



What You Need to Know About the Organ Procurement Organization Proposed Rule

What is being proposed?

The Centers for Medicare and Medicaid Services (CMS) is proposing changes to how Organ Procurement Organizations (OPOs) are regulated by the federal government. Under these proposed changes, OPOs would have better incentives to seek out possible organs for transplant from a larger pool of deceased donors and ensure these organs are transplanted by transplant centers, rather than discarded. The proposal also includes new policies for holding OPOs accountable for their conduct by establishing performance benchmarks, more frequent assessments of performance, and processes for quality improvement for OPOs that do not meet these standards.

What's the nitty gritty of the proposal?

The regulations for OPOs are outlined in their Conditions for Coverage. Currently, the Conditions for Coverage include three outcome measures that OPOs must meet every four years in order to receive payment from the federal government. The proposed changes would replace the three outcome measures with two: a transplant rate measure and a donation rate measure. Both would be based on a denominator of inpatient deaths among patients 75 years or younger from any cause of death that is consistent with organ donation. This denominator is objective, transparent, and reliable and will allow for better understanding of OPO performance.

Under the proposal, CMS would review OPO performance every 12 months, in addition to the four-year recertification cycle inspections. OPOs would have to meet a threshold of performance based on the donation and transplantation rates of the top 25 percent of OPOs. OPOs with rates that are statistically significantly below the top 25 percent would be required to improve their rates through a quality assurance and performance improvement (QAPI) program that CMS would assess annually.

Why does this matter to patients?

There are 113,000 patients waitlisted for organs, 95,000 of whom are waiting on a kidney. Many of these patients will die or become too sick to be transplanted while waiting for an organ. CMS estimates that the proposed changes will make thousands more organs available for transplant each year. Patients have also voiced a desire to understand OPO performance and how it impacts their likelihood of receiving a transplant.

OPOs have an essential role in the transplant system of evaluating patients who may become deceased donors and making sure their organs are transported to transplant centers that can use them. The proposed changes are intended to make the system more efficient, to make sure that OPOs are seeking out as many deceased donor organs as possible, that transplant centers are using them, and that OPOs that are not operating efficiently improve their performance.

Why is this happening?



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Over the past year, much attention has been paid to OPOs and their performance. While many OPOs do a great job recovering organs, supporting donor families, and transporting organs to transplant centers, there have been concerns that other OPOs are leaving valuable organs behind, not being held to an enforceable performance standard, and thus are contributing to the organ shortage. The proposed regulation fulfills a requirement of the [Advancing American Kidney Health initiative](#) directing the Department of Health and Human Services to propose a regulation that would revise the regulatory requirements for OPOs to enhance procurement and utilization of organs.

What has NKF done on this issue in the past and what are next steps?

Maximizing the use of kidneys for transplant is a longstanding NKF policy priority. NKF's ["Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards"](#) published in October, 2018, provided the first nationwide roadmap to reducing kidney discards. In addition, we have been concerned that the current regulations for OPOs are not leading to as many organs being procured from deceased donors as possible. In 2019, NKF released a [position statement](#) and submitted [comments](#) to CMS emphasizing both the need for changes to the OPO regulations and a more holistic look at how all the partners in transplant system can work hand-in-hand to more efficiently deliver organs to patients in need.

NKF will be working with our Public Policy Committee to respond to the proposal. We welcome your feedback, which can be sent to Miriam Godwin (Miriam.godwin@kidney.org).

Where Can I Learn More?

Read NKF's [press statement](#) on the proposed rule. View CMS' [summary](#) of the proposal or view the [full document](#). Also, feel free to reach out to NKF's Government Relations team at Miriam.godwin@kidney.org.