May 29, 2026

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

Re: OPTN Response to Pediatric Heart Allocation Critical Comment

Dear Dr. Nair,

Thank you for the opportunity to respond to your letter dated May 1, 2026. OPTN policies are designed to ensure the equitable allocation of organs and adhere to all requirements within the Final Rule (42 C.F.R. § 121). In the sections below the OPTN has provided detailed responses to the questions posed by the Health Resources and Services Administration (HRSA), acting for the U.S. Department of Health and Human Services (HHS) Secretary.

(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.**

The following sections set forth an evaluation and analysis of pediatric heart transplant data from the Scientific Registry of Transplant Recipients (SRTR) for the period spanning January 1, 2022, through December 31, 2025 (the "Review Period").

Volume of hearts donated from deceased pediatric organ donors

The number of donated pediatric hearts that were recovered on an annual basis remained relatively stable throughout the Review Period. The vast majority of the hearts that were recovered were transplanted, and the high ratio of hearts that *were* transplanted to hearts that were *not* transplanted also remained relatively stable throughout the Review Period (Exhibit 1).

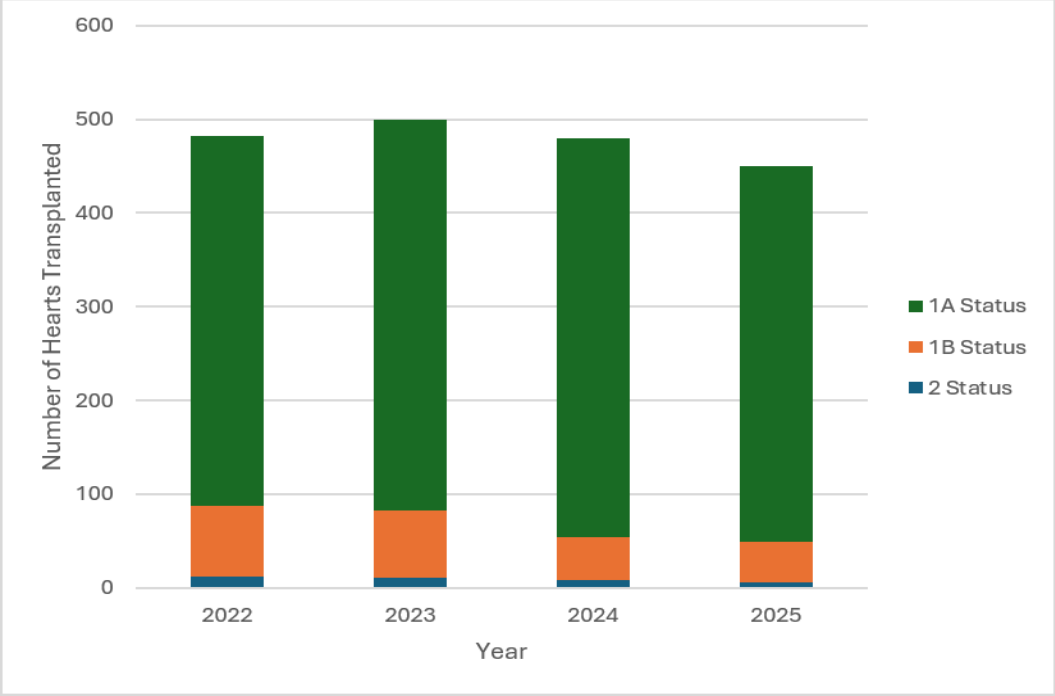
Exhibit 1. Number of pediatric heart donors from whom a heart was recovered for transplant

Year	Recovered and transplanted	Recovered but not transplanted	Total
2022	537	4	541
2023	537	6	543
2024	547	8	555
2025	494	9	503

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

The vast majority of pediatric heart transplant candidates (each, a "Candidate") who received a heart transplant during the Review Period were status 1A at time of their transplant (Exhibit 2). The percentage of status 1A Candidates being transplanted each year from 2022 to 2025 was 82%, 84%, 89%, and 89%, respectively.

