

February 21, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W., Room 314G
Washington, DC 20201

RE: CMS-3380-P: Medicare and Medicaid Programs; Organ Procurement
Organizations Conditions for Coverage: Revisions to the Outcome Measure
Requirements for Organ Procurement Organization

Dear Administrator Verma:

The American Society of Transplantation (AST), representing a majority of medical professionals engaged in the field of solid organ transplantation, appreciates the opportunity to comment upon Medicare and Medicaid Programs' [Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization](#).

We support the need for changes in current COP metrics and urge recognition that OPO and transplant center metrics need to be aligned. Currently, transplant centers and OPOs are regulated separately and independently, yet function in an interdependent "ecosystem." We recognize that a change in one system may produce unintended consequences in another.

For example, increased organ recovery needs to be linked with increased utilization of organs by centers. This may mean changing how we consent transplant candidates and creating additional stratification of risk groups in order to use kidneys that are viewed to be at higher risk (e.g. older donor kidneys). Additionally, donor hospitals are currently not held accountable and do not have a stake in the system despite serving a crucial function in the organ supply chain.

We share the following specific comments regarding this proposal:

- While the OPO Metrics Proposal has the potential to improve metrics regarding OPO performance, the rationale for the change is misguided and misleading.

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While there are issues to be addressed, the proposal loses sight of the fact that the U.S. has one of the highest rates of organ donation in the world. Caution should be exercised to ensure that new metrics do not unintentionally compromise the already prominent standing the US enjoys in comparison to most every other country.

- Metrics are important and necessary; however, it is difficult to develop a standardized metric to capture the essence of the interpersonal dynamic that is largely responsible for higher rates of organ donation over the last several years. At its core, the interaction between trained requestors and family members of deceased potential donors is critical to the high donation rates in the US. This critical element to the performance of OPOs is not mentioned in the proposal.
- The proposal suggests eligible death data can be gathered via death certificates, which are delivered by states to the CDC. We believe there are major limitations to the use of data from these death certificates, including limited granularity, completeness and accuracy of the data. Would CMS consider using patient-level data, which could be obtained at minimal effort and cost directly from hospitals? We believe that such patient-level data would be more granular, relevant, accurate, and timely. If death certificates are to be used, the accuracy of this data will require verification to ensure adequate quality of the information.
- We recommend that *Table 2—ICD-10 Codes Excluded from the Denominator* undergo further review. The infectious diseases included here appear to be somewhat arbitrary. For example:
 - West Nile Virus is not included as an exclusion, but rabies is;
 - Only three bacterial diseases are mentioned as exclusions, but there is no explanation as to why these three were specifically chosen;
 - We do not view streptococcal sepsis as an absolute contraindication if it has been treated; and
 - All tuberculosis is excluded. Does this include latent TB?

We strongly recommend careful review of this list by a working group that includes representation from the CDC, the OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee, and representatives of the OPO and transplant communities with knowledge related to infectious disease, malignancy and other potentially impactful conditions in order to address any areas of concern related to inclusion or omission.

- We have questions regarding the exclusion of donors in the numerator of the donation rate where the OPO recovered at least one organ intended for transplantation, but no organs were ultimately transplanted. This seems

counterintuitive— why would we not want these donors counted? We want to encourage OPOs to aggressively pursue every potential donor organ, even if it is hard to place because it is from a complex donor. This proposed change, if implemented, would be a disincentive to do so. While this would drive down the discard rate, we are unclear on why the discard rate is being addressed by this proposal focused on OPO metrics? The discard rate is inherently a transplant problem, not an OPO problem. The literature suggests that aggressively pursuing older potential donors and DCD donors is critical to increase the total pool of transplantable organs; however, this proposed change would make it less likely that OPOs would aggressively pursue these organs with this metric change.

- We believe there is value in the integration of risk-adjustments into OPO performance measures. In transplantation, performance measures are adjusted based on several risk variables. For instance, there is no consideration of age, ethnicity, education or cause of death as variables that significantly impact donor conversion rates. There are ample data to show that these two variables greatly impact how likely it is that a medically suitable potential donor will become an actual organ donor.
- We do not understand the specific request, “*We are seeking comments on the threshold rate cutoffs for determining success and our methodology for calculating the threshold rates.*” The 25% threshold seems unusual, as it seems to imply that an average performing OPO would not hit the threshold; therefore, it would come under regulatory scrutiny as “underperforming.” This seems to be an aggressive bar to reach and one that is arbitrarily set. The rationale for this threshold seems to be rooted in the discard rate, which ties back to the transplant program (i.e., surgeon refusal of organs) rather than an OPO performance problem.
- We have significant concern regarding the proposed plan for decertification of OPOs that fail to meet the two core metrics. How many OPOs currently meet the proposed metrics, and how many would be certified if this plan were in effect today? Second, and related to the first point, there is high potential for massive destabilization that could severely impact the procurement of transplantable organs while an OPO is decertified and the DSA then becomes an open competition among remaining OPOs. The legal, regulatory, operational, and financial processes for one successful “bidder” to take over a decertified OPO’s DSA seem daunting and incredibly time-consuming.

What happens to those potential organ donors in that DSA during this time? Is there a pathway for appeal if an OPO fails to hit the new targets?

We are concerned about the adverse impact on donor organ availability if this plan is implemented as proposed.

- There are many references to studies with questionable methodology, including some that have been rebutted with more granular and inclusive data. There seems to be a complete absence of assessment of the methodological quality of the studies referenced; rather, studies appear to be used to support positions already assumed. We were surprised to see a proposal written with so many non-empiric statements (e.g., “We believe...”) that are based on conjecture and the opinions of a few in the field.
- The proposal should recognize that the U.S. has one of the highest rates of organ donation in the world resulting from the tremendous commitment of OPO professionals to ensure that the wishes of every donor family are respected. We do not support the language suggesting that OPO professionals are acting otherwise.

We thank you for this opportunity to provide comment and believe that there is great value in bringing all stakeholders to the table in recognition of the potential for unexpected consequences when making changes to one part of the donation and transplantation care continuum. We request that patient representatives (donor families) and providers (donor hospital intensivists, transplant providers and OPOs) meet with representatives from government charged with overseeing the quality and performance of the donation and transplantation systems (Office of the Secretary, CMS, HRSA and OPTN and CDC) to discuss methods to make our system more focused on benefiting persons with organ failure.

We are convinced that a better system can be developed, but it must be in concert with one another, and not in silos. Otherwise, we believe there is true potential to disrupt the organ donation and transplantation system, leaving both potential organ donors and those in need of organ transplant in an inexcusable situation. We look forward to working with you to achieve the best care of maximizing the organ donor’s gift and the transplant recipient’s quality of life.

Sincerely,

A handwritten signature in cursive script, appearing to read "Emily Blumberg".

Emily A. Blumberg, MD
President
American Society of Transplantation