UNOS
UNITED NETWORK FOR ORGAN SHARING
Saving lives together

700 North 4th Street, Richmond, VA 23219
tel: 804-782-4800
fax: 804-782-4816
www.unos.org

Brian M. Shepard
Executive Director & CEO

February 1, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

RE: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities [CMS-3409-NC]

Dear Administrator Brooks-LaSure:

The United Network for Organ Sharing (UNOS) is pleased to submit a response to the *Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities* Request for Information as posted on December 3, 2021. United Network for Organ Sharing (UNOS) is the mission-driven non-profit serving as the nation's donation and transplant system, the Organ Procurement & Transplantation Network (OPTN), under contract with the U.S. Department of Health & Human Services. This all-volunteer network of patients, donors, donor families and professionals convene to establish and maintain the policies and bylaws that govern the U.S. organ donation and transplantation system. Working together, 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.

In addition to our work serving as the OPTN, UNOS provides research, analytics, and innovations solutions designed to support members' quality assurance and performance improvement initiatives, as well as to support system wide improvement. Attached, you will find the OPTN's response to this request for information, detailing ways in which it may support CMS' objectives from within the scope of the OPTN contract. In addition, we respectfully submit the below additional information two key areas in UNOS' value-added work in accordance with our mission: to unite and strengthen the donation and transplant community to save lives.

Organ Tracking

In the summer of 2021, UNOS launched an organ tracking program in answer to a desire for a centralized view into national organ transport. UNOS' program collects data about all organs tracked within the system and provides information on an organ's progress in transit. GPS-enabled tracking devices attach to organ packages and enable OPOs and transplant hospitals to view the shipment on a map in real time, identified by donor and intended recipient, and with integration into existing OPTN

systems (TransNet℠ and DonorNet®). At present, participating OPOs can scan a tracker to associate it with a particular donor organ and create a shipment that will provide email alerts for departure, delivery and other key events in transit. Flight information is included via FlightAware, ensuring users receive a notification if the intended flight has departed but the tracker still appears to be located at the airport. These notifications can be sent to the packaging OPO as well as the receiving transplant hospital. These notifications are a key factor in ensuring transparency for all parties, and providing timely monitoring of an organ in transit. A link to view the tracking map is made available to the receiving transplant hospital within the system used to review organ offers, so that they too can track the organ as it moves to their program and allows for better coordination of transplant center processes. The UNOS organ tracking system is designed to scale to other types of trackers and devices beyond the existing tracking provider, should that be necessary.

A future phase of the program, currently in development, will use a new form of tracking technology to enable "smarter" notifications for users and real time centralized tracking and data collection. Users will be able to view an estimated time to the next milestone in transit (e.g. arrival at the airport), rate of travel speed in real time, to detect "outliers" events in transit (e.g. a sudden stop in motion), significant changes in route, and double confirmation of delivery. These data and more will be visible via "command center" dashboard, where all organs in transit will be visible in real time. This new phase of the program is expected in 2023.

Currently, fifteen OPOs with service areas across twelve states are utilizing this solution, and to date over 1,700 organs have been tracked in their journey from donor to recipient. Over the course of the program, there has been one identified instance of an organ being rerouted so as not to miss its flight, and another instance of the organ being delivered to the wrong desk at a different part of a hospital. In both cases, tracking technology enabled the timely resolution and ultimate transplantation of these organs. In addition to this system, other private companies have released their own tracking solutions to OPOs, so a diverse array of options are currently available to OPOs. Tracking technology is increasing in frequency of use across the entire organ procurement community.

With improved data collection and anticipated program expansion will come improved understanding of national trends and effective practices in tracking donor organs. UNOS would be pleased to share its findings now and in the future as our program continues to develop.

Performance improvement data tools for OPOs and transplant programs

UNOS provides a suite of tools to support OPO and transplant program improvement initiatives, many of which are aligned with CMS' inquiries in the RFI. These are supported by transplant hospital payments to UNOS that are currently reimbursable by CMS. CMS should continue to support critical quality improvement efforts like these, whether they are provided by UNOS or other organizations. These research and data analytics are focused on supporting members' ability to better understand and visualize their own practices, improve their performance, and increase the number of transplants. Benchmark reports provide insights into OPO donor and candidate populations and allow OPOs to compare their activity and performance with others with similar characteristics to regional and national trends. For transplant hospitals, reports provide insights into twenty-four high-level indicators about a hospital and its trends over time, relating to waitlist additions, waitlist management, characteristics of organ offers accepted or declined for specific types of donors, recipient post-transplant length of stay, and others. Transplant programs can also receive reports benchmarking themselves against other

selected hospitals to visualize differences in wait list additions by candidate characteristics, wait list demographics and outcomes. Reports also provide programs information about the organs they turned down so they can see whether the organ was transplanted and outcomes related to that transplant. Ultimately, these reports and analytics help centers drive improvements directed at improving the transplant system for the benefit of patients waiting for an organ.

