

TRANSPLANT AND MEDICAL EXPERTS FIND CMS PROPOSED OPO REGULATIONS FAULTY, POTENTIALLY DAMAGING AND IN NEED OF FURTHER REVISION^{1 2}

THE CMS PROPOSAL IS MISGUIDED - OPOS ARE HIGH PERFORMING

American Society of Transplantation (AST), February 21, 2020.

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

“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.”

“[T]he 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.”

Northwestern Memorial Hospital, Chicago, February 17, 2020.

“[I]t is simply incorrect to state that the vast majority [of OPOs] are not performing well.”

“I am concerned that CMS is basing the need for drastic change in the structure of the organ donation system based on incomplete and unverified information.”

“I fear that the Department may decrease the availability of transplantable organs and undermine public trust in the national transplant program, by repeatedly citing a these publications that lacks scientific rigor and rely heavily on anecdotal information.”

Organ Procurement and Transplantation Network (OPTN), February 20, 2020

“It should be noted that 2019 was another record-breaking year in donation and transplantation. The U.S. saw a 10.7% increase in the number of deceased donors and an 8.7% increase in the number of transplants. From 2013 to 2019, deceased donation has increased by 44%. Deceased cardiac death (DCD) donors increased by 125% and deceased brain death donors increased by 30%.”

¹ These public comments can be found online: <https://beta.regulations.gov/document/CMS-2019-0187-0001/comment>

² Information from public comments submitted by individual Organ Procurement Organizations (OPOs) and the Association of Organ Procurement Organizations (AOPO) are not included in this document and can be found online at <https://beta.regulations.gov/document/CMS-2019-0187-0001/comment>

CMS' PROPOSED PERFORMANCE THRESHOLD IS ARBITRARY AND WILL CAUSE SEVERE DISRUPTION TO THE SYSTEM

American Society of Transplantation (AST), February 21, 2020.

"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.

"[T]here is high potential for massive destabilization that could severely impact the procurement of transplantable organs while an OPO is decertified ... What happens to those potential organ donors in that DSA during this time?"

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

American Society of Transplant Surgeons (ASTS), February 20, 2020

"[W]e cannot overstate the potential disruption that decertification of an OPO could cause for TCs and patients in an OPO's DSA."

"The uncertainty and potential disruption resulting from the decertification of an OPO has the potential to significantly and adversely impact our patients and potential patients in the affected DSA."

University of Minnesota Medical School, February 18, 2020

"The results of such a massive decertification, or anything even remotely resembling it, would significantly disrupt the system likely leading to a substantial decrease in donation. ... we suggest there be a cut-off that is based on statistically validated methods, such as a standard deviation variation from the mean."

Emory Healthcare, February 20, 2020

"We are concerned that the metrics as proposed would result in decertification of over half of the OPO's which could cause a major disruption to the ability to deliver organs for transplant that would have a negative impact on our ability to care for our patients."

Organ Procurement and Transplantation Network (OPTN), February 20, 2020

"In addition to concerns over the methodology applied, the OPTN has concerns over disruption to the system in the event of decertification of multiple OPOs simultaneously. While CMS acknowledges the possibility of disruption in donation services, the idea that the remaining OPOs would take over the decertified areas and immediately implement improvements in order to meet the top 25th percentile of performance for the next cycle is not realistic."

“[T]he OPTN expresses its concerns about the proposed definition of “donor;” the stability and validity of the proposed metrics and data source; and the proposed performance threshold and lack of accompanying transition plan to ensure system stability and continuous service following the possible decertification of more than half of the nation’s OPOs.”

“Even above-average performing OPOs would be defined as “low performing” and subject to decertification. Based on the data provided, this metric would lead to decertification of at least 64% of the OPOs in the country. This comparison threshold is unprecedented. While this metric could be an aspirational or stretch goal, it is an unrealistic basis for decertifying OPOs and CMS does not offer a rationale to support it.”

Northwestern Memorial Hospital, Chicago, February 17, 2020.

“There is not scientific or mathematical rationale given for this [top 25%] threshold. There are myriad of unintended consequences CMS must weigh against a perceived opportunity to drive improvement.”

