

January 27, 2023

The Honorable Carole Johnson Administrator Health Resources and Services Administration US Department of Health and Human Services 5600 Fishers Lane Rockville, MD 20857

Dear Administrator Johnson,

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for your leadership of the Health Resources and Services Administration (HRSA).

ASN is committed to maximizing patient access to kidney transplantation, and to ensuring that access is equitable for all patients regardless of geography, race/ethnicity, socioeconomic status, or other factors. The society appreciates your and HRSA's efforts to help achieve these objectives.

As ASN has shared in prior comments, the society believes it is crucial that the Organ Procurement and Transplantation Network (OPTN) and the OPTN contractor(s) who operate it have separate governance boards. In 2018, HRSA itself expressed a desire for this change, a recommendation that was also reaffirmed by the U.S. Government Accountability Office (GAO). Notably, that GAO report "found no basis to conclude that the OPTN and OPTN contractor must be the same entity," noting that HHS itself "argues that the OPTN and the OPTN contractor are not the same entity, and that NOTA [the National Organ Transplant Act] does not require that they be the same entity." If

ASN appreciates HRSA's continued consideration of the separation, including through its 2022 Request for Information. As ASN wrote, the current governance of the OPTN contractor is perceived by the kidney transplant community to be opaque.ⁱⁱⁱ The policy decision-making process at times lacks transparency and accountability and, as observed by the National Academies of Sciences, Engineering, and Medicine (NASEM) in its report *Realizing the Promise of Equity in the Organ Transplantation* System the process should be more inclusive and efficient.^{iv}

Nearly 100,000 Americans are on the waitlist for a kidney, and they deserve every aspect of the kidney health ecosystem, including the OPTN, to be functioning optimally. ASN believes establishing separate governance boards for OPTN and any contractors

is an important step in addressing these and other issues and urges HRSA to take any actions within its authority to support this change.

To discuss this recommendation further, please feel free to contact Rachel Meyer, ASN Strategic Policy Advisor to the Executive Vice President, at rmeyer@asn-online.org or 505-720-2009 or David White, ASN Regulatory and Quality Officer, at dwhite@asn-online.org or (202) 640-4635.

Sincerely,

Michelle A. Josephson, MD, FASN

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President

https://www.asn-online.org/policy/webdocs/ASNfinalMay23RFIOPTNContract (002).pdf

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^{iv} National Research Council 2022. Realizing the Promise of Equity in the OrganTransplantation System. Washington, DC: The National Academies Press. https://doi.org/10.17226/26364.