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

July 10, 2026

[redacted]

Dear Mr. [redacted]

This letter responds to the letter you sent to the Organ Procurement and Transplantation Network (OPTN) on March 27, 2026, on behalf of your clients [redacted] and their [redacted] (Tab A Exhibit A), and subsequent additional correspondence sent on April 21, 2026 (Tab A), April 27, 2026 (Tab B), June 5, 2026 (Tab C), and June 17, 2026 (Tab D). As we previously indicated, we consider these four letters together to constitute a critical comment pursuant to the National Organ Transplant Act of 1984 (NOTA), as amended, and U.S. Department of Health and Human Services (HHS) regulations at 42 C.F.R. part 121 ("the OPTN Final Rule").

The critical comment raises concerns about the pediatric heart allocation policy approved by the OPTN Board of Directors (OPTN Board). The fundamental question you posed to the Secretary of Health and Human Services (the Secretary) is whether the current OPTN pediatric heart allocation policy (OPTN Policy 6), "is allocating organs equitably in accordance with the mandate of ranking by medical urgency to the greatest extent practicable."[1] *See* Tab A at 5.

Across the correspondence you have also requested that the Secretary direct certain actions and posed several specific policy questions, which we summarize below:

- **Consideration of hospitalization status as a Status 1A criterion:** You requested that the Secretary direct the OPTN to adjust your clients' daughter's time in Status 1A to include all the time she spent at home before she was admitted to [redacted] on January 7, 2026, during which time she was listed as Status 1B but was not listed as Status 1A because she was not hospitalized and was instead receiving care including dialysis at home. *See* Tab A Exhibit A at 2, Tab A at 4, Tab C at 3-4. Specifically, you request that her Status 1A waiting time begin on October 8, 2024, when your clients were given the option of hospitalizing their daughter but declined to do so. Tab C at 3. You also requested that, going forward, the Secretary direct the OPTN to allow your clients' daughter "to leave the hospital, with the permission of her doctors, without losing 1A Status." *See* Tab A at 5, Tab C at 5.

- **Consideration of hospice status as Inactive Status rather than Status 1A:** You requested that the Secretary direct the OPTN to adjust your clients' daughter's accrued

[1] https://www.hrsa.gov/sites/default/files/hrsa/optn/optn_policies.pdf.

waiting time in Status 1A to include all the time since she was hospitalized on January 7, including when she "was taken off Status 1A twice in January and February [and moved to inactive status] [. . .] because her condition had deteriorated to the point where she was deemed unable to survive transplant." *See* Tab A at 4. Your request challenged the OPTN policy of categorizing hospice status as Inactive Status, claiming that this action "makes no sense because waiting status is supposed to correlate with medical need for a transplant." *See id*.

- **Contraindication to mechanical circulatory support devices (VAD) as a Status 1A criterion**: Currently, patients on a VAD are the only exception to the hospitalization requirement for pediatric heart patients to be listed as Status 1A. You requested that the Secretary direct the OPTN to re-order the list to allow non-hospitalized patients contraindicated for a VAD to be ranked ahead of non-hospitalized VAD patients. *See* Tab B at 2-3.

- **Consideration of dual organ candidacy status as a Status 1A criterion:** You requested that the Secretary direct the OPTN to adjust your clients' daughter's time in Status 1A to reflect eligibility for status 1A "as of the time she first began dialysis in 2021 at the age of 2," citing that "dialysis patients waiting for hearts have a higher mortality rate than other heart patients." *See* Tab C at 2–3.

- **Use of waiting time as a ranking criterion within each Status 1A classification:** Finally, your letters also challenge the use of waiting time to rank Status 1A patients in the same classification level, because waiting time is unrelated to medical urgency. *See* Tab A Exhibit A at 2, Tab B at 2.

In a letter dated May 1, 2026 (Tab E), the Health Resources and Services Administration (HRSA) sought the views of the OPTN on the issues raised in your critical comment. In a letter dated May 29, 2026 (Tab F), the OPTN submitted a detailed response to the questions posed in the May 1, 2026 letter.

