
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 111

Date: April 11, 2014

SUBJECT: State Operations Manual (SOM) Chapter 2 Policy Revisions For Organ Procurement Organizations (OPOs)

I. SUMMARY OF CHANGES: Revisions have been made to Chapter 2, Sections 2810-2819 to reflect current Survey and Certification policy regarding OPOs. Section 2812.1, Public Health Service (PHS) Grantees, and Section 2816, Interim Designations, have been deleted from this chapter. New Sections 2820 and 2821 have been added to reflect the outcome measures/data reporting and information management 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	2/Table of Contents
R	2/2810/Organ Procurement Organizations (OPOs) – Citations - Statutory Authority
R	2/2810.1/Definitions
R	2/2811/OPO Requirements for Certification
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D	2/2812.1/Public Health Service (PHS) Grantees
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R	2/2815/De-certification and Competition:
D	2/2816/Interim Designations
R	2/2817/Voluntary Termination of an Agreement:
R	2/2818/Involuntary Termination and Non-renewal of an Agreement:
R	2/2819/Appeals (§486.314)
N	2/2820/Outcome Measures/Data Reporting (§486.318, 486.328): NOT

	REVIEWED ON SITE
N	2/2821/Information Management (§486.330):

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

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

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

State Operations Manual

Chapter 2 - The Certification Process

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(Rev.111, Issued: 04-11-14)

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2810 - Organ Procurement Organizations (OPOs) – Citations - Statutory Authority

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

Section §1138 (b)(1) of the Social Security Act (the Act) authorizes the Secretary to provide payment under Medicare or Medicaid to hospitals/CAHs and transplant centers for the cost of organs procured from organ procurement organizations (OPOs) only if the organization:

- *Is a qualified OPO operating under a grant made under §371(a) of the Public Health Service Act (PHSA), or has been certified or recertified by the Secretary within the previous four years as meeting the standards to be a qualified OPO;*
- *Meets applicable requirements of Medicare or Medicaid for OPOs;*
- *Meets performance-related standards prescribed by the Secretary;*
- *Is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) designated by the Secretary pursuant to §372 of the PHSA. (The United Network for Organ Sharing (UNOS) operates the OPTN under a contract with the PHS);*
- *Allocates organs, within its service area and nationally, in accordance with medical criteria and the policies of the OPTN; and*
- *Is designated or re-designated by the Secretary as an OPO under §1138 of the Act.*

To be designated as the OPO for a service area, an organization must at the time of application and throughout the period of designation meet these statutory requirements. Further, the Act requires that the Secretary may not designate more than one OPO for each service area, as described in §371 (b)(1)(E) of the PHSA and §1138 (b)(2) of the Act.

2810.1 – Definitions

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

Certification means a CMS determination that an OPO meets the requirements for certification at **42 CFR 486.303**.

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at **42 CFR 486.303**.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under **Section 1138(b)(1)(F)** of the Act.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ Procurement Organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective beneficiaries for available organs.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Transplant Hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ **transplant centers** operating within the same transplant hospital.

Urgent need occurs when an OPO is non-compliant with one or more conditions for coverage and this has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

2811 - OPO Requirements for Certification

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

42 CFR 486.303 details the following requirements that an OPO must meet in order to be certified by CMS. A qualified OPO:

1. Must have received a grant under **42 U.S.C. 273(a)** or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO;
2. Be a non-profit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986;
3. Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals;
4. Have an agreement with CMS, as the Secretary's designated representative, to be reimbursed under Title XVIII for the procurement of kidneys;
5. Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005;
6. Have procedures to obtain payment for non-renal organs provided to transplant centers;
7. Agree to enter into an agreement with any hospital or CAH in the OPO's service area, including a transplant hospital that requests an agreement;
8. Meet or have met the conditions for coverage for OPOs, including both the outcome measures and the process performance measures; and
9. Meet the provisions of Titles XI, XVIII, and XIX of the Act, section 371(b) of the PHSA, and any other applicable Federal regulations.

2812 – OPO Designation Requirements

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

An OPO must be designated by CMS and must enter into an agreement with CMS in order for the OPO to be reimbursed under Medicare and Medicaid for the costs of organ procurement.

42 CFR 486.306(b) and (c) details the requirements that an OPO must meet for service area designation, service area location, and characteristics.

