



June 22, 2026

Suma Nair, PhD, MS, RD
Associate Administrator
Health Systems Bureau
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Rockville, MD 20857

Re: OPTN Follow Up Response to Pediatric Heart Allocation Critical Comment

Dear Dr. Nair,

Thank you for the opportunity to respond to your letter dated June 9, 2026. OPTN policies are designed to ensure the equitable allocation of organs and to adhere to all requirements of the Final Rule (42 C.F.R. § 121). Below, the OPTN provides detailed responses to the two questions posed by the Health Resources and Services Administration (HRSA), acting on behalf of the Secretary of the U.S. Department of Health and Human Services (HHS).

(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.

Between January 1, 2022, and April 30, 2025, a total of 2,360 pediatric heart candidates were listed for transplant, 63 of whom were dual-organ candidates. The breakdown by organ combination is shown in Exhibit 1.

Exhibit 1. Pediatric heart and dual-organ candidates listed between January 1, 2022 and April 30, 2025.

Candidate Type	Number	Percentage of Total Pediatric Heart Candidates
Heart-alone	2297	97.33%
Heart-Kidney	33	1.40%
Heart-Liver	21	0.89%
Heart-Lung	9	0.38%
Grand Total	2360	100%

Exhibits 2 and 3 depict one-year outcomes after listing for dual-organ pediatric candidates by organ pair and by age, respectively. The majority of heart-kidney candidates had received a multiorgan or single-organ transplant one-year after listing (Exhibit 2). The majority of dual-organ pediatric candidates were more than six (6) years old and had received a multiorgan or single-organ transplant within one (1) year

(Exhibit 3). By comparison, of the 2,297 heart-alone pediatric candidates (Exhibit 1), 132 died before transplant, 184 were delisted, 1,440 were transplanted, and 477 were still waiting.

Exhibit 2. One-year outcomes by dual-organ pediatric candidates listed between January 1, 2022 and April 30, 2025 by organ pair

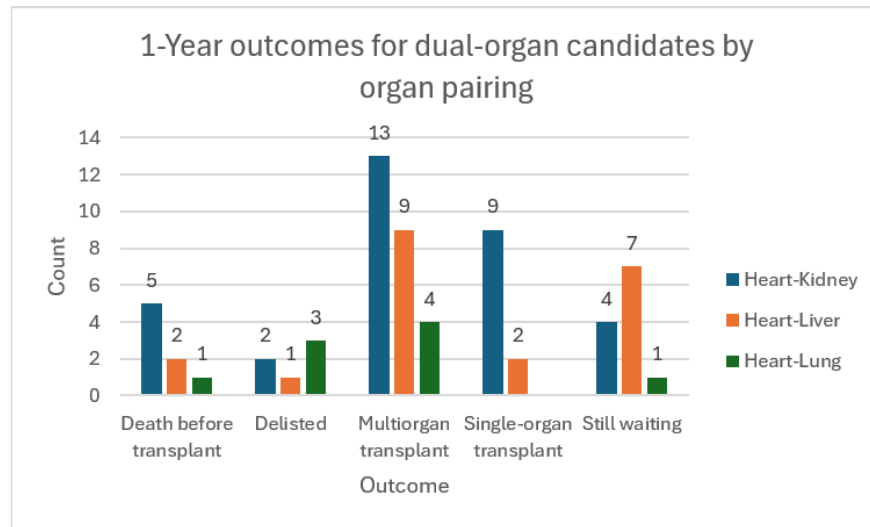
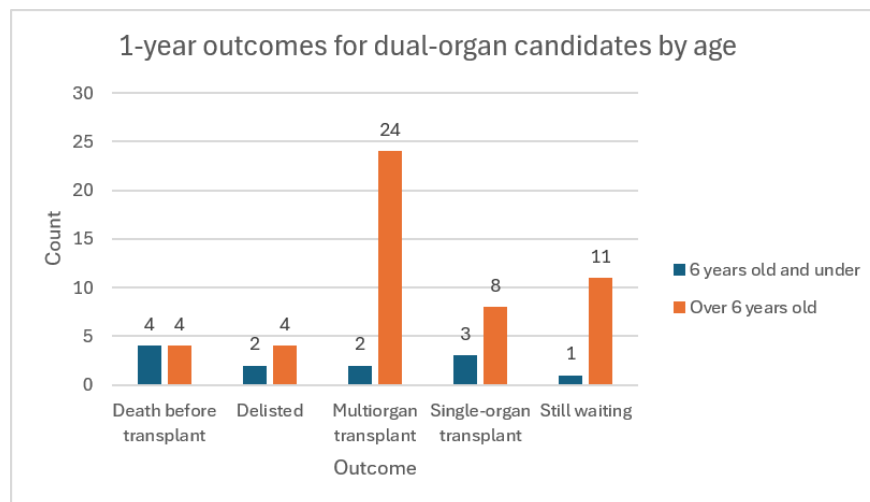
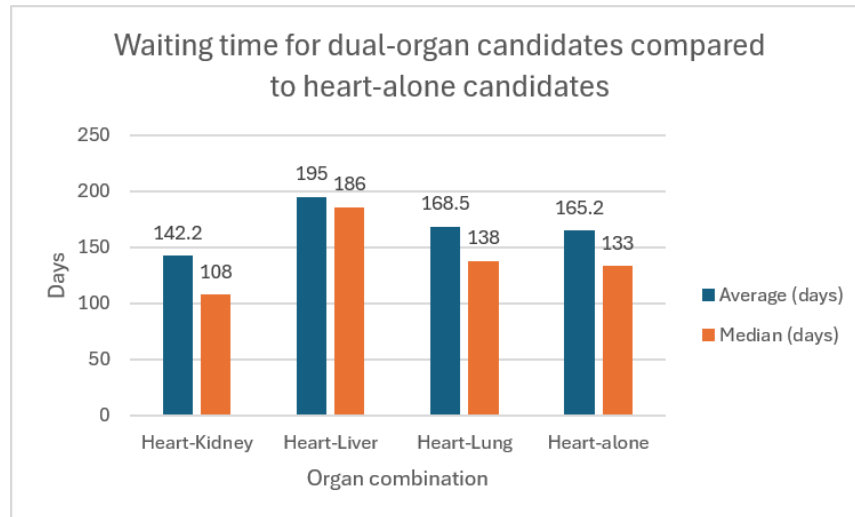


