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# Organ Procurement Rule Could Spur 'Perverse Incentives'

By **Mark Payne**

Law360 (October 6, 2026, 4:48 PM EDT) -- A Florida judge's green light for a new federal rule meant to cull poorly performing organ procurement organizations could trigger more turmoil for an industry already under intense public scrutiny.




The Centers for Medicare & Medicaid Services' rule that alters how organ procurers are rated will decertify the lowest performing organizations. (Sebastian Gollnow/picture-alliance/dpa/AP Images)

Last week, U.S. District Judge Kathryn Kimball Mizelle granted summary judgment to the Centers for Medicare & Medicaid Services, finding the agency didn't violate federal law when it finalized a 2020 rule that alters how organ procurers are rated.

Under the rule, the agency will decertify the lowest performing organizations, a system the donor groups and some experts say will create a "Hunger Games"-style competition for federal certification.

Kim Krawiec, a professor of law at the University of Virginia, told Law360 the system could create pressure on organizations to pursue donations in less-than-ideal circumstances.

Krawiec said she fears that may happen despite concerns over an organ system that has seen two procurers decertified in the past year for pushing forward with donations despite donors not officially pronounced dead.

"If there's just a bunch of pencil pushers focused on the bottom line, then that could lead to perverse incentives that create more problems rather than solve the ones we already have," Krawiec said.

The rule is meant to increase organ donation rates at a time when more than 100,000 people are on the organ transplant waiting list, according to the United Network for Organ Sharing, which oversees the nation's organ transplant system.

The rule incentivizes organizations that meet donation and transplantation metrics by placing them in the top tier and automatically awarding that group recertification while immediately decertifying those in the bottom tier.

**'Light a Fire'**

In a 96-page ruling, Judge Mizelle held that CMS didn't violate the Medicare Act or the Administrative Procedure Act when the agency finalized the rule in December 2020.

The ruling is a major loss to LifeLink Foundation Inc. and four other groups that challenged the agency.

The groups oversee seven of the nation's more than 50 organ procurement organizations. Each organization serves a distinct geographic region, called a donation service area, or DSA, which make up the nation's Organ Procurement and Transplantation Network.

Judge Mizelle found that the final rule doesn't violate 42 U.S.C. Section 273, which governs organ certification and recertification of procurement organizations. The judge held that Congress delegated this power to the U.S. Department of Health and Human Services and its secretary.

The rule also isn't arbitrary and capricious, and the agency responded to a reasonable number of comments, according to the ruling.

"Nothing in Section 273 prohibits the Secretary from establishing outcome performance measures that turn on relative performance compared to other OPS," Judge Mizelle wrote.

In December 2020, CMS finalized the rule at President Donald Trump's request.

It mandates that those in the top 25% of donation and transplantation rates of the national median will be recertified automatically. Groups falling just below this threshold, but still above the national median, will be placed in "Tier 2," where they will have to compete against other Tier 2 organizations to keep their DSA.

While the rest of the procurement organizations that fall below the national median will be lumped into "Tier 3" and automatically decertified, they can appeal.

LifeLink Foundation, OneLegacy, Iowa Donor Network, LifeCenter Northwest and LifeGift Organ Donation Center argued in an August 2025 complaint that this new rule will pit procurement organizations against each other, and potentially disrupt the national organ transplant system.

Federal lawmakers, the groups claimed, didn't grant CMS the authority to certify organizations based only on donation and transplantation rates.

"Congress also understood the danger that outcome-based performance targets often distort rather than enhance performance, especially when they collapse complex challenges into simplistic measures that are not reliable," the groups said in their complaint.

During oral arguments in the case in August, CMS said that the rankings are likely to be released before January, which marks the deadline when the existing contracts between CMS and the organizations are set to expire.

A spokesperson for the Association of Organ Procurement Organizations, a trade group representing the nation's 55 such organizations, told Law360 that the ruling threatens to upend the nation's organ donation and transplant system.

"Widespread decertification or replacement of existing OPOs could leave major service gaps, with no

guarantee that new OPOs are capable of stepping in and responding to the unique challenges of serving local communities," the spokesperson said via email.

Alex Capron, an emeritus professor of law and medicine at the University of Southern California whose research focused on the organ transplantation system, said the ruling could "light a fire" under the organizations to improve performance.

