Mid·America TRANSPLANT
inspired by life

Written Testimony:

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Chairman Wyden, Ranking Member Crapo, and Members of the Committee, my name is Diane Brockmeier, and I am the President and CEO of Mid-America Transplant, the organ procurement organization (OPO) serving Eastern Missouri, southern Illinois, and northeastern Arkansas. Thank you for the opportunity to submit a written statement.

I joined Mid-America Transplant in 1986 as a registered nurse talking to families about organ donation on the worst days of their lives. These donor families, and the organ transplant recipients whose lives they save, remain at the forefront of my thoughts every day.

At our organization, we follow the ethos of every donor, every time. Our clinical team is committed to giving donors and their families the care they deserve and stewarding their gifts to patients desperately in need. Mid-America Transplant depends on the broader national transplant system, administered by UNOS, to accomplish this work.

From 2018 to 2020, I served as a Board Member for the Organ Procurement Transplantation Network (OPTN). As an OPTN Board Member, I concurrently served on the UNOS board. My board experience revealed that UNOS's actions are often not aligned with its fundamental vision – *a lifesaving transplant for everyone in need.*

But change is possible; these problems can be corrected. It is critical that we urgently address patient safety, update the archaic IT system, remove conflicts to ensure good governance, and return the focus of the OPTN to providing high quality care and exceptional system performance to <u>all</u> patients, both donor patients and transplant waitlist patients.

We need to urgently address patient safety.

Each organ lost due to system failure or provider failure has a consequence to the thousands of patients waiting for a transplant. Furthermore, a discarded organ fails to honor the heroic gift from a selfless donor and compounds the family's sense of loss.

Errors and adverse events do happen in organ procurement and transplant, just like in any other field of healthcare. However, unlike the rest of healthcare, we have few, if any, mechanisms to protect patient safety and prevent adverse events. Specifically:

- There are <u>no</u> clinical training, licensure, or certification standards required for OPO staff, even those operating in matters that directly affect patient care.

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- There is no public adverse event reporting required of or by UNOS when patients are harmed, organs are lost, or the quality of patient care is unsafe.

UNOS lacks urgency and accountability around identifying and remediating the preventable loss of organs and addressing poor quality patient care. The process by which errors are reported and reviewed is woefully inadequate. Errors are not disclosed to the broader transplant community preventing practice improvement. In this environment, who is looking out for patients? Who is being held accountable for poor quality care? No OPO has ever been decertified, regardless of its performance or safety record.

While decertification falls to the Centers for Medicare and Medicaid Services (CMS), the entire system relies on member compliance from the OPTN. UNOS has failed to align its efforts to ensure patient safety at the system level. It is a decision with tragic and deadly consequences.

We must update an archaic technology system at UNOS.

As OPOs, we are required to work with UNOS's technology - DonorNet - every day. DonorNet is outdated, difficult to use, and often slow to function when every minute counts. Manual entry subjects it to error, and OPO and transplant center staff are not empowered with the right information when time is crucial.

I served in leadership roles on the OPO Committee from 2017-2022. Committee members and industry leaders voiced repeated requests to address the need for DonorNet improvements. Year after year, these requests were consistently met with the response that UNOS IT did not have the bandwidth to address this work.

The limitations of UNOS technology are delaying and denying transplants to patients dying on the waitlist. Poor technology impacts the disturbingly high kidney discard rate in the United States; where one in four never makes it to a patient for transplantation.[1]

Consider:

- UNOS policy requires use of their Organ Center for national kidney placement. The Organ Center is highly inefficient, although UNOS does not report data about the Center's effectiveness. At our OPO, we have consistently observed that the Organ Center is rarely successful at placing kidneys and often discards kidneys after failed placement attempts leaving many OPOs aware they are better off not using it at all. [2,3]

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[1] Available at: https://optn.transplant.hrsa.gov/about/committees/kidney-transplantation-committee/; OPTN Kidney Transplantation Committee Meeting Summary, June 24, 2022

[2] Noreen, SM, Klassen, D, Brown, R, et al. Kidney accelerated placement project: outcomes and lessons learned. *Am J Transplant*. 2022; 22: 210– 221. doi:10.1111/ajt.16859

[3] Mohan, S. and Schold, J.D. (2022), Accelerating deceased donor kidney utilization requires more than accelerating placement. *Am J Transplant*, 22: 7-8. https://doi.org/10.1111/ajt.16866