Baystate Medical Center, Beth Israel Deaconess Medical Center, Boston Medical Center, Brigham and Women’s Hospital, Boston Children’s Hospital, Dartmouth Medical Center, Hartford Hospital, Lahey Hospital and Medical Center, Maine Medical Center, Massachusetts General Hospital, New England Donor Services, Rhode Island Hospital, Tufts Medical Center, UMass Memorial Medical Center and Yale New Haven Hospital, February 19, 2020

“It takes training, strong organization culture and years of building a team, best practices, collaboration with donor hospital and transplant partners and instilling the importance of this mission and respect for the OPOs in the community to be successful .Disruption of such a system through precipitous decertification of OPOs without significant confidence that the assessment of performance is accurately calculated would come with a significant cost to donation and the availability of organs for transplantation.”

“It is concerning that an above average performing OPO is being categorized under the proposed regulations] as under-performing and subject to decertification. This concern is particularly acute given that the calculations under the [proposed regulations] have not been validated...”

Spectrum Health System, Michigan.

“Spectrum Health is concerned that the agency has not fully assessed the real impact of how many OPOs would be de-certified under the 25 percent performance requirement.”

Sanford Medical Center, Sanford Health, North Dakota, February 21,2020

“The proposed cut-off in which up to 75% of OPOs could face decertification does not seem based in science, but instead seems arbitrary and inexplicable. The results of such a massive decertification, or anything even remotely resembling it, would significantly disrupt the system.”

American Association of Tissue Banks (AATB), February 12, 2020

“AATB urges CMS to provide further rationale for setting a required performance threshold at the top 25%, especially given that it redefines above average performing OPOs (as a matter of math) as “low performing” and automatically puts the majority of OPOs at risk of decertification without opportunity to present mitigating factors or an improvement plan. As a result, the proposed measure if implemented could result in a large number of OPO de-certifications, which could significantly disrupt the existing system for tissue donation and procurement. The AATB is concerned that this type of destabilization to the existing system of OPOs may create an immediate and unnecessary shortage of tissue grafts available to heal people in need.”

Piedmont Transplant, Georgia, February 20, 2020

“The creation of a 25th percentile cutoff that could lead to decertification of up to 33 of 58 OPOs is too strong, and not the best method to enhance improvements from the proposed initiative.”

THE CMS PROPOSED METRIC IS FLAWED

American Society of Transplant Surgeons (ASTS), February 20, 2020

“[I]n light of the high transplant rate threshold described in the OPO Proposed Rule, we do not support a single metric system that would rely solely on the organ donor rate to assess OPO performance.”

“[I]t is not appropriate to hold OPOs solely responsible for the transplant rate associated with the organs it procures. In fact, area [transplant centers] nephrologists, dialysis facilities, and others all play a role in determining the transplant rate for organs procured by an OPO.”

American Society of Transplantation (AST), February 21, 2020

“We want to encourage OPOs to aggressively pursue every potential donor organ ... This proposed change, if implemented, would be a disincentive to do so.”

American Society of Reconstructive Transplantation (ASRT), February 21, 2020

“CMS does not include VCAs [face, hands, arms, etc.] under the definition of an “organ” for purposes of calculating the donation and transplant rates ... and could readily be included in its calculation of OPO donation and transplant rates.”

Baylor Scott and White Health, February 21, 2020

“Without addressing risk aversion, which OPOs have little control over, or other factors like a new allocation systems, the Proposed Rule may not accurately measure OPO performance.”

Greater New York Hospital Association February 20, 2020

“GNYHA recommends that CMS not adopt the proposed organ transplantation rate outcome measure because it will not lead to increased organ donation and transplantation.... CMS should instead retain the current observed-to-expected outcome measure.”

Sanford Medical Center, Sanford Health, North Dakota, February 21, 2020

“The proposed rule directs OPOs to increase the number of organs transplanted. We want that outcome as well, but we want to be clear that the decision to accept an organ rests with us, the transplant center, and not with the OPO.”

