

June 9, 2026

John Magee, MD
President, Board of Directors
Organ Procurement and Transplantation Network

Dear Dr. Magee:

The Health Resources and Services Administration (HRSA), acting for the U.S. Department of Health and Human Services (HHS) Secretary, is responsible for oversight of the Organ Procurement and Transplantation Network (OPTN), which is the unified transplant network established under the National Organ Transplant Act (NOTA) of 1984, as amended.

HRSA is sharing the attached letter dated June 5, 2026, which should be considered as part of the “critical comment” shared with the OPTN on May 1, 2026. As we previously notified the OPTN, under the HHS regulations at 42 CFR § 121.4(d): *“[t]he Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the critical comment related to OPTN policies or practices. Policies or practices that are the subject of critical comments remain in effect during the Secretary’s review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety.”* After this review the Secretary may:

- 1) Reject the comment;
- 2) Direct the OPTN to revise the policies or practices consistent with the Secretary’s response to the comment; or
- 3) Take such other action as the Secretary determines appropriate.

To assist in HRSA’s consideration of the pediatric heart transplant policy critical comment, I am seeking a response from the OPTN on the issues raised in this latest letter in light of the requirements of NOTA and the HHS regulations governing the OPTN, 42 CFR part 121. Please address the following aspects in the OPTN’s response:

- (A) Provide an evaluation or analysis of OPTN data regarding pediatric heart transplant candidates also listed for another organ since January 1, 2022, including outcomes for these pediatric dual transplant candidates.
- (B) Provide an explanation of whether and, if so, how the OPTN considers a candidate’s dual organ transplant candidacy in determining the patient’s eligibility for pediatric heart

allocation status 1A, including any relevant analysis on how dual transplant candidacy may affect the OPTN considerations of medical urgency as outlined in the OPTN response to my original inquiry on this critical comment dated May 29, 2026.

We ask that the OPTN provide its response by close of business on Monday, June 15. Given that my role as HRSA's Health Systems Bureau Associate Administrator is one of oversight, on behalf of the Secretary, I will review the OPTN's response considering the requirements of NOTA and the OPTN Final Rule.

Sincerely,

Suma Nair -S⁻⁵
Digitally signed by Suma Nair
Date: 2026.06.09 17:45:45
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Suma Nair, PhD, MS, RD
Associate Administrator

Cc: Doug Fesler
Executive Director, OPTN

Enclosures