In an email dated June 4, 2026 (Tab G), HRSA requested additional information from the OPTN to further clarify its responses in the May 29, 2026, letter and received the OPTN response in a letter dated June 8, 2026 (Tab H).

Finally, in a letter dated June 9, 2026 (Tab I), HRSA requested input from the OPTN to inform consideration of your letter dated June 5, 2026, in which your clients request that the Secretary "direct the OPTN to adjust [redacted] standing in the Status 1A" based on their daughter's status as a dual transplant candidate awaiting both a heart and a kidney transplant – an issue that had not been explicitly raised in earlier communications. In a letter dated June 22, 2026 (Tab J), the OPTN submitted a detailed response to the questions posed in the June 9, 2026, letter.

HRSA continues its longstanding practice of relying on the expertise of the OPTN and its members to consider and address the requirements of the OPTN Final Rule as organ allocation policies are developed and revised. The Secretary is obliged to consider critical comments on the OPTN in light of NOTA and the OPTN Final Rule and may: "(1) Reject the comments; (2)

Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or (3) Take such other action as the Secretary determines appropriate."[2]

To consider your critical comment, we carefully reviewed your critical comment letters, your supplemental communications, the relevant OPTN policies, prior OPTN policymaking materials, relevant peer reviewed literature, relevant data provided by the Scientific Registry of Transplant Recipients contractor, and the OPTN's responses in light of the requirements of NOTA and the OPTN Final Rule. Below, we have listed the six key issues raised in your letters and provided our response for each, along with our conclusion:

I. Whether the current pediatric heart allocation policy is compliant with NOTA and the OPTN Final Rule

In your April 21, 2026, letter, you argue that the OPTN pediatric heart allocation policy is not compliant with the requirements of NOTA and the OPTN Final Rule because the policy does not adequately consider medical urgency in prioritizing transplant candidates.

We reviewed the policy in light of the statutory and regulatory requirements and do not agree that the policy fails to adequately consider medical urgency.

NOTA requires the OPTN, a network of entities and individuals with expertise in organ transplantation, to establish a national system to allocate donated organs[3] and to "assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients."[4] To accomplish these goals, NOTA tasked the Secretary with providing for the continued operation of the OPTN to set organ allocation policy and to distribute organs.

The OPTN Board, which is charged with setting organ allocation policy, is comprised of a diverse cross-section of stakeholders and experts in the field of organ transplantation, including representatives of organ procurement organizations, "transplant centers, voluntary health associations, and the general public."[5]

The OPTN Final Rule, the HHS regulations implementing NOTA, became effective on March 16, 2000.[6] The regulations require the OPTN to develop "[p]olicies for the equitable allocation of cadaveric organs in accordance with [42 C.F.R. § 121.8]." [7]

Congress sought to ensure "an equitable national system" for development of OPTN membership criteria and allocation policies "operated by the transplant community" and "with oversight by HHS."[8] As a result, HHS does not prescribe specific organ allocation policies. Instead, HHS

[2] 42 C.F.R. § 121.4(d); 42 U.S.C. § 274(c)
[3] 42 U.S.C. § 274(b)(2)(A)(ii)
[4] 42 U.S.C. § 274(b)(2)(D)
[5] 42 U.S.C. § 274(b)(1)(B)(i)
[6] 42 C.F.R. 121
[7] 42 C.F.R. § 121.4(a)(1)
[8] 63 Fed. Reg. 16,296, 16,297–98 (Apr. 2, 1998)

regulations provide a list of factors the OPTN Board must adhere to in developing organ allocation policies.[9]

The OPTN Final Rule mandates that any organ allocation policy meet eight discrete requirements, including that policies "[s]hall be based on sound medical judgment," "[s]hall seek to achieve the best use of donated organs," and "shall not be based on a [transplant] candidate's place of residence," except as otherwise necessitated by the regulation.[10]

