

Proposal: Revised Bylaws and Management and Membership Policies

In the interests of transparency and accountability and pursuant to the Management and Membership Policies (Policy 5.8.5), ASTS requests that the timeline for responding to this proposal be extended to a full 45 day comment period and that the OPTN Executive Committee include in the request for comment a full description of the respective roles, authority, and responsibilities of INVEST, HRSA and the various contractors selected by HRSA in the governance and operation of the OPTN.

ASTS strongly supports modernization of the OPTN. 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 to guard against the real and potential conflicts of interest inherent in the prior OPTN structure. ASTS appreciates the effort made by the OPTN and HRSA to provide for Board continuity in 2024 and to retain the basic Bylaws and operational policies adopted by the OPTN under the prior organizational structure. We believe that the separation of the OPTN Bylaws from OPTN operational policies is appropriate and comports with well accepted legal standards.

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 the Final Rule.

Even more importantly, we are concerned that this and major governance and operational changes have been made without prior notice to and consultation with the transplant community. While we appreciate the OPTN's effort to subject the new Bylaws and operational policies to public comment, we strongly believe that **all** major changes affecting the transplant community at large 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 strongly 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 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 Modernization effort.

With respect to governance, we remain uneasy about the lack of clarity regarding the "Special Election" that we understand will occur in 2025 to select new Board members. We are aware that some organizations have called for OPTN Board members to be "appointed", which is inconsistent with the provisions of the new Bylaws, the Management and Membership Policy, and the Final Rule, which requires the **OPTN** to establish the Board. We are also aware that— without providing an opportunity for public participation as required by the Management and Membership Policy—the OPTN Board of Directors recently met with HRSA and AIR, the incoming Board Support contractor,



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to discuss a special process to be used to select nominees to replace the current duly elected Board members. Under these circumstances, we urge HRSA and the OPTN to publicly confirm that the nomination and election procedures set forth in the new Bylaws and Management and Membership Policy will be used for the Special Election. Any process under which either HRSA or any contractor has a role (other than administrative) in the selection of Board nominees or in the election of the Board is entirely inconsistent with the Final Rule and with the establishment of an independent Board. In fact, given the importance of nomination and election procedures, these should be incorporated into the Bylaws and not in the new Policy document.

Finally, we note that the new indemnification provision added to the Bylaws only provides for indemnification of OPTN Directors and Officers and does not provide for the indemnification of volunteers, including those that may serve on OPTN committees. Indemnification protection is necessary to ensure the continued participation of the volunteers who are the backbone of the OPTN. We urge the OPTN to extend the indemnification protection provided by the new Bylaws provision to all OPTN volunteers and others acting at the direction of the OPTN Board and to specifically denote those protections in the Bylaws.

ASTS continues to strongly support OPTN modernization and continue efforts to collaborate with the OPTN and with HRSA towards the shared goal of improving transplantation. However, we have the significant concerns detailed above. These concerns center on a desire for real transparency in policy development and decision making, the application of good governance principles to the operations of the OPTN, and the need for indemnification of the volunteers that form much of the OPTN to be elucidated in the Bylaws. The input of transplant professionals, patients, and donor families is critical to the formulation and monitoring of policy and must be integral to the governance of the OPTN. We look forward to ongoing, shared efforts by the transplant community in partnership with the OPTN to improve transplantation and transplant care for the patients we serve.