MIDWEST TRANSPLANT
Give Hope. Share Life.

September 26, 2019

The Honorable Seema Verma
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

Midwest Transplant Network (MTN) is pleased to provide comments in response to the CMS Proposed Rule 1717-P. MTN is a high performing, federally-funded Organ Procurement Organization (OPO) serving Western Missouri and the State of Kansas. MTN serves a population of 5.6 million individuals, about 78% of whom are registered donors. MTN's comments below focus solely on the proposed revisions to OPOs Conditions for Coverage (CfCs). MTN is committed to expanding the number of organs recovered and transplanted by aggressively pursuing opportunities for donation and engaging in continuous quality review.

After a record year in 2017, MTN also reported record donation growth in 2018, resulting in 271 deceased organ donors and 818 organ transplants from those donors. MTN has a robust donation after circulatory death (DCD) program and utilizes continuous improvement initiatives to enhance growth in organ donation. MTN supports all efforts to save more lives through organ donation and transplantation.

I. Proposed Revision of the Definition of Expected Donation Rate, 42 CFR 486.328

MTN supports the alignment of the definition of expected donation rate to correspond with the definition utilized by the Scientific Registry of Transplant Recipients (SRTR) which assists in measuring OPO performance and identifying opportunities for improvement.

The expected donation rate per 100 eligible deaths is the rate determined by CMS from SRTR data, reported as the rate expected for an OPO based on the national experience of OPOs serving similar eligible donor populations and DSAs including rate adjustments for age, gender, race, and cause of death among eligible deaths.

MTN understands the proposed revision only impacts the definition and will not affect how the metric may be applied to evaluate OPO performance. Current federal regulations require OPOs to meet two of three outcome measures, one of which requires that an OPO's observed donation rate metric must not be significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for OPO re-certification as calculated by SRTR. It is important to

note that utilizing the SRTR expected donation rate definition does not change the performance metric currently utilized, nor does the proposed revision propose specific language to define the term "significantly lower;" therefore, additional revisions are needed to clarify the language and standards used to establish OPO outcome measures.

II. Request for Information Regarding Potential Changes to the Organ Procurement Organization 42 CFR 486.301 through 486.630; and Transplant Center Regulations, 42 CFR 482.68 through 482.104

MTN strongly supports revisions to existing OPO performance metrics. MTN is encouraged by CMS' focus on OPO performance improvement and the opportunity to assist and collaborate in the development of new metrics. MTN supports validation of any new independently verifiable metric. Of the nearly 3 million people who die in the United States, less than one percent have the potential for organ donation; therefore, the development of an accurate assessment of donor potential is critical to evaluating OPO performance.

Do the current OPO outcome measures set forth at 42 CFR 486.318 accurately and reliably reflect an OPO's performance?

Currently, OPOs self-report data, for example, the number of donors eligible to donate organs, and this data is used to calculate outcome measures. Self-reported data is often argued to be unreliable and threatened by self-reporting bias which may be intentionally or unintentionally introduced and lead to invalid estimations.[1] For this reason, current outcome measures do not accurately reflect OPO performance due to the self-reported nature of the data used to calculate outcome measures. The standard definition of an eligible donor is subjective because the definition is not verifiable 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.

What are the impacts or consequences of the current outcome measure on: (1) OPO Performance; and (2) availability of transplantable organs?

Current outcome measures do not encourage or support OPO improvement. MTN is driven to increase the number of organs recovered for transplantation by setting internal goals based on actual donor eligibility. MTN evaluates organizational performance using an outcome measure more stringent than the measures required by CMS. MTN's performance is measured internally by calculating the ratio of actual recovered donors by the number of potential donors meeting specific criteria, including eligible donors ages zero to 80, DCD eligible donors, and patients who clinically appear to meet brain death criteria, but have not been officially declared. MTN staff members work directly with physicians to advocate for brain death testing which creates the

[1] Althubaiti A. (2016). Information bias in health research: definition, pitfalls, and adjustment methods. *Journal of multidisciplinary healthcare*, *9*, 211–217. doi:10.2147/JMDH.S104807

opportunity for MTN's Family Services team to approach a potential donor's family to discuss organ, eye and tissue donation.

MTN does not support any outcome measure which assesses the number of organs made available to research organizations because these measures do not accurately assess what should be the primary mission of an OPO—maximizing the number of viable organs for transplantation. Further, any performance metric that considers organs recovered for research to determine overall OPO performance falsely inflates OPO performance, which MTN believes to be true even if the number of organs recovered for research is not as heavily weighted as the number of organs recovered for transplantation. Pursuant to CFR 486.318(a)(3), OPOs are required to be no more than one standard deviation below the national mean pertaining to two of three yield measures, including:

1. the number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation (§486.318(a)(3)(i))
2. the number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation§486.318(a)(3)(ii); and
3. the number of organs used for research per donor, including pancreata used for islet cell research.