- Critical time is lost due to the inefficiency of DonorNet - wasting time on offers that will not be accepted and delaying or denying a transplant. Of course, an available organ should be offered to patients on the list in sequence. However, far too much of matching - particularly on harder to place organs from older donors - is left to individual OPOs and transplant programs to find each other despite, rather than facilitated by, UNOS technology.[4]
- UNOS has millions of data points that could, and should, facilitate faster, more efficient organ placement, providing the centers and OPOs with real-time information to increase transplants. Leveraging this rich data source is a national imperative to improving patient outcomes.
- Mid-America Transplant intentionally identifies surgeons who accept kidneys that have been declined many times. These are lifesaving options for those patients. In May 2022, one of these patients was number **18,193** on the list. Relying on DonorNet alone, that kidney never would have been placed, and a chance to save a life would have been wasted.
- It is worth noting that when an OPO goes out of sequence to place an organ that would otherwise be thrown away, UNOS requires an explanation. However, when organs are never recovered or placed at all, UNOS remains silent. **Organ Procurement Organizations are never penalized for discarding an organ. Conversely, they are penalized for placing organs out of sequence.**

We must remove conflicts to ensure good governance.

Serving on the board of the OPTN automatically assigns membership on the UNOS board. How can you fairly represent the country's interests and a contractor's interests at the same time?

- Board members are kept in the dark about critical matters, and are marginalized, particularly if they have views that differ from UNOS leadership. As a board member, I do not recall the subject of the Senate Finance investigation being raised by UNOS leadership.
- Preparatory small group board member calls were conducted prior to the board meetings to explore voting intentions on upcoming issues. If the board member was not in agreement with the opinion of UNOS and board leadership, follow-up calls were initiated. Fellow board members reported feeling pressured to vote in accordance with UNOS & Board leadership.
- Conflicts in the current structure, combined with the actions of UNOS leadership, have led to a deeply concerning perception that speaking out can lead to exclusion from critical decision making, or worse - retaliation.
- After I left the board, I was disturbed to see UNOS leadership lobbying against federal regulations for OPOs which would drive transparency, accountability, and improve performance.

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[4] Doby, BL, Ross-Driscoll, K, Yu, S, Godwin, M, Lee, KJ, Lynch, RJ. Examining utilization of kidneys as a function of procurement performance. *Am J Transplant*. 2022; 22: 1614– 1623. doi:10.1111/ajt.16985

I implore the Committee – along with CMS and HRSA – to ensure those who speak out in support of system reform are not penalized. Patients deserve a transparent, accountable system that works on their behalf.

We must refocus on patients.

To protect patients, I urge Congress and the Administration to:

- Separate the OPTN functions into different contracts so patients can be served by best-in-class vendors,
- Immediately separate the boards of the OPTN and the OPTN contractors,
- Require public disclosure of all potential conflicts for the contractor and board members,
- Ensure that patients are safeguarded through open data from both the OPTN and OPOs.

Inaction by UNOS causes real harm to patients. This harm is measured in how many patients die waiting for a transplant. Your immediate action on this matter will save lives. Thank you.

Diane Brockmeier, RN, BSN, MHA

President & CEO

Mid-America Transplant

Appendices for written testimony below:

Appendix A: Morning Consult opinion piece in support of the OPO rule, 13 October 2020
Appendix B: RFI response with other pro-reform CEOs to CMS re. OPOs, 1 February 2022
Appendix C: RFI response with other pro-reform CEOs to HRSA re. OPTN, May 2022

Appendix A: Morning Consult opinion piece in support of the OPO rule, 13 October 2020

Organ Donation Can Save More Lives Through Reform

By Ginny McBride & Diane Brockmeier
Last December, the Department of Health and Human Services proposed new regulations to reform the U.S. organ donation system. It would accomplish this by creating objective criteria by which to evaluate the government contractors, called organ procurement organizations, who are charged with recovering transplantable, lifesaving organs from deceased donors. These bipartisan reforms could save countless lives. It's important the Trump administration finalize them now.

As CEOs of two OPOs, this is an issue we have followed closely, and we applaud these measures as long overdue.

Our constituents are the more than 100,000 Americans currently waiting for a lifesaving transplant, with 33 dying every day for lack of an organ. Given that COVID-19 can cause organ failure, reform is even more urgent today than it was a year ago. HHS estimates that its proposal will mean an estimated 5,000 to 10,000 more life-saving organ transplants every year.

Central to the problem is that, historically, the government has not used objective criteria to evaluate OPO performance. OPOs are allowed to self-interpret and self-report our own performance data. As a result, no OPO has ever lost its government contract, even as wildly variable performance across OPOs has led to unnecessary deaths for patients in need of transplants.

Compounding the problem is that all OPOs operate as geographic monopolies, which means we have neither regulatory nor competitive pressure to provide high service to patients. And while there may be legitimate reasons for at least some monopolism (e.g., potential donor families should not have two OPOs competing for their attention), the trade-off must be increased transparency and oversight.

HHS's proposal, rightly, promises to implement much-needed accountability measures, with real consequence for our counterparts that fail to meet them — including replacing OPOs who simply do not get the job done. In response, many OPOs have responded with aggressive lobbying campaigns to block these proposed reforms by confusing the issue or proposing unworkable alternatives.

