A Field Guide to the CMS Clinical Conditions for Coverage

How OPOs Build Safe, Compliant, Survey-Defensible Systems — and How Competency Governance Aligns Practice to the Clinical Conditions for Coverage

A practical guide to understanding the CMS regulatory architecture that governs donor-side operations under CFR Part 486 Subpart G §486.344, §486.346, and §486.348.

INTRODUCTION

Why This Guide Exists

Organ procurement organizations operate within a federal regulatory system designed to ensure safety, consistency, and traceability across every donor case. The Conditions for Coverage (CfCs) form the backbone of that system — governing evaluation, management, recovery, transport, documentation, and Quality Assurance and Performance Improvement (QAPI).

This Field Guide clarifies how the clinical CfCs govern the donor-side workflow, why CMS oversight differs from the Organ Procurement and Transplantation Network (OPTN), operated by the United Network for Organ Sharing (UNOS), and why tissue and eye recovery fall under the Association for Advancing Tissue and Biologics (AATB) and the Eye Bank Association of America (EBAA). It also explains how competency governance provides the structure needed to align everyday practice to federal expectations.

It is not a policy manual. It is a practical map — designed to help OPOs see the regulatory system as CMS intends, and to understand how governed competency systems support safe, compliant, survey-defensible operations.

CHAPTER 1

The OPO Ecosystem: Why the Clinical CfCs Exist

Organ procurement organizations operate at the intersection of federal regulation, national allocation policy, accreditation standards, hospital expectations, and public trust. Understanding this ecosystem is essential for understanding why CMS created the three clinical Conditions for Coverage — §486.344, §486.346, and §486.348 — and why these sections govern everyday donor-side practice.

These clinical CfCs exist because CMS is responsible for ensuring that donor evaluation, donor management, recovery, transport, documentation, and QAPI occur safely, consistently, and traceably across every case. They define the operational requirements that protect donors, recipients, staff, and certification.

1. CMS — The Regulator That Determines Whether an OPO Exists

CMS is the only entity with the authority to certify or decertify an OPO. Its oversight focuses on the clinical CfCs because these sections govern the donor-side workflow and define the safety expectations OPOs must meet. CMS defines the Conditions for Coverage, conducts audits and surveys, evaluates performance and compliance, and determines whether an OPO may continue operating. Loss of CMS certification halts organ recovery because CMS governs the clinical operations that make transplantation possible.

2. OPTN/UNOS — Allocation, Not Clinical Oversight

OPTN, operated by UNOS, governs national organ allocation. It manages the waiting list, enforces allocation policy, governs match runs, and defines placement rules. OPTN controls where organs go; CMS controls whether an OPO may operate.

3. AATB and EBAA — Parallel Accreditation Systems

Tissue and eye recovery operate under separate accreditation bodies. AATB governs tissue recovery and EBAA governs eye recovery. Loss of accreditation halts tissue or eye recovery but does not affect organ operations. FDA regulates tissue and eye recovery; CMS regulates organ donation. This regulatory separation is why the clinical Conditions for Coverage focus exclusively on organ donation.

4. Why CMS Regulates Organ Donation

Organ donation is federally regulated because OPOs recover the organ, transplant centers pay a standard acquisition charge, and CMS or insurance reimburses the transplant center. CMS regulates organ operations because CMS dollars ultimately fund transplantation and because organ donation carries the highest clinical and regulatory risk.

5. QAPI — The Safety Engine Behind the Clinical CfCs

CMS assumes that if something is not documented, it did not happen; if it is not reviewed, the organization does not know it is broken; and if it is not fixed, the organization is unsafe. QAPI is the safety spine of the OPO and the mechanism CMS uses to evaluate whether donor-side operations are safe, consistent, and improving.

6. What CMS Expects QAPI to Demonstrate

Every OPO must show that when an adverse event occurs, required steps were completed, by whom, when each step occurred, what went wrong, what corrective actions were taken, and evidence that those corrective actions were effective. These expectations directly connect to §486.348, the clinical CfC CfCs governing QAPI.