Funded through grants as well as direct payments from members, at present, these tools are in use by hundreds of members across the country, who have integrated them within their organization's quality improvement initiatives. UNOS stands ready to provide CMS with insights into how these tools are used by our members and how members use data and analytics such as these to continue to improve.

Equity in Access to Transplant

UNOS continuously works to ensure access to transplant for waitlisted patients remains highly equitable. Access to transplant should not depend on who you are, where you live, or what you look like. UNOS publishes an Equity in Access to Transplant[1] dashboard so the public may view access to transplant for waitlisted patients based on several key social and clinical determinants of health. Further, UNOS agrees that access to transplant should never be denied to patients due solely to a disability, and support efforts to ensure this does not occur.

UNOS thanks you for your leadership in addressing these key challenges facing the U.S donation and transplant system with a collaborative, holistic, and patient-centric approach. We are eager to continue to support your efforts to improve the system.

Sincerely,

Matthew Cooper, MD
President, UNOS Board of Directors

Attachment:
OPTN Response to CMS-3409-NC

[1] Equity in Access to Transplant Dashboard. https://insights.unos.org/equity-in-access/

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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tel: 804-782-4800
fax: 804-782-4816
optn.transplant.hrsa.gov

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RE: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities [CMS-3409-NC]

Dear Ms. Brooks-LaSure:

The Organ Procurement & Transplantation Network (OPTN) is pleased to submit the following comment on the Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities Request for Information as posted on December 3, 2021.

The OPTN is the national network of organ donation and transplant professionals, patients, donors and donor families that convenes to develop, review, and improve U.S. organ allocation policy and operations, within the framework established by the National Organ Transplant Act (NOTA) of 1984 and its implementing regulations. As required by NOTA, membership on all of the OPTN's nineteen committees and its national board of directors include patient, donor, and donor family representatives as voting members, as well as representatives from the U.S. Health and Human Services Department in their oversight capacity. This system, as designed by Congress, ensures patient and donor affairs representatives, who make up one quarter of the board of directors, take part in system governance at all levels. As a direct result of this collaborative, patient-centric and data-driven approach to governance, access to transplant for waitlisted patients is highly equitable and our system continues to grow year after year. As a testament to the dedication and resilience of our members throughout a global pandemic, the OPTN recorded its 10th consecutive year of growth in transplant volumes in 2020. Then, in 2021, the U.S. surpassed that record once more, achieving more than 40,000 transplants in a single year for the first time in history, which included all-time record numbers of liver, kidney and heart transplants, and an eleventh consecutive year of growth in deceased donation.

The OPTN will maintain its commitment to both high performance and continuous improvement, and would be pleased to share an overview of our current and future work with CMS if it is of interest. In the interim, we offer the following comments in response to select inquiries within the RFI.

Equity in Donation and Transplantation

The OPTN fully supports CMS' focus on addressing health equity gaps in donation and transplantation. A key part of the OPTN strategic plan is dedicated to providing equity in access to transplants. As part of these efforts, the OPTN continually analyzes national transplantation data to identify inequities among transplant patient populations. This includes a publicly available Equity Dashboard, launched in 2020.[1] The equity dashboard monitors system-level and factor-level trends related to access to deceased donor transplants among waitlisted candidates in the United States. It offers insights into the impact of previous policy changes on disparities in transplant access and may help identify the need for future policy refinements. The data show that overall equity in allocation has improved over time. For example, disparities in access to kidney transplants declined by about 40 percent after implementation of the Kidney Allocation System. However, this is an area of constant focus as the OPTN develops, implements and monitors transplant policy changes. One of the OPTN findings is that many factors (e.g. public vs. private insurance type), highest level of education, and Community Risk Score of the candidate's zip code of residence, have practically no association with access to transplant *for candidates that are listed for transplant*. However, multiple studies have found that access to the transplant waitlist is significantly impacted by these factors and other factors including race and ethnicity. Addressing patient access to the transplant waitlist is beyond the purview of the OPTN, but this should be an area of focus by CMS to ensure providers of care to end-stage organ failure patients are appropriately referring for transplant and that transplant programs are appropriately evaluating and listing patients that could benefit from transplant. Accountability for these components would align with the OPTN's efforts and would greatly aid in the equitable delivery of transplantation to all patients in need.

