MIDWEST TRANSPLANT NETWORK

February 1, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244

RE: CMS-3409-NC

Dear Administrator Brooks-LaSure:

Midwest Transplant Network (MTN) is pleased to provide information in response to the Request for Information: Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations (OPOs), and End-Stage Renal Disease Facilities. MTN is a high performing, federally designated OPO serving western Missouri and Kansas. MTN serves a population of 5.6 million individuals, about 87% of whom are registered donors. MTN's exceptional staff is dedicated to continuously expanding the number of organs recovered and transplanted by aggressively pursuing opportunities for donation, developing relationships with hospital and transplant center partners, engaging in continuous quality review and connecting with the diverse individuals and communities that make up MTN's donor service area.

I have the pleasure of serving as MTN's President and Chief Executive Officer (CEO) and as the President for the Association of Organ Procurement Organizations (AOPO), a national organization which represents 48 federally designated, non-profit OPOs in the United States, which together serve millions of Americans. MTN is supportive of the comments submitted by AOPO, especially AOPO's comments related, but not limited to:

- increasing equity in organ donation and transplantation by incentivizing and establishing diverse boards and internal committees to guide OPOs and transplant centers; engaging in unconscious bias training for all professionals engaged in the organ donation and transplantation ecosystem; advocating for CMS to invest in qualified care navigators; requesting that CMS incentivize data collection to track the effectiveness of education and interventions designed to increase equity within the transplant system; engaging in culturally informed educational outreach to historically underserved communities regarding the organ donation process;
- implementing existing solutions for organ tracking, for example, GPS-enabled critical asset trackers; seeking CMS administrative and financial support for pursuing and implementing innovative shipping solutions; working with the Federal Aviation Administration to develop a standard manner for handling, tracking, moving, and releasing organs across the United States;

- broadening referral criteria for donor hospitals to "rule in" more donors; automating referrals to increase efficiency by quickly ruling out patients with clear medical contraindications to organ donation and to mitigate any effects of unconscious bias in the referral process; encouraging collaboration between donor hospitals, CMS and OPOs to expand OPO access to electronic medical records (EMRs); and
- increasing the number of organs recovered after circulatory determination of death (DCD) by recommending that CMS require and financially reward donor hospital support of the DCD process.

MTN is also supportive of recommendations advanced by AOPO which relate to procuring organs for research, considering "zero organ donors" and the effectiveness of organ recovery facilities. I now write to provide additional context and details that reflect the unique experiences and viewpoints of MTN in response to specific questions posed in the RFI.

I. Effectiveness of Organ Recovery Facilities and their Impact on Stakeholders

In order to improve outcomes for transplant patients, increase the average number of organs recovered from each donor and reduce the overall costs associate with organ recovery, many OPOs have constructed specialized donor care facilities (SDCFs), to which braindead donors are transferred to a SDCF for medical optimization and organ procurement. These SDCFs are often comprised of operating rooms for organ and tissue recovery, diagnostic testing facilities and donor intensive care units.

I am proud to share that MTN is finalizing construction of a state-of-the-art organ recovery center and donor care unit (DCU) which is slated to be completed in June of 2022. This summer MTN will begin transferring braindead (BD) donors from the hospital setting to a private center for organ recovery. MTN staff members and our hospital partners are thrilled about the future benefits of this project because it will free up donor hospital resources including staffing, supplies, and bed occupancy when organ donors are transferred to MTN's DCU.

Additionally, the COVID-19 pandemic elucidated the pressing need to support SDCFs, like MTN's DCU, in order to relieve pressure from heroic, but overwhelmed local hospitals. Moving BD donors to our DCU will make available desperately needed ICU beds, ventilators and hospital critical care staff so that these resources can be used for COVID-19 patients and other medically complex patients. Further, MTN's DCU will minimize the number of essential workers who report to local hospitals and reduce the number surgeons who may be required to travel from across the U.S. to surgically recover donor organs. Minimizing external staff in hospitals is safer for OPO and hospital staff members as well as patients.