The OPTN Final Rule also mandates as an allocation performance goal that

> [a]llocation policies shall be designed to achieve equitable allocation of organs among patients consistent with [42 CFR 121.8(a)] through the following performance goals:
>
> …
>
> (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, in accordance with paragraph (a) of this section, 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;[11]

Any OPTN policy under consideration by the OPTN Board may be adopted only after the solicitation (through publication on the OPTN website) and consideration of public comments. 42 C.F.R. § 121.4(b)(1). The Secretary exercises oversight in the adoption of all OPTN policies by, among other things, including non-voting "HRSA" representatives on the OPTN Board, and by considering and responding to any "critical comments" submitted in response to OPTN policies. 42 U.S.C. § 274(c); 42 C.F.R. § 121.4(d).

The current OPTN pediatric heart allocation policy, Policy 6.2 – Pediatric Status Assignments and Update Requirements, has been revised multiple times over the years. The latest revisions to Policy 6.2 were made in February 2022, though the last major revisions that are relevant to this critical comment were made in 2016.

The policy classifies heart candidates less than 18 years old in one of four categories: (i) Pediatric status 1A; (ii) Pediatric status 1B; (iii) Pediatric status 2; and (iv) Inactive Status.

The highest tier, status 1A, requires patients to 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.

[9] *See* 42 C.F.R. § 121.8(a)
[10] 42 C.F.R. § 121.8(a)
[11] 42 CFR 121.8(b)(2)

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[12].

Pediatric status 1A is valid only for 14 days from the date of initial registration without recertification by the transplant program every 14 days to extend the patient's 1A status.

In turn, status 1B requires at least one of the following criteria:

1. Requires infusion of one or more inotropic agents but does not qualify for pediatric status 1A. The OPTN maintains a list of the OPTN-approved status 1B inotropic agents and doses.
2. Is less than 1 year old at the time of the candidate's initial registration and has a diagnosis of hypertrophic or restrictive cardiomyopathy.

A candidate may retain status 1B for an unlimited period of time and recertification by the transplant program is unnecessary, unless the candidate's medical condition changes.

A patient's status matters because OPTN Policy 6 allocates hearts by assigning patients to ranked classification levels (there are 104 classifications for donated pediatric hearts); and a patient's classification level for a given donated organ is determined by a combination of their blood type compatibility with the donor, distance from the donor organ, and their medical urgency status. *See* OPTN Policy 6.6.

Within each classification level, patients are ranked by the total amount of waiting time the patient has accumulated in that medical urgency status. *See* OPTN Policy 6.6.C. A candidate's waiting time begins accumulating upon their registration as an active heart candidate on the waiting list and is calculated within each status. *See id.* If a candidate's status is upgraded, for example from status 1B to 1A, then the waiting time at a lower status is not transferred to a higher status. On the other hand, waiting time accrued at a higher status is transferred to a lower status if the candidate is assigned a lower status. *Id.* A patient does not accumulate waiting time at any status while they are on Inactive Status. *Id.*

Additionally, OPTN Policy 6.4 – Adult and Pediatric Status Exceptions provides for a process for consideration of exceptional circumstances not addressed in OPTN Policy 6.2. Under Policy 6.4, a pediatric heart transplant candidate qualifies Status 1A under an exception if the following criteria are met:

[12] This is also known as a Ventricular Assist Device (VAD)

a. The candidate is admitted to the transplant hospital that registered the candidate on the waiting list; and
b. The transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status

Based on our analysis, we agree with the OPTN Board's statement that the current policy represents an appropriate "balance of urgency, fairness, and utility." *See* Tab F at 5. The OPTN Final Rule requires the OPTN Board to develop equitable organ allocation policies based on medical urgency while balancing the demands of other factors such as the 'best use of donated organs', avoiding wasting organs, avoiding futile transplants, promoting patient access to transplantation, and promoting the efficient management of organ placement, among other factors. 42 CFR 121.8(a). These policies are required to set "priority rankings expressed, to the extent possible, through objective and measurable medical criteria." 42 CFR 121.8(b)(2). While the critical comment largely focuses on whether the OPTN heart policy ranks patients by medical urgency, the OPTN Final Rule's requirements are more nuanced and require OPTN policies to achieve an equitable balance of medical urgency and futility. Specifically, as the OPTN's May 29, 2026, letter to HRSA explains, adding additional medical urgency statuses or prioritizing medical urgency above the other factors enumerated under the OPTN Final Rule could result in more futile transplants and less access to transplant. *See* Tab F at 7 ("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. . . 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.").