Transplant Program COPs

The OPTN supports CMS' clear, patient-focused approach in seeking feedback on transplant program conditions of participation (COPs). Many of the objectives of this proposal align closely with those stated in the RFI, and a brief review of the OPTN's approach may be informative.

In December 2021, the OPTN Board of Directors approved new metrics for transplant program performance, incorporating, for the first time, pre-transplant metrics. This new set of metrics replaces the previous standalone post-transplant one-year graft and patient survival metric. This multi-year project was led by the OPTN Membership and Community Professional Standards Committee (MPSC), the performance improvement and monitoring body made up of over forty patient and professional representatives. The MPSC sought to develop a holistic set of metrics for transplant program performance that identified real-time patient safety issues and provided support and collaboration to transplant programs for identified opportunities for improvement.

At the inception of the project, the MPSC adopted a framework for evaluating proposed metrics. Any metrics considered had to meet the following criteria, so long as they were measures of care clearly within the authority of the OPTN:

- Measures aspects of care that the transplant program can impact
- Has a clear desired outcome

[1] OPTN Equity in Access to Transplant Dashboard. https://optn.transplant.hrsa.gov/data/visual-dashboards/equity-in-access/

- Does not require collection of new data or development of a new metric
- Measures a discrete aspect of transplant care provided by transplant programs
- Is risk-adjusted
- Incentivizes behaviors that will increase transplantation

The MPSC endorsed the use of risk adjustment for any metrics used in the evaluation of transplant program performance. The use of risk adjustment supports increased access to transplant by removing the effect of factors beyond the control of the program from the performance evaluation and focusing on differences in outcomes that the program can impact.

The MPSC selected four risk-adjusted metrics that the OPTN Board of Directors ultimately approved:

- Pre-transplant (waitlist management)
    - *Offer acceptance*: Measures a program's rate of accepting organ offers relative to the expected offer acceptance for donor and candidate characteristics.
    - *Pre-transplant mortality rate ratio*: Measures a program's rate of candidate mortality, from a candidate's registration date and before any subsequent transplant, relative to the expected mortality for candidate characteristics at the time of registration.
- Post-transplant outcomes
    - *90-day graft survival hazard ratio:* Measures graft survival from date of transplant to 90-days post-transplant, relative to the expected 90- day post-transplant graft survival for donor and recipient characteristics.
    - *One-year graft survival conditional on 90-day graft survival hazard ratio:* Measures graft survival from day 90 post-transplant to day 365 post-transplant, conditional on the graft surviving for the first 90-days post-transplant, relative to the expected graft survival for donor and recipient characteristics. The evaluation cohort excludes all transplants where the graft failed during the first 90-days post-transplant.

The addition of the pre-transplant metrics is rooted in feedback from the donation and transplant community as well as from the general public indicating a desire to measure these behaviors. These pre-transplant metrics received broad support in public comment, particularly among people that self-identified as having a personal connection to transplant. Notably, the offer acceptance metric is intended to encourage programs to only accept offers they may seriously consider for their patient, thereby enabling the OPOs to place the organ more quickly. More detail on the metrics selected, as well as those considered and not selected, are included in the *Enhance Transplant Program Performance Monitoring System Briefing Paper to the OPTN Board of Directors* (Dec. 2021).[2]

We encourage CMS to consider metrics such as these and others that take hospital behaviors impacting access to transplant into account and that align with the CMS performance metrics for OPOs. Accountability by all components of donation and transplantation is necessary to support and accelerate

[2] OPTN Membership and Professional Standards Committee. *Enhance Transplant Program Performance Monitoring System: Briefing Paper to the OPTN Board of Directors.* https://optn.transplant.hrsa.gov/media/yctffgt2/20211206-bp-mpsc-enhnc-tx-prgrm-prfrmnc-mntrng-syst.pdf. Accessed 9 January 2022.

significant systemwide improvement. Further, our members have long provided feedback that CMS regulatory and OPTN performance improvement metrics should not result in conflicting incentives.