*42 CFR 486.308 specifies that CMS designates only one OPO per service area and that the service area is only **open for competition** after the OPO designated for that area is de-certified and all administrative appeals have been completed under §486.314, or the OPO voluntarily withdraws from the program. A designated OPO may only change its service area boundaries as a result of a merger or consolidation with another OPO after advance approval by CMS as noted in §486.310 (a). An OPO must compete for an entire service area according to §486.316(c)(3).*

An OPO is normally designated for a 4-year agreement cycle. In the case of a voluntary termination of its agreement, CMS will open the service area for competition to fill the remaining term of the 4-year agreement cycle. A designation period may be longer than the 4-year agreement cycle in instances where CMS requires a longer period of time to select a successor to an OPO that has been de-certified or has voluntarily terminated.

2812.2 - Waivers

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

*A certified hospital/CAH must enter into an agreement only with the OPO designated for the service area in which the hospital/CAH is located, unless CMS has granted the hospital/CAH a **waiver** under §486.308(e). A hospital/CAH may request and CMS may grant a waiver allowing the hospital to have an agreement with a designated OPO outside of its service area. To qualify for a waiver, the hospital must submit data to CMS as detailed in **42 CFR 486.308(e)(1) and (2)**. In making a determination on waiver requests, CMS considers the requirement under **42 CFR 486.308 (f)(1)-(4)**:*

- *Cost effectiveness;*
- *Improvements in quality;*
- *Changes in a hospital's designated OPO due to changes in the definition of metropolitan statistical areas, if applicable; and*
- *The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.*

A hospital/CAH may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If the waiver is denied by CMS, the hospital/CAH must enter into an agreement with the OPO designated for its service area within 30 days of notification of the final determination as noted in §486.308(g).

2812.3 - Open Competition

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

To assure that the **CMS** RO is not designating more than one OPO per service area, it should plot the proposed service areas of all applicants prior to taking any certification action. Under the statute, it is critical that the service areas of OPOs not overlap. If an applicant designates a service area that crosses **CMS** RO boundaries, the physical location

of the OPO's main office determines which **CMS** RO controls the review of the application. In these situations, coordinate certification action between the appropriate **CMS** RO(s).

If there is no competition within a given service area and the applicant meets the statutory and regulatory requirements, the **CMS** RO sends the organization the Model OPO Approval Letter (see Exhibit 172). If the OPO is not hospital-based, assign a provider number with an alpha "P" in the third position of the provider number. For example, the **CMS** RO inputs the information 21P001 into the Online Survey Certification and Reporting System/Online Data Input and Edit (OSCAR/ODIE) systems.

NOTE: If the OPO is hospital-based, the hospital's Fiscal Intermediary/Medicare Administrative Contractor will service the OPO and no special provider number is needed.

If no OPO applies to compete for a de-certified OPO's open area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS will make its decision based on the criteria in §486.316 (d).

2812.4 - Criteria to Compete:

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

In order for an OPO to compete for an open service area, it must meet the following specific criteria:

- *The criteria in §486.316(a);*
- *A donation rate and yield outcome rate measure that is at or above 100 per cent of the mean national rate averaged over the 4 years of the re-certification cycle; A donation rate at least 15 percentage points above the donation rate of the OPO currently designated for the service area for which it is competing; and compete for the entire service area.*

An OPO in competition for an open service area must submit the following information:

- *Data and information that describes the barriers (e.g., geographical, cultural, religious, financial) in its service area;*
- *How the barriers affected organ donation;*
- *What steps the OPO took to overcome the barriers; and the results of the OPO's actions to overcome the barriers.*

2812.5 - Criteria for Selection of an OPO in an Open Service Area:

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

CMS designation for an open service area is based on the following criteria:

- *Performance on the outcome measures detailed at **42 CFR 486.318**;*
- *Relative success in meeting the process performance measures and compliance with the other conditions at **42 CFR 486.320** through **42 CFR 486.348**;*

- *Contiguity to the open service area; and*
- *Success in identifying and overcoming barriers (e.g., geographical, cultural, religious, financial) to donation within its current service area and the relevance of those barriers to barriers in the open service area.*

2813 - Re-Certification Cycle (42 CFR 486.309)

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

An OPO is considered re-certified if it meets the standards of a qualified OPO within the 4-year period beginning from August 1, 2006 through July 31, 2010; August 1, 2010 through July 31, 2014; August 1, 2014 through July 31, 2018; August 1, 2018 through July 31, 2022; and onwards.

