



American Society of Transplant Surgeons OPTN Modernization Initiative Guiding Principles

The ASTS supports and is committed to working with HRSA on efforts to improve and modernize the Organ Procurement and Transplantation Network (OPTN) to better serve transplant candidates, recipients, donors, and donor families. These efforts should prioritize changes needed to **increase access to transplantation and improve equity in access to both living and deceased donor transplantation.**

Alignment

- The modernized OPTN should be reconceptualized to manage coordinated efforts across all transplant-related governmental and private stakeholders to improve the transplant process for patients and their families.
- The OPTN should spearhead development of a National Transplant Strategy that includes national performance goals and associated metrics for the U.S. organ transplantation system; that involves all stakeholders; and that includes the involvement of all transplant-related governmental agencies and contractors.
- Priority should be given to ensuring that organ allocation policies and transplant center performance metrics adopted by any public entity are aligned with the national performance goals.
- Public-facing metrics related to transplant program performance should be structured to increase access to transplantation and to encourage utilization of hard-to-place organs.
- Duplicative regulation of transplant centers by the OPTN and CMS should be eliminated.

Engagement

- To restore and ensure the public's trust in the system, all stakeholders' voices should be considered not only through "response to comments" but also during the policy formation process.
- HRSA and CMS should collaborate to establish a single, comprehensive public-facing, integrated website that is responsive to the expressed patient need for user friendly information, especially information regarding waitlist criteria and individualized projections of likely waitlist times.
- Data needed for the assessment or modification of OPTN policy, including allocation policy, should be shared with stakeholders in a user-friendly, transparent format prior to use of such data in any OPTN deliberations.

Accountability

- HRSA should remain responsible for ensuring that the OPTN policies comply with NOTA and the Final Rule, and that progress is being made toward the national performance goals.
- The OPTN should remain responsible for fulfilling all the duties and responsibilities delegated to it by NOTA and the Final Rule, and conducting operations in a manner that achieves the national performance goals.
- HRSA should be responsible for ensuring that critical that OPTN operations, especially UNet, remain fully functional and operational without change or reduction in resources throughout the transition, including testing and implementation of any new IT system.
- Metrics should be established to measure the progress made by the OPTN and by each transplant-related governmental agency or contractor toward the achievement of the National Transplant Strategy's national performance goals, and progress should be regularly evaluated.
- The OPTN should function as a Board-driven organization that operates independently and engages in no activity other than OPTN policy development and operationalization.
- The modernization plan should prioritize the establishment of a representative, but significantly smaller, OPTN Board by the end of the transition period.
- The OPTN should directly employ an Executive Director and staff to support OPTN Committees. The OPTN Board should have complete authority to terminate staff that fail to meet Board expectations.
- The OPTN should remain solely responsible for assessing and collecting registration fees from member organizations and should retain the authority to determine how patient registration fees are utilized to achieve the National Transplant Strategy performance goals.
- We appreciate that HRSA plans to contract with entities that may or may not have expertise in transplantation to make "best in class" Information Technology (IT) and other specialized services available to the OPTN. HRSA should engage a separate contractor only if specialized expertise is needed and should engage a manageable number of such specialized contractors.
- HRSA should require that any such specialized contractor report to the OPTN and enter into a subcontract/cooperative agreement with the OPTN to ensure seamless implementation of OPTN policy.
- CMS should be held **responsible and accountable** for regulatory authority over transplant programs and the OPTN should be held **responsible and accountable** for dissemination of best practices, quality improvement, confidential peer review, oversight of rules related to waitlist management, and compliance with allocation policy.
- The role of the SRTR in data analysis and dissemination should be clearly defined and distinguished from the data-related role(s) of the OPTN.