

June 20, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra:

On behalf of the physician and medical student members of the American Medical Association (AMA) I want to express the AMA's strong concerns about recent developments at the Health Resources and Services Administration (HRSA) involving the Organ Procurement and Transplantation Network (OPTN). The AMA supports modernization of OPTN to ensure the donor and transplant system operates equitably, efficiently, and effectively in the best interest of patients and families. We believe in the importance of transparency and independence to this process. Up to this point, it is our understanding that HRSA has been operating collaboratively with OPTN, transplant surgeons, and other stakeholders to this end.

It has recently come to our attention, however, that in the last several weeks, there has been a notable shift in HRSA's tone and approach, with the agency becoming increasingly covert about its plans and significantly departing from previously announced policies without input from the OPTN, the broader donor and transplant community, or the general public, despite its stated goal of instituting greater transparency into the process.

As an example, despite [stating as recently as March 27](#) that it wanted OPTN to remain its own "separate legal entity" with its own independent Board of Directors, it is our understanding that HRSA recently communicated to OPTN leadership that it no longer supports retaining the OPTN itself as a separate and distinct legal entity, and instead seeks to set up a loosely defined network of government and non-government organizations. The only legally independent aspect of the OPTN would be its Board of Directors, which would be limited in authority and scope to a narrow set of issues such as [organ allocation policies and membership criteria and standards](#).

The AMA is deeply concerned about HRSA's inconsistent and ambiguous plans for the future organization of the OPTN and its Board, and the rushed nature with which these potentially substantial changes are being advanced, which according to [HRSA's June update](#) "will be implemented by June 30, 2024." In that same announcement, HRSA also states that these changes "will be followed in the future by a series of additional efforts to strengthen OPTN governance" which have yet to be further explained. We believe HRSA is undermining the integrity of the OPTN modernization process and risks rushing major changes to the system that, due to the lack of stakeholder input, could have widespread, unforeseen consequences that could cause major upheaval to the transplant community, potentially endangering patient lives. Given what is at stake, changes of this magnitude should be conducted transparently and with sufficient opportunity for stakeholder input through formal rulemaking, as is required under the Administrative Procedures Act.

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Furthermore, the AMA is concerned about the level of influence HRSA could seek to have over the OPTN structure and Board selection process under this new structure, which remains opaque. In a [previous update](#), HRSA said it will “develop a slate of candidates” and “conduct a special election to establish a new, independent OPTN Board of Directors.” HRSA says it will solicit public input as part of this process, but the agency is not beholden to explain how it makes its final determinations. We worry that giving HRSA this degree of influence over the OPTN organizational structure and Board election process does not strike the right balance and could risk politicizing the process. The AMA believes it is important to the integrity of the OPTN and donor and transplant community that the OPTN remain an independent member-driven organization with its own electoral process, with oversight, but not control, by HRSA.

While we agree with HRSA that process improvements and enhanced oversight are needed to improve and modernize the OPTN and have been for some time, we do not believe that HRSA’s recently modified plan nor its rushed approach to implement does justice to the donor and transplant community.

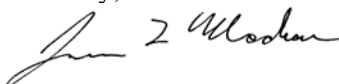
Therefore, we urge:

- HRSA revert to its [earlier structure](#) which would maintain the OPTN as its own legal entity that is independent from both contractors and the government and would work with HRSA to ensure appropriate oversight.
- The OPTN Board be elected by its peer membership through an independent, democratic process with oversight, but not interference, by HRSA.
- HRSA reaffirm its [prior commitment](#) to implement OPTN changes consistent with the National Organ Transplant Act and the [OPTN final rule](#), which, among other protections, includes parameters that the OPTN Board be comprised of a diverse representation of transplant and donor patients and family members, transplant physicians or surgeons, and other relevant voices from the donor and transplant community.
- HRSA develop a better process to openly communicate and engage with the organ donation and transplant community as it develops future changes to the OPTN structure or Board, or other significant changes to the U.S. transplant system. Any such changes should be pursued through public notice and comment so that clinician, donor, and recipient voices can weigh in on decisions that could significantly impact thousands of lives.

Thank you for your consideration of these comments. The AMA would like to work with HRSA to modernize the organ donor and transplant process so we can best serve donor and recipient families and welcomes future opportunities to collaborate with the agency toward this shared goal. To that end, we recently submitted comments echoing the above concerns through HRSA’s [general contact form](#) for the OPTN Modernization Initiative.

If you have any questions or need any additional information, please do not hesitate to contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,



James L. Madara, MD

cc: Carole Johnson