

February 20, 2020

Ms. Diane Corning
Ms. Alpha Banu-Wilson
Center for Medicare & Medicaid Services
Department of Health & Human Services
7500 Security Boulevard
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Ref. CMS-3380-P – *Revisions to the Outcome Measure Requirements for Organ Procurement Organizations*

Ms. Corning and Ms. Banu-Wilson:

The Organ Procurement and Transplantation Network (OPTN) is pleased to submit further comment on the Proposed Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, published in the Federal Register on December 23, 2019. The OPTN supports CMS' continued efforts to engage the donation and transplant community and the public at large on this important issue.

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%. While the opioid epidemic has impacted donation, this alone does not account for the majority of the growth in deceased donation; in the past two years, drug intoxication, including opioid overdose, accounted for only 13% of all donor deaths.¹ The system reflects seven consecutive years of growth as a result of the combined and continuous improvement efforts of OPOs and transplant programs alike.

The OPTN wishes to reiterate its support for the use of timely, consistent and independently-reported data applied with proven statistical methodologies for assessing the performance of and regulating the nation's transplant system, including OPOs. In the comments that follow, the 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. We also make several recommendations to CMS at the conclusion of our comments.

As was the case with the OPTN's September 17, 2019 submission to CMS, this letter is a result of the combined feedback of a broad cross-section of the OPTN Board of Directors and committee volunteers.

Discussion of Proposed Rules

Definitions

Definition of "Donor"

The proposal changes the definition of donor to one who has "at least one vascularized organ...transplanted," which differs from the definition used by the OPTN, the SRTR, and most countries in the world that perform

¹ Based on OPTN data as of February 9, 2020. "Donor organs recovered by donor mechanism of death."
<https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/>

transplants.^{2,3,4} Currently, the definition of “donor” is understood to be an individual from whom (an) organ(s) is recovered *for the purpose of transplantation* following declaration of death. Further, the proposed definition states that if the pancreas is recovered for research or islet cell transplantation, it is considered a transplanted organ. CMS gives three primary reasons for making this change: 1) to discourage the discarding of procured organs, 2) to encourage transplantation of every organ, including those from single-organ donors, and 3) because it is easier to verify the existence of a donor who had at least one organ transplanted compared with donors who did not have an organ transplanted. It is also asserted that “OPOs influence transplant hospital practice and the organizations should work together to increase the number of transplants. This can be done through education and sharing information.”

There are several problems with this proposed change and the assumptions made by CMS to support it. In order to continue to increase the number of organs transplanted, many things need to happen. OPOs must aggressively pursue the recovery of organs from all potential donors. Numerous studies have identified that the biggest opportunity for increases in deceased donation is within the pool of older, medically complex and non-brain dead potential donors;⁵ reports have shown that OPOs outperform the expected rate of donation from younger brain dead donors.⁶ OPOs that work to appropriately expand the pool of potential donors inevitably pursue donors where the procured organs are declined by all transplant centers. It is important to remember that declining an organ offer is a clinical decision made by transplant surgeon and is not within the control of the OPO. However, OPOs should be incentivized under the CMS regulations to pursue older, more complex and non-brain dead donors to expand the pool of available organs for transplantation. Yet it is this group of donors that, despite the OPO’s aggressive pursuit, are more likely to result in no transplants. Eliminating these “zero organ” donors from the numerator does not incentivize pursuing the pool of medically complex, older and non-brain dead marginal donors that have been identified as the largest opportunity for growth.

Additionally, the part of the definition change that considers a pancreas recovered for research a transplanted organ is concerning. With no standard definition for “recovered for research,” this flies in the face of the third primary reason for the change stated: the need for more verification. While we appreciate the statutory requirement for this element to be included in OPO performance measurement, we suggest that CMS consider moving this calculation outside of the donation and transplant rate into a third measurement, thereby satisfying the legal requirements without complicating the core performance measurement focused on transplantation.