But the more future-minded OPOs, like ours, are embracing change. HHS's new proposal signals something potentially game-changing for patients: allowing the highest performing OPOs to replace those who have proven themselves incapable of serving their communities. To the extent that an OPO is not able to rise to the challenge of a high standard, the focus of our attention and energy must be on better serving patients on the national waitlist, not on protecting specific OPOs.

This, of course, is threatening for OPOs who have grown a bit too comfortable. Some of our colleagues have tried to paint any changes as destabilizing and unprecedented, positing that it will lead to situations in which areas of the country do not have OPOs at all. But this is simply not grounded in HHS's proposal, which explicitly states that "our goal is to ensure continuous coverage of an OPO service area in the event an OPO is decertified."

There were originally 128 OPOs, and after decades of consolidations there are now 58 OPOs; never has this process been disruptive. Forcing OPOs to continually earn their contracts is a patient-centric accountability mechanism, ensuring that OPOs operate with the urgency befitting the life-and-death consequences of this work.

Additionally, many OPOs have argued that the standard for OPO performance HHS has proposed is "arbitrary." But the more important question is whether the improvements HHS seeks to drive are realistically achievable, and we believe unequivocally that they are; HHS data show the difference between the best and worst OPOs is almost 500 percent. Put another way, some OPOs recover 4 or 5 times as many organs as their peers.

So if we accept that higher performance is possible — and we understand that it would also be lifesaving — realizing these gains is not simply a policy question, but a social imperative. As patient advocates have argued, and with which we whole-heartedly agree, "In a chronically underperforming system, patients should fear a perpetuation of the status quo, not a disruption of it."

It's time that HHS unleashed the best weapon it has against the life-threatening organ shortage: OPOs who have already proven themselves motivated and capable. HHS should finalize its proposal as urgently as possible, trusting the best among us to rise to that challenge. Any weakening of HHS's proposed standard will — definitionally — result in lives lost, which is directly antithetical to our mission. Patients deserve nothing less.

Ginny McBride is the CEO of OurLegacy, a Florida-based OPO. Diane Brockmeier is the CEO of Mid-America Transplant, which serves parts of Missouri, Illinois and Arkansas; she also is the past president of the Association of Organ Procurement Organizations.

Appendix B: RFI response with other pro-reform CEOs to CMS re. OPOs, 1 February 2022

Date: 1 February 2022

To: Administrator Chiquita Brooks-LaSure, Centers for Medicare and Medicaid Services

From: Diane Brockmeier, Mid America Transplant
Virginia McBride, OurLegacy
Patti Niles, Southwest Transplant Alliance
Kelly Ranum, Louisiana Organ Procurement Agency
Matt Wadsworth, Life Connection of Ohio
Janice Whaley, Donor Network West
Jennifer Erickson, Federation of American Scientists

The **FAS Organ Procurement Organization Innovation Cohort** is committed to using data science and transparency to accelerate improved patient outcomes and to inform ongoing, data-driven policy development.

The seven organ procurement organizations who are leading in opening up their data include: Donor Network West, Life Connection of Ohio, LiveOn New York, Louisiana Organ Procurement Agency, Mid-America Transplant, OurLegacy, Southwest Transplant Alliance.

During a transformative period in the organ procurement industry, the Innovation Cohort will help shape the future of organ recovery in America, improving OPO practice and informing OPO policy. Most importantly, the Innovation Cohort will strive toward new heights of operational excellence in order to increase organ transplants in an effort to best serve the public, organ donors, donor families and patients waiting for transplants.

The FAS Organ Procurement Organization Innovation Cohort has publicly committed to:

- ***Transparency**: public sharing of data/analysis in order to set a standard to which all OPOs can be held;*
- ***Accountability:** support for the OPO final rule, and any efforts to move up implementation date so all parts of the country can be served by high-performing OPOs as soon as possible in 2024; and*
- ***Equity**: commitment to analyzing/publishing data to ensure all parts of community served.*

Reducing disparities - p. 68599

1. Are there revisions that can be made to OPO CfCs to reduce disparities in organ transplantation?

Given bipartisan Congressional leaders have called for accelerations of reforms of the donation and transplant ecosystem as an "urgent health equity issue" exacerbated by the COVID

pandemic, we call on CMS to make the public disclosure of all OPO process data a requirement of the OPO CfCs immediately.

