

September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: File Code: CMS-1717-P; Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage (“Proposed Rule”).

Dear Administrator Verma:

On behalf of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST), we are pleased to have this opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) on Organ Procurement Organization (OPO) and Transplant Center (TC) metrics, in response to the Request for Information (RFI) included in the Proposed Rule. ASTS is a medical specialty society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. The mission of ASTS is to advance the art and science of transplant surgery through patient care, research, education, and advocacy. AST is an organization of more than 4,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, organ donation, and service to the community.

ASTS and AST commend CMS and the Administration more generally for recognizing the potential for increased kidney transplantation to transform the lives of those living with Chronic Kidney Disease (CKD). We strongly support increasing the availability of kidney transplantation, and we appreciate that both the Proposed Rule and the July 10, 2019 Executive Order on Advancing Kidney Health (AKH Executive Order) recognize the role of OPO and TC metrics in increasing patients’ access to kidney transplantation.

The Proposed Rule includes both an RFI on the Organ Procurement Organization (OPO) and Transplant Center (TC) outcomes metrics and a solicitation of comments on a proposal to align the current Medicare certification regulations’ definition of “expected donation rate” with that used by the Scientific Registry of Transplant Recipients (SRTR).¹ We support aligning the SRTR and OPO Conditions for Coverage (CfC) definitions of “expected donation rate” as described in the Proposed Rule. The more critical questions raised by the RFI are addressed below.

¹ The OPO Conditions of Certification (CfCs), at 42 CFR 486.302, define “expected donation rate” as: the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas (DSAs), which is then adjusted based on certain hospital characteristics. The SRTR determined that a more precise method to calculate an OPO’s expected donation rate would be to base it on the national experience for OPOs serving similar eligible donor populations and DSAs and then adjust for patient characteristics, that is age, sex, race, and cause of death. CMS is proposing to revise the CMS regulations to incorporate the SRTR definition of “expected donation rate.”

The current OPO CfCs and TC OPTN outcomes requirements contribute to the lack of adequate access to transplantation in distinct but interrelated ways. First, as noted in the Proposed Rule, OPO performance is currently assessed based on “eligible donors” and “eligible deaths” as self-reported by OPOs. As noted in National Kidney Foundation’s (NKF’s) “Position Statement on Reform of OPO Metrics,” this leads to “ambiguous, noncomparable statistics on donor data.”² Second, while CMS regulations encourage OPOs to increase the number of all types of organs from all types of donors (from ideal to organs at risk of discard, brain dead, or donation after cardiac death (DCD)), TCs are incentivized to accept organs selectively, for fear of “flagging” by the OPTN or a drop in SRTR “star ratings” (which may trigger loss of contracts from non-Medicare third party payers). The inconsistency between OPO and TC outcomes requirements have led to calls for cross-cutting outcomes measures, with some calling for outcomes measures that also include dialysis facilities in a population-based approach.⁴

It is critical that each of these problems be addressed in concert for modification of outcomes metrics to increase kidney transplantation rates. **If OPO metrics are modified but TC outcomes requirements continue to discourage TCs from using organs at risk of discard, the availability of kidney transplantation for our vulnerable patients is not likely to increase appreciably, if at all.**

I. OPO Outcomes Metrics

The current CfCs for OPOs (at 42 CFR 486.318(a) and (b)) require that an OPO meet two of the three following outcome measures:

- The OPOs donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle;
- The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re–recertification, as calculated by SRTR;
- The OPO data reports, averaged over the 4 years of the re-certification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield.

Thus, the current OPO metrics measure three different aspects of OPO performance: The first measures OPO performance in comparison with the performance of other OPOs (donation/comparative performance); the second measures OPO performance in relation to expected donation for the OPO patient population (donation/potential performance); and the third measures OPO performance as it relates to transplanted organs (“yield”).⁵

² <https://www.kidney.org/news/position-statement-reform-organ-procurement-organization-opo-metrics>

⁴ Schold JD, Buccini LD, Phelan MP, et al. Building an Ideal Quality Metric for ESRD Health Care Delivery. Clin J Am Soc Nephrol. 2017;12(8):1351–1356. doi:10.2215/CJN.01020117. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5544503/>.

