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The OPO Rule and Your Hospital's Business Model

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VIEWPOINT TOPICS

- Health Care

The US Department of Health and Human Services (HHS) is rebuilding the Organ Procurement and Transplantation Network (OPTN) system on a compressed timeline, and the changes reach past a transplant program's four walls into every donor hospital's emergency department, ICU, and compliance office. For hospitals on either side of the Organ Procurement Organization (OPO) relationship, including those that refer potential donors and those that transplant the organs those donors provide, this represents a rapidly evolving set of policy, operational, financial, legal, and reputational considerations. Deadlines are already in motion, and hospitals that understand the landscape and engage early will be far better positioned to navigate the changes ahead.

For four decades, one federal contractor and 55 single-service-area OPOs ran the organ transplant system end to end, and each hospital's OPO relationship was effectively permanent. That model is being dismantled in real time.

The Centers for Medicare & Medicaid Services' (CMS) recent proposed rule, **CMS-3409-P**, would tie an OPO's certification to the performance of its designated service area (DSA), rather than the OPO itself. As a result, a donor hospital's or transplant center's OPO partner can change through a process the hospital itself does not control.

CMS anticipates finalizing the rule in late 2026, with recertification and decertification actions for underperforming OPOs to follow and current OPO agreements expiring in January 2027. Hospitals that understand these dynamics now, rather than after the final rule publishes, will have more room to plan for whatever comes next.

The proposed rule lands differently depending on which side of the OPO relationship a hospital sits on. **Donor hospitals**, including many community and regional hospitals with no transplant program at all, are responsible for identifying and referring potential donors, honoring families' decision-making time, and coordinating with the OPO CMS assigns to their service area. **Transplant hospitals** depend on that same OPO relationship for organ supply, and separately carry their own listing, allocation, and Condition of Participation obligations under a modernized federal contracting structure. Both now answer, in different ways, to the same rule.

Six Emerging Developments Every Hospital Should Be Tracking

Each of the following developments is already in motion and affects policy, finance, legal exposure, or public reputation for donor hospitals and transplant hospitals alike.

1. OPO Partner Discontinuity

Under CMS-3409-P, performance tiers attach to the DSA, not the OPO. One OPO could hold multiple DSAs and choose whether to merge or manage them separately; an OPO left holding only bottom-tier DSAs faces decertification, while one with a top-tier DSA is automatically recertified for that area.

For a donor hospital, this could mean a new OPO, new referral protocols, and no institutional history with emergency department or ICU staff, arriving with limited notice. For a transplant hospital, it could mean a disrupted organ pipeline mid-transition. With current OPO agreements running through January 2027, hospitals on both sides should know exactly in which DSA they sit and better understand risk factors.

2. Donor Hospital Compliance and Referral Obligations

CMS has issued new guidance, including a Quality, Safety & Oversight Group memorandum and updated State Operations Manual interpretive guidance, clarifying donor hospitals' Condition of Participation obligations. These obligations include referring every potential donor, providing full medical care regardless of donor status, and giving families time to decide without pressure or coercion.

CMS has also directed surveyors to cite noncompliance the moment it is identified, even if corrected before the survey ends. Donor hospitals would benefit from documenting referral timing, consent, and family communication protocols well before a survey.

3. Referral Technology on the Horizon

The **Organ Donation Referral Improvement Act** (H.R. 330) would, if enacted, direct HHS to study hospitals' use of automated electronic referrals to OPOs. This could be an early step toward requirements that reshape how donor hospitals identify and refer potential donors and how transplant hospitals and OPOs coordinate on the back end.

4. Growing Public Visibility

The Health Resources and Services Administration (HRSA) must begin publishing quarterly public reports in 2026 that name transplant centers alongside their registration fee payments, made permanent by the **Mikaela Naylon Give Kids a Chance Act**.

Donor hospitals face a parallel dynamic. CMS has said publicly it is watching for reports of rushed consent conversations or pressure on grieving families. A donor hospital's referral and consent practices can therefore become part of the same public trust narrative. This visibility extends beyond the transplant service line or the donor hospital emergency department to the health system's broader reputation.

5. New Billing and Reconciliation Obligations

HRSA has moved registration fee billing in-house for transplant hospitals, meaning centers now pay HRSA directly rather than through a contractor. Any gap between a hospital's internal billing process and HRSA's new system becomes visible quickly and feeds directly into the public reporting described above and is worth a standing item on the finance and revenue cycle agenda rather than an annual review.

6. Listing and Nondiscrimination Policies Becoming Survey Criteria

Fast-moving OPTN actions on donor testing, allocation sequencing, and perfusion techniques are becoming survey criteria faster than most policy review cycles can track.

At the same time, the **Charlotte Woodward Organ Transplant Discrimination Prevention Act** (H.R. 1520/S. 1782) would bar transplant centers and OPOs from denying or restricting transplant access based solely on disability. It would also require an individualized physician evaluation before disability could factor into a listing decision.

This bipartisan measure passed the House in June 2025, and the Senate companion was ordered reported on June 17, 2026. Full Senate action could follow quickly. Transplant hospitals may want to review their listing criteria and disability-related documentation before enactment.

How We Got Here

A 2022 Senate Finance Committee investigation found that operational failures in the OPTN had contributed to patient deaths and exposed deep weaknesses in oversight, technology, and equity.

Congress responded with the **Securing the U.S. Organ Procurement and Transplantation Network Act**, which was signed into law in September 2023. The law ended the single-contractor model, opened OPTN functions to competitive bidding, lifted a funding cap, and separated governance to strengthen independent oversight.

The law also launched HRSA's OPTN Modernization Initiative. As a result, the infrastructure every donor and transplant hospital depends on for referrals, listings, allocations, and compliance is being rebuilt while

hospitals continue to use it.

Where Things Stand

HRSA has finalized a new operations contract with United Network for Organ Sharing (UNOS) for core functions such as the matching system, while competing out other functions, including patient safety and committee support, to additional vendors.

HRSA is also rebuilding the data backbone, aiming eventually to unify the OPTN and Scientific Registry of Transplant Recipients systems, which currently operate separately. On the OPO side, CMS's new guidance is already shaping how surveyors evaluate donor hospital referral and consent practices ahead of the CMS-3409-P final rule expected in late 2026.

A Window Worth Using

The formal comment deadline on CMS-3409-P has passed, but transplant and donor hospitals still have room to influence how the final rule is implemented, monitored, and funded. They can also weigh in on the related bills that are still moving through Congress.

Hospitals that engage during this window are better positioned to protect patient access, preserve referral and allocation continuity, and plan for transition timelines and successor OPO scenarios grounded in real-world clinical and operational workflows.

Beyond the legislation discussed above, other bills would directly affect how transplant and donor hospitals operate. **The Expanding Support for Living Donors Act**, introduced in March 2026, would expand financial support for living donors and would be relevant to any transplant hospital operating a living donor program.

A Senate companion bill to the Naylon Act, **S. 3302**, is also moving through Congress and could reach the President's desk with little notice.

Taken together, these developments touch every function of a donor or transplant hospital, including clinical operations, compliance, finance, legal, and communications — on a timeline that rewards early engagement. The hospitals best positioned for 2027 will be those that use 2026 to understand the changing landscape and prepare accordingly.

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