7. The OPO Workflow — The Operational Spine of the Clinical CfCs

Sequential high-level actions that comprise organ recovery workflow follow:

Referral → Evaluation → Authorization → Donor Management → Recovery → Packaging and Transport → Case Closeout → QAPI Review

The clinical CfCs were written to govern this exact workflow. They define what must happen at each step and how OPOs must demonstrate compliance.

8. Competency Governance — The Essential Infrastructure

A CMS-aligned competency system defines required steps, identifies qualified personnel, tracks validation, reveals failure points, structures remediation, and demonstrates sustained improvement. Competency governance is not training; it is the regulatory infrastructure that aligns everyday practice to §486.344, §486.346, and §486.348.

CHAPTER 2

The Donation Environment: Why the Clinical CfCs Focus on Organ Donation

Organ, tissue, and eye donation share a common purpose, but they operate in different regulatory environments. Only organ donation falls under the three clinical Conditions for Coverage — §486.344, §486.346, and §486.348 — because organ recovery carries the highest clinical complexity, the highest regulatory risk, and the greatest need for validated personnel performing protocol-driven interventions. Understanding these differences clarifies why CMS regulates organ donation directly and why competency governance must be domain-specific.

1. Death Determination

Organ donation operates under two clinical pathways: neurological death and controlled Donation after Circulatory Death (DCD). Neurological death involves physician declaration and ventilator support, enabling multiorgan recovery. Controlled DCD involves withdrawal of life-sustaining treatment, cessation of circulation, a mandatory waiting period, and rapid OR transition. Tissue and eye donation require circulatory death only. This distinction is foundational: §486.344 governs donor evaluation and management because organ donation requires active clinical intervention.

2. Recovery Environments

Organ recovery occurs in a sterile, time-critical operating room environment. Tissue recovery occurs in funeral homes, morgues, or recovery suites. Eye recovery occurs in funeral homes, hospital rooms, or morgues. The clinical CfCs apply only to organ recovery because CMS regulates environments where active clinical management occurs.

3. Recovery Personnel

Organ recovery involves surgeons and OPO clinical staff. Tissue recovery requires AATB-credentialed technicians. Eye recovery requires EBAA-credentialed technicians. Organ recovery requires validated clinical personnel performing protocol-driven tasks, which is why competency governance is essential and why CMS regulates organ operations directly.

4. Time Sensitivity

Organ donation is measured in minutes. Tissue donation is measured in hours. Eye donation has the longest viability window. Organ donation's time sensitivity drives the requirements in §486.344 and §486.346, including timely evaluation, protocol-driven management, accurate verification, sterile packaging, chain of custody, and transport integrity.

5. Regulatory Bodies

Organ donation is overseen by CMS and OPTN. Tissue donation is overseen by AATB and FDA. Eye donation is overseen by EBAA and FDA. Only organ donation is governed by the clinical CfCs, which define the operational requirements OPOs must meet to maintain CMS certification.

6. Documentation Requirements

Organ documentation errors can affect CMS compliance and certification. This is why §486.344, §486.346, and §486.348 require complete documentation, traceability, verification, and QAPI review. Tissue and eye documentation follow different accreditation standards and do not fall under the clinical CfCs.

7. Transport Requirements

Organ transport is the most time-sensitive and risk-sensitive mode of transport in the donation ecosystem. §486.346 defines packaging, labeling, chain of custody, transport integrity, and two-person verification. These expectations do not apply to tissue or eye transport.

8. Risk Profiles

Organ donation carries the highest clinical risk, regulatory risk, operational complexity, documentation burden, and time sensitivity. The clinical CfCs exist to govern these risks and ensure safe, consistent donor-side practice.

9. Competency Implications

Competency governance must be domain-specific. The competencies required for organ donation differ substantially from those required for tissue or eye recovery. This is why competency systems must align directly to §486.344, §486.346, and §486.348 — the clinical CfCs that define everyday OPO practice and require governed, validated competency.

