



## CMS NEWS

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### **CMS Finalizes Policy that will Increase the Number of Available Lifesavings Organs by Holding Organ Procurement Organizations Accountable through Transparency and Competition**

Today, the Centers for Medicare & Medicaid Services (CMS) is finalizing a rule that is designed to increase the supply of lifesaving organs available for transplant in the United States by requiring that the organizations responsible for organ procurement be transparent in their performance, highlighting the best and worst performers, and requiring them to compete on their ability to successfully facilitate transplants.

The rule enacts sweeping reform of the Medicare Conditions for Coverage (CfCs) for Organ Procurement Organizations (OPOs). OPOs, which are entities that seek organs for the 113,000 Americans on waitlists, must meet minimum quality measure thresholds in the CfCs to receive Medicare and Medicaid payment. The current measures are based on self-reported data and disincentivize OPOs from aggressively seeking any and all available organs. The rule creates new measures designed to hold OPOs accountable for seeking – and ensuring transplant of – as many organs as possible, and the calculation of the measures is based on objective data. The rule is designed to increase the number of organs available for transplant, helping tackle one of the longstanding problems in the organ transplant system, namely that the need for organs greatly exceeds the supply. Indeed, as the capstone of President Trump’s July 2019 [Executive Order on Advancing American Kidney Health](#), the rule is the last of a long list of Trump Administration actions designed to increase the supply of donated organs for Americans on waitlists for lifesaving transplants.

“Thousands of Americans are languishing on organ waitlists, and twenty Americans every day die waiting for an organ. This is unacceptable and the Trump Administration is acting. Today’s final rule is an opportunity to improve the quality of life for millions of Americans,” said CMS Administrator Seema Verma. “Organ transplants offer hope for a fuller life untethered from dialysis machines and waiting lists. We’re helping to increase the supply of donated organs available for transplant by making sure OPOs are performing at optimal levels.”

Under current rules, OPOs must meet minimum thresholds of two of three outcome measures: the donation rate of eligible donors, the observed – or actual – donation rate, and donor yield (meaning the number of procured organs donated per donor). The existing measures are calculated using data self-reported from OPOs. CMS had heard from stakeholders that these measures and the self-reported data disincentivized OPOs from seeking as many organs as possible, like less-than-perfect organs that would nevertheless be lifesaving for some recipients. CMS is replacing the existing three quality measures with two new measures, and calculating them based on objective data. The first new measure is a donation rate measure; it measures the number of organs an OPO has procured from eligible donors in its donation service area. It is designed to ensure OPOs pursue all potential donors, even those only able to donate one organ. The second measure is an organ transplantation rate measure. No longer will OPOs be required to simply procure an organ; it must actually be transplanted. This creates an incentive for OPOs to transplant and use all viable organs. The measures are calculated using objective data from the Health Resources and Services Administration (HRSA) and the Centers for Disease Control (CDC). Under the new rules, underperforming OPOs will compete for their organizational contracts – which are necessary for them to function as OPOs – and the worst performers will be unable to renew their contracts.

The number of Americans on waiting lists far exceeds the number of available donor organs. The long wait for organs can be devastating for patients and families, especially those suffering with kidney disease. Many of these patients progress to late-stage kidney failure, face high mortality rates, only have treatment options that are expensive and do not produce an acceptable quality of life, and, perhaps most disappointing, are unable to receive transplants because there are not enough kidneys donated to meet the current demand for transplants. This final rule directly benefits each person currently waiting for a transplant because it will increase the supply of available organs by encouraging OPOs to procure as many organs as possible, a goal of the President's Executive Order.

A key part of the organ donation system, OPOs are non-profit organizations responsible for evaluating and procuring organs for transplant from deceased donors. These organizations also provide support to donor families, clinical management of organ donors, and professional and public education about organ donation. Currently, there are 58 OPOs in the United States, each assigned to its own DSA. Several government agencies, including CMS, regulate different aspects of the U.S. organ transplant system. Federal law tasks CMS with conducting surveys of OPOs and recertifying them (no less frequently than every four years) based on whether they meet the OPO CfCs, which include outcome and process measures.

While OPOs are a critical part of the organ donation system in the United States, some stakeholders have argued that many are underperformers and have faced few consequences for their poor performance. Current organ recovery and transplantation measure regulations are outdated and allow OPOs to subjectively report organ recovery rates. For example, currently OPOs can self-report eligible donor pool numbers. This means that they can exclude data for donors that have a lower likelihood of providing a viable organ. This self-reporting means they may be able to manipulate their measure performance in a way that makes it appear better than reality.

The specific areas in which CMS is finalizing changes to OPOs include the following:

- The first measure change is to the donation rate measure. The changes encourage OPOs to pursue all potential donors, even those who are only able to donate one organ.

- The second measure change is to the organ transplantation rate measure. OPOs will no longer receive credit for simply procuring an organ – it must be actually transplanted to count. This creates an incentive for OPOs to procure and match all viable organs with recipients. CMS is also no longer accepting self-reported data from OPOs and will instead calculate outcome measures using death certificate data, a more reliable verifiable data source to calculate OPO's outcome measures.
- CMS is making outcome measure performance public to increase transparency. This will highlight OPOs that fall outside of the top 25% in donation and transplantation rates and helps OPOs identify areas for improvement, giving them an opportunity to take timely action to save more lives. The increased accountability – to the public and to CMS alike – promises to incentivize OPOs to procure more organs for transplantation.
- Under the final rule, OPOs are encouraged to match the lowest donation and transplantation rates of the top 25% of OPOs, a ranking that will be publicly available annually. OPOs with rates that are below the top 25% will be required to take action to improve their rates through a quality assurance and performance improvement (QAPI) program. Reviewing OPO performance every 12 months will allow CMS to more quickly identify OPOs that need improvement.

Today's final rule is only one of many actions the Trump Administration is taking through CMS related to kidney care and organ donation. The agency is also working to improve outcomes for transplant candidates and patients, as well as thousands of Medicare beneficiaries who undergo costly and burdensome in-center dialysis treatments. Many of CMS's efforts were announced in President Trump's 2019 [Executive Order on Advancing American Kidney Health](#), including a CMS-led stakeholder learning system, as part of the [End-stage Renal Disease \(ESRD\) Treatment Choices Model](#). The learning system, which was finalized on September 29, 2020, will work with participants in the ETC Model and other key stakeholders, such as transplant centers and OPOs, and use learning and quality improvement techniques to help increase the availability of deceased donor kidneys for transplant.

For a fact sheet on the final rule (CMS-3380-F), please visit:

<https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos>

To view the final rule (CMS-3380-F), please visit: <https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf>

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