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# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

Transmittal 112

Date: April 11, 2014

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**SUBJECT: State Operations Manual (SOM) Chapter 3 Policy Revisions For Organ Procurement Organizations (OPOs)**

**I. SUMMARY OF CHANGES:** Revisions have been made to Chapter 3, Section 3012.2 – Termination of Organ Procurement Organizations (OPO) to reflect current Survey and Certification policy. In addition, 3012.2C has been added to discuss the appeal procedures for OPOs.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: April 11, 2014**

**IMPLEMENTATION DATE: April 11, 2014**

*Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)**

**(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	3/Table of Contents
R	3/3012.2/Termination of Organ Procurement Organizations (OPO)
R	3/3012.2A/Termination Procedures
R	3/3012.2B/Reconsideration Procedures
N	3/3012.2C/Appeal Procedures

**III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.**

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>One-Time Notification -Confidential</b>
	<b>Recurring Update Notification</b>

**\*Unless otherwise specified, the effective date is the date of service.**

# **State Operations Manual**

## **Chapter 3 - Additional Program Activities**

### **Table of Contents**

*(Rev.112, Issued: 04-11-14)*

#### **Adverse Actions**

*3012.2A - Termination Procedures*

*3012.2B - Reconsideration Procedures*

*3012.2C - Appeal Procedures*

## **3012.2 - Termination of Organ Procurement Organizations (OPO)**

*(Rev. 112, Issued: 04-11-14, Effective, 04-11-14, Implementation: 04-11-14)*

If an OPO voluntarily terminates its agreement, it must send a written notice *to the CMS RO* with the proposed effective date. The *CMS RO* approves the proposed termination date or sets a different date no later than 6 months after the proposed effective date *or sets a date less than 6 months after the proposed effective date if it determines that a different date would prevent a disruption of services to the service area*. When an OPO ceases organ procurement services in its service area, this *will be considered* a voluntary termination by the OPO. The *CMS RO* determines the effective date and notifies the OPO.

OPOs are involuntarily terminated when they fail to meet the *requirements of certification at 42 CFR 486.303, including one or more conditions for coverage (CfC) or when they are not in substantial compliance with and any other applicable Federal regulations or provisions of titles XI, XVIII, or XIX of the Social Security Act (the Act)*.

The *provider agreement between the OPO and the Secretary may be involuntarily terminated at anytime during the 4-year certification cycle or at the end of a cycle may not be renewed (re-certified) for another 4 year cycle*. The *CMS RO* notifies CO, the *FI/MAC* and the Organ Procurement Transplantation Network (OPTN) that the OPO has been terminated and the *effective* date of the termination. The *CMS RO* follows the termination procedures detailed below.

### **3012.2A - Termination Procedures**

*(Rev. 112, Issued: 04-11-14, Effective, 04-11-14, Implementation: 04-11-14)*

1. *If the OPO is determined to be out of compliance with one or more CfCs, initiate termination of the provider agreement. CMS RO notifies the OPO of the pending termination date and the timeframes for submitting any additional information to support that appropriate corrections have been made and compliance achieved.*
2. If the OPO achieves compliance, *as determined through an onsite or desk review*, send Model Letter: Organ Procurement Organization Approval. (See Exhibit 172.)
3. If the OPO fails to achieve compliance, send Model Letter: Organ Procurement Organization Notice of Termination. *(See Exhibit 173.)* The letter informs the OPO of:
  - a. *Reasons for the determination;*
  - b. The effective date of the determination;
  - c. The deficiencies cited and the requirements not met;

- d. *The OPOs right to seek reconsideration*; and
  - e. *The timeframe for submitting additional data.*
4. Open the service area for competition. (See §2812.3 and Exhibit 175.)
  5. Publish a public notice in the newspapers.
  6. Send copies of the *public* notice with a cover letter to:
    - a. Association of Organ Procurement Organizations  
*1364 Beverly Road, Suite 100*  
*McLean, VA 22101*;
    - b. Current Organ Procurement and Transplantation Network (OPTN)  
  
The current OPTN is:  
UNOS  
*Post Office Box 2484*  
Richmond, VA 23225;
    - c. *CMS Central Office*
    - d. Hospitals that have a working relationship and agreements with the OPO;
    - e. Bordering OPOs;
    - f. Medicaid/Medicare State Agencies; and
    - g. *FI/MAC* of the terminated OPO.

### **3012.2B - Reconsideration Procedures**

***(Rev. 112, Issued: 04-11-14, Effective, 04-11-14, Implementation: 04-11-14)***

*The OPO may appeal the termination decision under 42 CFR 486.314.*

*The CMS RO mails notice to the OPO of a termination initial determination. The notice contains the reasons for the termination action, the effective date of the termination, and the OPO's right to seek reconsideration. If the OPO is dissatisfied with the termination action, it has 15 business days from receipt of the notice of the termination action to submit its request in writing to the appropriate CMS RO to seek reconsideration of that determination from CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for the disagreement.*

*An OPO must seek reconsideration before it is entitled to seek a hearing before a hearing officer. If an OPO does not request reconsideration or its request is not made timely, the OPO has no right to further administrative review.*

*The CMS RO will make a written reconsidered determination within 10 business days of receipt of the request for reconsideration, affirming, reversing, or modifying the initial determination.*

*An OPO dissatisfied with the CMS reconsideration decision, must file a request for a hearing before a CMS hearing officer within 40 business days of receipt of the notice of the reconsideration determination. If an OPO does not request a hearing or its request is not received timely, the OPO has no right to further administrative review.*

### ***3012.2C - Appeal Procedures***

***(Rev. 112, Issued: 04-11-14, Effective, 04-11-14, Implementation: 04-11-14)***

*If the OPO submits a request for a formal hearing, the CMS RO sends a complete administrative record that includes any additional materials submitted by the OPO, and a copy of the reconsideration decision and sends the supplemental administrative record to the CMS hearing officer.*

#### ***CMS will provide the hearing officer with:***

- a) A copy of the CMS OPO Database report ranking of all OPO(s) utilizing the most recent data collection period, based upon compliance with the regulatory data requirements at §486.318 through §486.328.*
- b) Copies of all written correspondence between the OPO and the CMS RO relevant to the certification action under appeal;*
- c) All relevant e-mail correspondence between the OPO and the RO;*
- d) Any pertinent entries from a correspondence log if utilized; and*
- e) Relevant Survey and Certification Memoranda and guidance.*