Organ Procurement Organizations Conditions for Coverage

The OPTN appreciates CMS providing the public with another opportunity to provide perspective on recently implemented OPO Conditions for Coverage (CfCs). The OPTN would refer CMS to our comments previously submitted on September 17, 2019, February 20, 2020, and March 1, 2021 for our complete technical feedback on the OPO CfCs.

The OPTN wishes, however, to reiterate its request that CMS provide detailed guidance for, at minimum, how competition for open Tier 2 DSAs and Tier 3 decertified DSAs will be coordinated by CMS to ensure that organ recovery in the donation service areas (DSA) of any decertified OPO will continue without disruption or patient harm. The OPTN notes in the recently released 2019 CMS data[3], more than half of the OPO DSAs (31 out of 58) would be simultaneously open to competition between Tier 2 and Tier 3 assignments. The OPTN urges CMS to consider clarifying the competitive process for Tier 2 OPOs and assess under what circumstances the benefits of selecting a new OPO would clearly outweigh the cost of a transition and risk of disruption to the community and hospital partners in a DSA, particularly in light of the 2019 data showing that 60% of the OPOs in Tier 2 are performing above the Tier 1 threshold level for one of the two metric rates. As written, the rule makes several assumptions about the operations of the system in the midst of OPO decertification and the award of DSAs through competition but does not offer guidance about how donation may be facilitated in the event OPO(s) cannot maintain staffing levels after losing a competitive process or decertification but before a new OPO is transitioned to serve the DSA. There is also no information as to how CMS will proceed if there are no competitors for a given decertified service area. As written, the rule endangers these critical, lifesaving services without this added guidance.

Donor Referral Process

The OPTN notes the publicly reported results of automated donor referral pilot projects from OPOs across the country with interest. [4,5,6] In addition to the potential to provide more transplantable donor organs, automated donor referral serves as an efficiency to the donation process and a promising potential data source to inform future OPO CfCs and beyond. As automated donor referral is an emerging technology solution, OPOs and hospitals around the country have developed different approaches, depending in part on their existing information systems, technology capability, and

[3] https://qcor.cms.gov/

[4] "Cleveland Clinic, Lifebanc and Transplant Connect Develop Automated Donor Referral Process." 30 April 2021. https://newsroom.clevelandclinic.org/2021/04/30/cleveland-clinic-lifebanc-and-transplant-connect-develop-automated-donor-referral-process/. Accessed 20 Jan. 2021.

[5] Niles, Patricia; Hewlett, Jonathan; Piano, John; Liu, Wade. "Automated Electronic Referrals are Changing Donation." Transplantation: September 2020 - Volume 104 - Issue S3 - p S259
doi: 10.1097/01.tp.0000699788.52410.58

[6] Glazier, A., Moss, M., & Martin, L. (2021). "Electronic Health Records Can Improve the Organ Donation Process." Retrieved 20 January 2022, from https://hbr.org/2021/12/electronic-health-records-can-improve-the-organ-donation-process

available resources. To date, the OPTN is aware of six OPOs with service areas in sixteen states that have entered into partnerships with donor hospitals to automate at least a portion of their referrals. CMS should consider automated referrals through incentives for OPOs and donor hospitals to participate in order to support wide-scale adoption of this emerging effective practice.

Increasing Utilization and Reducing Discards

The OPTN has recognizes that increased efficiency in the process of donation and transplant has significant potential to improve outcomes both quantitative and qualitative. In 2019, the OPTN approved three strategic policy priorities, one of which is focused on increasing efficiency in the matching process. This has resulted in a number of OPTN projects to improve the matching system. These priorities brought implementation of "tools" like organ offer filters[7,8] designed to speed the matching process, particularly for harder to place organs from medically complex or older donors, and the clarification of "rules," like how provisional acceptance of organs should be conducted during the allocation process. All of these components affect the potential for a recovered and offered organ to be discarded, and relatedly, whether an OPO's donation and procurement efforts nonetheless ultimately result in a zero organ donor. The OPTN suggests that CMS consider the balance between incentivizing aggressive procurement of organs by OPOs and accountability for utilization of these organs by transplant programs in light of acceptable risk for transplant candidates. Alignment of these incentives is necessary to optimize the overall performance of the system. For these reasons, the OPTN supports consideration of zero organ donors in assessment of OPO process performance as a companion to the outcome metrics. Aggressive pursuit of procurement as measured by a rate of zero-organ donors could be used by CMS for example in the assessment of OPOs competing for DSAs.