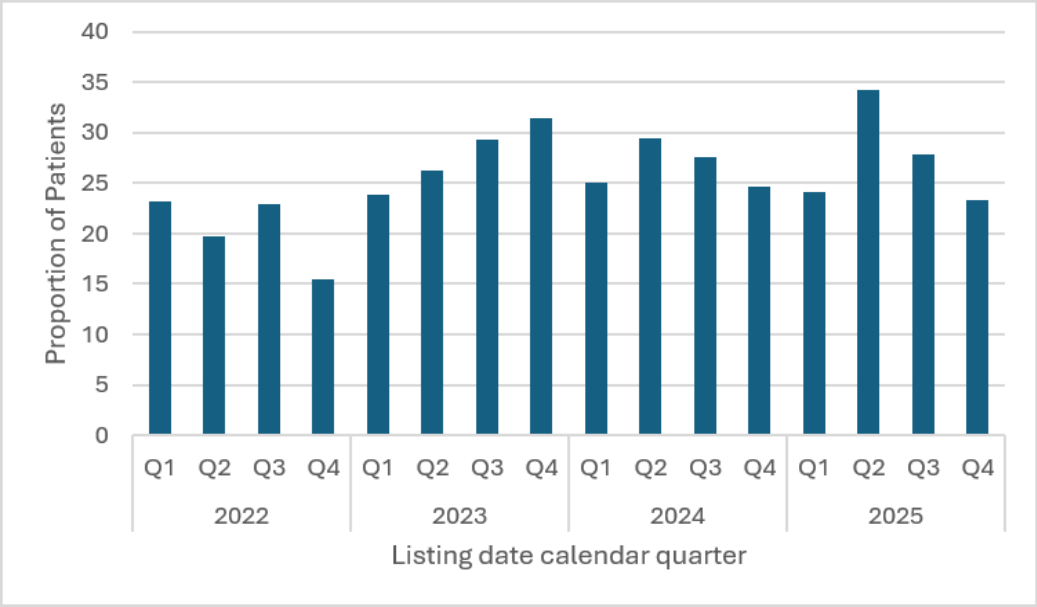
Exhibit 2. Number of Pediatric Hearts Transplanted by Waitlist Status at Time of Transplant



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

The percentage of Candidates who have required a VAD while listed for a transplant has fluctuated from 15% to 34% during the Review Period (Exhibit 3). It is important to note that data relating to VAD usage is collected at the time a Candidate is listed for a transplant and at the time they are removed from the list. Therefore, for Candidates who remained listed at the time of data cut-off, it is not possible to fully ascertain VAD usage at "any time while listed" (i.e., because they have not yet been transplanted).

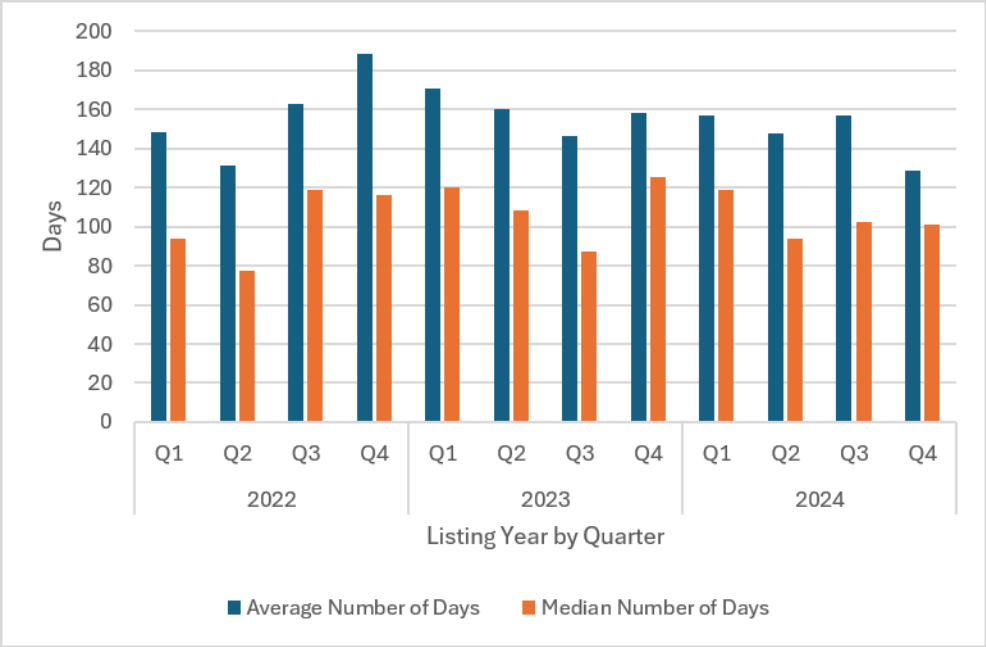
Exhibit 3. Proportion of Pediatric Heart Transplant Candidates With a VAD at Any Time While Listed: By Listing Date Calendar Quarter



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

Exhibit 4 shows the average and median waiting times for patients who received a transplant after being listed in 2022, 2023, and 2024. Data from 2025 is not depicted in Exhibit 4 as any measure of time to transplant for patients listed in 2025 is not representative of all the candidates listed in that year (i.e. the time between listing and transplant would only reflect patients who received a transplant within that year). The shorter length of follow up after listing for Candidates listed in 2025 would create the illusion of a decrease in time to transplant.

