

## **CMS Finalizes New OPO Certification Regulations Requiring Significant Improvements in Donation and Transplant Rates**

On November 20, 2020, CMS made public new OPO outcomes standards to go into effect for the 2022-2026 OPO certification cycle. The finalized standards are substantially similar to those proposed earlier this year, and the new measures demand significantly improved performance by the Nation's OPOs. If the new standards were applied today, 22 OPOs would be de-certified and an additional 12 would be at risk of losing their contracts through an open bidding process.<sup>1</sup>

The final regulation adopts two measures for evaluating OPO performance: The "Donation Rate" and the "Transplant Rate." The new Donation Rate measure will officially eliminate the prior disincentive for OPOs to pursue single organ donors, but unlike the current measure, will count as donors only those from whom at least one organ is retrieved. The new Transplant Rate measure incentivizes OPOs to retrieve pancreata for islet transplants, since such pancreata "count" as an organ for the purpose of determining donation and transplant rates. Likewise, the new rule incentivizes OPOs to retrieve lungs and kidneys "en bloc" to retrieve both kidneys, and to retrieve Kidney, Intestine, Liver, Lung, and Pancreas Segments 1 and 2, since these "count" as two organs under the new Transplant Rate measure.

Both the Donation Rate and Transplant Rate are measured based on "donor potential." Donor potential is the number of inpatient deaths within the DSA among patients 75 and younger with a primary cause of death that is consistent with organ donation. Despite strong objections from AOPO and many individual OPOs, the donor potential in an OPO's service area is determined based on death certificate information obtained from the Center for Disease Control and Preventions' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of Death (MCOB) file. The accuracy of MCOB data is highly questionable but this data is readily available without imposing additional reporting requirements on hospitals.

The final regulation adopts a three- tier classification system for evaluating OPO performance on these two measures. In order to retain certification (and its contract) without going through an open bidding process, an OPO's performance on Donation Rate and Transplant Rate measures must meet or exceed a threshold established based on the performance of the top 25% of OPOs during the year prior to the OPO performance year (Tier 1). An OPO that fails to meet the thresholds for one or both measures but whose performance is at or above the median for all OPOs on both measures will not be renewed automatically but will be able to bid for renewal of its contract through an open bidding process (Tier 2). An OPO whose performance on either of the two measures is below the median for all OPOs will receive a notice of de-certification, which will be subject to appeal.

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<sup>1</sup> To determine where your OPO would stand if the new standards were applied today, see Table 3 published as part of the Regulatory Impact Statement accompanying the final rules, and included as Attachment A. Those OPOs indicated in italics would be at risk of losing their contracts and those in italics and **boldface** print would be de-certified.

The new outcome measures will be implemented on August 1, 2022, to coincide with the start of the next certification period; however, CMS will begin to provide OPOs with data on their performance under the new standards before the new certification period begins. OPOs will receive results of their 2019 performance on the outcome measures in the first quarter of 2021. Thereafter, assessments will be provided annually during the first quarter based on the OPO's performance two years prior, and each OPO that fails to meet the thresholds will be required to "identify opportunities for improvement and implement changes that lead to improvement" in the applicable measure(s).

Whether or not an OPO will be recertified after the 2022-2026 certification cycle will be based on performance data for 2024, with threshold rates determined based on data from 2023. An OPO will not know the actual threshold rates that will be utilized to determine which "Tier" it is in until after its 2024 assessment period is complete. Since recertification decisions will be made based on performance data for 2024, underperforming OPOs essentially have from 2021 through 2023 to institute the necessary changes.

Even those OPOs that are identified as meeting the thresholds based on the data in the final rule cannot rest on their laurels. While the final rule indicates which OPOs would need to improve (and by how much), based on the data available today, the thresholds that must be met will change each year based on the performance of the top 25% of OPOs. The thresholds that will have to be met for an OPO to retain certification after the end of the 2022-2026 certification period likely will be higher than the thresholds published in the final rule, and only a handful of the top performing OPOs are likely to consider themselves safe. Thus, the system is designed to exert strong pressure on OPOs to improve their performance.

The adoption of new OPO standards—and especially the adoption of the new Transplant Rate measure—has the potential to significantly impact Transplant Centers. OPOs are likely to significantly increase pressure on area Transplant Centers to accelerate decision making and to accept organs at risk of discard. In this respect, the new OPO certification measures are in direct conflict with the SRTR's five star rankings and the current OPTN trigger for MPSC review, both of which are based on patient and graft survival and both of which strongly discourage Transplant Centers from accepting organs at risk of discard or transplanting high risk recipients. Modification or elimination of these disincentives has now become critical not only for Transplant Centers but for OPOs as well. ASTS has long advocated for elimination or modification of these outcomes requirements and anticipates renewed efforts along these lines in the year to come.