Definition of Potential Donors (“Denominator”)

The community recognizes the benefit of independently-verifiable data to measure performance. However, there is also a need for the data to have enough clinical precision to accurately assess performance, and for the data to be timely enough to be fair and actionable. The CDC MCOD data meets this first requirement in that they are independently reported, but they are insufficiently precise or timely to be used in the manner they are being proposed for *regulatory* application. First, the administration of mechanical ventilation, a prerequisite for deceased donation, is not captured in this dataset. The probability that an in-patient death was a ventilated death is variable based on age, cause of death, etc., and these characteristics may not be consistent nationwide, creating

² Organ Transplantation & Procurement Network. Policy 1.2: Definitions. <https://optn.transplant.hrsa.gov/governance/policies>. Accessed January 31, 2020.

³ World Health Organization. Global Glossary of Terms and Definitions on Donation and Transplantation. November 2009. Available at: <https://www.who.int/transplantation/activities/GlobalGlossaryonDonationTransplantation.pdf?ua=1>. Accessed January 31, 2020.

⁴ Domínguez-Gil B, Delmonico FL, Shaheen FA, et al. The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. *Transpl Int*. 2011;24(4):373-378.

⁵ Klassen DK, Edwards LB, Stewart DE, Glazier AK, Orlowski JP, Berg CL. The OPTN Deceased Donor Potential Study: Implications for policy and practice. *American Journal of Transplantation*. 2016; 16(6):1707-1714.

⁶ “OPOs exceed expectations when collecting organs from young brain-dead donors.” *Lives Lost, Organs Wasted*, *Washington Post*. December 20, 2018.

variation that directly impacts true “donor potential” that will be masked by using this dataset. This could lead to a metric that is not accurate as applied across OPOs located in different regions of the country. Second, the data as reported from this particular source is not sufficiently timely to be actionable. For example, the most recent data available from this set is from 2018, released just this month. If an OPO were up for evaluation in February 2020, it would be evaluated based on performance practices from over two years ago, regardless of any improvements it may have made since. With significant annual increases in organ donation over the past seven years, this lag in evaluation could result in falsely identifying OPOs as low performing and it could also miss identification of OPOs whose recent performance has dropped. Additionally, with the time delay in availability of data required to calculate the denominator for a donation rate, if the proposal were in effect today, OPOs would just now be learning what the donation rate and organ transplantation rate goals are for 2019. More frequently-available data would improve the applicability for evaluating performance in today’s environment. Alternatively, it may be that CMS is considering applying the data for donation performance (numerator) to a denominator over a different, earlier time frame. This too raises significant concerns as a valid methodology given that donor potential in any one DSA can vary significantly from year to year. Third, MCOD data lacks the relevant clinical information that may be associated with actual donation potential. Finally, the administrative reporting of cause of death codes is known to vary by state, particularly depending on whether death data are reported through a centralized medical examiner’s office versus a local coroner. Such variations could impact the accuracy of a donation metric calculated at the OPO level from this data source.⁷

Other studies have used the MCOD data to estimate donor potential. The OPTN Deceased Donor Potential Study (DDPS)⁸ convened experts in donation and transplantation to assess donor potential in the US. One part of that study used the MCOD data along with a set of exclusion codes to exclude patients with a cause of death that is a contraindication to donation. The CMS proposal also uses a set of exclusion codes, however it is a small subset of the codes used in the DDPS. It is unclear how CMS arrived at their set of exclusion codes. The DDPS also developed a more refined estimate, first by using a set of inclusion codes to determine if a patient had a cause of death consistent with organ donation, and second by including a probability of ventilation. The OPTN would recommend that CMS consider a wider range of exclusion codes to better adjust for actual donor potential as calculated using this dataset.

Alternatively, the OPTN recommends CMS consider a different more direct and granular dataset to calculate donor potential. To remove possible biases associated with OPO self-reporting of data in the absence of a precise definition of “potential donor,” the OPTN recommends that ventilated in-patient death data be transmitted independently, preferably directly from the donor hospitals’ electronic medical records (EMRs) to the OPTN with sufficient clinical detail to assess if a death met the proposed definition (“conditions consistent with organ donation”). As mentioned in the OPTN’s September comment, other stakeholders have also recommended access to this dataset as an available and more accurate mechanism for assessing and improving OPO performance.^{9,10}

Overview of Proposed Metrics

Currently, the existing CMS measures are designed to assess two distinct aspects of OPO performance. The current donation rate is intended to measure an OPO’s ability to identify, authorize, and recover organs from

⁷ Warner M, Paulozzi LJ, Nolte KB, Davis GG, Nelson LS. State variation in certifying manner of death and drugs involved in drug intoxication deaths. *Acad Forensic Pathol.* 2013;3(2):231–237

⁸ Klassen DK, Edwards LB, Stewart DE, Glazier AK, Orlowski JP, Berg CL. The OPTN Deceased Donor Potential Study: Implications for policy and practice. *American Journal of Transplantation.* 2016; 16(6):1707-1714.