CHAPTER 3

The OPO Workflow: The Operational Spine of the CfCs

The clinical Conditions for Coverage — §486.344, §486.346, and §486.348 — were written around the donor-side workflow. They define what must happen at each step, who must be qualified to perform each action, how each step must be documented, and how the organization must demonstrate improvement. CMS uses this workflow structure to evaluate whether donor-side operations are safe, consistent, and aligned with federal expectations.

The donor-side workflow proceeds through eight sequential stages:

Referral → Evaluation → Authorization → Donor Management → Recovery → Packaging and Transport → Case Closeout → QAPI Review

1. Referral

Referral is the first regulated step in the donor-side workflow. CMS expects accurate donor evaluation, complete referral documentation, and qualified personnel determining suitability. §486.344 governs the clinical requirements that begin at referral, including verification, testing, and early collaboration with transplant centers.

2. Evaluation

Evaluation includes legal death verification, chart review, suitability assessment, required testing, and consultation with transplant centers. CMS expects Clinical Laboratory Improvement Amendments (CLIA)-certified testing, blood type ×2, and two-person verification. These expectations exist because evaluation errors create downstream clinical and regulatory risk. Competency governance ensures that only validated personnel perform evaluation tasks.

3. Authorization

Authorization is the legal foundation of the donor case. CMS expects accurate documentation, clear scope, traceability, and alignment with Uniform Anatomical Gift Act and state law. Authorization errors create regulatory exposure, which is why competency governance defines who is qualified to obtain, document, and verify authorization.

4. Donor Management

Donor management includes ventilator management, hemodynamic support, lab trending, imaging, and communication with transplant centers. CMS expects validated personnel performing protocol-driven interventions. §486.344 governs these clinical requirements because donor management directly affects organ viability, safety, and compliance. Competency governance ensures that staff performing donor management tasks are validated, documented, and aligned to protocol.

5. Recovery

Recovery marks the transition from §486.344 (evaluation and management) to §486.346 (preparation, packaging, labeling, and transport). CMS expects accurate verification, complete documentation, and traceability. Competency governance ensures that personnel involved in recovery understand verification requirements, documentation standards, and chain-of-custody expectations.

6. Packaging and Transport

Packaging and transport are governed entirely by §486.346. CMS requires sterile, watertight packaging, correct labeling, two-person verification, chain of custody, and transport integrity. These requirements exist because transport errors create immediate clinical and regulatory risk. Competency governance ensures that staff performing packaging and transport tasks are validated and consistently aligned to protocol.

7. Case Closeout

Case closeout includes complete documentation, accurate OPTN data entry, and traceability across the entire workflow. CMS evaluates whether documentation is complete, accurate, and aligned with protocol. Competency governance ensures that personnel responsible for closeout tasks understand documentation standards and verification requirements.

8. QAPI Review

QAPI review is governed by §486.348. CMS expects root cause analysis, corrective actions, and evidence of sustained improvement. QAPI identifies issues; competency governance ensures they are fixed. Together, they form the safety spine of the OPO.

CHAPTER 4

The Clinical Conditions for Coverage: The Regulatory Architecture Behind Donor-Side Operations

Three sections of the federal CfCs govern donor-side clinical practice: §486.344, §486.346, and §486.348. These subsections define what must happen during evaluation, management, recovery, packaging, transport, documentation, and QAPI. They form the regulatory spine of organ donation and the foundation for CMS-aligned competency governance.

The clinical CfCs were written to govern the exact workflow every OPO follows. Understanding these subsections is essential for aligning practice, documentation, and competency validation to federal expectations.

§486.344 — Donor Evaluation and Management

§486.344 governs donor evaluation, donor management, testing, verification, and collaboration with transplant centers. CMS expects written protocols, thorough evaluation, appropriate management, CLIA-certified testing, blood type ×2, two-person verification, and structured communication with transplant centers. Competency governance ensures that personnel performing these tasks are validated and aligned to protocol.

