HRSA
Health Resources & Services Administration
Health Systems Bureau
5600 Fishers Lane
Rockville, MD 20857

May 1, 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 considers the attached letters (dated March 27, 2026, April 21, 2026, and April 27, 2026) to be a "critical comment" under NOTA (42 U.S.C. § 274(c)) and the HHS regulations at 42 CFR § 121.4(d). Under the HHS regulations, *"[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 critical comment, I am seeking a response from the OPTN on the issues raised in the letters 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 pediatric heart transplant data since January 1, 2022, including:

1) Volume of hearts donated from deceased pediatric organ donors.

2) Waitlist status at time of transplant for pediatric patients listed for heart transplantation.

3) Proportion of Ventricular Assist Device (VAD) use among pediatric patients listed for heart transplantation.

4) Average and median time to transplant for pediatric patients listed for heart transplantation.

5) Proportion of pediatric heart candidates awaiting transplantation at 1, 3, 6, 12 months post-time of waitlist addition.

(B) Provide the OPTN's views as to whether the current OPTN pediatric heart allocation policy, which ranks patients within each respective status by waiting time without regard to relative medical urgency, complies with the regulatory requirements at 42 C.F.R. § 121, including balancing 42 C.F.R. § 121.8(b)'s requirement to rank candidates, to the extent possible, through objective medical criteria from most to least medically urgent. Please include a robust justification for the OPTN's views.

(C) Provide the OPTN's views as to whether current OPTN pediatric heart allocation policy, which currently has three different statuses reflecting medical urgency (1A, 1B, and 2), complies the regulatory requirements at 42 C.F.R. § 121, including 42 C.F.R. § 121.8(b)'s requirement to have "a sufficient number of categories (if categories are used) to avoid grouping together patients with substantially different medical urgency." Please include a robust justification for the OPTN's views.

(D) Provide the OPTN's views as to whether OPTN Policy 6.2.A, which requires a candidate to either be hospitalized or on a mechanical circulatory support device (VAD) in order to be assigned Status 1A, is consistent with the regulatory requirement to rank candidates from most to least medically urgent to the extent possible. Please also provide the OPTN's views as to whether this OPTN policy should include consideration of additional factors for patients who do not meet either of these criteria, including patients who are not eligible for a VAD (i.e. due to risk for collateral bleeding or other medical or surgical contraindications), receiving in-home care, or in hospice. Please include a robust justification for the OPTN's views.

(E) Provide an explanation of the rationale for the standardized exception policy as described in OPTN Policy 6.4, as opposed to a policy providing for individualized review of exceptional cases. Provide the OPTN's views as to whether OPTN Policy 6.4, which requires a candidate to be hospitalized in order to qualify for heart Status 1A exception status, is based on a clinical rationale consistent with the regulatory requirements at 42 C.F.R. § 121, including the medical urgency requirements under 42 C.F.R. § 121.8(b). Please also provide the OPTN's views as to whether there should be additional exceptions allowed for patients who are not hospitalized, including for patients who are temporarily made inactive due to being too sick to transplant and later recover. Please include a robust justification for the OPTN's views.

(F) Comment on the data, findings, and assessment of the Stanford study cited in the critical comment letters or other relevant studies regarding the use of exceptions among pediatric patients listed for heart transplantation.

(G) Suggest other actions, if any, the Secretary should take to address any inequities or potential issues under the HHS regulations at 42 CFR part 121 that are relevant to the issues raised in the letter.

(H) Provide comments on whether the OPTN would consider additional research and dialogue on the topics discussed in the letter, consistent with the OPTN policy making process.

Given the additional time that may be required to access complete system-level data, please provide the response to (A) – (H) by Friday, May 22. HRSA will ensure the OPTN Board Support and Operations contractors are available to support the OPTN, in accordance with their contracts. 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

Digitally signed by Suma Nair -S
Date: 2026.05.01 09:48:14 -04'00'

Suma Nair, PhD, MS, RD
Associate Administrator

Cc: Doug Fesler
Executive Director, OPTN

Enclosures