⁵ AOPO actively sought and supported a change in yield metrics from Organs Transplanted per Donor (OTPD) to a more reliable and validated metric of Observed organs recovered for transplant vs. Expected organs transplanted (O/E). The O/E reflects performance relative to the acceptance patterns and behaviors of US transplant centers. CMS currently utilizes the O/E metric in assessing OPO performance.

We believe that current OPO outcomes measures with respect to donation do not accurately or reliably reflect an OPO's performance because these metrics rely upon definitions of "eligible death" and "donor" that are self-reported and subject to reporting bias. These terms are used to define the denominator of the donor conversion ratio, which is one of the principal metrics by which OPOs are judged. The donor conversion ratio is generally defined as the number of donors per eligible deaths within an OPO's territory. For the purposes of these regulations, a "donor" is defined as a patient whose organs are recovered with the "intent to transplant," while an "eligible death" is currently defined as a hospitalized, brain-dead patient ≤ 75 years of age (previous cutoff was ≤ 70 years of age) without contraindications to donation. These metrics are subjective, allow for misinterpretation of data, and may wrongly incentivize "cherry-picking" of deceased donors or the utilization of donation after cardiac death (DCD) donors to maximize statistics.

These definitions are fatally flawed. First, eligible deaths and donors are self-reported by OPOs with little oversight. More importantly, the definition masks missed opportunities for donation. Having a patient formally declared brain dead that is not routinely performed for every in-hospital death, that requires extra documentation and testing, and that a hospital may not pursue if there is no interest or potential for donation. If an OPO fails to aggressively pursue potential donors, then many potentially brain-dead donors will never be formally declared brain dead and thus will not be counted as eligible. Such a situation represents a missed opportunity for organ donation but will not be counted under current OPO performance metrics.

We strongly believe that it is necessary to measure OPO performance using reliable, objective, verifiable, and practicable definition of all potential deceased donors. By contrast, the current OPO donation metrics are subjective, fraught with vagary, and not founded upon measurable or validated data. This is the fundamental flaw in the current OPO assessment system.

Unfortunately, it does not appear that any existing database is perfectly suited for use in the assessment of OPOs. The Proposed Rule requests comments on an OPO performance measure that would be based on available data on inpatient deaths derived from the CDC Detailed Mortality File and the National Center for Health Statistics' National Vital Statistics Report.

We agree that CDC inpatient mortality data and any other relevant publicly available data sources should be carefully evaluated for possible use in assessing OPO performance. There are a number of key advantages of using the CDC inpatient mortality data (with appropriate exclusions for conditions incompatible with transplantation) for the purpose of OPO assessment, and the feasibility of using this CDC data has been assessed by at least two OPOs.⁶ Hospitals routinely report all inpatient deaths to the CDC, so using this data for the purposes of OPO assessment would not impose any new reporting requirements on hospitals, and the CDC data source captures potential Donation after Cardiac Death (DCD) donors. While the current metric does capture DCDs that end up being donors, it misses those who are DCD but not considered as a potential donor. In light of the increasing trend toward the use of DCD donors (20% in 2019), it appears likely that consideration of all DCDs that meet inclusion criteria would result in the performance of additional DCD transplants.

