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Regulatory Uncertainty Ahead For Organ Transplant System

By **Rachel Park and Troy Barsky** (January 22, 2026, 6:04 PM EST)


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In the final months of 2025 and amid intensifying scrutiny from the federal government and public alike, organ procurement organizations, or OPOs, initiated multiple legal challenges against a final rule issued by the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services in November 2020.

The OPOs allege that the regulation will introduce disruptive competition into a cooperative organ procurement system, lead to the mass decertification of existing OPOs and cause widespread disruption across the organ transplantation ecosystem in 2026.

While it remains to be seen whether the courts overseeing the pending cases will find the challengers' arguments compelling, there can be little doubt that decisions made this year will pose significant implications for OPOs and transplant hospitals.

Inspiration for the final rule at issue originated in 2019, when President Donald Trump — then in his first term — issued Executive Order No. 1387.[1]

The order directed the secretary of the U.S. Department of Health and Human Services to, within 90 days, propose a regulation that would revise OPO rules and evaluation metrics to establish more "transparent, reliable, and enforceable objective outcome measures" and enhance the procurement and utilization of organs available — despite deceased donation — for the purposes of delivering more organs for transplantation and doubling the number of kidneys available for transplant by 2030.

To accomplish this goal, the final rule introduced a new, competition-centric model for assessing OPO performance that ranks participating organizations based on their relative performance on two measures: organ donation rate and transplantation rate.

As directed by the final rule, the Centers for Medicare & Medicaid Services place each OPO within one of three tiers according to how the organization compared with the top 25% of donation and transplantation rates for OPOs; this ranking is subject to a confidence interval to account for any statistical errors in the calculation.

CMS assesses OPOs' performance each year by reviewing data from two years prior and the most recent 12 months of data from the Center for Disease Control and Prevention's multiple-cause-of-death files, though such data will have a one-year time lag. However, only the final year of the cycle will be used to

determine recertification and competition. The tiers are described in Title 42 of the Code of Federal Regulations, Section 486.318.

- Tier 1 encompasses OPOs with donation rates and organ transplantation rates statistically at or above the top 25% threshold rate. These OPOs will be considered to have met the outcome measures for recertification, and their designated service areas will not be opened for competition so long as the organizations meet other conditions of coverage during the recertification survey.

- Tier 2 encompasses OPOs with donation rates and organ transplantation rates statistically at or above the median threshold rate, but not high enough to rank the organization within Tier 1. Their designated service areas will be opened for competition, and the OPOs must demonstrate that they have made necessary changes to justify recertification.

- Tier 3 encompasses OPOs that have one or both measures that are not statistically equal to or greater than the median rate. These OPOs will receive notification of decertification at the end of the recertification cycle, and their designated service areas will be opened for competition following any administrative appeal.

Under the final rule, all but the OPOs ranked in the agency's top tier face potential loss of their designated service area and decertification in 2026, when their existing 4-year certifications are subject to renewal.

By CMS' own estimate in the final rule, only 24 of the then 58 OPOs would be placed in the top tier; the designated service areas for all remaining OPOs would be open to competition and possible takeover by other OPOs.

Under the prior regulation, a designated service area for an OPO was not opened for competition until that organization had been decertified and exhausted its administrative appeal rights under Title 42 of the Code of Federal Regulations, Section 486.314.

However, under the final rule, a Tier 2 OPO's designated service area will be opened for competition once the OPO is designated as Tier 2, while a Tier 3 OPO's designated service area will be opened for competition after exhaustion of any administrative appeal. A decertified OPO cannot compete for any open designated service area.

Legal Challenges and Government Responses

In preparation for an expected wave of decertification in 2026, several OPOs have united to file litigation against the 2020 final rule. A few challenges are currently ongoing: LifeLink Foundation v. Kennedy in the U.S. District Court for the Middle District of Florida; New England Donor Services v. HHS in the U.S. District Court for the District of Columbia; and HonorBridge v. CMS in the U.S. District Court for the Eastern District of North Carolina.

The litigation challenging CMS' final rule identify ways in which the regulation could be found to be inconsistent with statutory law, congressional intent and prior agency rulemaking.

Plaintiffs in the LifeLink case, filed on Aug. 1, 2025, argue the final rule radically changes the certification system in violation of the Administrative Procedure Act by relying on only two overly simplistic and

closely correlated performance measures — donation rate and transplantation rate — that fail to meet statutory requirements for an evidence-based certification process with multiple outcome and process measures.

The OPOs further contend that the final rule ignores critical geographic, socioeconomic and donor-specific factors affecting donation and transplantation rates across different designated service areas, relies on flawed and outdated state death certificate data to determine donor potential, creates mathematical bias against larger OPOs, and bases certification decisions solely on the final year of the certification cycle without accounting for prior yearly improvements.

The plaintiffs warn that the final rule will cause immediate and irreparable harm by forcing decertification of high-performing OPOs and transforming the cooperative organ procurement system into a "Hunger Games" situation that threatens chaos and disruption to the entire organ and transplant ecosystem in 2026.