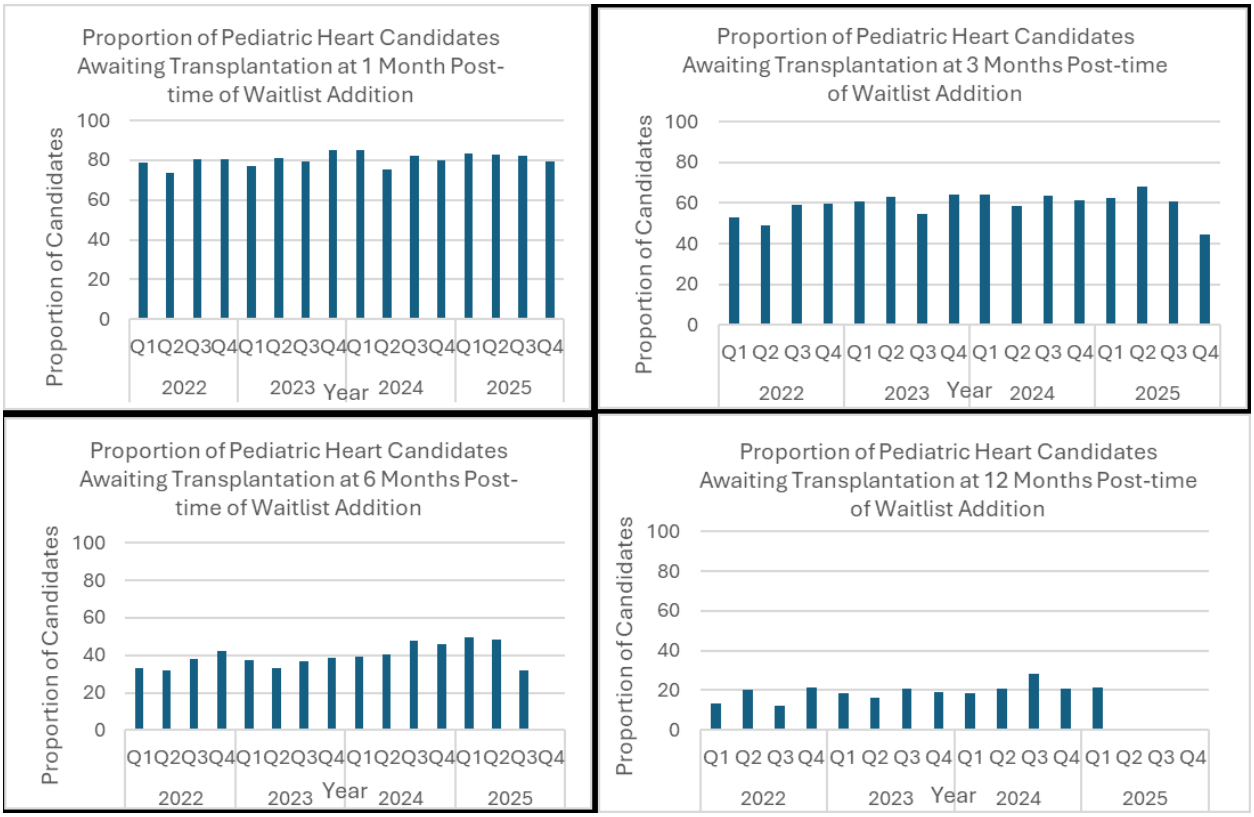
Exhibit 4. Average and Median Time to Transplant for Pediatric Heart Patients by time of Listing Quarter



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

During the Review Period, between 73% and 85% of Candidates were typically waiting for a transplant one month after being added to the waitlist; 45% to 68% were still waiting after three months; 32% to 49% were still waiting after six months; and 12% to 28% were still waiting after one year (Exhibit 5).

Exhibit 5. Proportion of Pediatric Heart Transplant Candidates Awaiting Transplantation at 1, 3, 6, and 12 Months Post-time of Waitlist Addition by Listing Calendar Quarter



Note: Data is not yet available for 6 Months Post-time of Waitlist Addition for Q4 2025 and 12 Months Post-time of Waitlist Addition for Q2, Q3, and Q4 2025.

(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.

The current OPTN pediatric heart allocation policy (the "Policy") complies with applicable law as it reflects the balance of urgency, fairness, and utility that is required under the Final Rule. In particular, the OPTN must ensure that its policies help provide for the "equitable allocation of cadaveric organs among potential recipients." To do so, the OPTN must design its policies to: (i) be based on sound medical judgment; (ii) seek to achieve the best use of donated organs; (iii) preserve the ability of a transplant program to decline an offer of an organ or not use the organ for the potential recipient in accordance with applicable law; (iv) be specific for each organ type or combination of organ types to be transplanted; (v) avoid wasting organs, avoid futile transplants, promote patient access to transplantation, and promote the efficient management of organ placement.[1] 42 C.F.R. § 121.8(b)