To reduce disparities in organ transplantation, it is critical to enforce the final rule as quickly as possible, and to update CfCs:

- The metrics contained in the Final Rule, are already best suited to measure OPO performance and hold OPOs accountable to the highest performance and to the idea of pursuing every donor and organ every time to save as many lives as possible.
- It is critical that the Final Rule be:
    - Enforced as quickly as possible, moving up the implementation date so that all parts of the country can be served by high-performing OPOs;
    - Not be revised in a way that dilutes or distorts its impact.
        - CMS should maintain its earlier correct judgment disallowing both race-based adjustments (which could harm patient outcomes) and zero donors (which could allow for gaming of metrics).
- To have evidence of effective and equitable service, CMS should make all OPO process data publicly available.
    - It is undeniable that a number of the questions raised in the RFI could be answered or resolved if all OPO process data were required to be made public, giving regulators the opportunity to understand and identify where performance gaps and inequitable service and outcomes exist.
    - This data-driven transparency would ensure all OPOs are accountable to the highest levels of operational excellence, and would offer opportunities to design interventions to address particular gaps in service.

OPO metrics/performance - p. 68601, 68602, 68603

1. Independent of CMS' specific outcome measures, what other metrics or attributes reflect a model or highest performing OPO?; 2. What are quantitative or qualitative indicators of excellent performance and how can CMS incorporate these with outcome measures when assessing OPOs for recertification purposes?; 3. Should CMS consider additional metrics, such as those that measure equity in organ donation or an OPO's success in reducing disparities in donation and transplantation, and how should this be measured?; 4. Are there ways to scale, or rate, performance of other (new) factors that CMS may consider in assessing OPO performance? 3. Can the OPO CfCs address the issue of organs that are lost during transport to a transplant program?

In answer to the above questions: CMS should look for evidence of effective and equitable service as seen in open and transparent OPO process data.

The OPO Innovation Cohort is committed to transparency, accountability, and equity, and is already taking steps to make these commitments a reality through its collaboration with the Massachusetts Institute of Technology to make de-identified process data publicly available.

This level of transparency should be required of all OPOs. This addresses the questions above as well as a range of questions related to OPO operational practices (e.g., organ tracking and lost organs; operational differences between high and low performing OPOs; standardization of definitions and practices; the potential impact of organ recovery centers; best practices regarding automated referrals, and so on).

Competition - 68601

1. Are there additional factors or criteria that CMS should consider when determining which OPO should be selected for an open service area?; 2. Should CMS consider other performance measures when selecting an OPO for an open DSA?; 6. What would be the anticipated impact from consolidation or expansion of the OPO community? Would consolidation or expansion of OPOs facilitate increased competition and improved performance or have a negative impact?; 7. Any other helpful information that could inform potential changes to the current recertification and competition processes.

Appreciating the principles of the Biden Executive Order on Competition, the FAS OPO Innovation Cohort agrees with bipartisan Congressional leaders that given COVID makes reform an "urgent health equity issue", all parts of the country deserve to be served by high-performing OPOs as soon as possible.

As CMS considers elements for competition, transparency, accountability, and equity are critical. In addition to overall donor and recovery rates, through requiring all OPO process data to be publicly available, CMS will have evidence of an OPO's ability to equitably serve all donors in a designated service area (including by race/ethnicity), as well as improvements over potential, and transparency of key financial and organizational data to understand capacities to best serve DSAs (including transparency in any conflicts that may exist in an OPO's governance structure).

The FAS OPO Innovation Cohort has already committed to these principles, and extending these practices to all OPOs via CfCs can allow CMS to best evaluate OPOs as they compete for serving an underserved community.

For example, publicly available OPO process data via CfCs will allow CMS to consider evidence of effective and equitable treatment of donor patients/families (e.g., no disparities in response rates/times based on race/ethnicity).

The anticipated outcome of both increased competition as well as replacing lower performing OPOs with higher performing OPOs would be more lives saved. See:

- the Bridgespan Group guidance on how CMS can oversee and implement the DSA competition process in a manner that is pro-patient and foregrounds racial equity;
- OPO CEOs in the news:
    - Diane Brockmeier and Ginny McBride in Morning Consult: *"HHS's new proposal signals something potentially game-changing for patients: allowing the highest*

performing OPOs to replace those who have proven themselves incapable of serving their communities. To the extent that an OPO is not able to rise to the challenge of a high standard, the focus of our attention and energy must be on better serving patients on the national waitlist, not on protecting specific OPOs… forcing OPOs to continually earn their contracts is a patient-centric accountability mechanism, ensuring that OPOs operate with the urgency befitting the life-and-death consequences of this work."

- Patti Niles in the Dallas Morning News: *"The performance gaps seen in the OPO community would not be acceptable in any other sector of health care. There is no reason to accept them in the life-and-death context of organ donation. Many organ procurement organization leaders are on the record in favor of reform. We have worked together with patient groups, doctors, researchers, senior Obama and Trump administration officials, philanthropies and bipartisan members of Congress to get this right… Lives are at stake. Patients deserve better. Our communities deserve better. We must do better."*

Oversight - p. 68601

5. Are the current CMS requirements for a governing body and advisory board adequate for OPO governance? Have OPOs included additional board positions or structures beyond what is required by CMS to improve operations? What structure best serves accountability, and efficient and effective organ procurement?

