



Health Resources & Services Administration

Health Systems Bureau/Division of Transplantation

5600 Fishers Lane
Rockville, MD 20857



December 18, 2025

John Magee, M.D.
President, Board of Directors
Organ Procurement and Transplantation Network

Dear Dr. Magee:

On October 7, 2025, the Health Resources and Services Administration (HRSA) was notified of an Organ Procurement and Transplantation Network (OPTN) member organization reporting that patients may have experienced harm through actions undertaken by the OPTN member. Specifically, the OPTN member (emphasis added):

“reported that four of their heart patients were discovered to have a minimum acceptable donor age of 98 and a maximum of 99 on an audit, effectively ensuring that they would not receive [organ] offers.”

After receiving this notice, HRSA performed a preliminary review of OPTN data to determine whether other instances currently exist of patients waitlisted for organ transplants with parameters that might be inconsistent with receiving offers of donated organs (“potentially ineffectively listed”). We are writing to inform the OPTN of our findings and provide remediation actions which the OPTN should undertake to address both OPTN-member and system-level impacts of patients ineffectively listed for organ transplantation.

Preliminary analyses conducted by HRSA identified over 100 waitlist registrations with defined listing parameters that may be inconsistent with receiving offers, as of September 1, 2025:

Listing parameters	Registrations (Active)	Centers
Donor age - Maximum < 20 yr (adult recipient) - Minimum > 40 yr - Range ≤ 5 yr (adult recipient)	47 (26)	17
Donor BMI - Maximum ≤ 20	8 (5)	7
Donor weight	40 (28)	8



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<ul style="list-style-type: none">- Minimum > 90 kg (pediatric recipient or adult recipient < 90 kg)- Maximum < 30 kg (adult recipient > 45 kg)- Range ≤ 10 kg (adult recipient)		
Donor height <ul style="list-style-type: none">- Minimum > 6 ft (pediatric recipient or adult recipient < 6 ft)- Maximum < 4 ft (adult recipient > 4 ft)- Range ≤ 10 cm	29 (27)	7
Total	104 (74)	32

HRSA subsequently requested additional analysis from the OPTN operations contractor, met with the contractor to review methodology, and requested additional documentation to evaluate the implications for patient safety, data accuracy, and system oversight. Communications between HRSA and the contractor on this matter are ongoing.

2024 investigation

The acceptable donor age range of 98 to 99 described in the October 7, 2025 report appeared in over 700 active registrations across 16 centers in 2024 through 2025. This practice was also recognized by an OPTN Membership & Professional Standards Committee (MPSC) investigation into potentially ineffective listing in 2024. Five out of nine members reviewed by the MPSC in that investigation referenced an OPTN communication in April 2020 that stated (emphasis added):

*“Your program may decide that some of your individual transplant candidates should not receive organ offers at this time **due to issues relating to COVID-19**. In those cases, you have the option of either temporarily inactivating them or temporarily setting your screening criteria to make them ineligible for organ offers... Candidates can be listed at the appropriate medical urgency status, and transplant programs can eliminate organ offers for these candidates by ensuring that they are screened from matches. The recommendation is to set the acceptable donor age acceptance criteria to 98 years (minimum) and 99 years (maximum).”*

As the analysis presented above shows, despite the COVID-19 context of the April 2020 communication, this potentially ineffective listing practice has continued well beyond the



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immediate emergency of the pandemic. The April 2020 communication remained on the OPTN website until at least September 8, 2024, after which it was removed. HRSA is unaware of any guidance provided by the OPTN to members on the permissibility (or lack thereof) of ineffective listing practices post-pandemic.

All of the centers' responses to the 2024 MPSC investigation asserted that patients were intentionally ineffectively listed so that they would accrue wait time while they were unable to receive a transplant. However, despite centers' best intentions, unintentional patient harm was observed in at least one instance (emphasis added):

"The remainder of patients had acute presentation of comorbid conditions requiring evaluation that should be time limited. However, there was a gap in the established auditing safety net process in place creating a longer time frame for two candidates due to a temporary staffing leave of absence"

Conclusion

The ongoing use of potentially ineffective waitlist parameters, rather than a formal OPTN policy and process allowing patients to accrue wait time without receiving offers, presents quantifiable and ongoing risk of potential harm to patients. This problem has persisted despite an extensive MPSC investigation, indicating that patient safety monitoring and compliance enforcement actions to date have been insufficiently effective.

Given the implications of potentially ineffective listing for the safety of patients awaiting transplant, system functionality, and public trust, HRSA requests the OPTN's attention and support regarding the following responsive OPTN actions:

1. Determine criteria for identifying potentially ineffectively listed patients, to inform compliance monitoring activities.
 - a) Confirm the preliminary criteria evaluated in the table above, and/or recommend amended or additional criteria, and
 - b) Determine whether additional parameters (e.g. for acceptable ischemic time, organ-specific characteristics, etc.) should be included in the criteria.



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2. Establish policy for wait time accrual for patients who are active on the transplant waitlist but are temporarily unable to accept organ offers.
 - a) Establish criteria for when (if ever) patients should accrue wait time without receiving offers, and
 - b) Identify required technical and/or policy changes to implement (e.g., the creation of one or more new waitlist statuses).
3. Support communications to OPTN members about this issue.
 - a) Attached to this letter, please see:
 - i. Draft of targeted communications to programs whose patients were flagged in the analysis, asking them to review and update listings as appropriate; and
 - ii. Draft of a community-wide communication to raise awareness of potential ineffective listing.
 - b) When these communications are finalized, HRSA will send to individual programs and/or to all OPTN members as an OPTN Communications message.
4. Identify potential technical updates to the OPTN IT system to reduce future risk of potential ineffective listing. Note that the system already supports both a) enforcing hard limits on listing criteria, and b) raising a warning to users who specify listing criteria beyond a specified limit. HRSA believes that implementing additional limits or warnings using the same functionality should be straightforward and require low effort.

HRSA is committed to continuing this work in close collaboration with the OPTN. We welcome your input on the items above and are available to meet at your convenience. Please let us know if you would like our team to present preliminary analyses to the Board of Directors leadership, or if there are additional analyses that would further support your action on this matter.

Thank you for your continued partnership in advancing the safety, integrity, and transparency of the national organ procurement and transplant system.

Sincerely,



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Brianna Doby, MPH
Chief, Organ Transplant Branch (Acting)
Division of Transplantation

Cc: Christine Jones
Principal Researcher, AIR

Attachments:

1. Draft letter to all transplant programs notifying of potential ineffective listing
2. Draft letter to transplant programs flagged by potential ineffective listing analysis