
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 179

Date: July 6, 2018

SUBJECT: Revisions to the State Operations Manual (SOM) Chapter Two for Organ Procurement Organizations (OPOs)

I. SUMMARY OF CHANGES: The SOM Chapter Two for OPOs has been revised to update the instructions on opening the OPO Donation Service Area (DSA) for competition. Section 2812.3 has been revised to provide clarification on opening the OPO DSA and putting out the announcement for competition. Sections 2812.4 and 2812.5 have been revised to provide instructions on the application process and review. Sections 2812.6 through 2812.8 have been added to provide instructions on the selection process, the transition process, and when no OPO applies for the open DSA.

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 6, 2018

IMPLEMENTATION: July 6, 2018

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	2/2812.3/ Opening the Donation Service Area (DSA) for Competition (42 CFR 486.316)
R	2/2812.4/Application
R	2/2812.5/Application Review
N	2/2812.6/Selection Process
N	2/2812.7/OPO Transition
N	2/2812.8/No OPO applies for the open DSA

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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(179, Issued: 07-06-18)

Transmittals for Chapter 2

Organ Procurement Organizations

- 2812.3 – *Opening the Donation Service Area (DSA) for Competition from other OPOs
(42 CFR 486.316)*
- 2812.4 - *Application*
- 2812.5 – *Application Review*
- 2812.6 - *Selection Process*
- 2812.7 - *OPO Transition*
- 2812.8 - *No OPO applications for the open DSA*

2812.3 – Opening the Donation Service Area (DSA) for Competition from other OPOs (42 CFR 486.316)

(Rev. 179, Issued: 07-06-18, Effective: 07-06-18, Implantation: 07-06-18)

The CMS RO opens an OPO's DSA for competition if:

- a. CMS terminates or de-certifies the OPO (involuntary termination) during the current certification period due to non-compliance with the Conditions for Coverage;*
- b. The normal four year certification period has ended and CMS declines to renew its agreement with the OPO under §486.316 (non-renewal of an agreement); or*
- c. An OPO ceases to operate or CMS has reasonable grounds for anticipating it will cease to operate (voluntary termination by the OPO).*

For a voluntary termination including a cessation of business, the RO opens the DSA for competition on the CMS-approved effective date of the termination. For an involuntary termination of an OPO or the non-renewal of an OPO's agreement, the RO will open the area for competition either on the date of the completion of the administrative appeals process which upholds the termination action or once the time to file an appeal has passed and the OPO has declined to do so. A de-certified OPO cannot compete for its open area or any other open area.

Simultaneously with opening the DSA for competition, the RO will request a transition plan from the non-renewed OPO that provides details on how all aspects of the OPO operation will be transmitted, including time frames, to a new OPO (see SOM Section 2812.4(a)-(l) below).

The CMS RO will announce the opening of the DSA in an email to all currently certified OPOs and the Association of Organ Procurement Organizations. The following entities will be copied on the communication:

- The CMS Center for Medicare;*
- The CMS Medicare Administrative Contractor for the non-renewed OPO (Form CMS-2007 Provider Tie-In Notice) (required);and*
- The Health Resources and Services Administration (HRSA).*

The announcement will specify what information must be submitted by any OPO applicant, the deadline for submission of an application (which will be set at 45 calendar days from the date of the announcement), and the expected timeframe for selection of an applicant (which will generally be 30 calendar days from the application closing date). In the case of involuntary termination or non-renewal of an agreement, CMS may extend the agreement of the de-certified OPO to facilitate transition to a new OPO.

In order to apply for an open DSA, an applicant OPO must meet the following criteria:

- a. Be in compliance with two out the three outcome measure requirements at 42 CFR 486.318;*
- b. Be at or above 100 percent of the mean national rate averaged over the years of the re-certification cycle for the outcome measures at 42 CFR 486.318;*
- c. Be at least 15 percentage points higher than the donation rate at 42 CFR 486.318 of the OPO currently designated for the service area;*

- d. *Be in compliance with the requirements for certification at 42 CFR 486.303, including the conditions for coverage at 42 CFR 486.320 through 42 CFR 486.348; and*
- e. *Compete for the entire service area.*

2812.4 – Application

(Rev. 179, Issued: 07-06-18, Effective: 07-06-18, Implantation: 07-06-18)

The applicant must submit the following information to the CMS RO by the deadline set out in the open competition announcement:

- *Completed CMS -Form 576A;*
- *Transition plan that includes timelines for all aspects of the transition including, but not limited to:*
 - a. *Physical location (office);*
 - b. *Policies for community outreach;*
 - c. *Coordination with transplant hospitals in the DSA;*
 - d. *Coordination with donor hospitals in the DSA;*
 - e. *Coordination with tissue and eye banks in the DSA;*
 - f. *Constitution of an Advisory Board;*
 - g. *Governing Body oversight of the successful transition of the DSA;*
 - h. *Plan for staff retention or additions to ensure adequate and trained staff coverage in the open area;*
 - i. *Transfer of donor data;*
 - j. *Name of Medical Officer;*
 - k. *A plan for prompt response to hospital referrals; and*
 - l. *Plan for identifying and addressing the unique challenges of the DSA which impact the performance of the OPO.*

2812.5 - Application Review

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The applicant OPO must submit its application by the specified deadline to the CMS RO for review. The RO will assemble a panel to review the applications. Each application will be reviewed according to the following criteria at 42 CFR 486.316(d):

- a. *Compliance with the outcome measures at 42 CFR 486.318;*
- b. *Compliance with 42 CFR 486.320 through 42 CFR 486.348;*
- c. *Contiguity to the open service area; and*
- d. *Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.*

2812.6 - Selection Process

(Rev. 179, Issued: 07-06-18, Effective: 07-06-18, Implantation: 07-06-18)

The CMS RO will complete a review of all applications within 30 calendar days of the application closing date. The RO will either make a selection of a successor OPO for the DSA or decline to accept all applications (see below at SOM Section 2812.8). The OPO selected will be notified of this selection in writing by the RO and the DSA will be redesignated to the selected OPO. The following entities will be copied on the communication to the OPO:

- *The CMS Center for Medicare;*
- *The CMS Medicare Administrative Contractor (Form CMS-2007, Provider Tie-In Notice);*
- *The Association of Organ Procurement Organizations (AOPO); and*
- *The Health Resources and Services Administration (HRSA).*

2812.7 - OPO Transition

(Rev. 179, Issued: 07-06-18, Effective: 07-06-18, Implantation: 07-06-18)

The newly designated OPO will submit a monthly summary to the CMS RO to report on its transition activities. The CMS RO will monitor the transition process to ensure successful oversight and management of OPO operations. The RO will conduct a full survey of the newly designated OPO within six months of the transition to determine compliance with the Conditions for Coverage.

2812.8 - No OPO applications for the open DSA

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If no OPO applies for an open DSA or if CMS declines to accept all applications, CMS may select a single OPO to take over the entire open DSA or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open DSA. The RO will make its decision based on the selection criteria at 42 CFR 486.316(d).