⁹ Doby BL, Boyarsky BJ, Gentry S, Segev DL. Improving OPO performance through national data availability. *American Journal of Transplantation.* 2019 Oct; 19(10):2675-7.

¹⁰ Neil, H., Overacre, B., Rabold M., Haynes CR. PDF file. “Table 9: OPO Metrics Beyond Organ Yield.” *OPTN Ad Hoc Systems Performance Committee Report to the OPTN Board*, 10 June 2019 (p. 9). https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf

potential donors in its service area. The current organ yield metric is intended to assess an OPO's ability to get organs placed and transplanted from actual donors.

The two proposed metrics, *donation rate* and *transplantation rate*, use the same denominator, rendering them too closely related to accurately and distinctly measure these different components of OPO performance. Blending the two aspects of performance reduces the ability to assess OPOs based on either metric. The reasoning for these two overlapping measures is stated in the proposal: "We selected both donation rates and transplantation rates in order to reduce the risk that resources would be diverted to focus on one measure rather than increasing overall efforts to address both types of measures, which we believe could result in more single-organ donors and minimizing discarding of transplantable organs." However, based on the proposal, OPOs must "pass" both metrics. If an OPO is required to "pass" both metrics, it ensures that an OPO could not solely focus on one of them. If the proposed donation rate metric accurately assesses an OPO's ability to convert potential donors into donors, it would be better to have the second metric measure a distinctly different area of performance: placement of organs for transplantation from the pool of actual donors.

Donation Rate Metric

The concept of a donation rate metric is to measure how well an OPO is able to convert a potential donor into an actual donor. This metric, if accurately calculated, is an important measure of performance. However, the definitions of donor and potential donor that CMS has proposed are problematic as described above. Based on an analysis of the 2017 data using these definitions, CMS shows that there is a wide variation in donation rates among OPOs. CMS asserts this variation is the result of factors within the control of OPOs. In addition to the concerns over the donation rate, the OPTN does not see evidence that this assertion is founded in fact. OPOs do not control who dies within their DSA, and without adequate risk adjustment, the donation rate may be reflecting underlying differences in potential rather than OPO performance. Deaths compatible with donation and offer acceptance rates have been shown to vary across the country, and the proposed metrics disregard the impact these factors have on available organs.¹¹

Organ Transplantation Rate Metric

It is also important to point out that transplant programs, not OPOs, make the medical decision on whether to accept an organ offered for a specific patient. This is the practice of medicine. Organ utilization is most appropriately understood in the context of doctor/patient decision making, recognizing the importance of preserving doctor and patient autonomy. Metrics and policies that are not well constructed have the potential to drive clinical decision making in ways that impinge on this autonomy and harm healthcare provider/patient relationships. As such, OPOs should be held accountable for performance related to aggressive placement of organs for transplant, but the metric should evaluate that performance recognizing that the transplant program is ultimately responsible for utilization.¹² The organ yield model appropriately adjusts for that reality by factoring in expected transplant rates based on organ donor factors.

The proposed organ transplantation rate metric is too closely correlated with the donation rate metric and fails to account for the variation in the number of organs transplanted from actual donors due to clinical considerations outside the OPO's control. For example, a 55 year old, diabetic, DCD donor is unlikely to have as many organs transplanted as a previously healthy 20 year old brain dead donor. The proposed regulations assume that these two donors have the same organ transplantation potential and that the percent of these donors is the same across all DSAs, a significant assumption not supported by the data. If one OPO has 20% of its donor potential in the category of a 20 year old brain dead motor vehicle accident donor and another OPO has 5% of its donor potential

¹¹ Sheehy E, O'Connor KJ, Luskin RS, Howard RJ, Cornell D, Finn J, Mone T, Selck FW, Delmonico FL. Investigating geographic variation in mortality in the context of organ donation. *American Journal of Transplantation*. 2012 Jun; 12(6):1598-602.

