Dear [Senator or Congressman or Congresswoman] and Staff,

In response to this unprecedented public health emergency, every area of healthcare has worked swiftly to overcome obstacles and challenges in order to provide for those in need. As the President and CEO of Midwest Transplant Network (MTN), the designated Organ Procurement Organization (OPO) for your constituents, I assure you we are committed to providing desperately needed organs not only for [Kansans or Missourians], but also for those awaiting these lifesaving gifts across the United States. MTN has adapted well during the pandemic by developing a robust telecommuting plan, continuing communications with potential donor families virtually and hosting virtual outreach and community education events. In fact, MTN has been able to sustain operations throughout the pandemic without applying for or receiving any federal COVID-19 economic assistance. MTN is a good steward of federal funds, including Medicare reimbursements, as evidenced by MTN's balanced budget, healthy cash reserves and reasonable executive salaries which are routinely audited by a third-party company. MTN leadership expects that Board members are dedicated to MTN's mission and offers only nominal payment to Board Members for participation and meeting attendance which often requires travel.

MTN and the fifty-seven other OPOs nationwide have continued the important work of recovering organs and facilitating organ transplants during the pandemic. Similar to the heroic efforts of healthcare workers employed by hospitals, MTN's clinical staff has continued to respond onsite to Kansas and Missouri hospitals to engage in donor care management and ensure an efficient and effective organ donation and transplantation process throughout the pandemic. MTN experienced a significant drop in transplants from March to June of this year, with 284 transplants during this four-month period versus 357 transplants in 2019 during this same timeframe. MTN's recent decline in transplants is, in part, due to transplant centers inactivating patients and transplant programs for fear of potentially exposing immunocompromised patients to COVID-19.

I am writing today to provide you with information which I feel is crucial for you to understand as you contemplate the necessity for a standardized OPO performance metric, consider OPO performance nationwide and evaluate how the COVID-19 pandemic is impacting OPOs.

Hurdles to Reliably Measuring OPO Performance

OPO performance is measured and tracked to ensure compliance at regular intervals by the Centers for Medicare and Medicaid Services (CMS). Unsurprisingly, OPO outcomes and OPO performance vary across the U.S. for a variety of factors including, population demographics in an OPO's Designated Service Area (DSA), the percentage of individuals who register as donors in each state, the consistency with which OPOs respond to hospital referrals and build relationships with local hospitals, and the efforts OPOs put forth to maximize each and every opportunity to procure lifesaving organs. Donor potential is an extremely important value in determining OPO performance because it allows OPOs to anticipate how many deaths within a given DSA are medically suitable for donation and therefore provides a denominator against actual donors. However, the OPO community does not currently have standardized, transparent and enforceable method by which donor potential can consistently be calculated in each OPO's DSA.

Under the current system, OPOs directly report data, for example, the number of donors eligible to donate organs (donor potential), and this data is used to calculate outcome measures. Self-reported data is often argued to be unreliable and threatened by bias which may be intentionally or unintentionally introduced and lead to invalid estimations.[1] For this reason, current outcome measures may not accurately reflect OPO performance due to the data source used to calculate outcome measures. The standard definition of an eligible donor is subjective because the definition is not consistent or known across all OPOs. MTN supports a metric that is verifiable and independently reported by a respected data source to avoid the use of subjective data based on each OPO's definition of an eligible donor.

MTN is Consistently a High Performer

MTN serves a population of 5.6 million individuals, about 78% of whom are registered donors, in part, due to the relationships MTN has cultivated with local DMVs within its DSA; about 98% of those who register to be organ donors do so at these DMVs. MTN remains committed to expanding the number of organs recovered and transplanted by aggressively pursuing opportunities for donation and engaging in continuous quality review. Accordingly, MTN has experienced constant improvement as demonstrated by a fifty-seven percent (57%) increase in organ transplantation over the past five (5) years. Moreover, MTN achieved record numbers in 2019, consisting of 282 deceased organ donors and 929 organ transplants from those donors. When compared to the other fifty-seven (57) federally designated OPOs operating in the U.S. from 2011-2018, MTN was consistently ranked one of the top six OPOs in the nation based on organ donation rates.[2] In 2017, 2018 and 2019, MTN was ranked first in the nation based on its organ donation rates.[3] Even more exemplary of MTN's commitment to excellence is the fact that CMS has never found MTN to be out of compliance with any CMS performance measure.

