

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 253	Date: APRIL 25, 2008
	Change Request 5953

SUBJECT: Local Coverage Determinations (LCDs) Responsibility Transition From Durable Medical Equipment (DME) Program Safeguard Contractor (PSC) to DME Medicare Administrative Contractors (MAC)

I. SUMMARY OF CHANGES: The LCD workload is transitioning from the DME PSCs to the DME MACs; effective March 1, 2008.

NEW/REVISED MATERIAL

EFFECTIVE DATE: NOVEMBER 2, 2007

IMPLEMENTATION DATE: May 27, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. 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 is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	13/13.1.4/Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of LCDs Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

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

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

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SUBJECT: Local Coverage Determinations (LCDs) Responsibility Transition From Durable Medical Equipment (DME) Program Safeguard Contractor (PSC) to DME Medicare Administrative Contractors (MAC)

Effective Date: November 2, 2007
Implementation Date: May 27, 2008

I. GENERAL INFORMATION

A. Background: Effective March 1, 2008 the DME PSC will no longer develop, revise or recommend LCDs to the DME MACs. In accordance with this chapter, the DME MAC will have full responsibility for developing and revising LCDs, maintaining the LCD record, and responsibility for LCD challenges.

B. Policy: This change request provides information on LCDs that will no longer be recommended by the DME PSC but will be the responsibility of the DME MACs. The DME MACs shall develop new LCDs and revise existing policies that are consistent with all applicable Medicare statutes, rulings, regulations, and national coverage, payment and coding policies.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
5953.1	During the transition phase, the DME MAC shall have ongoing communications and coordination with the DME PSCs as they transfer the LCD workload.		X								X DME PSC
5953.2	Effective March 1, 2008, the DME MACs shall resume all LCD responsibilities in accordance to chapter 13 of the Program Integrity Manual (Pub. 100-08).		X								
5953.3	The DME MACs shall develop identical LCDs.		X								
5953.4	The DME MACs shall maintain the LCD record as a new LCD is being developed or when an existing policy is being revised.		X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / M	D M	F I	C A	R H	Shared-System Maintainers			

13.1.4 - Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of LCDs Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)

(Rev. 253; Issued: 04-25-08; Effective Date: 11-02-07; Implementation Date: 05-27-08)

The DME PSCs shall ensure that the LCDs they recommend to the DME MACs are developed and revised in accordance with this chapter. This section applies to the:

- DME PSCs that develop new policies and revise existing policies.
- DME MACs.
- DMERCs that have not yet transitioned to the DME MACs.

All references made to DME MACs in this section apply to DMERCs. The DME PSCs shall have on-going communication with the DME MACs as a new policy is being developed or when an existing adopted policy is being revised. CMS requires that the recommended LCDs developed by the DME PSCs be identical for each region to ensure uniformity for DMEPOS suppliers that operate nationally.

The DME PSCs shall maintain an LCD record as a new policy is being developed or when an existing adopted policy is being revised. The DME PSCs shall submit the LCD record, which includes a copy of the final draft of the recommended LCD, to the DME MACs, prior to adoption of the recommended LCD. The DME MACs shall ensure that the LCD record is received prior to adoption of the recommended LCD.

The LCD record shall consist of any document or material that the DME PSCs considered during the development of the new or revised LCD, including, but not limited to, the following:

1. The LCD

2. Any medical evidence considered on or before the date the LCD was recommended to the DME MACs for adoption, including, but not limited to, the following:

- Scientific articles
- Technology assessments
- Clinical guidelines
- Documentation from the FDA regarding safety and efficacy of a drug or device

with the exception of proprietary data and privileged information

- Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice

3. Comment and Response Documents (a summary of all comments received by the DME PSCs concerning the recommended LCD). This applies only to new LCDs or revised LCDs that were sent for comment.

The DME MACs shall have someone available with a clinical background to review the recommended LCD by the DME PSCs and determine if the recommended LCD shall be adopted or rejected. The DME MACs shall have on-going communication and shall coordinate with the other DME MACs to ensure that a uniform decision is made to adopt or reject a recommended LCD across all DME MAC jurisdictions. The DME MACs shall notify the DME PSCs of their decision to adopt or reject the recommended LCD. The DME MACs shall ensure that the adopted LCDs are identical among the DME MACs.

If the DME MACs reject the recommended LCD by the DME PSCs, they shall explain in writing to the DME PSCs why the LCD was rejected. If the DME PSCs decide to modify the rejected LCD based on comments received from the DME MACs, the DME PSCs shall make the appropriate modifications and shall submit a final copy of the recommended LCD to the DME MACs.

In addition, the DME PSCs shall publish the adopted LCD via the Medicare Coverage Database (MCD). The DME MACs shall provide an Internet link on their contractor Web site to the MCD to provide access to the adopted LCD.

If an aggrieved party challenges an adopted LCD, the DME PSCs shall support the DME MACs in their efforts to defend the adopted LCD during the appeal. For example, if the DME MACs need the DME PSCs to provide oral testimony during an appeal, the DME PSCs shall provide such testimony. Questions concerning the extent of the DME PSCs' support to the DME MACs during the appeals process shall be directed to the appropriate Primary and/or Associate GTL(s).

The active LCD record shall be maintained by the DME PSCs until the LCD is retired. When an LCD is retired, the DME PSCs shall submit the retired LCD record to the DME MACs. The DME MACs shall retain the retired LCD record for 6 years and 3 months. The DME MACs shall have a mechanism for archiving retired LCDs. This mechanism shall allow the DME MACs to respond to requests and retrieve the LCD record. The DME MACs shall post on their Web site information regarding how to obtain retired LCDs. The DME MACs shall provide an Internet link on their contractor Web site to the MCD to provide access to the retired LCD. The LCD record shall be destroyed 6 years and 3 months from the date the LCD is retired. However, the DME MACs shall not destroy the retired LCD record if it relates to a current investigation or litigation/negotiation; ongoing Workers' Compensation set aside arrangements; or documents which prompt suspicions of fraud and abuse of improper over-utilization of services. This will satisfy evidentiary needs and discovery obligations critical to the agency's litigation interests.

As referenced in Pub. 100-08, chapter 4, section 4.28, the joint operating agreement developed by the DME PSCs and the DME MACs shall be modified to address the major roles and responsibilities DME PSCs and DME MACs will delineate in order for the DME MACs to adopt or reject LCDs recommended by the DME PSCs.

Effective March 1, 2008, DME PSCs will no longer develop, revise or recommend LCDs to the DME MACs. In accordance to this chapter, the DME MACs will have full responsibility for developing and revising LCDs, maintaining the LCD record, and responsibility for LCD challenges. CMS requires that LCDs developed and revised by the DME MACs be identical for each jurisdiction to ensure uniformity for DMEPOS suppliers that operate nationally.