The FAS OPO Innovation Cohort believes the principle of transparency should apply throughout the entire ecosystem, and that it is critical for CMS to:

- Release information related to OPO performance quickly and in an understandable way so that boards are aware and can exercise fiduciary responsibilities;
- Require transparency of potential conflicts of interest throughout the entire donation and transplantation ecosystem as a top priority, following the transparency commitment of FAS OPO Innovation Cohort.

Appendix C: RFI response with other pro-reform CEOs to HRSA re. OPTN, May 2022

To: HRSA Administrator

From: Diane Brockmeier, Mid America Transplant
Ginny McBride, OurLegacy
Kelly Ranum, Louisiana Organ Procurement Agency
Matt Wadsworth, Life Connection of Ohio

This letter is in response to a Request for Information (RFI) regarding the contract to operate the national Organ Procurement and Transplantation Network (OPTN). Each of our organ procurement organizations (OPOs) supports HRSA's stated objectives of:

- Increasing accountability in OPTN operations, including board governance, financial structures, data transparency, and policy development;
- Enhancing the usability and performance of the OPTN IT system and related tools;
- Strengthening equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process.

With the above objectives in mind, key recommendations for HRSA to reform the OPTN in such a way that best serves patients, focusing on core competencies and removing conflicts, include:

- Ensure patient-centered governance of the OPTN, separating the OPTN board from any contractor(s) serving OPTN functions; and
- Revise the OPTN contract so that it subdivided into areas where the OPTN contractors can provide critical and expert functions:
    - Policy: reforming OPTN governance (above) is critical to de-conflicting policy. Policymaking by an OPTN contractor should then be transparent, fueled by openly available data, aided by experts in government and the wider community, and with all potential conflicts publicly known and acted on accordingly.
    - IT: the IT components of OPTN operations be outsourced by HHS in ways that are independent of, but complimentary to, the rest of the OPTN contract
        - The Office of the National Coordinator (ONC) at HHS should work with the tech contractor on matters critical to national/health IT and organ donation/transplantation, including exploring better use and/or integration of hospital EMRs.
    - Organ placement and shipping: these should be separate from existing OPTN contract, with best in class options available for OPOs to opt into as appropriate.

  Note: the Membership and Professional Standards Committee should cease its activities to evaluate OPO performance and conduct peer review, with OPO oversight being the purview of CMS, instead of fractured between CMS and OPTN.

- All of the above functions - both from HHS and OPTN contractors - should have strengthening equity, access, and transparency at their core, including ensuring all de-identified data are publicly available to best serve patients, and enable continuous innovation and improvement.

A. *OPTN Technology - IT System: (A.1-4)*

We are acutely aware OPTN technology lags significantly behind other technology platforms because our OPOs use it every day. As citizens of the U.S. we enjoy the use of numerous corporate IT platforms to perform the most basic functions of life. These platforms have been developed by enterprising companies whose survival relies on capturing market share. Ease of use, convenience and continuous innovation are among the most prized factors. Companies compete against each other to satisfy and retain customers. Poor performers do not survive.

Companies succeed because they prioritize continuous, rapid IT system improvement because IT is a core function. The current OPTN contractor has not positioned itself to provide state-of-the art service and does not view evolving technology as a priority. The OPTN Board of Directors and committees and the current contractor's board and committees lack the needed expertise to make the necessary changes because the OPTN Bylaws restrict the involvement of individuals who could expand its capabilities. From an IT perspective, the current OPTN contractor is slow and reactive.

It is our recommendation that the IT components of OPTN operations be separated from the monolithic OPTN contract by HHS in ways that are independent of, but complimentary to, the rest of the OPTN contract. HRSA could require any other OPTN contractors to incorporate the services of the independent technology provider into its workflows. That independent contractor should be answerable to and benefit from digital service experts within the government - including HHS and the ONC - who can competently exercise oversight on behalf of patients and taxpayers.

The flow of information among OPOs, donor hospitals, transplant programs and the OPTN in support of successful donation and transplantation, while constant, remains fractured. Donor hospitals and transplant hospitals utilize their own electronic health record systems. OPOs and transplant programs utilize customized, built-to-purpose databases that interact with the OPTN only to transfer donor, candidate and recipient data that are, for the most part, not used for the critical functions of organ matching, offer and acceptance. The OPTN database operates in a one-way fashion in which members provide data but very little information is provided directly to them in return, and the entire process is hindered by the current OPTN contractor's inability to deploy APIs.