[1] 42 C.F.R. § 121.8(a).

further clarifies that allocation policies "shall be designed to achieve equitable allocation of organs among patients consistent with" the following performance goals (truncated):

> *"(1) Standardizing the criteria for determining suitable transplant candidates through the use of minimum criteria (expressed, to the extent possible, through objective and measurable medical criteria) for adding individuals to, and removing candidates from, organ transplant waiting lists;*
>
> *(2) Setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent (taking into account, ... and in particular in accordance with sound medical judgment, that life sustaining technology allows alternative approaches to setting priority ranking for patients). There shall be a sufficient number of categories (if categories are used) to avoid grouping together patients with substantially different medical urgency;*
>
> *(3) Distributing organs over as broad a geographic area as feasible ... and in order of decreasing medical urgency; and ..."*

The Policy considers medical urgency first and foremost in accordance with the above legal factors and criteria. This focus on medical urgency is clearly reflected in the materials that were developed for discussion and briefing purposes in connection with the 2016 pediatric heart allocation revision (the "Revision") process that resulted in the current version of the Policy. By way of example, these materials stated: "To reduce pediatric heart candidates' waiting list mortality, this proposal recommends redefining which candidates qualify as pediatric heart Status 1A and Status 1B, so that the criteria for each respective status includes candidates with compatible levels of medical urgency. This will facilitate the allocation of hearts to the most medically urgent pediatric candidates and minimize the role that waiting time contributes to this process."[2] They further clarified, "Redefining pediatric heart Status 1A and Status 1B criteria will decrease waiting list mortality as the proposed changes yield an allocation system that is more dependent on a candidate's medical urgency rather than the candidate's waiting time."[3]

Under the Policy, Candidates are placed into one of three status categories (1A, 1B, and 2) based on a determination of medical urgency by the physicians at the listing transplant center using objective verifiable criteria (Policy 6.2). After a Candidate's center has assigned them as status 1A, 1B, or 2, they are further classified based on whether the donor is less or greater than 18 years old, whether the Candidate is a primary or secondary ABO blood type match, and the number of nautical miles from the donor's location to the center at which the Candidate is registered (Policy 6.6.D and 6.6.E). It is only after the candidates have been assigned a status (1A, 1B, or 2) and a specific classification as described above (of which there are 104 total classifications for donors who are greater than 18 years old and 68 classifications for donors who are less than 18 years old), are they then sorted within their classification

[2] "Proposal to Change Pediatric Heart Transplant Policy," Briefing Paper (Page 3) OPTN Thoracic Organ Transplantation Committee and Pediatric Transplantation Committee
[3] "Interim Report of the Minority Affairs Committee Meeting," Page 6, OPTN/UNOS Minority Affairs Committee Meeting (Mar. 19, 2013).

based on the total amount of waiting time that the Candidate has accumulated at that status (Policy 6.6.C).

Your letter suggests considering the feasibility of identifying patient characteristics that help predict if a given Candidate is more ill, and at higher risk of death on the waiting list, than other patients listed within status 1A. The medical criteria used to set priority rankings must be "objective and measurable" per 42 C.F.R. § 121.8(b)(2). Implementing robust criteria for additional pediatric urgency status levels through objective and measurable criteria is problematic for three key reasons:

1) All Candidates assigned status 1A are critically ill and in urgent need of a transplant. As a result, increasing the urgency level for any subgroup will conversely decrease the urgency for another critically ill group of patients.

2) The reclassification of status 1A Candidates would require robust risk factors based on systematically collected data to be fairly applied. Such systematic changes require large amounts of aggregate data which simply do not exist for pediatric heart transplantation.

3) Creating additional urgency status levels could have unintended and profound consequences as patients fluctuate in their degree of illness across the various disease states that lead to the need for heart transplantation. For example, it is known that there are Candidates in status 1A that, as a group, face a higher risk of mortality than other status 1A Candidates. Such Candidates include those supported by ECMO, a single ventricle VAD with end organ dysfunction, or mechanical ventilation. By identifying and transplanting Candidates systematically at their most ill moment, there is a risk of performing more futile transplants and decreasing the beneficence of donated organs. Because of the insufficient number of donors hearts for all Candidates in need, giving hearts preferentially to only the Candidates identified as the most urgent would generally result in a scenario where other hospital bound Candidates would not be transplanted. As noted above, 42 C.F.R. § 121.8(a)(5) requires that an allocation policy, "Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement." Deprioritizing hospitalized status 1A Candidates who show slightly less risk of waiting list mortality would limit access to transplantation to a group of children who urgently require access to transplant.

In light of these considerations, the manner in which the Policy assigns each Candidate a status and classification and then further sorts them within their classification adheres to the balance of urgency, fairness, and utility that must be considered under the Final Rule. Additionally, the Policy relies on the clinical team at a Candidate's centers for determinations as to whether a particular Candidate is sufficiently stable to endure a transplant operation at a given moment.

