



September 17, 2024

The Honorable Morgan Griffith
The Honorable Debbie Lesko
The Honorable Kathy Castor
Subcommittee on Oversight and Investigations
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

Delivered Electronically

Dear Representatives Griffith, Lesko, and Castor:

On behalf of the American Society of Transplant Surgeons (ASTS) I am writing to you in response to the Oversight Committee's hearing held on September 11, 2024, focusing on the Health Resources and Services Administration's (HRSA's) implementation of the H.R. 2544 *Securing the Organ Procurement and Transplantation Network Act*. ASTS is a medical specialty society representing approximately 2,000 professionals dedicated to excellence in transplantation surgery. Our membership composition and clinical expertise comprehensively spans the patient's transplant journey inclusive of medical and surgical evaluation for transplant eligibility, deceased donor organ surgical procedure, living donor surgery, donor organ assessment and transplant surgery, and post-transplantation care. Thus our organization has great commitment and investment in the success of the OPTN Modernization Initiative to benefit our patients. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS strongly supports OPTN Modernization and has been integrally involved in [sharing the principles that should guide implementation of this important and complex HRSA initiative](#). We are encouraged by the progress made by HRSA in separating the OPTN and United Network for Organ Sharing (UNOS) Boards and HRSA's recent selection of a new Board Support contractor. We believe that these are important and necessary first steps in eliminating the inherent conflicts of interest arising from the prior structure, under which the same individuals by statute served on both the UNOS and on the OPTN Boards.

ASTS strongly believes that, moving forward, OPTN Board members should continue to be nominated and elected by the transplant community and not appointed by Congress or by any administrative agency. The OPTN Board currently consists of 42 members. In accordance with applicable regulations, approximately 50% of Board members are transplant surgeons and transplant physicians and about 25% of Board members are transplant candidates, transplant recipients, organ donors and family members. In addition, the

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governing regulations require the Board to include representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public. *The large number of transplant community stakeholders underscores the complexity of the transplant system and necessitates a modernization approach that values and empowers members of the transplant community to guide policy and assess system efficiency and quality of performance.*

OPTN Modernization presents the opportunity to streamline the OPTN governance structure while maintaining its broadly representative composition. In fact, one of the first tasks to be undertaken by the Board Support contractor recently selected by HRSA is to review the OPTN governance structure and to recommend potential structural improvements for approval by the Board. Under the Memorandum of Understanding between the OPTN Board and HRSA, a new Special Election will be held (likely next year) to select a new Board of Directors, to fill the seats on the new, restructured Board. HRSA has retained the authority to ensure that any individuals who are nominated to fill Board positions are fully vetted for conflicts of interest, and any nominations will be bound by the OPTN's new conflict of interest policy. In addition, the Board Support contractor, under HRSA's direction, is charged with monitoring and ensuring against Board conflicts of interest on an ongoing basis moving forward. *We are confident that these steps, which are scheduled to be taken next year, will fully address the serious conflicts of interest concerns that have been raised by Congress.*

At the same time, it is critical that Board members continue to be nominated and elected by the transplant community and not selected by administrative or political appointment. The work of the OPTN Board under the new structure will focus on improving organ allocation policy and on member oversight—both of which are tasks that require significant clinical expertise and credibility within the community. The accomplishment of these tasks relies on the selfless dedication of more than 300 transplant professionals who volunteer their time and expertise to serve on OPTN committees and task forces. *In order to maintain and expand the efforts of and allegiance of this extraordinary volunteer workforce, it is critical that OPTN leadership continue to be representative of the transplant community so that the breadth of community stakeholders have a meaningful role in data collection and analysis, assessing system performance, promoting best practices, and rectifying deviations from quality standards for the benefit of patients they serve.*

In this regard, we note that the OPTN evolved from a voluntary private matching system put in place by transplant programs to maximize access to transplantation. When transplant program participation became mandatory as a condition of Medicare certification, the system was reconceptualized to function as public-private partnership under which the OPTN established transplant policies and operated the transplant system, subject to governmental oversight and with federal contractor support. Under OPTN Modernization, the role of the government is increasing substantially. Under the new system the transplant system will be operated by multiple contractors selected and overseen solely by HRSA without clinical oversight. Even though 90% of OPTN funding comes from transplant program members in the form of patient registration fees and not from government appropriations, the transplant community will only have input with respect to certain aspects of transplant policy, and that input will be heard solely through the actions of the Board. Member selection of the OPTN Board is critical to ensure that some meaningful element of the public-private partnership established by Ronald Reagan and envisioned by Congress remains intact, as highlighted by Representative Larry Bucshon, MD, a primary sponsor of HR 2544, the *Securing the Organ Procurement and Transplantation Network Act*, during the hearing.

It is equally important to recognize that any process under which OPTN Board members are appointed rather than elected by the transplant community will inevitably politicize the OPTN. While the witnesses at the hearing did not



discuss who would appoint the Board, it seems there are essentially two possibilities: The Board could be appointed directly or indirectly either by HRSA or by Congress. In either event, there is significant potential for political considerations to become part of the process. The policymaking role to be performed by the OPTN Board under the new structure, while limited, is highly sensitive from a political perspective. Organ allocation policy may advantage or disadvantage constituencies in different geographic areas and membership oversight must be administered objectively and without political influence to be credible. Political considerations have no place in organ allocation policy, in member oversight, or in any other aspect of transplant policymaking. Appointment of OPTN Board members by any political body threatens to undermine public trust and to increase (not decrease) the risk of conflicts of interest.

Moreover, appointments of the OPTN Board are inconsistent with the governing regulations and the OPTN Bylaws. The [OPTN Final Rule](#) provides that “the OPTN shall establish a Board of Directors of whatever size the OPTN determines appropriate.” This provision clearly places the responsibility of establishing the Board of Directors with the OPTN, and not with any administrative or political body. The OPTN Bylaws (which cannot be amended without member approval) provide for the nomination of Board members by a nominating committee and election by OPTN members. For these reasons, appointment of Board members by any external body would abrogate the rights of OPTN members under the regulations and OPTN Bylaws that were only recently adopted and that were approved by HRSA.

Finally, we are extremely concerned about allegations made by witnesses at the September 11 hearing regarding serious patient harm. We urge the Committee to use its full subpoena power to investigate whether and to what extent these appalling occurrences can be confirmed. Any occurrences of such practices that can be confirmed certainly should be reported to law enforcement officials and, as appropriate, to the Membership and Professional Standards Committee of the OPTN. Such alleged occurrences do not reflect common experiences in the transplant community. We share Congresswoman Lesko’s concern about the unintended consequences of such allegations on organ donation to help patients with end stage organ failure.

We appreciate the effort made by the Oversight Committee to ensure that OPTN modernization proceeds under Congress’ watchful eye and look forward to working with HRSA to ensure that the modernized OPTN expands transplant access and prioritizes process transparency and equity for the patients we serve. We also look forward to broader stakeholder engagement in future hearings related to the OPTN Modernization Initiative.

Respectfully submitted,

Ginny L. Bumgardner, MD, PhD

cc: The Honorable Cathy McMorris Rodgers and the Honorable Frank Pallone, House Energy & Commerce Committee

The Honorable Larry Bucshon and the Honorable Robyn Kelly
Dept. of Health and Human Services Secretary Xavier Becerra
Carole Johnson, HRSA Administrator