Exhibit 3. One-year outcomes for dual-organ pediatric candidates by age listed between January 1, 2022 and April 30, 2025



For pediatric heart-alone transplant candidates, average and median waiting times are 165 days and 133 days, respectively. As shown in Exhibit 4, waiting time for heart-kidney pediatric candidates is lower than for heart-alone pediatric candidates, while waiting time for heart-liver pediatric candidates is higher.

Exhibit 4. Average and median waiting times for dual-organ pediatric candidates compared to heart-alone pediatric candidates for candidates listed between January 1, 2022 and April 30, 2025



For heart-alone pediatric transplant recipients, 92.6% were alive one (1) year post-transplant. The percentage of dual-organ pediatric transplant recipients alive one (1) year post transplant was lower (Exhibit 5). However, because the total number of dual-organ transplant recipients is small, it is not possible to draw strong conclusions from this data.

Exhibit 5. Survival status post 1 year of pediatric heart transplant between January 1, 2022 and April 30, 2025

Organ combination	Alive (n)	Alive percentage	Died (n)	Died percentage	Total
Heart-alone	1470	92.6%	118	7.4%	1588
Heart-Kidney	10	76.9%	3	23.1%	13
Heart-Liver	10	83.3%	2	16.7%	12
Heart-Lung	4	57.1%	3	42.9%	7

(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.

The OPTN does not consider a candidate's dual-organ transplant candidacy in determining eligibility for pediatric heart allocation status 1A. Patients are eligible for status 1A based on criteria specified in OPTN Policy. An urgent heart transplant candidate listed as status 1B who also needs a kidney transplant could be considered for elevation to status 1A through an exception application provided the candidate requires inpatient care and is believed by their care team to be of similar medical urgency and potential

for benefit as compared to other status 1A candidates. The rationale for the inpatient care requirement was outlined in our previous response. For a patient already at status 1A, there is no additional priority based on dual-organ listing status.