Additionally, upon review of the record, HHS believes the record makes clear that the current OPTN policy heavily weighs medical urgency and categorizes pediatric heart transplant candidates by compatible levels of medical urgency based on the best available data and sound medical judgment of the experts of the OPTN. These medical urgency rankings are captured by three status levels (1A, 1B, and 2). The OPTN states in its May 29, 2026, response that it believes the "three status categories (1A, 1B, and 2) are sufficient given current technological, clinical, and data constraints" given that "[c]andidates suffer from a diverse number of causes of heart failure" making "it challenging to further subdivide status categories because the natural history of these conditions is highly variable."

The OPTN also states in its June 22, 2026, response that "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." For example, the OPTN notes that there were only 63 dual-organ pediatric heart candidates out of 2,360 total pediatric heart candidates listed in a three-year stretch; and the small data size makes it difficult to establish objective medical criteria that could make further medical urgency determinations among dual-organ candidates in status 1A or between dual-organ and single-organ candidates in status 1A, all of whom would be considered critically ill. For these reasons, it would not be possible for the

OPTN's medical experts to "consider [your clients' daughter's] circumstances and those of other patients waiting for organs and make specific decisions of medical urgency," as suggested in your March 26, 2026 letter, without introducing significant inconsistency and subjectivity. *See* Tab A Exhibit A p. 2.

While the OPTN policy endeavors to establish objective and consistent criteria for inclusion at each status level, the policy also acknowledges that exceptional circumstances exist that cannot be adequately addressed and therefore created the Pediatric Status Exception policy (OPTN Policy 6.4), which allows physicians providing care for individual pediatric heart transplant candidates to petition for a status upgrade to Status 1B or Status 1A. This exception policy acknowledges the need for individualized medical judgment and further acknowledges medical urgency as determined by the candidate's medical providers, while maintaining minimum standards (such as hospitalization) and review by a national exception review board to ensure consistency and fairness in application.

II. Policy requirement that Status 1A candidates be admitted to the hospital

In your critical comment, you also questioned the OPTN policy requirement that a pediatric heart transplant candidate be hospitalized in most circumstances to be eligible for Status 1A.

We reviewed the policy in light of the statutory and regulatory requirements and have determined that the current policy is consistent with those requirements.

In particular, prior to 1999, the OPTN used only a two-tier system of medical urgency in pediatric heart policy (Status 1 and 2). In 1999, the OPTN revised the pediatric heart policy into a three-tier system of medical urgency, subdividing Status 1 into Status 1A and 1B, to better prioritize the sickest patients.

However, until 2016, hospitalization was not required under any of the qualification criteria for Status 1A. In the last major policymaking effort on pediatric heart policy, which began in 2013 and was finalized in 2016, the OPTN intentionally *added* hospitalization as a requirement to most of the Status 1A criteria. *See* OPTN Thoracic Organ Transplantation Committee and Pediatric Transplantation Committee's Proposal to Change Pediatric Heart Policy (Tab K) for a redline of the changes. In explaining its motivation for making this revision, the OPTN stated it was precisely to "create an allocation system that is more dependent on a candidate's medical urgency rather than the candidate's waiting time." *See* OPTN Policy Oversight Committee Feb. 19, 2013 Interim Report (Tab L). Under the pre-2016 policy, because a "substantial portion" (around 70%) of candidates qualified for Status 1A, and waiting time was used as a tiebreaker among patients with the same medical urgency status, allocation to Status 1A candidates was heavily dependent upon their waiting time. *See id.* By adding an objective medical requirement to Status 1A such as hospitalization, the OPTN could reduce the proportion of candidates listed as Status 1A and ensure that only the most medically urgent candidates continued to qualify for Status 1A.