As written, OPOs may meet any two of the three yield measures to obtain recertification; however, the third outcome measure, which assesses organs recovered for research, draws focus away from OPOs' obligation to recover organs for transplantation and fails to incentivize OPOs to pursue aggressive recovery practices, including DCD recoveries, which increase the number of organs recovered for transplantation and the number of lives saved.

MTN strongly supports the recovery of organs to aid researchers in developing therapies and cures for life-threatening disease and conditions, many of which eventually result in organ failure. In fact, MTN recovered 75 organs for researchers in 2018 and consistently recovers more organs for research than required by CFR 486.318(a)(3); however, despite that fact that MTN benefits from achieving the outcome measure related to organs recovered for research, MTN opposes the inclusion of this metric because it detracts from the overall mission of OPOs and does not accurately reflect or capture an OPO's ability to recover viable organs for transplantation.

What impact, do the certification and decertification processes for OPOs have on organ procurement and transplantation?

The certification and decertification processes play a crucial role in ensuring OPOs are prepared and accountable for providing lifesaving and life-enhancing services. Underperforming OPOs and OPOs that do not meet certification requirements are not only concerning to MTN but also represent a direct threat to the hundreds of thousands of Americans awaiting lifesaving transplants. The recertification process would be strengthened by clear, independent and verifiable metrics designed to accurately evaluate OPO performance. Further, MTN advocates for a re-certification system in which CMS engages OPOs that are unable to meet the CMS criteria for re-certification in a mandatory performance improvement process which includes a monitored

corrective action plan devised to achieve compliance with federal regulations and improve overall OPO performance.

Are there any potential, empirically based outcome measures, that could be used either in addition to, or instead of, the current outcome measures for OPOs?

MTN has been involved in the UNOS Region 8 Project over the past 12 months with the goal of establishing a consistently used definition of "eligible organ donor" to avoid the variability in OPO performance outcomes which occurs because each OPO defines "eligible organ donor" based on a subjective review of clinical information. MTN continues to support an independent, verifiable definition or metric to measure "eligible organ donor;" however, the Region 8 Project which analyzed data reported by hospitals on ventilated, in-patient deaths (ages zero to 75), combined with an in-depth clinical data review of medical records has not produced a firm recommendation for the definition of eligible donor.

MTN supports using state vital statistics reported to the CDC and published by the National Center for Health Statistics (NCHS) as the denominator to calculate OPO outcome measures. MTN further supports the development of a more granular metric which would include evaluating the effect on the eligible donor definition when applying patient ventilator status and co-morbid factors that exclude organ donation. Lastly, MTN supports a CMS data submission requirement that mandates hospitals provide data on all deaths of patients (ages zero to 75) who die from conditions consistent with organ donation to OPOs in a timely manner.

In addition to the outcome measures, are there other indicators of quality that could be used for OPOs in the CfCs?

MTN recommends using the Observed vs. Expected (O/E) organ yield metric developed by the SRTR and the Organ Procurement Transplantation Network (OPTN). This metric is risk-adjusted, based on known acceptance patterns and behaviors of surgeons at transplant centers nationwide, and more accurately reflects OPO performance in a manner likely to improve the number of organs transplanted nationwide. This performance metric is currently used by CMS to asses OPO performance and has a statistically high accuracy level.

Are there any transplant center CoPs that conflict with or should be harmonized with the OPOs CfCs? If yes, identify the specific requirements and how they would harmonize or otherwise modify the requirements.

The Federal Register 42 CFR, Part 512 lists two interesting goals: decreasing the national discard rate by 15% and decreasing the net Medicare expenditure by $88 million for the care of beneficiaries. MTN recommends several initiatives to support comments on the proposed changes to the Conditions for Coverage (CfCs) for OPOs and the Conditions of Participation (CoPs) for transplant programs.

Initiatives for Transplant Centers

1. Removal of the threat to transplant centers as imposed by a systems improvement agreement (SIA) for poor performance if increased risk kidney transplants lead to a poor outcome for the transplanted organ.
2. Support initiatives that allow a reduction in the cost of transplantation. One such effort is the expansion of OPO based recovery centers which have the potential to decrease the cost of transplanted organs realized from a cost savings from organs recovered in those facilities. The transplant centers are disincentivized to transfer donors to the OPO facility due to their inability to count the donor on the cost report, even though the donor originated and was declared brain dead in the hospital/transplant center.
3. Remove financial barriers for transplant centers for the transplantation of increased risk kidneys, such as, those recovered from DCD donors or those from complex donors.
4. Encourage financial incentives for transplant programs in the care of transplant patients who receive increased risk kidneys. This may include patient education programs detailing success rates as well as incentives for the use of organs from more complex donors.
5. Support education for patients encouraging living donation, which may include cooperation with the National Kidney Foundation's Big Ask, Big Give program to recruit non-related kidney donors; methods to allow for reimbursement of expenses incurred by living donors, including lost wages.
6. Support incentives for Transplant Centers and HLA Laboratories to jointly develop a program to increase living donation, especially as it pertains to paired donation and multiple kidney donor chain transplants.