The use of multiple databases to operate a network dependent on timely and accurate communication to achieve maximum performance is not efficient. The OPTN technology contractor should be working toward seamless integration from hospital EHR to OPTN database. The rules of engagement with the OPTN database should be changed so OPOs are no longer required to maintain an additional database to collect and store donor information. OPOs should be able to transfer donor clinical information directly from the hospital EHR to the OPTN database for the purpose of communicating donor evaluation information and organ allocation. OPOs should be able to enter and extract data from the national database utilizing their own internal capabilities, aided by APIs, rather than pay for an expensive database 'middleman'. Additionally, there should be mutually agreed upon national OPO datasets that can be used for research and analysis purposes (see earlier response to CMS RFI on data

transparency). Data availability and transparency are key to improving organ procurement. The database should be managed by the OPTN technology contractor in a way that prioritizes data transparency. The current OPTN contractor has not proven capable of this function.

Historically, motivation for the OPTN to accelerate improvements to its technology platform have come from outside the OPTN. Pressure to create DonorNet came from HRSA. More recently, calls to implement a GPS system to track organ movements went unheeded by the OPTN until media accounts exposed the lack of a systematic method to protect vulnerable organs while in transit. Incorporation of technology requirements into a single OPTN contract has not sufficiently served the needs of OPOs, and the noncompetitive monopoly structure has relieved all pressure from the current OPTN contractor to keep current with even basic technology standards, creating risks to patient safety and data security. HRSA must create opportunities to incorporate a wider array of contractors to serve technology needs, including by opening the pool to the widest range of innovative applicants. There are numerous U.S. companies with the ability to track and deliver packages. It would serve the interests of organ sharing better if one of those companies could establish a national organ shipping system that would monitor the progress of all shipments in real time on behalf of OPOs that opt in.

B. Data Collection Activities: Describe how you would/how vendors could develop performance metrics and benchmarks for the organ donation, procurement, allocation and transplant system, including through expert consultation, subcontracting, and engagement with transplant candidates, transplant recipients, organ donors and their families about the metrics they value. 2. Describe how you would/how vendors could structure data collection and reporting mechanisms for the system: a. To report OPTN performance metrics including process, outcome, and patient engagement measures. b. To establish OPTN member performance benchmarks. c. To capture patient and donor demographics, including race, ethnicity, language, and socioeconomic factors. d. To create public OPTN national, regional and local performance dashboards. e. To track long-term patient outcomes and health and non-health-related factors that contribute to outcomes.

CMS recently finalized new, objective OPO regulations which we supported along with patient groups, bipartisan Congressional leaders, and equity advocates. The performance measures recently published by the CMS are already having substantial influence on OPO performance. One case in point is the Arkansas Organ Recovery Agency (ARORA), an OPO which had never recovered organs from more than 77 deceased donors in a single year. Because of leadership changes driven by years of underperformance, a new executive director achieved 108 deceased organ donors in 2021. It seems unlikely this leadership change would have occurred without external pressure from CMS to change course.

HRSA, and other HHS entities, must establish national goals in collaboration with leading experts external to the OPTN but can use the donation and transplantation community as sources of data, information and insights. Additionally, all de-identified OPTN data should be publicly available to allow for oversight, innovative research, and donation/transplantation stakeholders to improve patient outcomes based on data.

Additionally, we and the aforementioned groups have advocated for HHS to publish OPO process data (see CMS RFI response), which will not only inform best practices for OPO management, but help inform policy considerations at the intersection of multi-stakeholders, including in regards to best practices and thoughtful regulation related to donor hospital referrals

and organ discards. Regardless of whether HHS takes on some of these responsibilities directly (including potentially through an Office of Organ Policy), or outsources them to an external vendor, all metrics and benchmarks should be informed by transparent process data, in line with international best practice standards.

C. (d) OPTN Finances

The OPTN board and any OPTN operational contractor board must achieve complete separation. The OPTN board, populated mostly by transplantation professionals, does not have the expertise or background to oversee a financial, technological, human resources, customer service enterprise. UNOS' performance as the OPTN contractor bears this out. Its ability to keep pace with technological advances has been in question for many years, as evidenced by board and OPTN members who are frustrated at the time it takes to implement policy changes. The current board does not have the background enabling it to build wider corporate relationships enabling it to achieve strategic goals. The OPTN community has suffered as a result. UNOS' current strategy of using one board to serve two purposes must be abandoned. Any new contractor boards should commit to develop an independent operational plan that focuses on human resources needs, financial strategies, corporate IT objectives and other strategies to enable goal achievement that allows for HHS to meet its objectives for the transplant community. The OPTN board and staff should be financed by OPTN registration fees. Because both the OPTN board and the contractor operational board would be in accountability relationships with HRSA, they both would report on successes and barriers in meeting the strategic objectives of the OPTN. This reporting process could be extended to all elements within HHS with a stake in the operations of the OPTN to ensure alignment of goals and communication transparency. Ideally, NOTA should be updated, including to create a financing structure that aligns incentives for any OPTN contractors with the actual goals of HHS and patients in mind, which is to constantly increase transplant availability through improved stakeholder performance, something which is not accomplished in the current financing structure.

