A Modern Field Guide to the Conditions for Coverage

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

A practical guide to understanding the regulatory architecture that governs organ procurement organizations

INTRODUCTION

Why This Guide Exists

Organ donation operates inside one of the most complex regulatory environments in healthcare. Every donor case must be evaluated, managed, documented, verified, transported, and reviewed in alignment with the federal Conditions for Coverage (CfCs).

Most OPO teams know the citations.
Few understand the regulatory architecture behind them.

This Field Guide explains the CfCs the way CMS intends them to be understood: as a unified safety system governing the entire donor-side workflow — and as the foundation for competency governance.

It is not a policy manual.

It is a practical map of how the CfCs shape donor evaluation, donor management, recovery, transport, documentation, and QAPI — and how a governed competency system aligns practice to federal expectations.

CHAPTER 1

The OPO Ecosystem: Why the 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 the Conditions for Coverage exist — and why CMS oversight is fundamentally different from OPTN, AATB, or EBAA.

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

CMS is the only entity with the authority to certify or decertify an OPO.

CMS:

- Defines the Conditions for Coverage
- Conducts audits and surveys
- Evaluates performance and compliance
- Determines whether an OPO may continue operating

Loss of CMS certification halts all organ recovery.

> *CMS governs whether an OPO exists.*
> *OPTN governs allocation.*
> *AATB/EBAA govern tissue and eye recovery.*
> *Only CMS can shut an OPO down.*

2. OPTN/UNOS — The National Allocation System

OPTN, operated by UNOS, governs national organ allocation:

- Manages the waiting list
- Enforces allocation policy
- Governs match runs

- Defines placement rules

> *OPTN controls allocation.*
> *CMS controls certification.*

3. AATB and EBAA — Parallel Accreditation Systems

Tissue and eye recovery operate under separate accreditation bodies:

- AATB governs tissue recovery
- EBAA governs eye recovery

Loss of accreditation halts tissue or eye recovery, but not organ operations.

4. Funding Models Explain the Regulatory Divide

Organ donation is federally regulated because:

- OPOs recover the organ
- Transplant centers pay a standard acquisition charge
- CMS or insurance reimburses the transplant center

CMS regulates organ operations because CMS dollars ultimately fund transplantation.

5. QAPI — The Safety Engine Behind the CfCs

CMS assumes:

- If it is not documented, it did not happen
- If it is not reviewed, the organization does not know it is broken
- If it is not fixed, the organization is unsafe

> *QAPI is not a department.*
> *It is the safety spine of the OPO.*

6. The QAPI Spine — What CMS Expects to See

Every OPO must demonstrate:

- The event occurred
- Required steps were completed
- Who performed each step
- When each step occurred
- What went wrong
- What corrective actions were taken
- Proof that corrective actions were effective

7. The OPO Workflow — The Operational Spine

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

8. Competency Governance — The Missing Infrastructure

A CMS-aligned competency system:

- Defines required steps
- Identifies qualified personnel
- Tracks validation
- Reveals failure points
- Structures remediation
- Demonstrates sustained improvement

> *Competency governance is not training.*
> *It is regulatory infrastructure.*

CHAPTER 2

The Donation Domains: Three Industries, One Mission

Organ, tissue, and eye donation share a common purpose, but they do not share the same regulatory bodies, environments, personnel, timelines, or risk profiles.

1. Death Determination — The First Regulatory Divide

Organ donation operates under two pathways:

A. Neurological Death

- Declared by a physician
- Ventilator support
- Enables multiorgan recovery

B. Controlled DCD

- Withdrawal of life-sustaining treatment
- Cessation of circulation
- Mandatory waiting period
- Rapid OR transition

Tissue and eye donation require circulatory death only.

2. Recovery Environments — Three Distinct Worlds

- **Organ:** OR, sterile, time-critical
- **Tissue:** Funeral homes, morgues, recovery suites
- **Eye:** Funeral homes, hospital rooms, morgues

3. Recovery Personnel — Different Credentials

- **Organ:** Surgeons + OPO staff
- **Tissue:** AATB-credentialed technicians

- **Eye:** EBAA-credentialed technicians

4. Time Sensitivity — The Operational Clock

- **Organ:** Minutes
- **Tissue:** Hours
- **Eye:** Longest viability

5. Regulatory Bodies — Three Oversight Systems

- **Organ:** CMS, OPTN
- **Tissue:** AATB, FDA
- **Eye:** EBAA, FDA

6. Documentation Requirements — Different Stakes

Organ documentation errors can trigger CMS decertification.

7. Transport Requirements — Risk Drives Regulation

Organ transport is the most time-sensitive and risk-sensitive mode of transport in the donation ecosystem.