§486.346 — Organ Preparation, Packaging, and Transport

§486.346 governs organ preparation, packaging, labeling, verification, chain of custody, and transport integrity. CMS requires sterile packaging, correct labeling, two-person verification, complete documentation, and transport integrity. Competency governance ensures that staff performing these tasks are validated and consistently aligned to protocol.

§486.348 — QAPI and Demonstrated Improvement

§486.348 governs QAPI, adverse event review, corrective actions, and evidence of sustained improvement. CMS requires comprehensive QAPI, death record reviews, adverse event reporting, corrective actions, and proof that corrective actions are effective. QAPI identifies issues; competency governance ensures they are fixed.

Why These Subsections Matter

The clinical CfCs define what must happen during the donor-side workflow. Competency governance aligns personnel, practice, and documentation to these requirements by defining required steps, identifying qualified personnel, documenting validation, structuring remediation, and demonstrating improvement. The Competency Alignment System operationalizes this structure across §486.344, §486.346, and §486.348.

CHAPTER 5

Competency Governance: The Infrastructure That Aligns Practice to the Clinical CfCs

The clinical CfCs define what must happen during donor-side operations. The workflow defines when it must happen. Competency governance defines who is qualified to make it happen — and how that qualification is proven, documented, and maintained. Competency governance is not training. It is the regulatory infrastructure that aligns everyday practice to §486.344, §486.346, and §486.348.

1. Purpose of a Competency System

A competency system exists to protect donors, recipients, staff, and certification. It provides evidence to CMS that personnel performing donor-side tasks are qualified, validated, and aligned to protocol. CMS expects OPOs to show who is qualified, how they were validated, when validation occurred, what evidence supports validation, how failures are remediated, and how improvement is documented.

2. The Three Levels of Competency

Competency governance operates across three levels. Task-level competencies define the observable, auditable steps required for safe practice. Skill-level competencies define the abilities needed to perform those steps safely. Verification-level competencies define the evidence required to validate competence.

3. Role Definitions — Clear Scope, No Overlap

Role definitions prevent scope creep, inconsistent training, unvalidated practice, and regulatory exposure. They ensure that each role has clearly defined responsibilities aligned to §486.344, §486.346, and §486.348.

4. Mapping Competencies to the Workflow

Each step of the donor-side workflow has corresponding competencies that must be defined, validated, and documented. Competency governance ensures that personnel performing evaluation, management, recovery, packaging, transport, documentation, and QAPI tasks are qualified and aligned to protocol.

5. Mapping Competencies to the Clinical CfCs

Competencies must align directly to the requirements of the three clinical CfCs. §486.344 governs evaluation, management, testing, verification, and collaboration. §486.346 governs packaging, labeling,

documentation, chain of custody, and transport. §486.348 governs adverse events, root cause analysis, corrective actions, and improvement documentation.

6. Competency Validation Methods

Validation must be structured, documented, traceable, and role-appropriate. CMS expects OPOs to demonstrate how competence was assessed, who validated it, when validation occurred, and what evidence supports the outcome.

7. Competency Failure and Remediation

CMS expects structured remediation, removal from independent practice when needed, retraining, revalidation, and documentation. Competency governance ensures that failures are identified, corrected, and prevented from recurring.

8. Competency Documentation Requirements

Competency documentation must show what was assessed, how it was validated, who validated it, when it occurred, the outcome, remediation steps, and revalidation. Documentation must be complete, accurate, and aligned to protocol.

9. Integration With QAPI

QAPI identifies issues. Competency governance ensures they are fixed. Together, they form the safety spine of the OPO and the mechanism CMS uses to evaluate whether donor-side operations are safe, consistent, and improving.

10. A Complete Competency Governance System

A complete system includes role definitions, task-level competencies, skill-level competencies, verification-level competencies, validation methods, remediation pathways, documentation standards, QAPI integration, version control, and traceability to the clinical CfCs. The Competency Alignment System provides this governed, version-controlled structure, ensuring that competency expectations remain aligned with CMS requirements across every role, every case, and every audit cycle.