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BY COURIER

The Honorable Robert F. Kennedy, Jr.
Secretary of Health and Human Services
Department of Health and Human Services
Room 120F, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Urgent Request to Exercise Authority Under 42 C.F.R. § 121.4 to Correct Malfunctioning of National Organ Allocation System

Dear Secretary Kennedy:

I am writing on a matter of the utmost urgency, involving an apparently illegal malfunctioning of the Organ Procurement and Transplantation Network (OPTN) that could imminently lead to the death of a pediatric patient who desperately needs a dual organ transplant, but may not timely receive it because the OPTN's criteria is incorrectly underestimating her medical severity.

My clients are [redacted]. They are the parents of [redacted], who is hospitalized at the [redacted] suffers from end-stage heart disease, almost died on February 27 and was taken off of Status 1A (the highest priority category, which requires hospital admission) as too ill for a for a heart transplant so that she could return home for palliative care and hospice, but then her medical situation improved and she is now Status 1A again, waiting for a heart transplant (as well as kidneys due to renal failure). Clearly, she is critically ill and in urgent need of transplanted heart and kidneys. However, because her time waiting in Status 1A is limited, she

is unlikely to receive them for a year or more, during which time she will likely die or become too ill for transplant surgery, just as was the case in late February.

[redacted] parents recognize that there are many patients waiting for organs and that she has no right to be placed at the head of the line just because she is very sick and could die soon. As tragic as that is, they understand and can accept that. But they believe that the system is malfunctioning and treating her as less ill than she really is for purpose of organ allocation. This specific problem is addressed in a recently updated study led by doctors at Stanford University. See https://med.stanford.edu/news/all-news/2024/08/heart-transplant-pediatrics.html. As noted by the co-lead author of that study: "The current system is not doing a good job of capturing medical urgency, which is one of its specific goals." This precisely describes [redacted] situation, as patients within Status 1A are ranked by time waiting in Status 1A, without regard to medical severity, and she has had little time waiting in Status 1A despite needing a heart and kidneys (and being on dialysis, unlike most other patients) for approximately five years and being very close to death in late February due to collateral bleeding in her airways with the chance of that recurring at any time. It is highly likely that unless something is done to make the system function differently and rank [redacted] according to her actual medical urgency, as opposed to time spent in that category, she will die and during the interim between now and when that happens organs will be provided to patients who are otherwise less medically urgent. Stated differently, [redacted] is being unfairly and incorrectly treated as less medically urgent than other patients in the organ allocation system whose need is not as dire and as a result, she is likely to die.

From a legal perspective, [redacted] does not have a right to receive a new heart and kidneys, but she does have a right to be treated fairly with respect to the allocation of vital organs under the National Organ Transplant Act of 1984, 42 U.S.C. § 274, *et seq*., and HHS regulations at 42 C.F.R. §§ 121.1-13. Section 274(a) provides that "[t]he Secretary shall provide for the continued operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b)."

Subsection (b)(2) provides that the OPTN "shall":

> (A) establish in one location or through regional centers--

> (i) a national list of individuals who need organs; and
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> (ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs;
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> …
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> (D) assist organ procurement organizations in the nationwide distribution of organs **equitably** among transplant patients;
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> …
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> (M) recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children;
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> ….

42 U.S.C. § 274(b)(2) (emphasis added).

The regulations provide that OPTN shall be responsible for developing "Policies for the **equitable allocation** of cadaveric organs in accordance with § 121.8." 42 C.F.R. § 121.4(a)(1) (emphasis added.) Section 121.8(b)(2) calls for "[s]etting priority rankings [for organ transplant waiting lists] expressed, to the extent possible, through objective and measurable 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 rankings for patients)." (Emphasis added.)

In short, the OPTN's policies are required to allocate organs to the greatest extent practicable by ***medical severity***. Patients therefore have a right to expect that organs will be allocated equitably in accordance with this requirement. In [redacted] case, that right is apparently being violated by the system that makes her wait longer than other patients for arbitrary reasons when the reality is that she

presents as a very medically urgent case, more urgent than others who are ranked higher on the waiting list.

So, what do her parents want? They want the manner in which the system currently functions to be adjusted to treat her fairly as required by law. They want it to take into consideration the actual medical urgency of her situation in relation to others on the waiting list. How can that be done? One obvious way is that she could receive credit in Status 1A for all the time she spent at home before being admitted to [redacted] on January 7, during which time she was listed as Status 1B but was not listed as Status 1A simply because she was not "admitted to the hospital" and was instead receiving care including dialysis at home.

Had [redacted] been hospitalized during that same period (which was an option), she could have qualified for and accrued time in Status 1A. The distinction, therefore, is not grounded in medical necessity or urgency, but in the location of care, which is arbitrary and unrelated to her dire need for transplant.

Her parents also want her to be credited with time in Status 1A for all the time she has been hospitalized since January 7. For unknown reasons, she has not received credit for all her time since being hospitalized. Specifically, she was taken off Status 1A twice in January and February apparently because her condition had deteriorated to the point where she was deemed unable to survive transplant surgery but then she recovered and she lost time in Status 1A, which makes no sense because waiting status is supposed to correlate with medical need for a transplant.

