



December 23, 2024

Administrator Carole Johnson
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Delivered Electronically

Dear Administrator Johnson:

The American Society of Transplant Surgeons (ASTS) strongly supports modernization of the Organ Procurement and Transplantation Network (OPTN). However, we are concerned by the failure of the Health Resources and Services Administration (HRSA) to proactively engage the transplant community in advance of major structural changes to the system and to make plans for future changes transparent. We are particularly concerned about HRSA's recent decision to name the Nominating Committee that will determine the Special Election Board slate, without regard to the objections raised by ASTS, patient advocates, the OPTN Board, and others.

We believe that the engagement of multiple contractors has the potential to improve OPTN operations and to ensure that the transplant system works efficiently in the best interest of our patients. We likewise support the separation of the OPTN from HRSA contractors. At the same time, we remain concerned that the OPTN has been eliminated as a not-for-profit corporation responsible to transplant community members—a change that we continue to believe is legally problematic under NOTA and the Final Rule. Even more importantly, we are concerned that this and other major governance and operational changes have been made without prior notice to and consultation with the transplant community. **We strongly believe that all major OPTN changes should be thoroughly vetted before, not after, they are implemented.**

It is equally troublesome that major questions regarding the future of OPTN governance and operations remain unanswered. We urge HRSA and the OPTN to provide to the transplant community for public comment the designation agreement between HRSA and INVEST; a clear timeline for the transition to multiple contractors; a comprehensive description of the continuing role of UNOS (if any); a written description of what each of the recently chosen operational contractors will be doing (and when); and any other substantive or procedural changes in OPTN governance, operations and data collection anticipated as part of the OPTN Modernization effort.

With respect to governance, we are alarmed about the process that evidently will be used to choose a new Board of Directors through a Special Election to be held in the Spring of 2025 despite multiple written recommendations by ASTS and

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other stakeholders to follow the recently approved OPTN Bylaws and Management & Membership Policies. HRSA has made it clear that it intends to select a Board Nominating Committee that will determine the slate of Board candidates, with Nominating Committee members chosen through an informal process that involves outreach to selected groups (including ASTS) but without any public announcement that solicits nominations from the entire community.

While HRSA does have the authority to require that the OPTN hold a Special Election as a condition of the designation contract, we object to the process that we understand will be used.

- **Transplantation requires meaningful communication and teamwork among all providers and patients.** Representation of stakeholders on the OPTN Board needs to be determined by a Nominating Committee that has earned the respect and trust of the transplant community. Importantly, the Nominating Committee needs to include individuals with experience and expertise in organ acquisition and transplantation that is necessary to assess the qualifications of potential nominees.
- **The OPTN was established as a public-private partnership to ensure that highly sensitive policy decisions related to patient access, safety, and quality are made by the clinical and patient communities, independent of political influence.** HRSA has made it clear that its replacement of the OPTN Board is driven by exactly the kind of political considerations that the public-private partnership was intended to guard against. In this regard it is important to note that the OPTN Board makes organ allocation decisions that may impact different regions differently and that are therefore highly politically sensitive.
- **The OPTN Board makes decisions that are critical to patient care and access.** Many of these decisions require significant transplant clinical expertise, especially in the areas related to patient safety. A Nominating Committee chosen through a closed process by government officials subject to political pressure has significant potential to undervalue the need for clinical transplant expertise and experience in determining the Board slate.
- **The OPTN Board was advised by counsel that selection of the Nominating Committee by HRSA is inconsistent with NOTA and the Final Rule (and ASTS counsel agrees).** Accordingly, the OPTN Board and Executive Committee repeatedly requested HRSA to provide a written analysis confirming the legality of HRSA's Special Election processes, including its selection of the Nominating Committee. Selection of the Nominating Committee should not proceed until this written analysis of legality is received and any legal issues are resolved.
- **HRSA has indicated that it is necessary to completely change the OPTN Board composition to be more "patient-centered."** However, numerous

patient leaders have written to HRSA, indicating that “the broad transplant patient and donor community does not support the selection of transplant community leaders through a process that is heavily influenced by political considerations, or a decision-making process that takes place behind closed HRSA doors.” This patient leader input has been ignored. So have the numerous written comments filed by the OPTN’s professional associations and other stakeholders in response to an OPTN public comment solicitation focused on Bylaws changes.

- **The limited Nominating Committee and Board selection criteria made public by HRSA indicates that anyone who served on the OPTN Board during the past ten years will not be considered, based on “conflict of interest.”** HRSA has not explained the seemingly arbitrary selection of ten years as a basis for its conflict-of-interest concern or why any concerns it may have cannot be handled on a case-by-case basis. This exclusion will essentially leave the Board of Directors without any understanding of institutional history and expertise.
- **The future OPTN board should keep the current elected regional representatives.** The current process allows each of the 11 regions to hold a process to elect regional representatives to serve on the OPTN board. To require each region to complete a new nominations process within the newly proposed timeline would be nearly impossible and, in some regions, require the replacement of individuals who may have only recently started their terms of service.
- **The OPTN’s current Bylaws and Membership and Management Policy (Governing Policy), which was just recently approved by HRSA, does not provide for a Special Election, nor does it include any provision that would authorize selection of the Nominating Committee by HRSA.** Election processes that contravene the OPTN Board entity’s Bylaws and Governing Policies is inconsistent with good governance practices. If it is determined that established processes as set forth in these documents will not meet the objectives of the Special Election, the Bylaws and Governing Policy should be amended in accordance with their amendment provisions.
- **Transparency is essential, particularly during phases of system improvement.** For instance, the Freedom of Information Act (FOIA), introduced by President Woodrow Wilson, was a direct response to the lack of transparency in government, reflecting his belief that such secrecy often points to potential misconduct. True transparency, however, is not simply about transmitting information in one direction. True transparency requires open, two-way

communication where all stakeholders contribute to the process, ultimately leading to better outcomes. In the case of the transplant system, this means engaging with all relevant parties to ensure that policies reflect the real needs of patients and those working on the ground.

