

Proposal: [Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards](#)

The American Society of Transplant Surgeons strongly supports The *Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards* (the “**Board Proposal**”) put forth by the OPTN Executive Committee and posted for public comment on February 28, 2024. We believe that strict separation of the governance and operations of the OPTN from the governance and operation of any contractor is essential to maintaining the independence of the OPTN and that the proposed amendment of Section 2.8 of the Bylaws assuring that OPTN Board members are not members of the Board or employees of any contractor is an essential first step in this direction.

In fact, insofar as the proposed revised language of Section 2.8 provides an exception for the OPTN Executive Director, we do not believe it goes far enough: so long as the Executive Director is an employee or member of the Board of Directors of an OPTN contractor, that individual should not be allowed to serve as an OPTN Board member.

The complete separation of the OPTN and contractors engaged by HRSA to support the OPTN has been a focal point of the OPTN Modernization Initiative and will be critical for building and maintaining public trust in the system. The Executive Director of the OPTN serves crucial roles in ensuring that the policies and priorities of the OPTN are implemented in a manner consistent with the Board’s intent and in helping the OPTN establish priorities and frame issues for Board consideration. It is critical that the OPTN establish from the outset that it is not aligned with any one contractor and is thus free of a significant source of potential conflicts of interest. This principle is compromised by the possibility that the OPTN’s Board includes an Executive Director employed by any contractors. The inclusion of an Executive Director who is a contractor employee is especially problematic insofar as that Executive Director, as a Board member, has the right to participate in confidential Board deliberations—including deliberations that may directly or indirectly impact that ED’s employer. For this reason, we believe that no contractor employee should serve as an OPTN Board member (the Executive Director of the OPTN, regardless of his or her employer, may and should participate in OPTN Board meetings as invited by, and at the discretion of the Board.)

We are hopeful that the Executive Director ultimately will be employed directly by the OPTN and will have no conflict in serving on the OPTN Board. In this regard, while we recognize that the recently released draft Board Support Contractor PWS suggests that HRSA anticipates that the Executive Director of the OPTN will be employed by the Board Support contractor, it is not at all clear to us that this structure is consistent with the Final Rule. The Final Rule specifically requires that the Executive Director be appointed by the OPTN and, by implication, that the Executive Director be employed by the OPTN. Historically, this has been a distinction without a difference as the same corporate entity has served as both a HRSA contractor (UNOS) and as the OPTN. However, effective March 30, we believe that the Executive Director is required by the Final Rule to be appointed (and employed) by the OPTN as an independent legal entity.

In our view, this structure not only complies with the Final Rule, but is also necessary to achieve the OPTN independence that has been one of the stated objectives of the OPTN Modernization

Initiative. In fact, it is unclear to us how the OPTN can be viewed as independent of the contractor(s) so long as the Executive Director—who necessarily will play a key role in leading and overseeing the OPTN and in moderating any differences among the contractor(s)—is employed by one of them.

We also note that the establishment of an OPTN legal entity will require additional modification of the OPTN Bylaws. For example, the Bylaws define the OPTN as the corporation that currently serves as the OPTN contractor, a definition that clearly will not apply after March 30.

Finally, we urge the OPTN to take such action as may be necessary to establish a separate OPTN legal entity and to take that action prior to March 30. As set forth in the attached correspondence sent by ASTS to HRSA, ASTS believes that it is critical for an OPTN legal entity to be established for the OPTN to fulfill its statutory and regulatory obligations and to meet the needs of the patients we serve. Without a legal entity, there is no legally cognizable means for the Secretary to designate the OPTN or ensure that it functions in compliance with applicable law. Moreover, without a cognizable legal entity, the OPTN cannot impose or collect patient registration fees, enforce allocation or other policies; contract with any other entity; or otherwise represent the community effectively as anticipated by NOTA.

ASTS Position: Strongly Support