⁶Am J Transplant. 2019 Jun 14. doi: 10.1111/ajt.15492. [Epub ahead of print]

However, the CDC database does have a number of significant shortcomings⁷. As the Proposed Rule itself notes, using this data source “might include potential donors in the denominator who would never clinically qualify as organ donors” and for this reason may understate OPO success in retrieving transplantable organs. In addition, questions have been raised about the accuracy of hospital reporting of the cause of death and medical contraindications to organ donation,⁸ and such inaccuracies have the potential to make it difficult to reliably apply exclusion criteria and result in wastage of OPO resources. Nor is it clear that use of CDC inpatient mortality data accurately accounts for all geographic variation that may impact OPO performance. Variable consent rates, time constraints resulting from the proximity of the recovery team vis-à-vis the donor hospital, and local funeral home limitations that interfere with organ recovery may impact the use of CDC inpatient mortality data to assess OPO performance. Finally, it is not evident that CDC inpatient mortality data will capture potential donors who die in hospital emergency departments.

Recommendation: We recommend that representatives of CMS, HRSA (including representatives from the OPTN and SRTR), and the CDC form a Task Force to work with donor hospitals, OPO, and Transplant Center representatives to examine publicly available data sources, including CDC inpatient hospital mortality data, to identify and redress potential shortcomings of these data sources for use in conducting OPO assessments. The Task Force should assess the practicability of supplementing publicly available inpatient mortality data sources in a manner that would identify ventilated patients who die in the hospital as well as patients who die in emergency departments.

Recommendation: We also recommend that use of any new definition to replace the term “eligible death” (including but not limited to the use of CDC data to define this term) be phased in. Specifically, we recommend that during the initial period, OPOs should be provided with their performance data “as if” the revised definition of eligible death were in effect, but that this data should be provided for OPO information only and should not be used for CMS assessment purposes. The initial period should be used to refine the eligible death definition based on OPO feedback. Once the methodology for determining eligible deaths is refined, the distribution of OPO performance using the new eligible death denominator could be determined. (This distribution may vary significantly from the distribution using the current metric). At that point, a new minimum comparative performance metric might be defined. We would suggest that whatever definition is selected as a quality metric, there should be a mechanism in place for periodic review of the metric to assess it is functioning as intended and if it is not, that the necessary adjustments can be made.

II. Transplant Center Outcomes Requirements

We are grateful for CMS’ recent action to eliminate outcomes requirements for reapproval of transplant centers. Unfortunately, eliminating CMS outcomes requirements for TC reapproval alone is not likely to eliminate risk averse organ acceptance practices unless this change is accompanied by elimination or

⁷ This data base does not include deaths that occur outside the hospital setting; however, organs derived from deaths that occur outside the hospital setting would be extraordinarily difficult to recover since there are no current systems set up to connect OPOs with these smaller venues.

⁸ Lloyd J., Jahanpour E., Angell B., et al. Using National Inpatient Death Rates as a Benchmark to Identify Hospitals with Inaccurate Cause of Death Reporting — Missouri, 2009–2012. MMWR Morb Mortal Wkly Rep 2017;66:19–22. DOI: <http://dx.doi.org/10.15585/mmwr.mm6601a5>

modification of outcomes requirements imposed by the OPTN as a condition of TC membership and the elimination or modification of the SRTR TC star ratings methodology. Application of these requirements dissuades TCs from accepting organs associated with poorer outcomes, since “flagging” by the OPTN Membership and Professional Standards Committee (MPSC) can have important repercussions for a TC, including lengthy quasi-legal hearings and public designation of the TC as an OPTN member that is “not in good standing.” Likewise, the SRTR’s recent adoption of a five-star rating system, which is also based on one-year outcomes, creates a similar disincentive, since SRTR star ratings can impact patient access and the availability of non-Medicare payer contracts.⁹

Recommendation: *We recommend that OPTN TC outcomes requirements and SRTR star ratings be eliminated or revised to ensure that they do not incentivize suboptimal rates of organ utilization by discouraging use of organs at higher risk of failure that are otherwise safely transplantable.*

III. Toward an Integrated Metric

As noted above, the OPO and TC outcomes metrics currently work at cross purposes. Elimination of TC outcomes requirements from OPTN membership criteria and SRTR star ratings methodologies would go a long way toward reconciling this problem. This would likely increase acceptance rates of “organs at risk of discard,” which would go a long way in improving OPO metrics as well. However, we are hopeful that the TC and OPO community, working together, can go further. In addition, an integrated metric would also be appropriate to consider for the health systems that are responsible for referring patients for transplantation to better align metrics across the entire spectrum of ESRD care. The ASTS and the AST have convened a Joint Metrics Task Force to consider the potential for a common metric for OPOs, TCs, and dialysis facilities that would encourage collaboration toward the joint goal of increasing patient access to transplantation.