- **To date, much information shared by HRSA has not involved structured opportunities for input from key stakeholders. This lack of engagement can create a disconnect between decision-makers and the operational realities faced by those in the field.** When transparency is properly implemented, it fosters trust and accountability. It encourages everyone to contribute valuable insights, ensuring that the changes being made are both informed and inclusive. A collaborative approach not only strengthens the transplant system but also promotes a sense of shared responsibility and mutual respect among all involved.

In order to maintain the trust of the transplant community, it is imperative that all Board meetings not implicating a need for OPTN member or patient confidentiality be open to the transplant community and the concerned public. It is troublesome that HRSA has already eliminated the OPTN as an organization without prior notice to, or the input of, the transplant community. Moving forward, we hope and anticipate that HRSA will ensure that the transplant community and members of the public have the opportunity to attend all Board meetings at which OPTN operations or governance (including Board nomination and election procedures) are discussed.

While these concerns about the transparency of HRSA's processes and the politicization of OPTN governance are the most pressing, we also have broader concerns about the way HRSA has approached OPTN Modernization. The new model that has emerged from HRSA's modernization initiative is one under which HRSA will operate the transplant system, albeit through "operations" contractors, without the input of the OPTN or formalized input from the transplant community at large. We had understood that at least policymaking regarding such sensitive and complex issues as organ allocation and quality would remain in the hands of the transplant community, through OPTN members' election of the OPTN Board of Directors. HRSA's selection of the Board Nominating Committee places in doubt whether members' election of Board members will provide meaningful choice, leaving us to conclude that OPTN operations and policymaking both will be run by HRSA (through multiple contractors and Board influence), and that the system will be responsive to transplant community concerns primarily through the political process.

While ASTS continues to strongly support OPTN Modernization, we are concerned that the virtual elimination of any real public private partnership and substitution of a system operated by HRSA (with policymaking determined by a Board whose selection is directed by HRSA) will not achieve modernization's objectives. Congress approved an additional \$23 million in the FY 2024 budget for OPTN Modernization. HRSA has made essentially

no progress on modifying or upgrading the IT infrastructure that was the focus of considerable Congressional concern. However, over the past year, HRSA has:

- Obligated up to **\$17 million** in awards to nine contractors to study what reforms are needed and to support the expanded HRSA's internal operations that will be necessary to oversee the new system.
- Awarded a contract of **\$50 million** dollars over five years (approximately \$10 million per year), solely to provide administrative and other support for the OPTN Board.
- Estimated expenditures of up to **\$440 million**¹ over the next five years for up to **14 contractors** to operate the OPTN as it is, without counting the considerable expenditures that will be needed to improve the IT infrastructure of the system. This totals almost a half billion dollars (over \$490 million) to operate the system without any improvement, a considerable increase over current operating costs.

Yet, HRSA has failed to approve an OPTN budget for two years, thus freezing expenditures at 2022 levels. This has resulted in lack of funding for OPTN efforts to study the causes of non-use of hard-to-place organs, to utilize expedited placement to reduce non-use or to make the IT changes necessary to collect pre-waitlist data to improve waitlist access and equity. OPTN also has failed to fund implementation of a patient-friendly SRTR website that was designed to respond to patient concerns expressed at a consensus conference funded by HRSA itself (Task 5 Initiative). We are concerned that continuation down this road will result in unnecessary expenditures for contractors and expansion of HRSA internal resources, with few improvements in the care of the patients we serve.

While we recognize the importance of HRSA oversight over the transplant system, we do not believe that such oversight should be exercised in a manner that has the potential to undermine public and transplant community trust in the system. The input of transplant professionals, patients, and donor families through a process open to all is critical to the formulation and monitoring of policy and must be integral to the governance of the OPTN. Transplant surgeons in particular have the expertise to understand how the current system is working (not in theory but in practice), understand its shortcomings, because we experience them daily, but also understand the things that must be preserved for it to function efficiently and equitably. The ASTS, the body that collectively represents transplant surgeons, is wholly committed to the success of policy change and system modernization, but we strongly advocate that process change without transparency or the voice of those who make the current system work will lead to less

¹ <https://orangeslices.ai/14-prime-awardees-named-for-440m-in-hhs-hrsa-optn-operations-transition-idiqs/>.



than optimal results that require hasty remedies and that lead to lack of trust in a system that functions at its heart on the benevolence of donor families and the public.

We look forward to ongoing, shared efforts by the transplant community in partnership with HRSA and the OPTN to improve transplantation and transplant care for the patients we serve.

Sincerely,

Ginny L. Bumgardner, MD, PhD, FACS
President
American Society of Transplant Surgeons

Cc: The Honorable Xavier Becerra, Secretary of Health & Human Services
Suma Nair, Associate Administrator, Health Systems Bureau, HRSA
Richard Formica, MD, President, INVEST