In undertaking this policy revision, the OPTN specifically determined that hospitalization status was a medically objective factor that was largely correlated with medical urgency. *See* Proposal

to Change Pediatric Heart Policy – Briefing Paper (Tab M) at 50 (stating that "[a]dmission to the hospital is an indicator of the severity and urgency of the candidate's condition, as the candidate is under the constant care of his or her transplant team. With the exception of candidates supported by mechanical circulatory support devices (MSCD), candidates that have been discharged from the hospital are not as clinically urgent as those candidates that are admitted to the hospital"); *see also* Tab F at 10 ("pre-transplant mortality data supports than candidates who cannot leave the hospital have a higher level of medical urgency than those at home"). The OPTN also determined that hospitalization was important to ensure the efficient placement of organs, which is another factor required to be considered under the OPTN Final Rule. *See* Briefing Paper at 45 ("A candidate registered as Status 1A is extremely urgent and has a life expectancy of about 14 days. The candidate is potentially very unstable and should be under constant care by the transplant team. The transplant team needs to know the candidate's condition at all times, because if there is an organ offer, the candidate should be able to be transplanted very quickly. If the candidate is not admitted to the hospital that registered him or her, the candidate could potentially be very far away and render the transplant impractical. The Committees therefore think it is reasonable to require the candidate to be admitted to the listing hospital").

As the OPTN notes in its response dated June 9, 2026, the inpatient criterion is necessary since "candidates requiring intensive support and monitoring associated with inpatient care are generally considered to be more acutely sick than those who can be managed in an outpatient setting." Hospitalization is seen as a proxy for severity of illness that serves as a minimal requirement to allow for objectivity and uniformity in application of the exception process. In general, patients who are not hospitalized are considered to be less sick and at less risk than patients who require hospitalization. The noted exception is pediatric heart transplant candidates who require assistance of a mechanical circulatory support device (or VAD), whom, based on the available data and analysis, the OPTN has determined to be eligible for Status 1A as outpatients because "[w]hile 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."

Even though your clients would like the OPTN to provide exceptions to the hospitalization requirement for non-hospitalized patients, it is not clear that removing the hospitalization requirement would benefit your clients' daughter, as the removal of that criterion may potentially open Status 1A to many other non-hospitalized patients who are not currently listed as Status 1A, which is precisely what the 2013-2016 policymaking was meant to prevent.

III. Policy requirement that patients deemed too sick to transplant are ineligible for Status 1A

In your letter dated April 21, 2026, you also question why patients deemed 'too sick to transplant' are listed as Inactive Status and therefore do not accrue waiting time for Status 1A for the period that they are too sick to transplant.

We reviewed the policy in light of the statutory and regulatory requirements and have determined that current OPTN policy regarding Inactive Status is consistent with those requirements.

Specifically, the assignment of patients to Inactive Status when they are too sick to transplant is not unique to heart policy but exists in numerous OPTN organ allocation policies. While Status 1A eligibility is an indication of medical urgency, the OPTN must also address the requirement of the OPTN Final Rule that OPTN policies must be designed to "avoid futile transplants"[13] and to allocate organs to "patients who are medically suitable candidates for transplantation."[14] This requirement is in place because, unfortunately, the demand for transplantable organs far exceeds the supply; and use of a donated heart for a candidate who in the medical judgment of their providers is unlikely to survive a transplant would not be consistent with the concept of 'best use' of an organ and would likely preclude another patient from receiving a transplant. Even though it is undeniable that patients who are on hospice are medically urgent, we believe that treating hospice time as Inactive Status does comply with the OPTN Final Rule's requirements to balance medical urgency with efficiency (see 42 CFR 121.8 requirements to avoid wasting organs, to avoid futile transplants, and to achieve the best use of donated organs).

