



February 26, 2024

Suma Nair PhD, MS, RD
Associate Administrator
Health Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Associate Administrator Nair:

As President of the American Society of Transplant Surgeons (ASTS), I am writing to thank you for the opportunity to discuss with you the potential repercussions of the OPTN's proposed Expedited Placement Variance Policy and our concerns about the SRTR/OPTN modeling of the lung continuous distribution policy. We understand that the OPTN Expeditious Task Force has decided to delay consideration of the Expedited Placement Variance Policy at least until March and to conduct further public outreach regarding this proposed policy, and we very much appreciate any hand you may have had in this decision. We are hopeful that, in negotiating the extension of UNOS' OPTN contract, HRSA will incorporate a requirement that all critical modeling of organ allocation and other important OPTN policies be vetted by an outside third party, which would help to ensure that modeling errors of the kind that occurred in the case of the lung continuous distribution policy do not recur.

Since the time of our call, we have become aware that UNOS plans to bifurcate the UNOS/OPTN Board, effective March 30, 2024, timed to match the expiration of its current contract. We further understand that, effective March 31, the OPTN Board will be left without any corporate structure and will be forced to function as an unincorporated association, without legal protection from liability. Unless immediate action is taken, it is highly likely that most if not all of the current members of the OPTN Board may be forced to resign, jeopardizing the continued operation of the entity entrusted by Congress with oversight of the transplant system and the formulation of transplant policy.

We are extremely concerned about the implications of this possible course of events for the transplant community and, most especially for our patients. While we certainly agree that the OPTN Board structure is in need of reform, the OPTN is the mechanism that ensures that the voices of the transplant community— patients, transplant centers, OPOs, histocompatibility labs, concerned associations and community representatives—are reflected in transplant policy and in the operation of the transplant system. The separation

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of the OPTN from HRSA contractor(s) has been a center post of HRSA’s OPTN Modernization Initiative and was endorsed by Congress through its enactment of the *Securing the Organ Procurement and Transplantation Network Act* (PL 118-14) (the OPTN Modernization Act”). ASTS and the rest of the transplant community have universally embraced the need to separate the OPTN from contractor governance and operations. We urge HRSA to take such action as may be necessary prior to March 30 as to ensure that this goal is achieved with minimum disruption to the system and to the patients we serve.

Without a legal structure, the OPTN cannot continue to fulfill the responsibilities delegated to it by Congress. Cessation of, or significant disruption in the operations of, the OPTN would be plainly inconsistent with governing statute and regulations. While the OPTN Modernization Act increased the Secretary’s flexibility to contract with multiple entities to support the OPTN, this legislation also makes it clear that Congress anticipates the continued operation of the OPTN: As amended, the governing legislation states:

*The Secretary shall provide for the **continued operation** of the Organ Procurement and Transplantation Network which meets [statutory requirements].*

(Emphasis added). While NOTA does not specifically address the corporate status of the OPTN, it does specify the duties and responsibilities of the OPTN “Board of Directors”, a term typically utilized to describe the governing body of a corporate entity, not an unincorporated association. Further, and even more importantly, NOTA confers on the OPTN the responsibility to conduct operational activities in addition to policymaking (e.g. operating the donor matching system, enforcing membership criteria)—activities that clearly require the OPTN to be able to operate as a cognizable legal entity.

The Final Rule is more explicit, stating specifically that the OPTN shall “be a private, not-for-profit entity.”¹ While this regulatory requirement is no longer statutorily required, it remains in effect, as does the rest of the Final Rule, several provisions of which implicitly anticipate that the OPTN is to operate as a legal entity: The Final Rule confers on the OPTN the authority to, for example, establish and enforce membership criteria, appoint an Executive Director, and impose and receive patient registration fees, and these activities require the OPTN to have a cognizable legal status.² Furthermore, operation of the OPTN as an unincorporated association is inconsistent with both with the OPTN Charter and the OPTN Bylaws.³



ASTS

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We understand that both UNOS and the OPTN have for some time requested HRSA to facilitate the separation of UNOS and OPTN functions and the establishment of a separate OPTN legal entity, without response. Because it is critical for the OPTN to continue to have the capability to perform the tasks delegated to it by Congress without interruption, we request that HRSA immediately direct UNOS, as the current OPTN support contractor, to:

- Facilitate the incorporation of the OPTN as a not-for-profit corporation under state law;
- File all requisite documents necessary for the OPTN to obtain federal tax status as a 501(c)(3) organization and to obtain applicable non-profit organization exemptions from any otherwise applicable state or local tax liability;
- Procure Directors and Officers (D&O) and any other necessary insurance coverage for the OPTN and its Board, in the amounts and under terms acceptable to the OPTN Board;
- Facilitate the establishment of such bank accounts as may be directed by the OPTN Board, for the payment of OPTN organizational and other expenses; and
- Transfer to the new OPTN account(s) any patient registration fees collected from OPTN members, net of amounts due to UNOS as the OPTN support contractor, as of March 30, 2024.

In light of the imminent bifurcation of OPTN and UNOS, we would appreciate your providing assurances by March 9 that HRSA will take all necessary action to assure the continuity of the OPTN as a legal entity on and after March 31. We would very much appreciate your responding to this urgent request so that our members and other concerned members of the transplant community are able to rest assured that OPTN governance and operations will continue uninterrupted after the much-needed March 30, 2024 split between UNOS and the OPTN.

Respectfully yours,

Elizabeth Anne Pomfret, M.D., Ph.D., F.A.C.S.
President
American Society of Transplant Surgeons

¹ 42 CFR §121.3(c)(1).

² See 42 CFR §§121.9; 121.3 (a)(3); 121.5(c).

³ The OPTN Charter specifically describes the OPTN as a “a private, non-profit entity that has an expertise in organ procurement and transplantation.” The OPTN Bylaws not only describe the OPTN as a “corporation” but also delineate numerous tasks that could not be performed by a legal entity.