Candidates are not a homogeneous group that can easily be stratified by objective criteria. Pediatric transplant indications are highly diverse. Depending on the circumstances, they may include an array of primary cardiac muscle diseases; repaired and unrepaired heart defects; a combination of single ventricle Candidates with different physiologies including parallel circulation and serial partial mixing repairs; as well as Fontan circulation with a mixture of modes of failure spanning from pure pump failure to lymphatic failure, pulmonary arterial disease, and progressive cyanotic conditions. Transplant cardiologists have struggled for decades to accurately determine the medical urgency of these various conditions using objective criteria. However, each physiology has its own mode of heart failure, rescue

treatments, rate of progression, mode of deadly complication, and risk of medical and surgical intervention. Further, many of those at highest risk of death (e.g. Candidates in multiorgan failure supported by ECMO, acutely bleeding from AV malformations, with complex congenital heart disease) are also the least likely to survive a heart transplant. This unfortunate reality provides a conundrum and a conflict with the ethical concept outlined in the OPTN Final Rule to also consider beneficence of donated organs (in other words, to provide hearts not only to those in greatest need but those with the highest likelihood of surviving the operation and gaining long term benefit). Fundamentally, the diverse heterogeneity with respect to the underlying physiology across the Candidate population means simple approaches to stratifying patients with a one-size-fits-all approach will result in inequities across groups of patients.

(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.

As previously mentioned, the current Policy was developed with the intent to help facilitate the allocation of hearts to the most medically urgent pediatric candidates and minimize the role that waiting time contributes to this process.[4] Based on this intent, the OPTN views the three status categories (1A, 1B, and 2) within the Policy to be sufficient given current technological, clinical, and data constraints. Candidates suffer from a diverse number of causes of heart failure. These varied diagnoses make it challenging to further subdivide status categories because the natural history of these conditions is highly variable. 42 C.F.R. § 121.8(a) asserts that policy regarding the allocation of organs must be "equitable." Access to different forms of support for cardiogenic shock, including inotrope therapy or mechanical circulatory support, can vary by diagnosis. Utilization of the current three status categories balances the potential for rapid deterioration with the availability of rescue therapies as well as the burdens of support for advanced heart failure. For example, Candidates supported on a paracorporeal VAD (an outside the body blood pump that requires continuous hospitalization) may be at lower risk of mortality, but these Candidates remain at risk of infections, stroke, and impaired quality of life that could ultimately prevent them from being transplanted.

Currently, there is not enough granular data available on the most medically urgent pediatric patients. Due to the lack of measurable criteria, it is not possible to further subdivide the status 1A category in a manner that is equitable and based on objective and measurable criteria. It is the OPTN's view that any further subdivision that is developed and implemented without the benefit of a rigorous, data-driven approach would result in an arbitrary and capricious policy.

It is also important to note that Candidates, especially those listed as status 1A, may have rapidly changing medical stability. The circumstances of a status 1A Candidate who is medically unstable may be perceived as more urgent, but such a Candidate will also often have a much higher risk of transplant mortality. Ultimately, the Candidate's transplant hospital care team is responsible for determining if the

[4] *See* "Proposal to Change Pediatric Heart Transplant Policy," Briefing Paper (Page 3) OPTN Thoracic Organ Transplantation Committee and Pediatric Transplantation Committee; "Interim Report of the Minority Affairs Committee Meeting," Page 6, OPTN/UNOS Minority Affairs Committee Meeting (Mar. 19, 2013).

Candidate in question will ultimately benefit from an organ when one becomes available. It is also important to balance waitlist mortality with medical urgency. The number of futile transplants and percentage of transplant mortality would increase if only the most ill (i.e., medically urgent) patients are transplanted.

(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.

As per OPTN Policy 6.2.A, hospitalization is not solely sufficient to qualify for status 1A. A Candidate can be listed as status 1A if they are less than 18 years old at the time of registration and meet at least one of the following criteria:

> *"1. Requires continuous mechanical ventilation and is admitted to the hospital that registered the candidate.*
>
> *2. Requires assistance of an intra-aortic balloon pump and is admitted to the hospital that registered the candidate.*
>
> *3. Has ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion, and is admitted to the transplant hospital that registered the candidate.*
>
> *4. Has a hemodynamically significant congenital heart disease diagnosis, requires infusion of multiple intravenous inotropes or a high dose of a single intravenous inotrope, and is admitted to the transplant hospital that registered the candidate. The OPTN maintains a list of OPTN-approved congenital heart disease diagnoses and qualifying inotropes and doses that qualify a candidate for pediatric status 1A.*
>
> *5. Requires assistance of a mechanical circulatory support device."*