Relatedly, without affecting [redacted] time in Status 1A, her parents want to be able to take her out of the hospital to an apartment or living area close to the hospital where she can receive dialysis and care administered by her family, who would bring her immediately back to the hospital if needed. This is the same situation she was in prior to admission to [redacted] in January; there is no need for her to be hospitalized while she waits. Make no mistake, she is very sick and her medical condition could deteriorate at any time, as it did in January and February, in which case she would return to the hospital immediately. The reason for this request is simple: she may not live that much longer and her parents want her to be able to live somewhat normally to the greatest extent possible. It's miserable for anyone to be confined to a hospital for any time, and for a child even worse. The

only reason [redacted] is there now is to not lose time in Status 1A. This is arbitrary and unreasonable.

Before I approached you with this request, I wrote to the United Network for Organ Sharing (UNOS) with this request. A copy is attached as Exhibit A. UNOS directed me to the OPTN and the Health Resources and Services Administration (HRSA), which on March 29, 2026, sent me a letter (attached as Exhibit B) denying my request. The letter states: "Based on the information available to us, it appears that [redacted] current placement on the waitlist is consistent with the allocation policy." I have no way to judge what this statement means and in particular whether it means that OPTN believes [redacted] placement is in accordance with the medical severity of her circumstances as related to other patients, as required by law, and, if not, whether there is some compelling justification for the disparity. In other words, [redacted] current placement on the waitlist may be consistent with the "policy" but that does not answer the real question, which is whether the policy is allocating organs equitably in accordance with the mandate of ranking by medical urgency to the greatest extent practicable.

The OPTN letter also explains that any change in the allocation system has potential implications for other patients. My clients understand that reality, but that does not diminish the need to ensure that the system is allocating organs equitably.

Since the OPTN letter on March 29, I wrote to the OPTN and to the HRSA by email on April 10 and 15 asking for a chance to be heard on some very specific questions:

- Is there any way under the existing policy that [redacted] can be credited with additional time in Status 1A, such as the time she was receiving dialysis at home before being admitted to [redacted] and/or all of the time since being admitted at [redacted]?
- If she gets listed at another hospital, how will that affect her time in Status 1A?
- Would it be possible for [redacted] to be outside of the hospital close to the emergency room to improve the quality of her life, which regrettably could be short, without removing her from Status 1A?
- Is there any way to gauge when she might receive a heart and kidneys under the current policy?

A copy of the email correspondence is attached as Exhibit C. As you can see, on April 16, 2026, the OPTN advised they would get back to me as soon as possible; that has not yet happened.

Relatedly, knowing that no system is perfect, my clients question why the policies do not provide a mechanism for immediately addressing cases of evident unfairness, which they strongly believe to be the case here, based on what they have learned from discussions with the clinical care team at [redacted], who have told them that they think there is a significant problem with the OPTN system, that it is adversely affecting [redacted] chance to receive donated organs and live, and that change will not happen unless patients and their families speak up.

On the facts of the matter, given that [redacted] doctors advised on February 27 that she was deemed too critically ill to receive a transplant due to airway bleeding, a condition that has occurred four times since January 7 resulting in cardiac arrest on two occasions and could recur at any time, one would assume that she should be considered a case of very high severity as compared to other patients. And, as explained in the affidavit submitted with my letter to OPTN, (Exhibit A), knowing that she just began to accrue time in Status 1A when she became hospitalized at [redacted] in January of this year, and not even all that time has been on Status 1A (because they took her off Status 1A when she was too sick to be considered a candidate for transplantation), it is likely that there could be patients who are not as likely to die as soon as she is, but who are nevertheless ranked higher than her in Status 1A. This would mean [redacted] is ranked lower on the waiting list despite being a more medically severe case because other patients have been ranked in Status 1A longer than [redacted] for reasons that are essentially arbitrary (e.g., they were waiting for their transplant in the hospital while she was waiting and receiving dialysis at home).

Section 121.4 of the regulations provides as follows:

> (d) Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments 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.** The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under § 121.12. After this review, the Secretary may:
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> (1) Reject the comments;
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> (2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or
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> (3) Take such other action as the Secretary determines appropriate.

(Emphasis added.)

This section provides you with clear authority to order an immediate review of this situation. The requested review should specifically address whether [redacted] placement on the waiting list is in accordance with a reasonable evaluation of the medical severity of her condition in relation to other patients, if not whether there is some compelling reason for not addressing the apparent failure to rank her by medical severity, and whether it would be appropriate (equitable) in accordance with the principles that govern the OPTN's policies for her to be credited with time in Status 1A during the time she was at home before being hospitalized, listed as Status 1B, and undergoing dialysis on a daily basis, as well as all the time since she has been hospitalized since January 7. It should also consider whether there is any sound reason why [redacted] should not be allowed to live outside of the hospital but close by (so she can return quickly in an emergency) if she can receive dialysis and care outside and her doctors determine that there is no medical reason why she needs to be in the hospital, without losing time in Status 1A. I also respectfully request that any report of the review be shared with [redacted] parents so they can seek judicial review, if appropriate.

There is obviously a risk that [redacted] could die during the time that the requested review is ongoing, so on behalf of her parents I implore you and the other responsible officials to act promptly. As stated previously, [redacted] parents fully understand that they do not have a right to have their daughter moved up the waiting list simply because she is sick and could die, because that is true of other patients, and they do not seek special treatment. But the facts as explained herein and in the attached affidavit provided to OPTN suggest that [redacted] is low on the waiting list for arbitrary reasons having nothing to do with medical urgency, and if that is the case, she has a right to have her status adjusted, hopefully in time to prevent her death. In the meantime, if her doctors approve, she should be allowed to live outside the hospital, but close by, without losing time in Status 1A, so that she may maintain the highest possible quality of life while waiting for a new heart and kidneys.

Respectfully,

Stephen G. Harvey

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