sharing process that maximizes transparency while minimizing disruption and unnecessary delays in organ placement.

We appreciate the opportunity to comment on this important RFI, and look forward to continuing to work with HRSA to achieve improvements in the system while maintaining the system's hard won achievements.

Sincerely yours,



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