IV. Other Comments

Finally, we believe that it is important to address the role of donor hospitals in the organ recovery process. Unfortunately, trauma centers are the single most frequent source of donor organs, and hospitals have no financial or regulatory incentive to ensure that potential donors and their families are

⁹ Schold JD, Buccini LD. Five-tier futility: This should end any remaining debate. *Am J Transplant.* 2019; 19: 607; Schold JD, Buccini LD, Poggio ED, et al. Association of Candidate Removals From the Kidney Transplant Waiting List and Center Performance Oversight. *Am J Transplant.* 2016; 16: 1276-84; Schold JD, Arrington CJ, Levine G. Significant alterations in reported clinical practice associated with increased oversight of organ transplant center performance. *Prog Transplant.* 2010; 20: 279-87.; Schold JD, Buccini LD, Goldfarb DA, et al. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. *Clin J Am Soc Nephrol.* 2014; 9: 1773-80; Schold JD, Buccini LD, Srinivas TR, et al. The association of center performance evaluations and kidney transplant volume in the United States. *Am J Transplant.* 2013; 13: 67-75. Jay C, Schold JD. Measuring transplant center performance: The goals are not controversial but the methods and consequences can be. *Curr Transplant Rep.* 2017; 4: 52-58.; Schold JD, Miller CM, Henry ML, et al. Evaluation of Flagging Criteria of United States Kidney Transplant Center Performance: How to Best Define Outliers? *Transplantation.* 2017; 101: 1373-80; Comparing Scientific Registry of Transplant Recipients posttransplant program-specific outcome ratings at listing with subsequent recipient outcomes after transplant. Wey A, Salkowski N, Kasiske BL, Skeans M, Schaffhausen CR, Gustafson SK, Israni AK, Snyder JJ. *Am J Transplant.* 2019 Feb;19(2):391-398. doi: 10.1111/ajt.15038. Epub 2018 Aug 31. PMID:30053337; Schold JD, Andreoni KA, Chandraker AK, et al. Expanding clarity or confusion? Volatility of the 5-tier ratings assessing quality of transplant centers in the United States. *Am J Transplant.* 2018; 18: 1494-501..

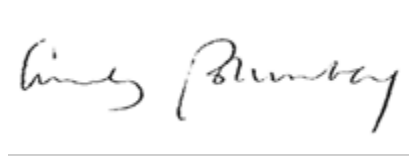
provided the opportunity to give the gift of life. We believe that the hospital conditions of participation should include more specific requirements for hospitals to notify OPOs of potential donors and to share relevant medical records. We also believe that the OPO CfCs should include a requirement that OPOs establish a process to monitor or audit donor hospital compliance.

We appreciate the opportunity to submit these comments and would be delighted to work with CMS to reform the OPO and TC metrics in a manner that would facilitate increased access to renal transplantation. If you have any questions or if we can be of any further assistance, please contact ASTS Advocacy Manager Jennifer Nelson-Dowdy at Jennifer.nelson-dowdy@asts.org or AST Executive Director Shandie Covington at scovington@myast.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "Lloyd E. Ratner".

Lloyd E. Ratner, MD, MPH
President
American Society of Transplant Surgeons

A handwritten signature in black ink, appearing to read "Emily Blumberg".

Emily Blumberg, MD, FAST
President
American Society of Transplantation