¹² Husain SA, King KL, Pastan S, et al. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Netw Open*. 2019; 2(8):e1910312. doi:10.1001/jamanetworkopen.2019.10312

in that same category, even with identical performance, the second OPO will look significantly worse under the CMS proposed transplant rate measure. In contrast, the organ yield models currently in use address this issue by adjusting for age and other clinical factors which impact the likelihood a particular organ will be transplanted from each donor. These models, developed by the SRTR and the OPTN, compare observed performance against what would be expected based on the clinical picture of the donor. These models not only assess OPO performance but have the added benefit of identifying areas for improvement at the donor level as well as at the individual organ level. These models are widely accepted within the transplant community.

CMS expresses concern that the current yield metric reinforces the status quo by calculating the expected yield based on the current national performance. Concern is expressed that OPOs would not be held to the standard of transplanting as many organs as possible if the chosen threshold reinforces the status quo. CMS could instead identify a more aggressive threshold above what is expected based on past data. This would be preferable to the organ transplantation metric proposed.

Risk Adjustment

The proposal states “Since our criteria for the denominator takes into consideration many of the clinical characteristics associated with possible organ donation (the age of the potential donor, the inpatient hospitalization, and contraindication to donation), we believe all appropriate risk-adjustments to the clinical characteristics of the donor potential have been made.” The restrictions used in the definition exclude deaths with little to no likelihood of resulting in donation and transplant, however they do not account for the variation in likelihood of donation *within* the population meeting the definition. Not all potential donors have the same probability of becoming a donor due to clinical considerations outside OPO control, like donor age. This could lead to incorrectly assessing OPO performance and thus decertifying OPOs that may not in fact be underperforming. We encourage a clinical review of the CDC MCOD data, or any data to be used for regulatory purposes, to identify clinical differences in populations outside OPO control across DSAs, and to risk adjust the proposed metrics based on these findings.

Performance Threshold and Decertification Methodology

It is the OPTN’s view that the best way to hold OPOs accountable is to develop an accurate, clear metric with a rationale that has been adequately justified. The methodology being proposed for identifying an OPO for decertification compares all OPOs to those performing at the top 25th percentile of performance based on the previous year of data. 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.

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. High performing OPOs have had years to attain their current level of performance. An OPO that absorbed one or more additional service areas would, for example, require time to assess staffing needs and conduct additional hiring if needed; assess and build resources required to operate; assess and make needed structural and process changes; and develop effective relationships with the community and donor hospitals before being able to demonstrate improvement. Without any regulatory relief from the performance measures, there is a disincentive for a higher performing OPO to take on such a significant operational change and expense. The OPTN suggests CMS consider incentives that at a minimum include regulatory relief from the performance measures while improving a lower ranking or decertified OPO’s performance.

Another significant concern with the proposal is the lack of any appeals process or structured improvement process. Based on 2017 data, 64% of the OPOs would be decertified based on one year of data that lacks clinical precision or any risk adjustment. Under the CMS proposal, OPOs would have no process for requesting consideration of mitigating factors or for demonstrating improvement between the assessment and decertification. OPOs that failed to meet the performance threshold would benefit from an opportunity to provide evidence of mitigating factors or demonstrate improvement through a process similar to the application for mitigating factors and system improvement agreement procedures provided to transplant programs that are identified for lower than expected one year post-transplant outcomes. Providing such a process would foster improvement in OPOs and minimize the potential for falsely identifying low performance that is actually attributable to factors beyond the OPO's control. Such a process would also avoid the disruption and inherent delay in improvement that would result from the decertification process, the application process for the open service area and the time required for the OPO awarded the service area to implement effective improvement.

More importantly, disruption to the system on any scale is dangerous – with over 113,000 people waiting for a transplant, reduction in service, even if temporary, inevitably means lives lost.