Certain types of mechanical circulatory support devices can be used outside of a hospital setting, such as a dischargeable ventricular assist device (VAD). VADs were designed and tested on adult patients; they were not made specifically for children. Because of this, the use of dischargeable VADs in the pediatric population is limited by patient size. Pediatric patients who rely on mechanical circulatory support devices are, by definition, highly medically urgent. Even when they become more medically stable with their VADs, their quality of life is typically poor as they cannot participate in normal childhood activities with the device in place. While VADs allow some (the largest) children to be discharged, complications with VAD usage (e.g., bleeding, blood clots) are higher in pediatric patients than in adults. Additionally, the risk of complications increases the longer a patient is on a VAD (i.e., risk is proportional to time on support).

If a Candidate has a medical contraindication for a specific therapy that would provide for status 1A designation (e.g., a VAD) and the patient is hospitalized, the Candidate's transplant care team can apply for a status 1A exception through the National Heart Review Board.

Pre-transplant mortality data supports that Candidates who cannot leave the hospital have a higher level of medical urgency than those at home. By way of example, OPTN data demonstrate that status 1B patients have lower per-100-day mortality risk compared with status 1A patients.[5] Candidates who develop unstable physiology and are believed to be at too high risk to be cared for at home are generally hospitalized by their physicians. However, pediatric inpatients are not automatically assigned status 1A; they must also meet at least one of the additional criteria outlined above.

Placing a patient in hospice care reflects a decision by the patient's family and the patient's clinical care team that no further medical intervention will benefit the patient. By placing that patient in hospice, the patient's clinical care team has made the decision that the patient would not benefit from a transplant. While the decision to transition to hospice care is an individual decision, this aligns with 42 C.F.R. § 121.8(a), which asserts that policy should be designed to avoid wasting organs and to avoid futile transplants.

(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.

The OPTN recognizes that applying one rigid set of criteria to identify varying levels of medical urgency within a given patient population will not always accurately capture the medical urgency of each individual patient (which is affected by unique factors on a case-by-case basis). The exception process outlined in Policy 6.4 is the primary mechanism that intends to address this issue. The ability to request an exception is important because of the significant variability of anatomy and physiology among Candidates.

Initiating an exception application under Policy 6.4 may be appropriate when the physician(s) caring for a Candidate determines that the Candidate's level of medical urgency and likelihood of benefit from a transplant merit a higher listing status and the Candidate does not otherwise fit the medical urgency

[5] Ahn, D, Attia, A, Nakayama, T. et al. Status Exceptions and Misalignment of Medical Urgency in U.S. Pediatric Heart Transplantation. JACC. 2026.

requirements delineated in Policy 6.2. The physician can submit an exception request for such a Candidate's designation to be updated to status 1A or status 1B (as appropriate). The exception request must be accompanied by a justification statement that describes: (1) the Candidate's current diagnoses and methods of support; (2) why the Candidate meets the exception criteria; (3) why standard therapies may not be ideal for the Candidate and why the Candidate's condition is not addressed by the pre-specified exception criteria; (4) why the Policy does not adequately account for the Candidate's particular situation and high risk of waitlist mortality; and (5) the timing of symptom changes in relation to the exception request. Importantly, a physician can only request an exception that would move a Candidate to a higher status. It is not possible to request that a Candidate be moved above status 1A or receive credit for additional waiting time.

The OPTN has created a National Heart Review Board ("NHRB") that assigns requests to unbiased peer reviewers who are responsible for reviewing each request and making determinations on whether to grant pediatric status exceptions (Policy 6.4.A). The OPTN has also implemented Heart Review Board Operational Guidelines to establish a standardized approach for these peer reviewers to follow, which promotes consistency, fairness, and rigor in the review process. In alignment with the requirement of 42 C.F.R. § 121.8(b) that Candidates should be ordered from most to least medically urgent, the Guidelines reflect that these peer reviewers should heavily weigh a Candidate's level of medical urgency as a factor in determining whether an exception should be granted. By contrast, the peer reviewers may not consider arbitrary factors, such as the center where a Candidate is receiving treatment or a Candidate's inpatient or outpatient status in determining whether an exception should be granted.

The OPTN believes this standardized exception process is the best approach to maximize fairness for Candidates. Arbitrary use of exceptions will introduce disparities at multiple levels.

We do not believe Candidates should qualify for exceptions based on their outpatient or inpatient status. We also do not believe Candidates who are designated as inactive on the waiting list due to being too sick to transplant and who subsequently recover and are reactivated should be able to use the exception process to accrue additional waiting time based on the length of their inactivity. Inactive status indicates patients are not transplantable at that point in time. A patient not being transplantable is not limited to being too sick to receive an organ (e.g., a patient could be too well, an emergent clinical factor). Indeed, the center is responsible for not providing futile transplants to their Candidates, and this is monitored on the basis of the center's transplant 1- year and 3-year outcomes data, compared with other centers in the SRTR database.