An OPO is surveyed once every four years and its service area is not opened for competition when the OPO:

- *Meets all 3 outcome measure requirements at 42 CFR 486.318; and*
- *Has been shown by the results of a survey to be in compliance with the certification requirements at 42 CFR 486.303, including the conditions for coverage at 42 CFR 486.320 through 486.348.*

2814 - Change in Control/Ownership or Service Area (42 CFR 486.310)

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

*The applicable CMS RO must be notified **before** a designated OPO implements a change in either ownership or control or in its service area. The OPO must provide information to the CMS RO that is specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation the CMS RO determines to be necessary for designation. A designated OPO considering a change in its service area must obtain prior CMS RO approval.*

*If an OPO's change of ownership or control is of such an extent that it no longer meets the requirements for designation as an OPO, as determined on **Form CMS-576**, CMS may de-certify the OPO and designate its service area an open area. The OPO may appeal such a de-certification under §486.314. The service area is not opened for competition until the conclusion of the administrative appeals process. The OPO must submit a revised **Form CMS-855** (Medicare Enrollment Application) to the FI/MAC with any change of control or ownership.*

*** See 2812.3 Open Competition**

When the CMS RO receives notification of a prospective change in control or ownership for a designated OPO, the CMS RO must determine, based upon the documents submitted, that the operation of the OPO will continue uninterrupted and continue to satisfy Medicare and Medicaid requirements during and following the changeover of ownership or control. The CMS RO will review all the documents submitted by the OPO, including its responses to the elements on Form CMS-576. If the RO approves the

CHOW/change of control and the OPO proceeds with change of ownership a new CMS Form 576 must be signed by the person designated by the governing body to be responsible for operations. The OPO should show evidence of transition planning to ensure continuity. Confirm with the Fiscal Intermediary/MAC that the OPO has submitted a revised CMS Form-855 and that the information has been accepted.

De-certification (42 CFR 486.312)

2815 - De-certification and Competition:

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

If an OPO does not meet all 3 outcome measures as outlined in 42 CFR 486.318 or if it has been shown by survey to be out of compliance with the requirements described in 42 CFR 486.320 through 486. 348, the OPO is de-certified. If the OPO does not appeal the de-certification, or if the OPO appeals and the reconsideration official and the CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The OPO that has been de-certified is not permitted to compete for its open area or any other open service area.

2817 - Voluntary Termination of an Agreement:

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implemetation: 04-11-14)

The OPO must submit to the applicable CMS RO a written notice of its intention to terminate its agreement and include a stated proposed effective date. CMS has the option to agree to the proposed effective date or set another termination date no later than six months from the OPO requested date, or set a different date less than six months after the proposed effective date if it determines a different date would not disrupt services in that area. If CMS determines that the OPO has ceased providing services to its donation service area, then that cessation of services is considered a voluntary termination by the OPO, with the effective date to be determined by CMS.

*After approval from CMS of the date for voluntary termination, the OPO must provide public notice of its voluntary termination in local newspapers within three (3) business days from the approval date. The notice should include the date the OPO will cease operations and services, a list of hospitals and CAHs in the OPOs service area, and the OPO telephone contact numbers for inquiries. The OPO must provide the CMS RO with copies of each public notice within **seven (7) business days** of CMS's approval of voluntary termination. No further payments under Title XVIII or XIX of the Act will be made with respect to costs attributable to the OPO on or after the effective date of de-certification.*

**** See also 2812.3 Open Competition***

2818 - Involuntary Termination and Non-renewal of an Agreement:
(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

During the term of an OPO agreement, CMS may terminate an agreement with an OPO at any time the OPO no longer meets the requirements for certification at 42 CFR 486.303. Additionally, CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at §486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at §486.303. If CMS determines that the OPO is out of compliance with one or more Conditions for Coverage and the OPO does not implement an approved plan of correction that re-establishes compliance prior to the end of a designated period of time, CMS will begin the process of de-certification. CMS may also immediately terminate an agreement in cases of urgent need as defined in 42 CFR 486.302. CMS will decertify the OPO as of the effective date of the involuntary termination or as of the ending date of the agreement in the case of non-renewals.