Any donation and transplantation clinician who is a member of the OPTN board and employed by an OPO or transplant hospital is in a conflict of interest when voting on certain OPTN policies. And since at least 50% of the board meets this criterion (because of OPTN Final Rule requirements for board composition), a method of addressing the conflict must be identified. Currently, conflicts are self-reported, narrowly defined, and not disclosed. One strategy specific to organ allocation could be that policies are voted on by non-OPO and transplant program members. This leaves patients, donor families, trade organizations (which would each get a single vote to represent each industry) and other non-allied members to vote. Board members would be prohibited from lobbying the patients and donor families to gain their votes. However, the best and most sustainable strategy would be to eliminate inherent conflicts entirely through subdivision of the OPTN contract. For example, organ allocation could be handled by a separate contractor with no financial or other business relationships to the stakeholders with a vested interest in the outcome of organ allocation policy.

D. Increasing Organ Donation and Improving Procurement: 2. Describe how you would/how vendors could structure, finance and staff an OPTN board of directors independent of membership of the OPTN operational contractor's board of directors. 2. Describe the conflict

of interest policies you would/vendors could implement to ensure independence of the OPTN board of directors. 3. Describe the reporting mechanisms you would/vendors could utilize to hold operational contractors' accountable for system performance and outcomes. 4. Describe the additional factors and process steps you would/vendors could take to ensure effective operations of such an independent board of directors.

The OPTN contractor should no longer be actively engaged in supporting OPO performance improvement activities. There should not be contract activities to support OPO performance and the Membership and Professional Standards Committee should cease its activities to evaluate OPO performance and conduct peer review. Neither of these activities has resulted in immediate and sustained donation increases and the OPTN has permitted some severely underperforming OPOs to continue practicing rather than make referrals to the HHS Secretary to decertify the underperformers. The MPSC began evaluating OPO performance many years ago at a time when CMS's OPO performance standards were vague and incapable of identifying poor performers. At HRSA's request, the OPTN and SRTR stepped in to develop measures that would identify low performing OPOs. Despite having a set of standards, the OPTN has done little to positively impact the number of donors and organs transplanted. This inability came into stark relief in 2003 when HRSA launched the breakthrough collaboratives and, with almost no assistance from the OPTN except data analysis support, achieved unprecedented donation increases. Any funding to improve OPO performance could be better spent and allocated through a formal CMMI process of the best available data-driven options. The OPTN could then stay focused on evaluating OPOs for compliance with OPTN policies, such as following official OPTN allocation processes.

CMS is already demonstrating with its new performance outcome standards that, despite the OPTN's 20-year history of OPO performance evaluation and improvement activities, more than a third of OPOs are failing. The Scientific Registry of Transplant Recipients (SRTR) data used by the OPTN MPSC to evaluate OPOs also seem ineffective in identifying poor performance. Therefore, it has been extremely ill-structured for the OPTN, rather than CMS, to have unique visibility into the day-to-day issues necessary for CMS to exercise such oversight responsibility. Given this, HHS should reabsorb all OPO oversight functions from the OPTN.

If, as alluded to earlier, HHS publishes full process data, this will help generate a multitude of solutions for remediating OPO performance failures during the course of a contracting cycle. For example, with specific deficiencies identified, including issues related to diversity, equity, and inclusion, OPOs will be able to engage external partners (including partners both traditionally within and outside of the OPO industry) to implement data-driven solutions. Such process data, in line with international best practice for data transparency, should include: whether OPOs are appropriately staffed to serve their communities; data about referral and request outcomes based on potential donor and family race; and other issues that could identify any deficiencies in any OPOs' service of communities of color. Using these data, HRSA could then also partner with multiple organizations to develop strategies to improve equity in organ donation at a systems-level.

E. Organ Usage: Describe how you would/a vendor could support the OPO performance improvement activities to decrease discarded organs and further increase the use of organs. 2. How can OPTN organ matching activities be modified to decrease non-usage (discards) of

procured organs? 3. Describe the steps you would/vendors could take to improve transparency around the organ matching and acceptance process for transplant candidates, transplant recipients, other affected patients, organ donors and family members served by the OPTN.

The most effective way to discourage OPOs from recovering organs is to ensure they don't get transplanted. This is the biggest problem facing the OPTN. From an OPO perspective, the OPTN is unintentionally enabling organ discards because organ allocation policies, particularly kidney allocation policies, prioritize how candidates are ranked on the waiting list rather than ensuring a transplantable kidney is implanted into a compatible recipient. The balance between ensuring equity in candidate selection and ensuring viable organs are transplanted has been lost. This is partly because the people driving kidney allocation policy development (the OPTN Kidney Committee) are predominantly transplant professionals. There are no OPO voices advocating for better kidney utilization during the policy development phase. Discard rates are also influenced by an OPOs inability to get an offer to a program willing to use the kidney in a timely manner. High KDPI kidneys are "at risk" from the moment of aortic crossclamp. But they aren't treated with sufficient priority. OPOs, or the Organ Center, must use precious time to wade through offers to transplant programs that rarely, if ever, use high KDPI kidneys. Kidney filters only do so much. Rather than rely on voluntary engagement of transplant programs to filter offers, high KDPI kidney allocation should prioritize the programs with a track record of using them.