Currently, waiting time does not accrue while a Candidate is inactive (Policy 6.5) although, in being designated as inactive, a Candidate does not lose any of the waiting time that they have already accrued as of the date on which they become inactive. A transplant center is responsible for continually evaluating their patients' suitability to undergo transplant surgery and deciding whether to inactivate a Candidate based on the center's determination that the Candidate is not able to receive an organ. These decisions are based on the Center's clinical decision-making and are not dictated by policy.

(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.

As a matter of practice, the OPTN does not formally review every published study, paper, or article that includes an analysis of organ transplant policy and/or the impact of recent policy changes. The professional volunteers who provide service to the OPTN are experts in their field, and they are aware of the relevant and emerging literature. In preparing this response to the critical comment letter, a cohort of OPTN pediatric heart transplant experts formally reviewed this Stanford study (the "Study").

The Study, which was authored by Power et al. in 2024,[6] used national OPTN/SRTR data to examine 12,408 children listed for isolated transplant from 1999–2023, divided into three allocation eras: 1999–2006, 2006–2016, and 2016–2023. The Study time intervals corresponded to the 2016 pediatric heart allocation revision (the "Revision"), which decreased priority for certain hospitalized Candidates in an effort to improve access for higher urgency patients (resulting in certain Candidates who had previously been granted status 1A defaulting to status 1B). In particular, the Study questioned whether this Revision independently reduced waitlist mortality, and whether the current three-tier system accurately prioritizes children by medical urgency. The central finding is that pediatric heart transplant waitlist mortality has improved substantially over the past two decades, falling from 21% in era 1 to 17% in era 2 and 13% in era 3. This represents an eight percentage-point absolute decline and a 38% relative reduction. Average waitlist duration also fell, from 190 days to 152 days. This is the strongest evidence in the Study that outcomes for listed children have improved meaningfully over time.

The Study claims that these improvements are not simply the result of the Revision. According to the Study, multivariable and fixed-effects analyses determined that the Revision was not independently associated with lower overall waitlist mortality. Instead, these improvements noted in the Study appear to result from a broader evolution in pediatric heart failure and transplant care: children in the contemporary era generally were less critically ill at the time of listing (as they may have been listed more proactively); had lower rates of ECMO use, ventilator use, and dialysis; and had better renal function.

Several specific changes in clinical practice were noted, and illustrate how the care of critically ill Candidates has improved. VAD use increased markedly, from 4% in era 1 to 17% in era 3, while mortality among children listed with VAD support fell from 19% to 10%. This suggests that pediatric programs have become more effective at using mechanical circulatory support to stabilize children and bridge them safely to transplant. Additionally, ABO-incompatible listing rose from 5% to 32%, and blood group O infant mortality fell by 13 percentage points. ABO-incompatible transplant is now recognized for certain populations to have equivalent outcomes compared with ABO-compatible transplant. This is important because blood group O infants historically had a major disadvantage; broader ABO-incompatible allocation helped reduce that barrier. The Study also documents improved equity, though not complete elimination of disparities. Mortality among non-White Candidates declined by 10 percentage points, and the authors identify narrowing racial/ethnic outcome gaps as one contributor to

[6] Power, A, Sweat, K, Roth, A. et al. Contemporary Pediatric Heart Transplant Waitlist Mortality. JACC. 2024 Aug, 84 (7) 620–632.

improved survival. However, non-White race remained associated with higher mortality in the contemporary era, so the improvement is incomplete.

A key nuance is that the Study is not a simple endorsement of the current allocation system. It argues that although outcomes have improved under the modern pediatric transplant ecosystem, the current three-tier status system still performs poorly as a risk-stratification tool. The authors assert that mortality varied more within status categories than between them. For example, according to the Study, contemporary status 1A patients ranged from very low-risk DCM patients on LVAD support to extremely high-risk CHD patients on ECMO. Match-run analysis showed poor correlation between actual allocation order and predicted waitlist mortality risk. The Study, while criticizing the current system, does not provide an example of how allocation can be made more fair. It suggests that a more stratified approach such as a continuous distribution model is needed, but it does not provide any data supporting how a continuous model will more accurately stratify urgency compared with the three-tier system. In fact, it can be argued that if there is difficulty in stratifying even three tiers correctly, that a system with more tiers will have even greater ability to inaccurately predict waitlist mortality for each independent group.