Assessment Based on One Year of Data

The OPO certification cycle is four years, and while CMS proposes to calculate these rates yearly, flagging for decertification is proposed to be based on the most recent one year of data available at the end of the cycle. While analyses for the proposed measures were provided based on 2017 data, it is not clear how stable the data used for calculation of these measures are over time. Is one year of data long enough to accurately measure an OPO's performance? Currently, OPOs are assessed using 3 years of data and the proposal does not provide any statistically-based justification for shortening the time period. Further, the proposed rules also express a desire to not "penalize OPOs that have improved their performance by using older data," though the proposed data source is significantly time-delayed. If the metric is not stable, then the shorter the time frame, the more likely an OPO is to fail by chance rather than as a reflection of performance.

OPTN Recommendations

The goal of creating metrics to better assess the performance of all aspects of the transplant system is fully supported by the OPTN. Like many other medical communities, the OPTN has made a concerted effort to proactively transition towards a "just culture"¹³ based on performance improvement that embraces partnerships between regulators and organizations with an emphasis on quality and systems improvement. The Membership & Professional Standards Committee (MPSC), the OPTN's membership and compliance governing body, has instituted a practice of partnering with members by providing feedback on and recommendations to improve members' performance, compliance, and quality systems. In contrast, the CMS proposal represents a step back to a punitive culture of blame in healthcare.

The OPTN recognizes the need for objective, verifiable measures that accurately assess performance with the goal of better serving the patients who depend on us. With that goal in mind and based on the metrics that CMS has proposed, the OPTN has the following recommendations:

1. The system should work towards collecting detailed clinical death data on all inpatient deaths to better assess the donation potential throughout the country and in each DSA in particular. While this would fill the need for better assessing an OPO's performance in converting a potential donor to an actual donor, it would also provide a wealth of information that could be used to identify specific areas for improvement for all OPOs. These data would be best obtained directly from the donor hospitals. It would require changes to both technology as well as processes. It would also require a regulatory action from CMS to

¹³ Committee on Quality of Health Care in America, and Institute of Medicine (US). *To err is human: Building a safer health system*. National Academies Press, 2000.

make this possible. It is understood that this is neither quick nor easy. However, the benefit of that data could help to propel the field of donation and transplantation forward while providing much more accurate metrics with which to assess OPO performance. If nothing is done now, the system risks being in the same position 5 years from now with no solution in sight. While acquiring these data from the donor hospitals is the goal, some OPOs have been able to obtain monthly electronic death reports from all of their donor hospitals with enough clinical detail to be able to identify actual donor potential.¹⁴ These reports, if standardized and required from all OPOs, could potentially be a source of the same data. While this would not be ideal state in terms of efficiency, it could be the beginning of a process that would allow for verifiability of the data being submitted.

2. Do not change the current definition of “donor”.
3. CMS should continue to use the current organ yield metric instead of the proposed organ transplantation rate. It is well-accepted in the community and has the benefit of rich risk adjustment because of all of the verifiable data that are already collected on actual donors. If CMS is concerned that the observed to expected yield leads to the status quo, they could carefully and scientifically adjust the threshold to higher than “average” performance.
4. Whenever possible, performance metrics should be risk-adjusted to be an accurate assessment of OPO performance rather than factors outside of OPO control.
5. An appeals process for OPOs that do not meet the performance threshold and are flagged for decertification should be included prior to decertification. This is especially true when that decertification is based on metrics that lack the precision to accurately assess performance. Mitigating factors must be considered prior to OPO decertification, with costs and system disruption, which may not ultimately result in improved performance by another OPO.
6. In the absence of the preferred foundational data for the donation rate metric (that is, ventilated death data reported directly from donor hospitals), the OPTN would make the following recommendations in the interest of furthering the conversation.
 - a. Conduct and provide the results of a clinical review of which causes of death should be included in the exclusionary codes proposed as well as the reason for those not included.
 - b. Consider the use of inclusion codes as described in the DDPS or in the CALC method referenced in the proposal.
 - c. Determine how to best risk adjust the metric given the data being used for the assessment.
 - d. Use the current definition of donor for the numerator.

The OPTN appreciates the opportunity to participate in the process for improving the overall organ donation and transplantation process. We applaud CMS requesting comment from all stakeholders through the public comment process, and welcome the opportunity to collaborate with CMS and the SRTR to further this effort.

Sincerely,



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¹⁴ *OPO Data Feasibility Study*. OPTN Contract Task 17 Report to HRSA, June 2016.