Unfortunately, because of outdated CMS guidance, Medicare Certified Transplant Centers (CTCs) may be reluctant to transfer BD donors to an SDCF because CTCs could be financially disincentivized by the transfer. The transfer of donors to an SDCF is disincentivized due to outdated cost report language in Medicare Guidelines which state that CTCs receive Medicare reimbursement for organs **recovered at the CTC** although "usable organs" include "organs sent to OPOs," without any reference to where the organs were recovered. 42 U.S.C. § 273. Local transplant centers remain willing to partner with MTN and are supportive of donation; however, some CTCs have expressed hesitancy in their willingness to transfer donor patients for fear that the CTC may be financially penalized after Medicare cost reports are submitted.

MTN strongly urges CMS to remove the disincentive from CTCs to clearly permit the transfer BD donors to organ recovery centers without a financial penalty and proposes two possible solutions to remove this barrier. First, CTCs, as the place where the donor was identified, declared by neurological criteria, and authorized by the donor family, should be able to continue to report the organs from the donor on their cost reports. The cost report should reflect declaration of death vs. excision of the organs to allow CTCs to continue to report the costs of these services on their Medicare cost reports without penalty.

Second, currently, under CMS sub-regulatory guidance, CTCs are barred from entering into under-arrangements or other types of agreements with independent OPOs. OPOs, whether hospital-based or independent, should be able to enter into such agreements for the purposes of recovery services. In order to expressly permit CTCs to engage in such agreements, a small change must be made to 42 U.S. Code § 273 - Organ Procurement Organizations, as follows:

> Section 371(b)(3) of the Public Health Act (42 U.S.C. 273(b)(3)) is amended—
> (1) in subparagraph (A) by adding at the end the following new subparagraph:
> **"(i) including agreements to perform recovery services, if applicable,"**
>
> (2) in subparagraph (C) is amended by adding at the end the following new subparagraph:
> **"(i) Such arrangements may include agreements to perform recovery services, if applicable,"**

MTN appreciates CMS' attention to this ongoing concern as it pertains to CTC reimbursement. Additionally, many of these important points regarding SDCFs have been included in a letter I drafted and signed along with nine other OPO CEOs, all of whom lead OPOs with SDCFs. These leaders similarly support CMS taking steps to expressly permit CTCs to report direct organ acquisition costs on their Medicare cost report while utilizing the SDCF recovery model.

II. How OPOs are Impacted by the Exclusion of "Zero Organ Donors" from Definition of "Donor" and Current Organ Acceptance Practices

MTN shares CMS' goal to expand the pool of eligible donors to procure and transplant as many organs as possible, thereby saving as many lives as possible. A critical component of this goal centers on policies pertaining to zero organ donors and organs recovered with intent to transplant that are ultimately discarded. This often occurs after an OPO has done everything right, but for circumstances outside of its control, transplantation does not occur. However, excluding zero organ donors from the definition of a donor has the unintended impact of disincentivizing OPOs from pursuing riskier donors and single-organ donors because OPOs will not be unable to count these individuals as donors despite committing countless hours and financial and emotional resources to obtaining authorization for donation, educating family members, engaging in complex donor management, and finally recovering the donated organ(s) for transplantation.

High-performing OPOs, like MTN, dedicated to consistently pursuing donors who have complicated medical histories or injuries that may increase the probability of these donors becoming zero organ donors, should not be penalized for their valiant efforts, which regrettably, do not always result in organ transplantation. By pursuing these complex donors, MTN proudly fulfills its mission by ensuring every organ available is being recovered for transplantation; however, currently, the exemplary efforts of MTN's staff members are not included to assist CMS in evaluating MTN's performance. Additionally, there are intervening and superseding causes independent of OPOs which result in organ discards including, transit

issues, anatomical anomalies, positive serologies, biopsy findings, surgical errors, preservation parameters, etc. which may be unknown when a donor enters the operating room.