Much of the problem also results from the frictionful and otherwise insufficient UNOS technology system over which organ offers as made, leading to calls from the House Appropriation Committee for HHS to promote competition for the IT component of the OPTN contract for this explicit reason.

Honoring donors and donor families by ensuring their kidneys are transplanted is our national obligation. Anything less is a disservice to those who have donated.

Not every OPO agrees that handing kidneys to the Organ Center for the purpose of national placement is an effective means of getting kidneys transplanted. OPOs generally are not confident that placement will occur when relying on the Organ Center. The Organ Center's organ placement outcomes are not widely shared and OPOs deserve to be better informed about the likelihood of their organs being placed and should have a choice about whether to ask the Organ Center for assistance. OPOs are more invested than the Organ Center in placing organs because we know the families who have donated them and we will work to get them placed. Unfortunately, current OPTN policy makes this difficult.

But there could be a different option to place difficult organs. Because transplant programs and OPOs are relying more frequently on staffing and operational support from third parties or call centers, it may be possible to create an organization whose sole purpose is to place kidneys. This organization could be operated under a separate section of the OPTN contract but receive financial support from OPOs that would be willing to utilize it (e.g., a fee-for-service, which would be optional for OPOs and applied on an opt-in, voluntary, case-by-case basis). The objective would be to place high KDPI kidneys faster. Such an organization could quickly learn which centers are more inclined to transplant certain organs and collaborate with the host OPOs to develop a placement strategy. We must develop an increased level of national urgency to place

the kidneys OPOs have successfully made available. It is our experience that transplant programs do not feel urgency when a kidney is at risk. But the OPOs feel that risk very acutely. Perhaps it is time to move away from the Organ Center concept and toward a more independent process.

3. Describe how you would/vendors could incorporate, to the full extent permitted under applicable law, the NASEM report's recommendations on increasing racial, ethnic, professional, and gender diversity on the boards and committees responsible for developing OPTN policies. 2. Describe how you would/vendors could engage with experts in quality improvement and stakeholder collaboration in executing OPTN deliverables. Page 6 of 7 3. Describe what you would/vendors could include in their code of business ethics and conduct for the entity that holds this contract to ensure the highest standards of conduct and integrity are observed. 4. What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?

F. OPTN Operations and Policy Development Improvements

We support NASEM's recommendation that improvements to the OPTN's policy-making process to increase racial, ethnic, professional and gender diversity on the OPTN's board and committees are urgently needed. This can be accomplished by increasing or changing the number or type of medical/scientific members or public members and permitting them, via the OPTN bylaws, to serve on committees and the board. HRSA and the OPTN should actively recruit membership of organizations with expertise in health care delivery to DEI communities. HHS should also clearly articulate its goals, as well as to foster a dynamic in which any OPTN contractor(s) understand that they will likely lose their contract should they fail to meet these goals.

Many OPTN members are losing confidence in the OPTN policy-making process. It seems that significant time and resources are devoted to changes that make only small, incremental differences in the number of organs donated and transplanted. Many policies are also perceived to be tainted by the conflicts of interest inherent in the current OPTN structure, which again underscores the need for HHS to subdivide the OPTN. Although OPTN policies are developed by members, their impact is felt far beyond OPTN membership. Their ability to success is dependent on factors also beyond the membership of the OPTN. If the OPTN is to improve its success it is essential that we allow those societal factors that can affect our success be part of the policy development process. And to do that, we must re-examine that process, specifically our public comment process. Currently, the OPTN is reliant on commenters coming to regional meetings or depositing feedback on a website to obtain public feedback. To build trust in our system, we must consider how we can more actively engage influential communities to help us understand how we can do better. OPTN policies aren't just medical policies, they are public trust policies. The OPTN must build a community that is willing and capable to provide honest feedback. And we must have a public comment process that honestly and transparently incorporates that feedback so participants feel heard and valued. We strongly support the involvement of organizations such as the National Academy of Public Administration to assess the OPTN's current policy making process and advise on strategies to diversify how its development is influenced.

Additionally, given how critical DEI is to all aspects of a high-functioning organ donation and transplantation system, all OPTN contractors should include DEI expertise within its core leadership and DEI metrics as part of its transparent reporting.

Creating strong foundations for the policy making process is what will drive how the OPTN ensures its code of ethics and integrity is maintained. Many perceive the OPTN's integrity has suffered and it is our belief that this is because the policymaking process lacks transparency and accountability.