The plaintiffs in the New England Donor Services case, filed on Dec. 12, reiterate the same basic arguments made in the Florida case but raise additional challenges focused on the competitive nature of CMS' new performance measures.

The organizations argue that statutory provisions make clear that market competition is fundamentally incompatible with organ donation and procurement, pointing to requirements that mandate each OPO to have a designated service area and prohibit the designation of more than one OPO for each service area.

The plaintiffs note that hospitals are required to work exclusively with their designated OPO absent a waiver from CMS following public notice and comment, and even if granted, such waivers would only apply to the requesting hospital. This geographic exclusivity, they contend, renders CMS' final rule fundamentally incompatible with congressional intent and statutory language.

Furthermore, the plaintiffs argue that CMS' final rule unconstitutionally makes competition a condition of federal funding, asserting that when Congress authorizes agencies to conduct competition for federal projects, it must do so explicitly — which it has not done in this context.

In the HonorBridge case, filed on Jan. 7, the plaintiff asserts all of the arguments made by plaintiffs in the above cases and adds that due to CMS' improper outcome measures, it has been placed in Tiers 2 and 3 in prior interim measures.

Allegedly, this not only creates an existential crisis for HonorBridge in 2026, but has already caused it harm in that a hospital in its designated service area sought and was granted a waiver from CMS to work with an OPO other than HonorBridge due to its interim ratings, prompting a **separate lawsuit** against CMS in March 2025.

The government has only advanced its perspective in the LifeLink case. In a responsive brief and cross-motion for summary judgment filed on Dec. 19, HHS argued that the court lacks jurisdiction because plaintiffs failed to exhaust administrative remedies, citing the U.S. Supreme Court's 2000 decision in Illinois Counsel v. Shalala as precedent for precluding preenforcement challenges to CMS regulations.

On the merits, the government defends the secretary's 2020 outcome measures as entitled due respect as it "rests on factual premises within the agency's expertise," citing the Supreme Court's 2024 decision

in Loper Bright Enterprises v. Raimondo.

HHS also contends that the regulation includes process measures that plaintiffs are time-barred from challenging pursuant to the Supreme Court's decision in Corner Post Inc. v. Board of Governors of the Federal Reserve System, also in 2024.

The agency further asserts that death certificate data is, despite acknowledged error rates, CMS' best available option for information that incorporates geographic differences. Notably, the government concedes that its current position — that CMS can certify entirely new OPOs — directly contradicts prior rulemaking, but argues that "the Secretary does not now believe that those statements reflect the 'single, best meaning' of the statute."

The government further defends the 25% threshold for Tier 1 OPOs as tailored to meet the benchmark of doubling kidney transplants by 2030 in accordance with Executive Order No. 13879.

This litigation introduces additional uncertainty in the organ transplantation system, which will only be exacerbated should the plaintiff OPOs prove to be successful and secure vacatur of the final rule.

Implications for Transplant Hospitals and Organ Procurement Organizations

Given that CMS has annually released OPO performance metrics, most OPOs should already have a preliminary idea of their performance and likely ranking. Organizations expecting to fall within Tier 2 or 3 in 2026 should be prepared to compete for their existing designated service area and consider available options to challenge any forthcoming decertification through administrative appeal.

Hospitals can also access CMS' public database to determine how the OPO assigned to their designated service area is performing. Facilities in designated service areas with underperforming OPOs may consider seeking a waiver from CMS that would permit them to work with an OPO outside of their area, as some hospitals have done.

This approach may ease any disruption to transplants, should their designated OPO face competition to retain their certification or be decertified by CMS.

Finally, tissue banks should monitor changes in OPO certifications in the coming year, as a change in the designated OPO may require a pivot to the newly selected organization.

Looking Ahead

Entities within the organ transplant ecosystem should also keep in mind that — regardless of ongoing litigation — CMS is currently planning to roll out a new proposed rule to govern OPO outcome measures.

The proposed rule is currently before the Office of Information and Regulatory Affairs and was developed following CMS' Dec. 3, 2021, request for information. Starting in September 2024 and as recently as Dec. 17, 2025, the agency scheduled and held several meetings with interested OPOs to discuss the topic.

Until CMS' proposed rule is published, the transplant community cannot know what changes CMS is planning to OPO performance measures, if any. However, if the questions CMS raised in its request for

information are any indication, the changes could be wide-ranging and significant.

OPOs and all other interested parties in the interwoven transplant ecosystem should be prepared to submit comments when the proposed rule is published to voice potential concerns before the rule is finalized.

Given the considerable pressure mounting on the federal government to address the long waiting lists for individuals in need of organ transplants, all ecosystem entities should consider paying close attention to breaking CMS communications and litigation updates, as adjustments to regulatory oversight could have a tremendous impact on OPOs, transplant facilities, tissue banks and other relevant stakeholders in the coming years.

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[1] https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to.

[2] LifeLink Foundation et al. v. Kennedy et al., 8:25-cv-02042-KKM-SPF (M.D. FL.).

[3] New England Donor Services, Gift of Life Michigan, and We Are Sharing Hope SC v. HHS, 1:25-cv-04329.

[4] HonorBridge v. CMS et al., 4:26-cv-00003 (E.D.N.C.)