MTN proposes three possible solutions to address this issue; CMS should incentivize the pursuit of zero organ donors as an important strategy to expand the availability of organs for transplant by: (1) counting these toward the donation metric, giving a fractional credit (e.g., 0.50 or 0.25 credit) for organs pursued with intent but not transplanted; (2) removing these organs from the denominator of the performance metric; or (3) accounting for these organs as an entirely independent metric. The fractional credit model also has the benefit of having the ability to incentivize tier two and tier three OPOs to pursue more complex donors and would benefit these OPOs by potentially lifting them to a higher tier. Further, the fractional model would benefit the transplantation system as a whole by increasing the total number of donors each year. On the other hand, removing the organs from the denominator of the performance metric would prevent OPOs who are already pursuing riskier donors from being penalized for these efforts in the performance donation metric. Aggressive OPOs, like MTN, should receive credit for pursuing these organs, which will spur OPO and donor hospital collaboration and further encourage the pursuit of all potential donors.

However, all of the solutions proposed above fail to address the reality that transplant centers determine whether an organ is discarded or transplanted. The current metrics disproportionately penalize OPOs for organs that are recovered by a transplant surgeon, but then not transplanted, with no performance impact to the transplant center. For example, in 2021, MTN reported 37 livers were discarded that were intended for transplant when MTN's clinical staff entered the operating room to assist in organ recovery. These declinations require MTN clinical staff members to engage in tremendous, expedited reallocation efforts while they are in the operating room. However, more important than the time spent by MTN staff reallocating organs, is the fact that not all organs can be reallocated, which is especially devastating because donation is a way for donor families to find meaning and peace during a time of loss. This brave and selfless choice should not be overlooked; every possible effort should be made by transplant surgeons and transplant centers to respect the heroic sacrifice and final wishes of donors and their families.

III. Supporting the Procurement of Organs for Research while Maximizing the Number of Viable Organs Recovered for Transplantation

MTN appreciates CMS' interest in assessing OPOs' efforts to support medical research. In order to meet the donor family's desire to support medical research to aid in the discovery of new or better treatments for debilitating and fatal diseases, MTN currently places organs to support the broad medical research ecosystem, including but not limited to:

- An FDA approved study conducted to evaluate the efficacy of a liver pump developed to extend the amount of time a liver can be outside of the body and remain suitable for transplant;
- A project which uses donated hearts to study the disease processes that lead to advanced heart failure; and
- Lung research which aims to find new ways to treat and overcome some of the most common airway diseases including cystic fibrosis, asthma, COPD and the effects of smoking and vaping.

Relatedly, MTN views CMS' identification of pancreata as the only organ, if recovered and sent for research, to be included towards the transplant metric as too restrictive and CMS' decision prioritizes pancreata over all other organs, clinical trials, and research projects.

Additionally, the fact that pancreata recovered for research purposes count towards OPO organ transplant metrics is problematic because CMS has not defined "research" or established parameters and/or guidelines for OPOs and research programs to ensure that pancreata recovered are used by reputable organizations for legitimate research purposes. CMS should also monitor research organs closely to ensure that OPOs are not incentivized to use internal or external resources to recover more pancreata for research in order to inflate the overall number of "donors" recovered.

Ultimately, MTN is supportive of CMS' efforts to support medical research that tangibly benefits organ recipients, including Medicare beneficiaries. However, CMS should prioritize incentivizing OPOs to carry out their important lifesaving mission—maximizing the number of viable organs *for transplantation*.

MTN is a proud member of the OPO Community and appreciates the opportunity to submit comments for CMS' consideration as it endeavors to improve the equity, efficiency and effectiveness of our organ donation and transplant system. MTN supports all changes which will truly lead to increased procurement opportunities for transplantation, increased organ utilization, and as a result, more lives saved.

Sincerely,

Jan Finn, MSN
President & Chief Executive Officer
Midwest Transplant Network