Executive Summary: CMS Final Rule on Organ Procurement Organizations

CMS-3409-F | 42 CFR Part 486 | October 30, 2026

Regulation: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage

Scheduled publication: November 3, 2026. Effective date: approximately January 2, 2027 (60 days after publication).

Full regulation: https://public-inspection.federalregister.gov/2026-22381.pdf

Overall Assessment

The CMS final rule revises oversight, certification, competition, and operational requirements for Organ Procurement Organizations (OPOs). It preserves the stricter performance standards established in 2020 while providing greater flexibility in how OPOs operate, compete for service areas, and transition when an underperforming organization loses its designation.

CMS estimates that approximately 35 of 55 donation service areas could become eligible for competition as the 2022–2026 recertification cycle concludes. This could result in changes to the OPOs serving hospitals and transplant programs.

Ten Most Important Provisions

1. The three-tier performance framework remains

Performance tier	Regulatory consequence
Tier 1 — Highest performing	Retains service area and may compete for additional areas.
Tier 2 — Intermediate	Must compete to retain its service area and may seek additional areas.
Tier 3 — Lowest performing	Loses its service-area designation, subject to appeal; an OPO with only Tier 3 areas faces decertification.

CMS continues to use donation and transplantation rates as performance measures. The framework links poor performance to potential loss of geographic service areas.

2. Approximately 35 service areas may face competition

CMS estimates that 35 of 55 service areas may become eligible for competition. Qualifying OPOs may seek these areas, with CMS considering performance, compliance, geographic proximity, and experience overcoming barriers to organ donation. Hospitals could face changes in referral arrangements, personnel relationships, and recovery operations.

3. Stronger OPOs may expand into multiple service areas

An OPO may operate in more than one donation service area, with different options for consolidation or separate operations. Performance is evaluated by service area, while organization-wide compliance is assessed across the OPO. The rule may enable regional consolidation.

4. CMS clarifies decertification authority

An OPO operating multiple areas may lose a Tier 3 designation without losing certification everywhere. CMS also may decertify organizations for failures to satisfy required operating standards. Routine decertification generally involves at least 90 days' notice; urgent patient-safety circumstances may permit as little as three calendar days' written notice.

5. Revised appeals and reconsideration procedures

An OPO generally has 20 calendar days to seek reconsideration and 15 calendar days after an unfavorable reconsideration determination to request a hearing. A hearing decision generally follows within 90 calendar days after the hearing, subject to extensions. CMS Administrator review is discretionary.

6. Transition requirements aim to prevent disruption

Outgoing and incoming OPOs must cooperate during service-area transitions. The incumbent and successor must submit transition plans, and the successor must provide progress and completion reporting. CMS may make a direct assignment when there is insufficient time for a full competition.

7. Adverse-event and patient-safety oversight is strengthened

Revised quality assessment and performance improvement requirements address events such as infection or malignancy transmission, avoidable donor loss, inappropriate evaluation or management, incorrect organ delivery or blood-type mismatch, transportation loss or delays, and organs arriving in unsuitable condition. OPO investigations may implicate hospitals and transplant centers.

8. Additional recordkeeping for research organs

OPOs must better document organs recovered and sent for research, including disposition and relevant institutional or investigator information. CMS also revises relevant definitions and no longer counts pancreata used solely for islet-cell research toward the transplantation-rate measure.

9. CMS drops two proposed requirements

The final rule does not adopt proposed definitions and reporting requirements for medically complex donors and organs. It also declines to impose a general licensure, certification, or registration mandate on all clinical OPO personnel. A narrower medical-director adjustment is finalized for multi-area OPOs.

10. CMS estimates limited incremental financial costs

Cost category	First year	Annual thereafter
OPO compliance and operations	$15.11 million	$7.56 million
CMS administration	$1.37 million	$0.34 million
Total	$16.48 million	$7.90 million

These are estimated incremental administrative and operational costs. CMS indicates the rule does not create new direct compliance obligations for small rural hospitals.

Source: CMS-3409-F, scheduled for Federal Register publication November 3, 2026. Summary based on the final-rule text.