

AOPO's OPTN Modernization Implementation Priorities

As we move to the next phase of "OPTN modernization" implementation, AOPO has identified key actions and policies that HRSA and the OPTN, collaborating with key stakeholders, should pursue to ensure that the new system meets the needs of all the stakeholders. AOPO's overriding principle is that **the donation and transplantation ecosystem should create processes to ensure every precious gift of a donated organ is maximized to provide the gift of life to the potential transplant recipients.**

HRSA

HRSA, CMS, and the OPTN must continue to foster a donation and transplant ecosystem that is transparent and engenders the public's trust. To achieve this, performance metrics for the three key stakeholders -- OPOs, transplant programs, and hospitals -- must be uniform, transparent, and consistently enforced.

HRSA should team with CMS, OPOs, other stakeholders, and a measure development entity such as NQF or a similar organization, to establish a common data collection tool for OPOs, validated metrics for assessing OPO performance, and a process for performance improvement prior to decertification.

HRSA should collaborate with CMS, OPOs, and hospitals to increase hospital accountability in the donation process including implementing electronic referrals, recognition of non-donor events as sentinel occurrences, and quality initiatives to improve organ donation.

The HRSA OPTN relationship must be sufficiently agile to ensure that decision-making and resource allocation are made promptly and consistent with Congressional intent. Bidirectional accountability, proactive participation, and input and oversight from organ donation and transplantation subject matter experts and stakeholders are key to ensuring the gift of every organ is maximized for procurement and transplantation.

HRSA should provide transparency into the efficiency and effectiveness of all contractors who support the entirety of the OPTN, ensuring the needs of the donation and transplantation community are being met, and that contractors are responsive to the guidance and direction of the OPTN Board of Directors. Clear alignment of each contractor's responsibilities and scope, as well as clearly delineated and transparent performance expectation and outcome goals in the execution of tasks in service of the OPTN and the donation and transplant community, must be prioritized so the gifts of donor organs available to potential recipients are maximized.

It is essential that a clearly defined level of autonomy is established for the OPTN and its Board of Directors relative to the numerous contractors assigned to servicing the OPTN to ensure no undue influence over the organization's operations, consistent with congressional intent and expectations for performance and outcomes.

OPTN

The OPTN Board of Directors and committee leadership should reflect equal representation amongst its key stakeholders (OPOs, patients, donor families, transplant surgeons, hospitals), creating an inclusive, robust, excellence-driven environment that provides direction to the greatest transplant and donation system in the world. Representation from government related and regulatory bodies (i.e., SRTR, HRSA, CMS) should actively provide feedback and guidance.

The members of the committees under the purview of the OPTN Board of Directors, in addition to the members of the OPTN Board of Directors, must have standard legal protections to ensure their ability to function.

The OPTN Board of Directors' authority and ability to prioritize and oversee the work of current and future contractors in partnership with HRSA must be maintained.

Non-Utilization

HRSA should tackle the burgeoning organ non-utilization issue by: 1) improving efficiency of the OPTN information technology systems used by OPOs to place organs; 2) support innovation in technology to facilitate more rapid decision making by transplant centers; 3) require mandatory use by transplant programs of systems designed to efficiently allocate organs, such as offer filters; and 4) implement a dynamic allocation/placement system which is efficient and responsive.

Donor organ utilization is of paramount importance; cases of non-use should be monitored and trigger quality improvement initiatives.

Policy Making

HRSA should optimize the policy-making process to ensure: 1) equitable representation from key stakeholders, including OPOs, transplant centers, recipients, donors and donor families; 2) additional public comment cycles to shorten the length of time from policy proposal to policy approval; 3) conclusion of the standard policy approvals pathway within one year of its inception (as is possible); 4) acceleration of the pathway for emergent policy needs that can be sunset as applicability is determined; and 5) creation of a track for tests of change without policy violation.

Modernization to improve the system must establish structures and processes that protect the use of science and inclusive, balanced, thoughtful decision-making. This should include increased communication and expertise sought from key stakeholders and subject matter experts.

Great care must be taken to ensure the most efficient operations and decision-making of the OPTN, promoting and balancing the interests of the patients over any profit motive, partisan bias, and destabilization of the system. The entire system should work in collaboration to simultaneously achieve system-wide goals that are in alignment with the various agencies that have oversight over the different aspects of organ donation and transplantation processes.

In closing, the policymaking and leadership function of the OPTN must be supported by a non-profit entity to ensure that improvement is driven by fairness and equity, as well as sound medical and financial principles without regard for making profit. Guidance and commitment must be sought from all parties that impact performance, innovation, and advancement including the OPTN and its members, the SRTR, CMS, FDA, and NIH. Communication and reporting must be transparent and ongoing with all parties to ensure they remain well informed of anticipated changes and timelines.