*** See also 2812.3 Open Competition**

*Except in cases of urgent need, CMS will give the OPO written notice of the intent to de-certify at least **90 days** before the effective date of de-certification. CMS provides public notice of the effective date of de-certification in local newspapers in the OPO's service area. The notice will state the reasons for de-certification and the effective date. No further payments under Title XVIII or XIX of the Act will be made with respect to costs attributable to the OPO on or after the effective date of the de-certification. In cases of urgent need, follow the procedures found in **Appendix Q: Immediate Jeopardy**.*

2819 Appeals (§486.314)

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

Involuntary Termination/Non-Renewal of Agreement:

An OPO may appeal an involuntary termination or non-renewal of an agreement on substantive and procedural grounds. CMS sends a notice of initial de-certification determination to the OPO which contains the reasons for the determination, the effect of the determination, and the OPO's right to seek reconsideration. The notice letter informing the OPO of de-certification and impending termination must include the appropriate appeal rights as well as instructions on how to file a request for reconsideration.

Reconsideration of a De-certification:

*An OPO has **15 business days** from receipt of CMS' notice of de-certification to seek reconsideration from CMS if it is dissatisfied with the de-certification determination. The OPO reconsideration request must state the issues or findings of fact with which the OPO disagrees, the reasons for disagreement and factual support for each finding with which they disagree, and the reasons for disagreement. The OPO may submit factual support for each findings with which they disagree as well as additional information and*

arguments as to why it should not be decertified. CMS then evaluates the submitted information to determine if the de-certification decision is upheld or reversed. An OPO must seek reconsideration before it is entitled to seek a hearing before a hearing officer. If the OPO does not request reconsideration from CMS, or fails to submit its request timely to CMS, the OPO has no right to further administrative review and the de-certification is final.

CMS Reconsideration Determination:

*A written reconsidered determination is made by CMS within **10 business days** of the request for reconsideration. This determination will affirm, reverse or modify the initial de-certification determination and the findings on which it was based and will determine whether the submitted documentation and information was sufficient to support a change in the initial decision. If the determination decision is reversed or modified, CMS notifies the OPO in writing with a revised Form **CMS-2567** to reflect the revised findings. If the decision is not reversed or modified, but is affirmed, CMS notifies the OPO in writing of the decision, including what materials CMS reviewed and why the submitted documentation did not justify a reversal or modification in the initial decision to de-certify. Additionally, CMS informs the OPO that it will not be eligible to compete for the current service area or any other service area opened for competition. CMS will augment the administrative record to include any additional materials submitted by the OPO and a copy of the reconsideration decision, and sends the supplemented administrative record to the CMS hearing officer. If the OPO timely seeks further administrative review (hearing), CMS forwards the initial request for reconsideration and all supporting documentation to the hearing officer.*

Administrative Hearing:

*An OPO that wishes to appeal the reconsideration decision of CMS must file a written hearing request within **forty (40) business days** of the receipt of the notice of CMS reconsideration decision. If a hearing request is not submitted or received timely by CMS, then the OPO has no further right to appeal or other administrative review. The Administrative Appeal Process is handled through the Office of Medicare Hearings and Appeals.*

Administrative Record:

The administrative record consists of, but is not limited to, (1) factual findings from the survey(s) on the OPO conditions for coverage; (2) data from outcome measures; (3) rankings of OPOs based on the outcome data; and (4) correspondence between CMS and the affected OPO. The hearing officer sends the administrative record to both parties within ten (10) business days of receipt of the OPO's written request for hearing.

2820 - Outcome Measures/Data Reporting (§486.318, 486.328): NOT REVIEWED ON SITE

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

Data measures as calculated by University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) utilizing the Scientific Registry of Transplant Recipients (SRTR) data and OPTN reporting data are entered into the OPO database for CMS CO/RO review for regulatory compliance.

2821 - Information Management (§486.330):

(Rev.111, Issued: 04-11-14, Effective: 04-11-14, Implementation: 04-11-14)

The OPO is required to keep and maintain donor and transplant recipient records in a human readable and reproducible paper or electronic format for a minimum of seven (7) years.