Allowing a patient who is temporarily too sick for a transplant to receive waiting time for the time that they were too sick to receive a transplant could also produce unintended consequences. For example, it could introduce significant subjectivity into organ policy by raising the question of whether every situation where a patient is temporarily too sick for transplant, but later recovers, should cause the patient to accrue waiting time for their Inactive Status time. Under the current system, it is a common occurrence for patients to be moved to Inactive Status whenever they are too sick to transplant or temporarily contraindicated for transplant. Because of how many patients' waiting time would have to be recalculated to allow them to accrue waiting time for Inactive Status time, it is not clear that such a policy change would produce a net benefit for your client's daughter.

IV. Policy regarding contraindication to VAD devices in relation to Status 1A

In your letter dated April 27, 2026, you also argued that a patient's contraindication for a VAD device should be considered by the heart policy. Currently, the pediatric heart policy's only exception to the hospitalization requirement for Status 1A is for patients on VADs. The OPTN explained in the 2016 policymaking that they retained this exception for VAD patients due to the limited data on the safety of long-term VAD usage. *See* Briefing Paper at 31 ("At this time, the [OPTN Thoracic and Pediatric] Committees believe that any child with a VAD should continue to qualify for status 1A irrespective of whether they are admitted to the hospital. Though the Committees agree it is a reasonable assumption that older pediatric candidates implanted with long-term VADs may be more stable, there is a lack of data and clinical experience to support the assumption").

The fact that a patient is contraindicated for a VAD, however, should not be a barrier to being listed as Status 1A. According to the OPTN, the percentage of candidates who have had a VAD when listed for transplant has fluctuated between 15 percent-34 percent in recent years. *See* Tab F at 3. Therefore, most candidates continue to qualify for Status 1A through the non-VAD criteria, including candidates who may be contraindicated for a VAD.

[13] 42 CFR 121.8(a)(5)
[14] 42 CFR 121.8(b)(2)

Additionally, contraindication for a VAD is also an appropriate factor that the OPTN and national review board can consider when a patient is applying for a Status 1A exception (provided that the patient is hospitalized).

For these reasons, we do not think the current policy merits revision to provide an automatic Status 1A exception for patients who are contraindicated for a VAD, since there are still numerous other criteria that allow patients to qualify for Status 1A that do not include being on a VAD.

V. Policy regarding dual organ transplant candidacy in relation to Status 1A

In your letter dated June 8, 2026, you question why a patient awaiting a kidney transplant as well as a heart transplant would not be eligible for Status 1A based on their status as a multiorgan transplant candidate. On June 24, 2026, you also asked that two emails from your clients' daughter's medical providers to the OPTN related to this issue (Tab N) be considered as part of our analysis.

We reviewed the policy and the emails in light of the statutory and regulatory requirements and have determined that the current policy is consistent with those requirements.

Organ transplant candidates are registered for each individual organ in accordance with OPTN policies as there is currently no separate multiorgan waiting list.

However, multiorgan candidacy status can sometimes affect a patient's rank in the single organ waitlists. In particular, OPTN Policy 5.10 defines the priority in which organs are to be offered in consideration to candidates requiring more than one organ from the same donor.

For certain patients, OPTN Policy 5.10.E (Allocation of Heart-Kidneys) does provide multiorgan candidates who qualify for a heart priority access to a kidney, as it provides:

> When an OPO [organ procurement organization] is offering a heart, and a kidney is also available from the same deceased donor, then the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a heart and a kidney at the same transplant hospital…