Initiatives for Donor Hospitals:

1. Support incentives to hospitals for the cooperative development of programs with OPOs aimed at an early referral and system evaluation of potential DCD donors.
2. Support incentives for hospitals to develop innovative ways for automated referrals to OPO's and electronic transfer of critical donor information.
3. Support First Person Authorization (FPA) and the requirement for OPO's and hospitals to honor legally binding authorizations.
4. Encourage regulations to require every hospital to support DCD donation and remove barriers to donation conversations, thus allowing donor hospitals and OPO's to partner on best practice approaches.

Initiatives for OPOs:

1. Improvement in the DCD process to include development of best practices in the utilization of DCD evaluation tools; streamlining the DCD process to meet donor family timeframes; and improved education in hospitals regarding DCD donation.
2. Evaluation of OPO performance relative to success with DCD programs. A data review should include the number of DCD donations, percentage of DCD donors relative to total

donors, the effectiveness of predicting death within timeframes to successfully recover organs, the actual number of successful transplants from DCD donors to include kidneys as well as lungs, liver and pancreas.

III. Comments regarding two potential OPO outcome measures:

a. Measure One: Actual deceased donors as a percentage of inpatient deaths among patients 75 years or younger with a cause of death consistent with organ donation.

MTN supports the science behind the OPO outcome measure using state vital statistics reported to the CDC as the denominator for the donor metric. The measure is independent and verifiable; however, it may not be consistently reported across all states. Further, MTN supports a more granular evaluation of the data with application of medical rule-outs and medical record coding to incorporate standard diagnoses and procedure codes uniform with causes of death consistent with organ donation.

b. Measure Two: Actual organs transplanted as a percentage of inpatient deaths among patients 75 years or younger with a cause of death consistent with organ donation.

MTN does not support using CDC death data as the denominator for organ yield metric. The current O/E metric accurately reports the effectiveness of an OPO in placing organs of all donor types and specific to each organ. The current O/E yield metric is independent, verifiable and can be used for performance improvement purposes. The O/E calculator was developed by the SRTR and OPTN and is verifiable based on data elements from donor characteristics, such as, age, type of death, lab evaluation of organ function and other risk factors. The metric is also validated during OPTN audits and objectively reported by OPOs to convey the number of organs transplanted per donor. CMS should consider the added value provided by two independent variables: Measure One, which utilizes CDC data, assesses OPO authorization effectiveness and/or donation performance, while Measure Two (the O/E metric) evaluates the effectiveness of an OPO in placing organs for transplantation. The effectiveness of Measure Two is dependent on transplant surgeons' willingness to consider all organs. The previously recommended initiative to remove the financial disincentives which plague transplant centers would increase the rate at which transplant surgeons accept organs classified as "increased risk" for transplantation.

MTN supports President Trump's Executive Order, Advancing American Kidney Health pledge and tenants to improve regulations and remove disincentives that stand in the way of increasing transplantation.

MTN continues to be a strong supporter of the Learning System Collaborative to promote rapid transfer of knowledge to all stakeholders, OPOs, transplant centers and donor hospitals. MTN endorses this voluntary program focused on increasing the availability of deceased donor kidneys for transplantation. MTN will support future teams and regularly convene, stakeholders, such as, transplant centers and large donor hospitals. The Collaborative presents the opportunity to

engage in broad scale learning, quality improvement techniques and the rapid, systematic spreading of knowledge and best practices which benefit the entire donation community.

MTN supports increasing the supply of kidneys made available for transplantation. This includes increasing the number of kidneys available from DCD donors, living kidney donation and decreasing the discard rate for recovered organs. In 2018, 5,083 organs were recovered for transplant nationwide, but not used by transplant centers, including 3,756 kidneys. Additionally, more patients can be transplanted by improving transplant center regulations and reimbursement.

MTN appreciates the opportunity to submit comments for consideration in the improvement of the OPO CfCs and transplant center CoPs. MTN supports the revision to the expected donation rate definition, development of an independently verified donation metric and utilizing the current SRTR definition of O/E (observed vs. expected) yield metric for measuring the number of organs transplanted.

Sincerely,

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