

VIA ELECTRONIC FILING — <http://www.regulations.gov>
July 15, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244-8016

Re: Proposed Medicare Payment Model: Increasing Organ Transplant Access Model (IOTA Model)

Dear Administrator Brooks-LaSure:

The United Network for Organ Sharing (UNOS) appreciates the opportunity to comment on the Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Proposed Rule (CMS-5535-P), published in the Federal Register on May 17, 2024. We support the IOTA stated goal to increase kidney transplants, maximize the use of deceased donor kidneys, and encourage living kidney donation.

UNOS is the mission-driven non-profit serving the nation's Organ Procurement and Transplantation Network (OPTN) under contract with and oversight by the federal government. We lead the network of transplant hospitals, organ procurement organizations (OPOs), histocompatibility laboratories, and volunteers who are dedicated to honoring the gifts of life entrusted to us and to making lifesaving transplants possible for patients in need. As the OPTN contractor, we leverage data and advances in science and technology to continuously strengthen the system, increase the number of organs recovered and the number of transplants performed, and ensure patients across the nation have equitable access to transplant. As UNOS, we develop new technologies and initiatives, conduct data-driven research and analysis, provide expert consulting services, advocate for patients, and lead the community together to save lives and honor donors.

This year, the OPTN announced another record year for organ transplants, with 46,632 transplants performed in 2023 thanks to the selfless and generous gifts from donors. In addition, 10,824 Black patients received transplants last year, more than any year prior. Last year marked the thirteenth consecutive year of record deceased donors. Additional milestones reached include:

- More than 16,000 individuals became deceased donors, making 39,679 deceased donor transplants possible. Nearly a 9% increase from 2022.
- There were 10,660 liver transplants performed in 2023- the most ever performed in a single year.
- There was a 30% increase from 2022 in donors aged 65 years and older, representing a greater acceptance by the transplant community and candidates to receive organs from more medically complex donors.

The increase in transplants in 2023 is the result of several initiatives that have helped increase

equity and enhance patient access to transplants, which were driven by the organ donation and transplant community and the Health Resources and Services Administration (HRSA), the federal government agency overseeing the OPTN. Some of these organ allocation policy updates and technological advancements include removing race from kidney function measurements¹, modifying waiting times for patients impacted by race-based kidney function measurements², and increasing equity in lung transplants through continuous distribution³. The community also made it easier for transplant programs to filter organ offers, which reduces the time between offer and acceptance to bring lifesaving organs to patients faster⁴.

The organ donation and transplant community's commitment to continuous system improvement drives the year-over-year increases in the number of lifesaving and lifechanging transplants performed. These improvements are necessary to ensure that each of the over 103,000 patients on the national waitlist can receive an organ transplant.

Our comments focus on patients, equity, and considerations for aligning the IOTA model with ongoing efforts to strengthen the national system.

UNOS Supports Transparency for Patients

- Model Reference: *Section III.C.8.a.(1). Publication of Patient Selection Criteria for Kidney Transplant Evaluations; Section III.C.8.a.(2). Transparency Into Kidney Transplant Organ Offers*

UNOS supports the transparency goals included for patients in the proposed IOTA model. Making appropriate information regarding patient selection criteria for kidney transplant evaluations and organ offer acceptance practices available to patients will empower patients to engage with their providers on decisions about their care. To ensure patient-centered transparency, it is important that CMS ensure such information is presented in a way that safeguards patients and their families. Any mechanisms for sharing such information should be developed carefully and with considerable input from the donation and transplant community.

The organ donation and transplant system is complicated to navigate, which is compounded by the physical and psychological stress an individual experiences during end stage organ failure and the associated care partner responsibilities. It is important that patients, living donors, caregivers, and families have access to direct services and resources that empower them to actively participate in their care and shared decision making.

¹ Understanding the proposal to require race-neutral eGFR calculations - OPTN. (n.d.). Optn.transplant.hrsa.gov. <https://optn.transplant.hrsa.gov/patients/by-organ/kidney/understanding-the-proposal-to-require-race-neutral-egfr-calculations/>

² Waiting time modifications for candidates affected by race-inclusive eGFR calculations - OPTN. (n.d.). Optn.transplant.hrsa.gov. <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/waiting-time-modifications-for-candidates-affected-by-race-inclusive-egfr-calculations/>

³ Lung transplant rates continue to increase six months post implementation of new lung policy. (December, 2023). UNOS. <https://unos.org/news/lung-transplant-rates-continue-to-increase-six-months-post-implementation-of-new-lung-policy/>

⁴ Offer Filters. UNOS. from <https://unos.org/technology/offer-filters/>

With this recognition, UNOS, as the OPTN contractor, engages with these critical stakeholders throughout all stages of organ allocation policy development and impactful system changes. Themes repeatedly heard from patients and their families include an interest in more accessible and understandable individualized information.