The ruling could "stir all of them towards trying to avoid the death sentence that comes with being categorized as a Tier 3 organization," he said.

**Loss of Public Trust**

The ruling comes amid a federal crackdown on organizations for unsafe practices.

Last year, CMS pulled the certification of Miami-based Life Alliance Organ Recovery Agency for alleged "unsafe" practices. That marked the first time the federal government had decertified an organization, and it signaled federal officials' growing interest in how the transplantation system operates.

In August, CMS also decertified Kentucky organ procurement organization Network for Hope after a federal investigation found the group had pressured doctors to move forward with a potential donation, despite the donor showing signs of life.

In the Kentucky case, hospital staff raised concern that a patient was showing "signs of consciousness." The staff raised the specter that pulling him off life support to harvest his organs amounted to "euthanasia, according to federal investigation documents from the Health Resources and Services Administration.

A staff member for Network for Hope, previously Kentucky Organ Donor Affiliates, allegedly urged the donation to move forward, according to HRSA. The patient ultimately survived the ordeal.

The new rule could pressure more organizations to push for donations to meet certification, according to Capron, leading to overreach and more trouble for an industry beset of late by disturbing allegations like those involving Network for Hope.

"Some of this is described as behavior where the OPO employees become more involved in the donor management, and they're not supposed to have anything to do with the determination of death," Capron told Law360.

Melodie Hengerer, a shareholder at Baker Donelson who has represented Network for Hope, told Law360 that the rule threatens to cause the loss of strong relationships between the organizations and hospitals, lead to the departure of qualified staff and leadership, and challenge corporate and legal considerations, which could diminish public trust and organ donation.

"With the potential for massive disruption to a system already suffering from a loss of public trust, it is critical that regulators carefully consider the practical implications of enforcement," Hengerer said via email.

Brian Smith, founder of Trident Health Law, told Law360 that the rule is unlikely to create the "perverse incentive" that would drive organizations to conduct unsafe organ procurement procedures to meet their donation and transplantation rates.

However, the agency and organizations must balance high demand for organs with ensuring safety for vulnerable patient populations.

"I think it would be ideal if those perverse incentives weren't in existence at all," he said.

**Impact on Organ Procurement Organizations**

According to CMS, the new rule threatens to result in the decertification of more than 40% of 55 oranizations.

Further, in addition to meeting metrics for donation and transplantation rates, organizations must comply with performance measures. These metrics were passed under a separate rule on Nov. 20, 2020.

Experts say the rule is expected to have a particular impact on Tier 2 organizations. Under the rule, those who fall into this level will have to compete for their donation service area with other Tier 2 organizations.

"Thus, even a winning Tier 2 OPO is harmed by the Final Rule's requirement that it expend resources to retain control of a DSA," Judge Mizelle wrote.

But that outcome could be worse for Tier 2 organizations that could lose out to other organizations competing for their donation service area, even if the organization isn't decertified.

"Losing Tier 2 OPOs suffer a worse fate," Judge Mizzelle wrote. "Set adrift without a DSA for the duration of the 2026–2030 recertification cycle."

Much remains unknown about how CMS will enforce the rule, according to Smith.

However, with the rule set to go into effect, "Tier 2 OPOs are going to have a bit of heartburn, at least in the initial years where enforcement is ramping up," Smith said.

Megan C. Culp, an attorney at Hall Render Killian Heath & Lyman PC, told Law360 that the ruling strengthens CMS' position in courts where the rule is facing a host of related legal challenges.

"This decision does not settle the underlying policy debate," Culp said.

In North Carolina, organ procurement organization HonorBridge also sued CMS; HHS and HonorBridge have moved for summary judgment, and a decision is pending.

Massachusetts-based New England Donor Services sued HHS in December 2025. That case is also at the summary judgment stage awaiting a ruling.

Upstate New York Transplant Services also sued HHS and Secretary Robert F. Kennedy over the rule in February and then moved for summary judgment in May. Oral arguments in that case are set for Nov. 6. Legacy of Life Hawaii filed its lawsuit against federal health officials in early August. Briefing in that case is ongoing.

While appeals to any ruling are likely, Hengerer said, CMS will have to move forward with the bidding and reassignment process during these legal maneuvers.

"Operationally, this will be a herculean task for CMS to undertake," she said.

HHS didn't respond to requests for comment.

--Editing by Alex Hubbard.

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