MTN relies on a rigorous internal metric to establish donor potential which is based on medical evaluation of the patient's neurological status, organ function and established age criteria. MTN internally evaluates every single hospital referral to determine if there is *at least* one transplantable organ. MTN's approach to rule *in* donors, including complicated potential donors. In fact, MTN regards active metastatic cancer as the only condition which results in an automatic rule out for organ donation. By pursuing complex donors, MTN is ensuring every organ available is being recovered for transplantation.

Despite MTN's efforts, there are occasions on which organs are discarded because a transplant center declines the organ based on its quality. This fact counters recent press insinuating that kidneys are discarded after being left behind on commercial planes or delayed while being shipped

[1] Althubaiti, Alaa. (2016). Information Bias in Health Research: Definition, pitfalls, and Adjustment Methods. *Journal of Multidisciplinary Healthcare*, 9. 211. 10.2147/JMDH.S104807.

[2] Niroomand, Elaheh & Mantero, Alejandro & Narasimman, Manasa & Delgado, Cindy & Goldberg, David. (2020). Rapid Improvement in OPO Performance: Potential for Change and Impact of New Leadership. *American Journal of Transplantation*, 11-12. 10.1111/ajt.16085.

[3] Niroomand 2020, pp. 11-12. Rankings for 2019 were not presented in the Niroomand et. al. article; however, when utilizing the same metrics with all 58 OPOs' 2019 data, MTN was again ranked number one.

on commercial flights which renders the organs unusable.[4] Moreover, MTN leases its own aircraft that is used to expedite the organ procurement process. On occasion, MTN has, at no expense to Medicare, used this leased aircraft to deliver organs to transplant centers when commercial flights were not available in order to honor the gift of donation. The intense scrutiny of US transplant programs provides an explanation for the high kidney discard rate; a transplant center can lose its credentials if its "one-year death and graft failure outcomes exceed predicted outcomes."[5] Additionally, transplant centers are financially disincentivized from accepting lower quality kidneys which could result in the patient having to recover from medical complications, and ultimately, prolong hospitalization.

It is unknown how each OPO determines donor potential; however, there is systematic speculation within from the media that some OPOs underreport donor potential, which has garnered national attention and has ultimately resulted in the categorization of these OPOs as poor performers.[6]

CMS Proposed Metric and OPO Requested Variances

In December of 2019, CMS submitted Proposed Rule 3380-P to revise OPOs' Conditions for Coverage (CfCs) to increase organ transplantation rates by replacing current performance measures with new transparent, reliable and objective measures. Most OPOs submitted comments regarding Proposed Rule 3380-P to CMS for consideration and some OPOs immediately requested to delay the implementation of the new outcome measure until the 2022-2026 recertification cycle (prior to the onset of the COVID-19 pandemic in the U.S.). Additionally, many OPOs voiced concerns regarding CMS' proposed metric which utilizes information obtained from state death certificates as reported to the CDC to establish donor potential.