The OPTN also supports CMS considering strategies to reduce the discard rate although cautions against any disincentive for OPOs to aggressively pursue procurement or any negative consequence for transplant programs turning down an organ offer based on appropriate medical judgement. As CMS is aware, organs from older donors, whose organs are often rejected by transplant hospitals in the U.S., are transplanted at higher rates in European countries with successful outcomes.[9] Transplant hospital COPs should utilize statistical risk assessment to align payments to hospitals with the complexity of the organs they choose to transplant. Some donor organs and some recipients can be expected to require longer hospital stays or additional care, and payment formulas should remove disincentives for taking on additional predictable expense. Though receiving an older donor's organ can create more expensive post-transplant care than getting a younger donor's organ, it is, in many cases, less costly than dealing with a chronic condition.

[7] "Better Screening Accelerates Organ Offers." 18 Jun. 2020. Accessed 20 Jan. 2022.

[8] "National rollout of Offer Filters for kidney now available." 27 Jan. 2022.

[9] Aubert, Olivier, et al. "Disparities in acceptance of deceased donor kidneys between the United States and France and estimated effects of increased US acceptance." *JAMA internal medicine* 179.10 (2019): 1365-1374.

CMS should focus on ensuring system wide accountability that all transplantable organs are in fact utilized. The OPTN continues to work on ways in which it can support this work and welcomes the opportunity to collaborate.

Donation after Circulatory Death (DCD)

The OPTN has long recognized that the most significant growth opportunity to expand the pool of potential organ donors is through donation after circulatory death (DCD).[10] Recently the OPTN has taken several steps to support and facilitate increases in DCD including a collaborative project (now in Phase 2).[11] OPO professionals recovered 4,187 DCD donors in 2021, an increase of 29.9 percent over 2020, itself a record-setting year for DCD donors that exceeded 2019's numbers by more than 18 percent. The OPTN supports CMS' efforts to align regulatory incentives with these practices by considering risk adjustment to the OPO transplant rate based on a DCD donor type. This would be consistent with the OPTN's approach, which is based on data that highlight when transplant program acceptance and transplant of DCD organs is significantly lower than that of braindead (BD) donor organs. For example, the discard rate of DCD organs recovered for transplant in 2020 was nearly twice that of BD organs in 2020, at 24.7% (2,004 of 8,112) for DCD organs compared to 12.9% (4,509 of 34,847) for BD organs. Harmonizing the CMS metrics with the OPTN metrics concerning DCD would provide an aligned environment for OPO performance consistent with the data.

Vascular Composite Allografts

The OPTN encourages CMS to harmonize its definition of "organ" to include vascular composite allografts (VCA) consistent with the OPTN Final rule and HRSA. This is an important step to ensure all components of the donation and transplant system are aligned to support VCA transplantation as a fledgling innovation in transplantation that continues holds much promise to patients in need. Counting procurement of VCAs as an "organ" under the OPO performance measures will incentivize OPOs to pursue VCA donation, which involves considerable time and resources, including a separate authorization process as required by OPTN policy as well as complex screening and matching processes not required for other organ types. The numbers of VCA transplants from deceased donors per year remain very low (less than 10 a year over the past 5 years), so this is unlikely to create disproportionate advantage to OPOs that pursue VCAs, or disadvantage those OPOs that are not proximate to a VCA transplant program (this is no different than OPOs that are near single kidney programs versus OPOs near a number of programs that are approved for multiple organs). In regard to survey and certification of VCA programs, the OPTN suggests that CMS consider adopting the OPTN framework in place for VCA programs that takes into account low volume and some of the unique aspects of VCAs when measuring outcomes (such as the temporary nature of the graft for uterus transplant).

The OPTN thanks you once again for your attention to these critical components of the donation and transplant system. If it would benefit CMS, the OPTN stands ready to provide any additional information desired and discuss options for future coordination to ensure the impact of all future improvement initiatives continues to move the system forward. The OPTN convenes the diverse donation and transplant community to further strengthen equitable access and continuously improve the national

[10] Deceased Donor Potential Study https://pubmed.ncbi.nlm.nih.gov/26813036

[11] https://optn.transplant.hrsa.gov/news/second-phase-of-national-dcd-procurement-collaborative-project-ready-to-launch/

system. Please do not hesitate to contact us if we can be a resource for you as you consider these improvements for the benefit of all patients.

Sincerely,

Matthew Cooper, MD
President, OPTN Board of Directors