Contrary to the Study, the OPTN asserts that the Revision has, in fact, directly impacted and been a primary force driving the improvements in waitlist mortality. In general, allocation policies will always lag behind clinical expertise and the clinical environment, as policy changes and updates must be data-driven and supported by rigorous evidence. With respect to a pediatric population in particular, which has a smaller sample size, it takes time to amass enough data to assess the impact of policy and determine if additional changes are required. As stated above, the OPTN feels the three-tiered status system is adequate at this time, and provides fairness, respect for persons, and maximizes the beneficence of donated organs.

Due to the fluctuating medical stability and varying diagnoses of Candidates, there is not enough data to further separate and differentiate Candidates in a fair manner based on medical urgency. The medical stability of each Candidate in need of a transplant will invariably fluctuate over their time spent waiting for a transplant. Unfortunately, reduced medical stability and increased degree of illness frequently correspond with the periods of greatest futility of transplant. Candidates with infection, bleeding episodes, or end organ failure are most likely to suffer mortal complications if transplanted at that time, and can therefore be seen as the patient population with the least potential beneficence of transplanted organs. It is the treating physicians' duty to inform the Candidate and family of the risks and benefits of waiting for a transplant, and to serve the Candidate by providing the level of care needed to support a needed transplant. Transplant programs are monitored for their centers' survival data, which incentivizes each center to provide the correct priority for listing for their Candidates, and not to provide futile transplants at times of critical instability. Over the past several decades, as the Study illustrates, centers have successfully worked within the allocation system to bring more of their Candidates to transplant with lower pre-transplant mortality and better post-transplant outcomes.

The OPTN provides the allocation system, but the treating physicians are responsible for the care of the Candidate and proper listing and prioritization of the Candidate on the waiting list. It is not the duty of the OPTN to predict the possible deterioration of an ill patient and provide proactive allocation priority based on complications that may or may not occur, as such a proactive stance would be at the expense

of providing organs to Candidates already hospitalized and at mortal risk. If a Candidate has unique risks, transplant physicians can apply for a status exception via the NHRB.

Finally, it is critical to note that while The Study is peer reviewed, the quotation used in the original critical comment letter to validate their points, ""The current system is not doing a good job of capturing medical urgency, which is one of its specific goals," is not part of the peer reviewed manuscript, but rather a statement from the author as a part of the article's press release. The quote itself is not based on evidence and is not the main point or conclusion of the study.

(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; and (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.

The OPTN is committed to continually reevaluating policy and always open to additional research and dialogue on these topics and other topics impacting transplants. However, any discussions and procedures related to allocation policy changes must be conducted in a deliberate, transparent, and rigorous way, as the implementation of any such changes inevitably decreases some Candidates' chances of receiving an organ.

In accordance with 42 C.F.R. § 121.8, the OPTN is committed to developing and implementing allocation policies that are equitable, prioritize medical urgency, avoid wasting organs and futile transplants, and are assessed routinely by reviewing performance indicators. Like all health care and medical fields, transplantation is a shifting landscape. It will be vital for the OPTN Heart Transplantation Committee and the OPTN Board of Directors to continue to monitor transplant performance measures and evaluate emerging data, evidence, care methods, and technology that may impact the field of heart transplantation and could warrant a reassessment of the Policy.

As stated above in the section describing pediatric heart status exceptions, it is not possible to address every possible patient risk or unique situation within one policy, and the exception system allows for patients with atypical situations to achieve greater priority in the allocation system. However, the OPTN is a national organization that is obligated under statute to develop and implement policies that are equitable for everyone. The OPTN asserts that the existing version of the Policy is rooted in fairness and prioritizes medical urgency to the most reasonable extent possible given the current data and evidence available. The OPTN Heart Transplantation Committee continues to monitor and assess the three-tier status system for Candidates.

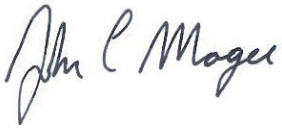
The OPTN recognizes there are far more Candidates than there are pediatric heart donors, and Candidates face significant waitlist mortality as a result. This unfortunate reality is not a reflection of any failure in the Policy or the allocation system itself, but it complicates and raises the stakes of designing and implementing a system that promoted equity, maintains respect for Candidates and their families, and prioritizes the most urgent Candidates without wasting organs on futile transplants. The OPTN understands that a high-level of scrutiny will remain on heart allocation and on changes to the Policy as a result.

The current Policy is equitable, provides organs first to hospital-bound and critically ill children at highest need for transplant, and takes into account efficient use of organs while avoiding many futile

transplants. Changes to this Policy must be rooted in data and evidence to avoid changes or revisions that are arbitrary and capricious. The OPTN is committed to continually reevaluating the Policy to ensure that the pediatric heart allocation system remains as flexible, dynamic, and equitable as is possible and the Policy continues to meet the needs of Candidates and their families.

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 to all, honors the gift of life, and adheres to NOTA and the Final Rule.[7]

Sincerely,



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

cc: Doug Fesler
Executive Director, OPTN

[7] 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.