The CDC has proposed an OPO performance metric in which the numerator is the number of actual deceased donors in an OPO's DSA who had at least one organ recovered for transplant and the denominator is the total number of inpatient deaths within the DSA among patients 75 years old and younger with a cause of death that would not be an absolute contraindication to organ donation. CMS has proposed to derive this death data from state death certificates obtained from the CDC's National Center for Heath Statistics' Detailed Multiple Cause of Death Database. However, many individual OPOs and the Association of Organ Procurement Organizations (AOPO) have spoken out against the use of death certificates because some researchers have found these certificates to be inaccurate and insufficient in details regarding secondary diagnoses, which are not the cause of death, but are relevant because the diagnoses could organ preclude donation.[7]

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[4] Aleccia, JoNel. 2020. Lost Luggage: How Lifesaving Organs for Transplant Go Missing in Transit. *NBC News*, Retrieved July 13, 2020, from https://www.nbcnews.com/health/health-news/lost-luggage-how-lifesaving-organs-transplant-go-missing-transit-n1130891

[5] Aubert O, Reese PP, Audry B, et al. Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance. *JAMA Intern Med.* 2019;179(10):1365–1374. doi:10.1001/jamainternmed.2019.2322

[6] Karp, Seth & Segal, Greg & Patil, D. (2020). Fixing Organ Donation: What Gets Measured, Gets Fixed. *JAMA Surgery*, E1. 10.1001/jamasurg.2020.0748.

[7] Lloyd J, Jahanpour E, Angell B, Ward C, Hunter A, Baysinger C, Turabelidze G. Using National Inpatient Death Rates as a Benchmark to Identify Hospitals with Inaccurate Cause of Death Reporting – Missouri, 2009-2012. *Morbidity and Mortality Weekly Report 2017*: 66(1): 19-22 ("an average of 45.8% of reviewed death certificates

Currently, the proposed CMS metric for assessing donor potential is subject to debate within the OPO community. In part because several OPOs have called attention to a study by researchers conducting a review of select Missouri hospital in-patient deaths found that the underlying cause of death noted on hospital-issued death certificates was inconsistent with the CDC's Guidelines for Death Certificate completion and resulted in an error rate of at least twenty percent (20%).[8] Additionally, the Chief of the Mortality Statistics Branch at the CDC's National Center for Health Statistics has recently questioned the accuracy of death certificates in light of the recent pandemic considering "inaccurate death reporting is a long-standing problem."[9]

MTN appreciates that the United States has been hit especially hard by the COVID-19 pandemic and acknowledges OPOs experienced a substantial reduction in transplant activity nationwide during March and April of 2020. However, after experiencing an initial decrease in transplant activity in the beginning of 2020, MTN achieved record breaking months in March, May, June and July. By comparison, in Spain—often cited as the world's leader in organ donation—the weekly average number of kidney transplants fell from 65.8 transplants to 6.7. during its COVID-19 peak in March and April.[10]

MTN understands the difficulties of performing this work during a global pandemic and continues to support the application of verifiable, independent metrics aimed at increasing donation and transplantation while acknowledging the challenge of developing an accurate and accepted metric to govern OPO performance. MTN is focused on opportunities for improvement because the cost of poor performance is truly a matter of life and death. A decision to delay the implementation of a new performance metric must be weighed against the serious negative impacts to both organ transplantation and donation caused by underperforming OPOs and the longstanding lack of accountability within the OPO community. However, holding low performing OPOs accountable and incentivizing improved OPO performance must be balanced with the need for OPOs to continue operating together as one of the greatest transplant systems in the world. Additionally, Policymakers should be guided by the understanding that decertification is an important element of any performance improvement process but decertifying too many OPOs at once would inevitably destabilize the U.S. transplant system which could lead to longer waitlists and more deaths indefinitely.

Further, I urge you to consider the fact that the OPO community, like every industry, has its own unique challenges and benefits which vary from region to region; however, each OPO is charged

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were completed incorrectly"). McGivern L, Shulman L, Carney J, Bundock E. Death Certification Errors and the Effect on Mortality Statistics. *Public Health Reports 2017*; 132(6): 669-675 (53% of the 601 original death certificates examined had major errors).