DEATH CERTIFICATE DATA IS INACCURATE AND SHOULD NOT BE UTILIZED BY CMS FOR AN OPO PERFORMANCE METRIC

Connecticut Office of the Chief Medical Officer, February 14, 2020

“A literature review reflects that 30-60% of death certificates inaccurately reported the cause of death (COD). Even setting aside the number of death certificates filed in the US each year that have COD errors, CMS must take into account that [Cause of Death] statements on DCs are only a distillation of the decedent’s clinical course and, therefore, incomplete when evaluating for organ donation potential or exclusion.”

Vermont Department of Public Health, Office of the Chief Medical Examiner, February 20, 2020

“Death Certificates do not require secondary diagnoses which may include medical conditions that would preclude donation. Absent these secondary diagnoses, the decedent who would never be medically acceptable for donation and transplant could be counted in the donation rate denominator, artificially and negatively impacting the OPO’s performance under the proposed donation rate metric.”

“Such a degree of inaccuracy in cause of death statements may result in MCOD inaccuracies and an unreliable denominator for the proposed donation rate metric. This is especially concerning given CMS intent to use the donation rate metric to compare OPO performance across jurisdictions with differing death investigation systems, likely resulting in inaccurate assessments of OPO performance.”

Greater New York Hospital Association February 20, 2020

“Death certificates often contain inaccurate and insufficient information. Most death certificates are completed by hospital physicians who have not been trained on how to complete a death certificate. Additionally, death certificate instructions do not call for reporting secondary diagnoses that are unrelated to the cause of death, and can affect organ donation potential.”

Bergen County Medical Examiner Office, New Jersey, February 19, 2020

“Using death certificates as the only or main metric for OPOs, the listed information on the death certificates would be misleading, useless and not productive for OPO purposes.”

American Society of Transplant (AST), February 21, 2020

“We believe there are major limitations to the use of data from these death certificates, including limited granularity, completeness and accuracy of the data.”

American Society of Transplant Surgeons (ASTS), February 20, 2020

“[I]t is our understanding that the MCO uses state data on inpatient hospital deaths and that each state has different rules for the collection of this data. If state databases are not collecting data using uniform reporting rules, they may be unsuitable for use to compare OPO performance in different states.

[R]efine the MCO data files before they are used for the assessment of OPO performance and to consider whether there are other inpatient hospital death data sources available that might be more suitable for this purpose.”

Renal Support Network, February 21, 2020

“We are deeply concerned about the proposed rule which relies upon a state-provided death certificate as the deceased donor’s cause of death information. Death certificates are broadly reported as inaccurate. Death Certificates exclude secondary diagnoses, like cancers, that did not cause the death, but regularly rule out deceased organ donation. Death certificates include no information on the most critical factor required for organ donation: neurological injury that leads to brain death. “

Riverside County Sheriff Coroner, February 21, 2020

“I have significant concerns about using cause of death (COD) on a death certificate as a metric for OPO performance. Even setting aside the number of death certificates filed in the US each year that have COD errors, CMS must take into account that COD statements on DCs are only a distillation of the decedent's clinical course and, therefore, incomplete when evaluating for organ donation potential or exclusion.”

Hospital Espanol Auxilio Mutuo Transplant Center, Puerto Rico, February 21, 2020

“ [U]nless a massive educational effort is undertaken by the government to reach any person responsible for filling certificates of death as to the information that must be documented, using strictly all applicable ICD 10 Codes, the denominator for donation rates will not allow to exclude donor with contraindications for organ donations in the DSA.”

SYSTEM-WIDE PERFORMANCE IMPROVEMENT APPROACH TO REFORM MISSING FROM PROPOSAL

Organ Procurement and Transplantation Network (OPTN), February 20, 2020

“[T]he CMS proposal represents a step back to a punitive culture of blame in healthcare.”

American Society of Transplant Surgeons (ASTS), February 20, 2020

“We are concerned that unintended system consequences may follow from well-intended changes that address only one component of the complex transplant ecosystem.”

“While we agree that OPO metrics revision is necessary, the desired system change is unlikely without a more comprehensive approach: A broader system metrics change is necessary if transplant care is to be optimized.”

National Kidney Foundation (NKF), February 21, 2020

“As proposed, however, the regulation is unlikely to achieve its intent without significant unintended effect. It is imperative that CMS pairs the new OPO measures with the development and implementation of a new accountability framework for transplant centers.”