

March 7, 2024

Carole Johnson
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

Delivered electronically

Dear Administrator Johnson:

As organizations that have representation on the Board of Directors of the Organ Procurement and Transplantation Network (OPTN) and concerned OPTN member organizations, we are writing to thank you for your work on the OPTN Modernization Initiative and call your attention to an urgent matter requiring immediate attention. We share our strong belief that the process of reforming the transplant system must maintain continuous transplant access for patients and minimize disruptions to patient care. In that spirit, we ask that you take action as soon as possible to minimize legal exposure that, if not addressed immediately, has the potential to derail OPTN modernization efforts and unnecessarily throw the transplant system into turmoil. The undersigned urge decisive actions be taken to establish the OPTN to assure the continuity of the OPTN Board pending future potential Board reform, and to take all other actions to ensure the OPTN remains fully functional on and after March 31, 2024.

Separation of the OPTN from HRSA contractor(s) has been a focal point of HRSA's OPTN Modernization Initiative, has been strongly endorsed by Congress (as evidenced by enactment of the *Securing the Organ Procurement and Transplantation Network Act* (PL 118-14) (the "OPTN Modernization Act")), and has been universally supported by the transplant community, including the OPTN Board. This objective has been the subject of extensive discussions involving the HRSA representatives, the OPTN Board and United Network for Organ Sharing (UNOS) staff over the past two years, culminating in a recent membership vote approving the separation of UNOS from the OPTN Board effective March 30, 2024, timed to coincide with the expiration of the current UNOS contract.

Effective March 31, the OPTN Board will be left without any corporate structure and forced to function as an unincorporated association, without legal protection from liability and without any clear pathway for OPTN Board members to obtain Directors' and Officers' liability insurance. The OPTN Board consists of 42 dedicated volunteers, including not only representatives of our organizations, but also program administrators, clinicians, patients, patient family members, living donors and others, who dedicate their time and expertise to improving our Nation's transplant system. Without legal protection, many, if not all, OPTN

Board members will be forced to resign, jeopardizing the continued governance of our nation's organ transplantation system.

Without a legal structure, the OPTN cannot continue to fulfill the responsibilities delegated to it by Congress and cannot continue to meet the needs of donors and patients awaiting lifesaving transplants. As recently as last year, in the OPTN Modernization Act strongly supported by HRSA, Congress emphasized the need for the "continued operation" of the OPTN. Moreover, regulations implementing the National Organ Transplant Act (42 CFR §121.3(c)(1)) specifically require that the OPTN be a private, not-for-profit entity. Therefore, operation of the OPTN Board as an unincorporated association is inconsistent with the OPTN Charter and Bylaws, both of which describe the OPTN as a legal entity.¹

Over the past several years, both UNOS and the OPTN repeatedly have requested that HRSA authorize and facilitate the establishment of a legal entity separate and apart from the OPTN contractor(s) in order to address the universally decried conflict(s) of interest that have arisen as the result of the current structure and in order to provide a solid foundation for implementation of OPTN modernization. Now, at the eleventh hour, it is critical that decisive action be taken to establish an OPTN legal entity to fulfill the responsibilities delegated to the OPTN by statute, to guarantee the continuity of the OPTN Board pending future potential Board reform and ensure the OPTN remains fully functional on and after March 30. We would very much appreciate your immediate responsive action to this urgent request to assure the transplant stakeholder community that OPTN governance will continue uninterrupted as we all work together to implement a modernized transplant system.

Respectfully,



Elizabeth A. Pomfret
President, American Society of Transplant Surgeons



Colleen McCarthy
President, Association of Organ Procurement Organizations

Jennifer Reese

Jennifer Reese, MSN, APRN-CNP, CCTC
President, NATCO: The Organization for Donation and Transplant Professionals

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Donald S. Karcher, MD, FCAP
President, College of American Pathologists

cc: Xavier Becerra, Secretary, Department of Health and Human Services
Suma Nair, Associate Director, HRSA