8. Risk Profiles — Why the CfCs Focus on Organ Donation

Organ donation carries the highest clinical and regulatory risk among the three donation domains.

9. Competency Implications — One Size Does Not Fit All

Competency governance must be domain-specific. The competencies required for organ donation differ substantially from those required for tissue or eye recovery.

CHAPTER 3

The OPO Workflow: The Operational Spine of the CfCs

Every OPO follows the same operational sequence. The CfCs were written to govern this exact workflow.

1. Referral — The Entry Point

CMS expects:

- Accurate donor evaluation
- Complete referral documentation
- Qualified personnel

2. Evaluation — The Foundation of §486.344

Includes:

- Legal death verification
- Chart review
- Suitability assessment
- Required testing
- Transplant center consultation

CMS expects:

- CLIA-certified testing
- Blood type ×2
- Two-person verification

3. Authorization — The Legal Fulcrum

CMS expects:

- Accurate documentation

- Clear scope
- Traceability
- Alignment with UAGA and state law

4. Donor Management — The Clinical Core

Includes:

- Ventilator management
- Hemodynamic support
- Lab trending
- Imaging
- Communication with transplant centers

CMS expects validated personnel performing protocol-driven interventions.

5. Recovery — The Transition to §486.346

CMS expects:

- Accurate verification
- Complete documentation
- Traceability

6. Packaging & Transport — The Domain of §486.346

CMS requires:

- Sterile, watertight packaging
- Correct labeling
- Two-person verification
- Chain of custody
- Transport integrity

7. Case Closeout — The Documentation Spine

CMS expects:

- Complete, accurate documentation
- Timely OPTN data entry
- Traceability

8. QAPI Review — The Safety Engine

CMS expects:

- Root cause analysis
- Corrective actions
- Evidence of sustained improvement

CHAPTER 4

The Conditions for Coverage: The Regulatory Architecture

Three CfCs shape all donor-side operations:

- §486.344 — Donor Evaluation, Management, Placement, Recovery
- §486.346 — Organ Preparation, Packaging, Labeling, Transport
- §486.348 — QAPI

§486.344 — How the Donor Case Must Be Run

CMS expects:

- Written, current protocols
- Thorough evaluation
- Appropriate management
- CLIA-certified testing
- Blood type ×2
- Two-person verification
- Structured collaboration with transplant centers

§486.346 — How the Organ Must Be Prepared and Transported

CMS requires:

- CLIA-certified testing
- Complete documentation
- Watertight packaging
- Correct labeling
- Two-person verification
- Chain of custody

- Transport integrity

§486.348 — How the OPO Must Prove Improvement

CMS requires:

- Comprehensive QAPI
- Death record reviews
- Adverse event reporting
- Corrective actions
- Evidence of sustained improvement

CHAPTER 5

Competency Governance: The Missing Infrastructure

The CfCs define *what* must happen.
The workflow defines *when* it must happen.
Competency governance defines *who* is qualified to make it happen — and how that qualification is proven.

1. Purpose of a Competency System

A competency system exists to:

- Protect donors and recipients
- Protect staff
- Protect certification
- Provide evidence to CMS
- Ensure consistent operations

CMS expects OPOs to show:

- Who is qualified
- How they were validated
- When they were validated
- What evidence supports validation
- How failures are remediated
- How improvement is documented

2. The Three Levels of Competency

A. Task-Level Competencies
Observable, auditable steps.

B. Skill-Level Competencies
Abilities required to perform tasks safely.

C. Verification-Level Competencies
Evidence required to validate competence.

3. Role Definitions — Clear Scope, No Overlap

Role definitions prevent:

- Scope creep
- Inconsistent training
- Unvalidated practice
- Regulatory exposure

4. Mapping Competencies to the Workflow

Each workflow step has corresponding competencies that must be defined, validated, and documented.

5. Mapping Competencies to the CfCs

§486.344 — Evaluation, management, testing, verification, collaboration.

§486.346 — Packaging, labeling, documentation, chain of custody, transport.

§486.348 — Adverse events, RCA, corrective actions, improvement documentation.

6. Competency Validation Methods

Validation must be:

- Structured
- Documented
- Traceable
- Role-appropriate

7. Competency Failure and Remediation

CMS expects:

- Structured remediation
- Removal from independent practice when needed

- Retraining
- Revalidation
- Documentation

8. Competency Documentation Requirements

Documentation must show:

- What was assessed
- How it was validated
- Who validated it
- When it occurred
- The outcome
- Remediation
- Revalidation

9. Integration With QAPI

> *QAPI identifies issues.*
> *Competency governance ensures they are fixed.*

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
- Traceability to the CfCs

A governed, version-controlled competency system provides this structure, ensuring that competency expectations remain aligned with CMS requirements across every role, every case, and every audit cycle.