



Conditions of Coverage (CfC) and Conditions of Participation (CoP): For Hospitals, OPOs, and Transplant Centers

Hospitals

OPOs

- [Final Rule: May 31, 2006](#)
- [Final Rule: November 20, 2020](#)

Transplant Centers

(Note: This was originally published in 2007. Since then, there have been several revisions to different sections of the final rule. These can be viewed on the e-CFR link above. The dates of revisions are shown just below the relevant section and can be used to search the Federal Register for all of the public commentary, rationale and analyses of the changes.)

For additional references & resources; or to learn more, please visit:
www.organdonationalliance.org/insights/alliance-spotlight-series/



Receive more insights each week. Subscribe to The Alliance Communications.



THE Alliance

www.organdonationalliance.org/

SPOTLIGHT EDITOR

Deanna Fenton

Program Manager, The Alliance
dfenton@organdonationalliance.org

CMS Legislation:

An Overview of Organ Donation and Transplantation Regulations

The Centers for Medicare & Medicaid Services' (CMS) latest publication of a final rule updating the Conditions for Coverage for Organ Procurement Organizations (OPO) released on November 20, 2020, is generating many questions and discussions in the donation and transplantation community. To understand the impact of such a release, it is helpful to clarify the following questions: 1 – What exactly are final rules? 2 – How are Conditions for Coverage (CfCs) and Conditions of Participation (CoPs) related to final rules? 3 – How are final rules incorporated into the State Operations Manual and associated Interpretive Guidelines?

Final Rules Overview

Final rules are new or revised legislative requirements, executed and published by a Federal agency (e.g., CMS, FDA, etc.). It may also be a rescindment of an existing regulation. As final rules are Federal regulations, all identified parties in a given rule, e.g. hospitals, transplant centers, and OPOs, are held accountable to them. Final rules are rewritten and revised using a structured rulemaking process that elicits written public comments on proposed rules prior to the issuing of a specific final rule.(1)

The Federal Register and the Electronic Code of Federal Regulations

Final rules are published in the Federal Register after an agency has reviewed public comments and has concluded that its proposed solution will help accomplish established goals or solve problems that have been identified. Final rules are required to consider whether any alternative solutions would be more effective or cost less. Final rules must follow a specific format in order to be published in the Federal Register. (2) That format includes:

- A **Preamble** that provides a summary of the agency's rationale for the rule.
- The **Effective and Compliance Date(s)** – effective dates are usually within 30 days after being published in the Federal Register.
- **Supplemental Information** that provides the basis and purpose of the rule.
- **Statement of Authority** that identifies the Federal agency's legal authority to issue the rule.
- A **Full Text of the Final Rule** and any **Interim Final Rules**.

The [Federal Register](#) is often referred to as (FR or Fed. Reg.) and it is the official daily legal publication for rules, proposed rules, and notices issued by Federal agencies and organizations, as well as executive orders issued by the President.(3) The Electronic Code of Federal Regulations (e-CFR) is a web version of the Code of Federal Regulations (CFR) and is updated daily. It is an editorial compilation of CFR material and Federal Register amendments and is not an official legal edition of the CFR. (4) The eCFR related to the Organ Procurement & Transplantation Network (OPTN) are found under [Title 42 – Public Health, Chapter 1 – Public Health Service \(PHS\), Department of Health and Human Services \(DHHS\), Subchapter K and Part 121 – Organ Procurement and Transplantation Network](#).

Conditions of Coverage (CfC) and Conditions of Participation (CoP)

Final rules may reflect changes in CfCs and CoPs. CfCs and CoPs are specific CMS standards health care organizations must meet in order to be able to participate in CMS programs and to receive CMS reimbursement. These requirements are intended to protect the health and safety of patients and to improve the quality of care. The CfCs are the provisions that State Survey Agencies (SA) use to determine an organization's (e.g. hospital, OPO, transplant program, etc.) compliance with standards to obtain initial approval or re-approval status to receive reimbursement from CMS for services provided to patients. CoPs are Federal regulations associated with the provision of patient care with which the CMS participating organizations must comply.

The State Operations Manual (SOM) and Associated Interpretive Guidelines (IGs)

The **SOM** contains the CMS primary survey and certification rules and guidance for health care organizations. The **IGs** can be thought of as a blueprint for surveyors to use in determining whether an organization has met their required CoPs. IGs define or explain the relevant statute and regulations and do not impose any requirements that are not otherwise stipulated in CfCs or CoPs. Organization specific IGs are located in the SOM Appendices and are updated whenever there is a new or updated hospital, OPO or transplant center final rule. SOM and IG links of interest for hospitals, OPOs, and transplant centers include:

- [Complete State Operations Manual](#)
- Complete list for the [Medicare State Operations Manual](#)
- [Survey Protocol, Regulations, and Interpretive Guidelines for Hospitals](#) – Appendix A Rev. 200, Dated: 02-21-20 (see §482.45 Condition of Participation: Organ, Tissue and Eye Procurement)
- [Guidance to Surveyors: Organ Transplant Programs](#) – Appendix X Rev. 200, Dated: 02-21-20
- [Organ Procurement Organization \(OPO\) Interpretive Guidance](#) – Appendix Y Rev. 180, Dated: 08-24-18
- [Organ Procurement Organization \(OPO\) Conditions for Coverage Final Rule: Revision to Outcomes Measures for OPOS CMS – 3380-F](#) - Dated: 11-20-20
- [Organ Procurement Organization Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations. Final Rule, Public Comment Period, and Delay of Effective Date: CMS – 3380-F and CMS 3380-F2](#) Dated: 03-20-21
- [Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance](#) Dated 03-04-19 – Appendix Z



Content Editor: Hedi Aguiar, BSN, RN, CCRN-K, Program Consultant, The Alliance

The Alliance Spotlight Series is a monthly one-page publication for front-line healthcare professionals, offering quick-takes on critical topics affecting the field of organ donation and transplantation. The Alliance grants permissions for the distribution and reproduction of this educational communication.

Donate Life is a registered trademark of [Donate Life America](#).