Patients have expressed interest in having insight into the volume and type of organ offers received and declined for them. They have also expressed frustration at not having easy access to information regarding whether they are in an active or inactive status on the waiting list. Transplant hospitals, which know their patients best, make the decision about whether to temporarily inactivate a transplant candidate, meaning that the candidate will not receive organ offers while in that status. Neither UNOS nor the OPTN are involved in any decision to inactivate or reactivate an individual candidate. UNOS does not communicate with patients about their placement or status on the waitlist. The transplant hospital is responsible for all phases of the patient's treatment and serves as the first and most authoritative source of information for patients and their caregivers⁵.

As part of UNOS' Action Agenda⁶ to strengthen the U.S. organ donation and transplant system, we recommend that HRSA require the OPTN to offer more expansive patient empowerment tools as part of the next OPTN contract. The current contract obligates the OPTN contractor to provide web-based patient education materials on the OPTN website, which contain information about how organ allocation works, what to expect during the transplant process, the wait list, resources by organ, and a patient hotline.

UNOS Supports Increasing Equity for Patients

- Model Reference: *Section III.C.5.c.(3). Health Equity Performance Adjustment*

UNOS supports increasing equity within the national donation and transplant system. We also recommend CMS identify barriers in access to the transplant waitlist. Such information will inform CMS' development of interventions that will improve equity throughout all stages of the transplant process.

Research shows there are inequities in transplant access and variation across transplant programs with respect to transplant access^{7,8}. The extent to which these inequities are due to patient characteristics or to program characteristics is unknown because the OPTN has historically not had the authorization to request the Secretary to authorize the OPTN's collection of pre-waitlist data since 2021.

Data on patients before they are added to the waitlist data could provide important insight into patient, population, and transplant program-level factors that may contribute to inequities in

⁵ [UNOS Statement for the Record Senate Finance Health Subcommittee Hearing \(20 July 2023\)](#)

⁶ Actions to strengthen the U.S. organ donation and transplant system. UNOS. <https://unos.org/transplant/improve-organ-donation-and-transplant-system/>

⁷ Gander, Jennifer C., Xingyu Zhang, Laura Plantinga, Sudeshna Paul, Mohua Basu, Stephen O. Pastan, Eric Gibney, et al. "Racial Disparities in Preemptive Referral for Kidney Transplantation in Georgia." *Clinical Transplantation* 32, no. 9 (2018). <https://doi.org/10.1111/ctr.13380>

⁸ Hutcheson SS, Phillips V, Patzer R, Smith A, Vega JD, Morris AA. Impact of insurance type on eligibility for advanced heart failure therapies and survival. *Clin Transplant*. 2018;32(8):e13328

transplant access. These data could also expand knowledge of end-stage organ failure and its burden, including the prevalence, incidence, mortality, and barriers that patients face to being included on the waitlist. Furthermore, the data could allow for additional research, quality improvement, and other initiatives for OPTN members to address these inequities in practice.

In February 2024, the Secretary of Health & Human Services issued a directive that would require transplant centers to share information with the OPTN contractor when a patient is referred to them for an organ transplant. It will also require OPOs to provide the OPTN contractor with information on all ventilated patients referred to them from hospitals in their donation service area. The proposed new data collection is anticipated to be published by the Office of Management and Budget (OMB) for public comment soon.

Continuous Distribution: A New Approach to Deceased Donor Organ Allocation

- Model Reference: *Section III.C.5. Performance Assessment*

The OPTN is implementing a new, more equitable system of allocating deceased donor organs called continuous distribution. **UNOS recommends CMS consider how the IOTA model's performance review period will be impacted by the implementation of a continuous distribution framework for kidneys which is currently under development.**

Under the current system, certain characteristics – such as pediatric status, distance from the donor hospital, or waiting time – can place the patient on one side of a hard boundary that prevents their further prioritization on the match run. A “match run” is a generated list that identifies potential recipients that are a biological match for that organ.

Continuous distribution will make it possible to balance multiple factors when determining the best fit for a transplant. Instead of placing patients into rigid categories, continuous distribution considers a variety of factors all at once to arrive at an overall score, ensuring that no single attribute determines a patient's ability to receive a transplant. The OPTN Kidney Committee is currently determining the best way to prioritize candidate traits to increase offer acceptance and decrease non-use. Continuous distribution will provide the sickest patients with even better access to lifesaving organs⁹.

Aside from the already implemented lung framework, the development of continuous distribution frameworks for the remaining organs, including kidneys, is underway. The frameworks for each organ will go through the full robust OPTN public process for policy changes ensuring the most inclusive opportunity for public feedback.

Technical Considerations: Organ Non-Use

- Model Reference: *Section III.B.3.g. Non-Acceptance and Discards in Kidney Transplantation*

⁹ Continuous Distribution OPTN. <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#:~:text=The%20Organ%20Procurement%20and%20Transplantation%20Network%20is%20developing>

Any organ not ultimately transplanted represents a profound loss, both for the selfless donor's family and the patient waiting. That is why UNOS, working in collaboration with members of the organ donation and transplantation community, is pursuing a variety of innovative strategies to improve organ acceptance rates at hospitals, get to more "yeses" on organ offers, and save more lives.