[8] Lloyd, Jennifer & Jahanpour, Ehsan & Angell, Brian & Ward, Craig & Hunter, Andy & Baysinger, Cherri & Turabelidze, George. (2017). Using National Inpatient Death Rates as a Benchmark to Identify Hospitals with Inaccurate Cause of Death Reporting — Missouri, 2009–2012. *Morbidity and Mortality Weekly Report (MMWR)*, 19. 66. 19-22. 10.15585/mmwr.mm6601a5.

[9] Priest, Jessica. 2020. One in 3 Death Certificates Were Wrong Before Coronavirus. It's About to Get Even Worse. *USA Today*. Retrieved July 13, 2020, from https://www.usatoday.com/story/news/investigations/2020/04/25/coronavirus-death-toll-hard-track-1-3-death-certificates-wrong/3020778001/

[10] Domínguez-Gil B, Coll E, FernándezRuiz M, et al. COVID-19 in Spain: Transplantation in the Midst of the Pandemic. *Am J Transplant*. 2020;00:1–6. https://doi. org/10.1111/ajt.15983

with maximizing the positive elements of its DSA and overcoming challenges which provide opportunities for creative problem solving and improvement. MTN supports President's Executive Order on Advancing American Kidney Health which aims to significantly increase kidney transplants as well as efforts to improve or replace underperforming OPOs. Further, MTN encourages innovative approaches to enhance the availability of organs, otherwise encourage donation, and further improve the organ transplantation process, including through consultation with other Federal agencies and by conducting a review of the technology system over which organ offers are promote the efficient and seamless continuation of lifesaving services.

MTN Continues to Evolve in Efficiency

Lastly, I want to share with you that MTN is continuing its legacy of innovation, and efficiency by constructing a Donor Care Unit (DCU) which will open in 2022. Mid-America Transplant (MAT) in St. Louis, Missouri was the first OPO to open a surgical recovery center for organ recovery in 1999, and MAT's center has been a major success. Similar to MAT's facility, MTN's DCU will allow braindead donors to be transferred from the hospital setting to a private center for organ recovery. DCUs are effective in minimizing organ recovery costs, increasing organ yield and improving the satisfaction of donor families and transplant surgeons with the recovery process.[11] Unfortunately, because of outdated CMS guidance, Medicare Certified Transplant Centers (CTCs) are reluctant to transfer donors to an OPO's donor care unit or organ recovery center. This is because CTCs are financially disincentivized from transferring donors to OPOs due to outdated cost report language in Medicare Guidelines.

These Guidelines provide that CTCs only receive Medicare reimbursement for organs recovered at the CTC and not for organs recovered at an organ recovery center of an OPO. CTCs remain willing and able to work with OPOs and are supportive of OPO organ recovery centers; however, CTCs can be hesitant to transfer potential donors for fear that the hospital may be financially penalized after its Medicare cost report is submitted. This remains true although Medicare guidelines provide that "usable organs" include "organs sent to OPOs," without any reference to where the organs were recovered.[12] As a [Senator or Congressman or Congresswoman] serving [Kansas or Missouri], you are in unique position to propose changes to the language in federal regulations, specifically Section 371(b)(3) of the Public Health Act, which unnecessarily complicates the organ transplantation process. In the alternative, MTN and the OPO community at large would appreciate your support in requesting and advocating for interpretive guidance from CMS which would remove the disincentive for CTCs to transfer braindead patients to organ recovery centers operated by OPOs without a financial penalty by permitting CTCs to "count" organs recovered at an OPO's recovery center.

[11] Organ Donor Recovery Performed at an Organ Procurement Organization (OPO)-Based Facility Is an Effective Way to Minimize Organ Recovery Costs and Increase Organ Yield. *Journal of the American College of Surgeons.* DOI: http://dx.doi.org/10.1016/j.jamcollsurg.2015.12.032

[12] 42 U.S.C. § 273.

MTN stands ready to work with you and your staff in a proactive way to improve the organ donation and transplant system. Please do not hesitate to contact me if you have questions or would like to discuss this letter in more detail.

Sincerely,

Jan Finn, RN, MSN
President & CEO
Midwest Transplant Network

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