This policy is justified by the fact that heart-kidney transplant candidates generally have a more urgent medical need than transplant patients experiencing renal failure alone. *See* Tab J at 4. In contrast, OPTN policies currently do not provide patients who qualify for a kidney transplant priority access to a heart, since many patients who need kidney transplants can survive for a long time on dialysis, and are often less medically urgent than patients who need a heart transplant, who have much lower survivability on average. Even so, it does not appear that heart-kidney candidates are currently being unfairly disadvantaged compared to single-organ heart candidates. As provided by Tab J Exhibit 4, the median waiting time for a heart for heart-kidney candidates

is around 108 days, while the median waiting time for a heart-alone candidate is currently around 133 days.[15]

While it is noted that candidates in need of more than one organ often have circumstances that increase complexity of treatment and can increase medical urgency, all candidates (whether dual-organ or single-organ) assigned to Status 1A are critically ill and the OPTN must consider medical urgency in the context of other factors required in the OPTN Final Rule (as discussed above).

Also, as discussed above, OPTN policy includes provisions to allow for transplant candidates with exceptional circumstances, such as those described in the two emails from your clients' daughter's medical providers, to qualify for Status 1A through the exception process – provided that the candidate is hospitalized.

VI. Policy regarding waiting time to rank candidates in the same status

Finally, the critical comment asserts that the consideration of waiting time in the OPTN's pediatric heart policy to rank patients is arbitrary and unrelated to medical urgency.

We believe use of waiting time, as currently used in OPTN pediatric heart policy to rank patients, is compliant with the OPTN Final Rule because waiting time is solely used as a tiebreaker for patients who have the same medical urgency status and classification level (and there are 104 classification levels). *See* Briefing Paper at 3 (explaining that waiting time is only used as a tiebreaker to rank candidates who are "tied" after all other sorting and screening criteria are applied (a candidates' urgency status, a donor's geographical proximity, a donor's physical descriptors, etc.)). The OPTN uses waiting time not as a measure of medical urgency but as an equitable solution to rank candidates who cannot be ranked further using objective medical criteria. Some ranking system is still required to rank candidates whose medical urgency status is tied. In this context, the use of waiting time in no way detracts from the fact that the policy still primarily focuses on medical urgency.

For this reason, HHS believes the limited use of waiting time in OPTN pediatric heart policy as an equitable tiebreaker is acceptable under the OPTN Final Rule.

Conclusion

Given that the demand for donated organs tragically exceeds the supply, it is understandable that there are inevitable and constant disagreements within the transplant community about candidate waitlist priority.

[15] Note that the time for individual patients can vary because a patient's blood type match, distance from the donated organ, and other medically relevant considerations as determined by the transplant team (such as organ size compatibility) can affect how long a particular candidate can wait for an organ.

Even so, the OPTN is charged with developing equitable allocation policies that apply nationwide to best serve patients awaiting the precious resource of donated organs. HHS believes that the current pediatric heart allocation policy, which is the result of decades of continuous refinement by the experts in the OPTN, achieves equitable allocation of organs among patients in a manner that is compliant with the OPTN Final Rule.

While we are undoubtedly sympathetic to your client's situation, as the OPTN notes in its May 29, 2026, response, "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."

Appropriate consideration of further changes to OPTN policy requires robust discussion, consideration of the latest available data, and advances in clinical care and technologies. In its oversight capacity of the OPTN, HHS will continue to welcome input from patients and their families, clinicians, and other stakeholders as the OPTN continues to evaluate and update its policies.

Upon careful review of all of the materials presented in this matter, and upon our review in light of the statutory and regulatory requirements that apply to organ allocation, we are resolving your critical comment without further action at this time. HHS will continue, in its oversight role over the OPTN, to work with the OPTN to consider whether future changes to heart policy are warranted as additional data and clinical advances become available, including the consideration given to multi-organ candidates.

In the meantime, we wish the best for [redacted] and her family and hope that she receives a transplant soon and recovers quickly.

Sincerely,

Suma Nair -S
Digitally signed by Suma Nair -S
Date: 2026.07.10 13:29:59 -04'00'

Suma Nair, PhD, MS, RD
Associate Administrator

Cc:
John C. Magee, M.D. (OPTN President)
Doug Fesler (OPTN Executive Director)

Enclosures