In honoring the gift of life and the wishes of donors and their families, UNOS references the organs that are recovered but not ultimately transplanted as "non-use" rather than the outdated term "discard." **UNOS recommends CMS use the term "non-use" instead of discard in the final rule.**

References to the rising non-use rate throughout the IOTA model proposal pertain to the unadjusted non-use rate. Unadjusted non-use rates reflect the number of kidneys recovered for transplant but not ultimately transplanted. They do not consider differences in donor factors between cohorts. Adjusted non-use rates require modeling that adjusts for the effect of donor characteristics, which evolve every year, to ensure year-to-year comparisons are made among similar groups of donors. For example, the Proposed Rule discussed how changes in the donor pool and certain clinical practices explained about 80 percent of the increase in non-utilization of deceased donor kidneys from 1987-2015¹⁰. The fully adjusted model shows that more than 90% of the increase can be explained by those factors, not 80%. **UNOS recommends CMS monitor the adjusted non-use rate to account for changes in the donor pool when making time-based comparisons of organ non-use.**

The primary reason for organ non-use reported to the OPTN is that the waitlist has been exhausted. An organ may have been offered to all matching patients on the waitlist, but because too much time elapses while hospitals consider accepting it, other potential transplant hospitals will decline it because there is not enough time to transport the organ while it remains viable.

Another factor contributing to non-use rates amongst kidneys and livers pertains to procurement practices. Sometimes kidneys and livers are recovered from a donor before their biopsy results are known because they are viable outside of the body for longer than other organs. This is done in the interest of patients in need to maximize the availability of lifesaving donor organs. Occasionally those kidneys and livers are determined to be not medically suitable for transplant after they have been recovered from the donor, which also contributes to the non-use rate for those organs.

It is important to remember that there is no standard definition for a "transplantable" kidney, and discussions of non-use rates should be framed within that context. Not every kidney that goes unused is likely to be transplantable. **UNOS recommends that CMS work with organ donation and transplant community to define "transplantable."**

Additional Recommendations to Maximize the Gift of Life

Recent allocation policy changes have allowed organs to travel further to reach the sickest patients in need of a transplant. Thus, our nation's donation and transplant system has become increasingly reliant on commercial airline cargo processes that were not designed to handle this lifesaving gift. Current protocols require organs to be transported as cargo, which occasionally causes logistical

¹⁰ Stewart et al. (2017). 575.

problems that may result in damaged or delayed organs. Modernizing these protocols will reduce the chance of donor organs being rendered unusable due to logistical issues associated with air travel. Though year-over-year records in the number of organ transplants show that most organs arrive safely at the transplant center, some experience cargo handling-related issues. Even in a perfect world, delays due to weather are uncontrollable, but delays due to cargo processes, failures to load on initial or connecting flights, and misdirected shipments are avoidable.

In the UNOS Action Agenda, we called for Congressional support in developing security protocols to enable couriers and OPOs to deliver donor organs directly to an aircraft, returning to in-cabin transport. In response, Congress included a provision to the Securing Growth and Robust Leadership in American Aviation Act (HR. 3935) that requires the U.S. Department of Transportation and the Federal Aviation Administration to convene a working group to identify best practices and hindrances for the transportation of donated organs, primarily kidneys and livers, in the passenger cabin instead of in the cargo hold of an airplane. The bill, including the organ transportation provision, passed Congress on May 15, 2024, and was signed into law on May 16, 2024. UNOS was joined by 21 organizations representing patients, organ donors and donor families, and transplant and medical experts involved in the organ donation and transplant community in securing this important step to improving organ transportation. **UNOS urges CMS to work with the FAA and DOT Working Group to swiftly issue recommendations to allow organs to fly in the cabin once again, as transportation challenges can lead to non-use due to the organ being unable to reach the patient in time.**

Conclusion

Effective coordination among transplant centers, OPOs, histocompatibility laboratories, the OPTN, and other entities involved in donation and transplant will be critical to achieving the goals of the proposed IOTA model. Such stakeholders are already working on several initiatives to improve organ offer acceptance, increase equity within the system, and maximize the gift of life- many of which will be implemented during the proposed model's performance review period. UNOS urges CMS to consider how those implementations will impact mandated participants and centers functioning as the IOTA model's control group. Overall, UNOS supports the goals of the IOTA model that aim to increase kidney transplants, maximize the use of deceased donor kidneys, improve transparency and equity within the system, and encourage living kidney donation. Thank you for considering UNOS' recommendations as CMS finalizes the proposal.

Sincerely,



Alicia Hennie, Vice President External Affairs
United Network for Organ Sharing