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OPTN MODERNIZATION: GUIDING PRINCIPLES 2.0 FOR LEGISLATIVE DISCUSSIONS

Approved by the ASTS Council: April 2026

IMPROVING INTRA-AGENCY COORDINATION:

SET NATIONAL STRATEGY AND GOALS

- **Reduce duplicative regulation and ensure agency accountability by designating separate roles for CMS, HRSA, and the Organ Procurement and Transplantation Network (OPTN).**
 - Clarify that under the current agency configuration, CMS is responsible for transplant programs and OPO operational standards, surveys, and regulatory enforcement.
 - Clarify that HRSA/OPTN is a public private partnership responsible for increasing access to living donor transplantation, facilitating efficient operation of systems for organ listing, acquisition, matching, data collection and dissemination, and providing for confidential peer review and feedback regarding compliance with membership policies.
- **Require the Secretary to solicit public comment on and adopt a five-year National Transplant Strategic Plan. This Plan should:**
 - Establish specific and realistic targets for increasing access to, and equity of, deceased and living donor transplantation by organ.
 - Identify policy changes necessary to achieve the targets.
 - Create a timetable for policy changes and increased access.
 - Require intra-agency coordination with public participation.
 - Produce an annual report to Congress on progress in implementing the Strategic Plan.
- **Establish a Joint Public/Private Steering Committee**
 - The Joint Steering committee should consist of an equal number of OPTN Board members and representatives appointed by the Secretary.
 - At a minimum, the committee should:
 - Establish annual OPTN priorities consistent with the Strategic Plan.
 - Formulate an annual budget for OPTN functions (including contractor activities).
 - Determine registration fees that, together with appropriations made by Congress for OPTN operations, are sufficient to cover the budget.



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- Establish a reporting mechanism for OPTN operational contractors to report to the Joint Committee and the Board on a regular basis.
- Establish conflict of interest policies and other policies to ensure that allocation and other OPTN policies are made based solely on clinical considerations.

PRESERVING AND BOLSTERING THE OPTN AS A PUBLIC-PRIVATE PARTNERSHIP

- **Clearly define the OPTN as a non-profit membership corporation with a Board elected by the members and that the OPTN Board's fiduciary duty is to transplant patients, donors, and family members.**
 - The Board has an obligation to make decisions independent of political pressure.
 - The Board should be empowered to make decisions based on clinical considerations.
 - The Board and committees must include robust patient, donor family, and clinical representation.
- **Require the OPTN to levy membership fees distinct from patient registration fees to support its own operations to hire staff to provide administrative support to OPTN Board and Committees.**
- **Clearly define the functions of the OPTN Board to include the following:**
 - Determine budget and membership fees necessary for OPTN Board and Committee administrative support.
 - Appoint the OPTN Nominating Committee in accordance with the OPTN Bylaws.
 - Adopt (after opportunity for public comment) policies related to organ listing, acquisition, matching, data collection and dissemination.
 - Adopt procedures for confidential peer review of members and member compliance feedback.
 - Perform general supervision of OPTN contractors with HRSA oversight.
 - Ensure representation by the OPTN President and other OPTN leadership to serve on the Joint Public/Private Steering Committee.
- **Protect patient safety.**
 - Ensure the continued payment of any OPTN contractor charged with recipient listing, matching or protection of patient safety, regardless of the availability of appropriated funds (i.e. a government shutdown).



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ENSURING CONTINUED ACCESS TO OPTN DATA

- **Require that the SRTR and public retain full access to all public data related to transplantation, including OPTN raw data.**
 - All data currently collected and maintained by the SRTR must remain publicly available in its entirety and without restriction, independent of any changes in federal contracting arrangements or agency oversight structure.
 - Any proposed restriction on public data access — including changes to data sharing agreements, variable availability, or researcher access protocols — must be subject to a public comment period before taking effect.
 - Data should be made available for any purpose only if and so long as the data recipient agrees not to use the data to identify any individual patient or donor.
 - Reasonable charges for such data should be authorized only to the extent necessary to recoup the costs of responding to a data request.
- **Require that any simulation of the potential impact of an allocation policy modification is public and reliable.**
 - Such analyses must be performed by the SRTR for the OPTN's review.
 - Algorithms, data sets, and other information must be made publicly available in sufficient detail to permit independent replication by a third party.
 - An independent third party should be considered to check all allocation changes before going live to ensure patient safety.

ENSURING TRANSPARENCY

- **In collaboration with HRSA, develop and communicate the OPTN budget and membership fees necessary for OPTN Board and Committee administrative support.**
 - Neither HRSA nor OPTN should solely create or approve the budget, and any budgetary items should be provided for public comment.
 - The final, approved budget should be made available to the public and communicated to OPTN members.
- **Require that all OPTN Board and Committee meetings be open to the public** unless individual member performance or other confidential information is discussed.
- **Require that all changes to allocation policy or algorithms be subject to public comment,** along with a rationale for any such changes and simulation(s) of the potential impact of the proposed change on access.
- **Require that the OPTN publish any policy changes or additions** recommended by the Secretary along with the rationale for the proposed change/addition.



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- **Require that the OPTN publish the names and scope of work of contractors** engaged to perform OPTN functions.
- **Require that the Secretary reports to Congress the use of funds appropriated by Congress for operation and modernization of the OPTN.**

INCREASING ACCESS TO LIVING DONOR TRANSPLANTATION

- **Improve living donor transplantation.**
 - Clarify OPTN authority to adopt policies to increase living donor transplantation.
 - Advance the Living Donor Protection Act to remove financial and employment disincentives to transplant.
 - Provide a tax deduction for living donor expenses for those ineligible for the Living Organ Donation Reimbursement Program assistance that does not provide a perverse and unethical financial incentive for donors to donate organs.

ENHANCING THE ROLE OF DONOR HOSPITALS IN ORGAN PROCUREMENT AND IN PROTECTING DONOR SAFETY

- **Require that donor hospitals follow protocols and engage in educational activities necessary to ensure the safety of potential organ donors.**
 - Require donor hospitals to adopt protocols to stop organ recovery upon observing signs of life.
 - Require donor hospitals to cooperate with OPOs in effectuating OPTN DCD protocols.
 - Establish protocols consistent with professional declaration of death standards).
- **Require donor hospitals to send automated alerts and grant EHR access to OPOs for potential donors as required in HR 4470 (Removing Burdens from Organ Donation Act).**

ENHANCING THE PERFORMANCE OF ORGAN PROCUREMENT ORGANIZATIONS (OPOs)

- **Create a transition plan for any OPO changes.**



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- Provide that prior to the de-certification of any OPO or change in the OPO designated for any DSA for any reason, the Secretary shall publish a transition plan to ensure continuity of organ procurement in the affected DSA and waive any otherwise applicable CMS or OPTN requirements as necessary to facilitate stability of organ procurement in the DSA.
- **Require OPOs to abide by HIPAA requirements** applicable to Business Associates, with respect to PHI of donors, recipients, and candidates.
- **Require OPOs to adopt and audit compliance with protocols to protect the safety of DCD organ donors** (e.g. protocols allowing any OPO staff to pause organ procurement in case there are signs of life.)
- **Authorize the Secretary to certify new OPOs but only** non-profit entities which meet the requirements set forth in the law (e.g. inclusion of transplant physicians/surgeons from all DSA transplant programs on the Board).
- **Consider establishment of regulatory standards and surveys of Donor Recovery Units (DCUs)** owned and operated by OPOs or by any group.