In the case of heart transplantation, potential dual-organ candidates are placed on the waiting list for each individual organ that their clinical team believes they need, in accordance with OPTN policies. There is no separate multiorgan waiting list. Allocation priority for each candidate is driven by organ-specific criteria. A patient awaiting a heart and another organ transplant is not placed ahead of a heart-alone candidate solely because they require two organs; rather they are ranked in order of allocation priority for each organ independently. In the pediatric system, when a heart-kidney candidate is allocated a heart, the kidney from the same donor will also be allocated to that patient. However, a kidney allocation does not confer priority for the same donor's heart.

The OPTN must consider equity in developing allocation policy. *See* 42 CFR § 121.8(a). It would be inequitable to prioritize candidates who will receive two organs above those awaiting a single organ without considering all components of medical urgency, fairness, and utility. All such candidates are in need of transplantation.

As referenced above, one example where medical urgency for dual-organ transplant candidates supersedes that of single-organ transplant candidates is heart-kidney patients on the kidney waiting list. A candidate receiving a combined heart-kidney transplant will receive preferential access to deceased donor kidneys above patients awaiting kidney transplant alone. This is justified by the fact that heart-kidney candidates have a more urgent medical need than patients experiencing renal failure alone.

In considering allocation priority, the OPTN must also account for post-transplant outcomes. *See* 42 CFR § 121.8(a)(5). The OPTN is charged with balancing the medical urgency of individuals awaiting transplantation against the overall utility of a scarce resource for all patients in need.

Organ allocation policies are not static; they undergo refinement as sufficient, robust data emerges to warrant change. The ability to keep small children with life-threatening medical conditions related to organ failure alive is constantly advancing. These advances alter the characteristics of the patient population in need of transplantation and change the relative impact of specific risk factors. Importantly, these risk factors do not exist in isolation. They interact with one another and with individual patient characteristics. The significance of any individual factor may vary and often reflects unique clinical circumstances associated with a single patient. While the OPTN is acutely aware that these circumstances differ between patients, allocation policy must be developed to objectively serve the population of patients in need as a whole. As stated in our previous response, the OPTN considers all principles embodied in the Final Rule, including medical urgency, equity, and utility.

As new literature is published, the OPTN discusses and critically evaluates new findings. The OPTN continuously engages the professional community through multiple mechanisms, including service on OPTN committees. In addition to relevant peer-reviewed literature, the OPTN evaluates OPTN data, as

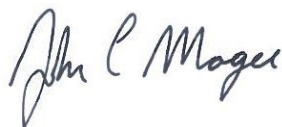
such evaluation is an important mechanism for identifying trends, confirming findings of external investigators, and improving allocation policy.

Decisions to alter allocation policy must be made thoughtfully, after evaluation of available data and robust discussion across the community. Because changes in OPTN allocation policies are made in response to updated data, changes in the outcomes of medical care will always precede changes in allocation policy. Allocation policies are not changed ad hoc on the basis of a single analysis. Additionally, the impact of changes in medical care typically requires time to become substantial enough to generate data-driven allocation policy improvements. Random or reactive changes to allocation policy without sufficient evidence and consensus would undermine public trust.

The ability to identify very sick patients who are at risk of death in the short term, as distinct from patients who can safely wait for transplant, is conceptually straightforward and has largely been accomplished within the categories set forth in the current OPTN Policy (e.g., status 1A vs status 1B vs status 2). Within those categories, however, it is much more difficult to consistently and reliably stratify risk (and benefits/utility) among small cohorts of critically ill patients. As shown in Exhibit 1, the number of pediatric patients requiring multiorgan transplantation is small. Additionally, this patient population is heterogeneous with respect to physiology and risk factors, making it difficult to develop sufficiently robust data to further prioritize candidates objectively and equitably for a life-saving organ.

The OPTN welcomes the opportunity to continue to partner with HRSA and HHS to ensure the U.S. organ procurement and transplantation system is patient-centered, equitable, honors the gift of life, and adheres to NOTA and the Final Rule.¹

Sincerely,



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

cc: Doug Fesler
Executive Director, OPTN

¹ In connection with its preparation of this response letter, the OPTN requested pediatric heart transplant data from SRTR. The OPTN reserves the right to modify or supplement this response letter in general, and specifically in the event that it learns any of the data it requested was incorrect or incomplete, or if new data becomes available.