

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 186	Date: JANUARY 26, 2007
	Change Request 5410

SUBJECT: Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs).

I. SUMMARY OF CHANGES: DME PSCs shall recommend LCDs to the DME MACs for adoption or rejection.

NEW / REVISED MATERIAL

EFFECTIVE DATE: For the DMERCs – September 11, 2006

For the DME MACs – Effective upon release of the contract modification

IMPLEMENTATION DATE: February 26, 2007

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/Table of Contents
R	13/13.1.4/Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs).
R	13/13.12/Retired LCDs and the LCD Record

III. FUNDING:

Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 186	Date: January 26, 2007	Change Request: 5410
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SUBJECT: Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs).

Effective Date:

For the DMERCs – September 11, 2006

For the DME MACs – Effective upon release of the contract modification

Implementation Date: February 26, 2007

I. GENERAL INFORMATION

A. Background: The DME PSCs shall ensure that LCDs they recommend to the DME MACs are developed and revised in accordance with Pub.100-08, chapter 13. This CR adds a new section to chapter 13, which applies to the:

- 1) DME PSCs that develop new policies and revise existing policies;
- 2) DME MACs; and
- 3) DMERCs that have not yet transitioned to the DME MACs.

All references made to DME MACs in this section apply to DMERCs.

This CR clarifies the requirements for retired LCDs and the LCD record.

B. Policy: This CR provides information on LCDs that will be recommended by the DME PSCs to the DME MACs for adoption or rejection. The DME PSCs shall develop new policies and revise existing adopted policies that are consistent with all applicable Medicare statutes, rulings, regulations, and national coverage, payment, and coding policies and submit the recommended LCDs to the DME MACs for adoption or rejection.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)															
		A	D	F	C	D	R	Shared-System Maintainers				OTHER - DME PSC					
		/	M	I	R	A	M	H	R	E	H	F	M	V	C		
		B	E		R	E	R	I	R	E	I	I	S	S	M	W	
		M	M		I	C						S	S	S	F		
		A	A		E												
		C	C		R												
5410.1	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.		X					X									X

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B	D M E	F I	C A R R I E R	D M R I C	R E H I	Shared-System Maintainers				OTHER - DME PSC
								F I S S	M C S	V M S	C W F	
5410.2	The DME PSCs shall develop identical LCDs.											X
5410.3	The DME PSCs shall maintain an LCD record as a new policy is being developed or when an existing adopted policy is being revised.											X
5410.4	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.		X			X						X
5410.5	The DME MACs shall ensure that the LCD record is received prior to adoption of the recommended LCD.		X			X						
5410.6	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.		X			X						
5410.7	The DME MACs shall have on-going communication and coordination with the other DME MACs to ensure that all recommended LCDs are consistently reviewed for adoption or rejection across all DME MAC jurisdictions.		X			X						
5410.8	The DME MACs shall notify the DME PSCs of their decision to adopt or reject the recommended LCD.		X			X						X
5410.9	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.		X			X						X
5410.10	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.		X			X						X

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A C	D M B M A C	F I I E R	C A R R I E R	D M R R I E R	R E H R I E R	Shared-System Maintainers				OTHER - DME PSC
								F I S S	M C S	V M S	C W F	
5410.11	The DME PSCs shall publish the adopted LCD via the MCD.											X
5410.12	The DME MACs shall provide an Internet link on their contractor Web site to the MCD to provide access to the adopted LCD.		X			X						
5410.13	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.		X			X						X
5410.14	The active LCD record shall be maintained by the contractors until the LCD is retired.	X		X	X		X					X
5140.15	When an LCD is retired, the DME PSCs shall submit the retired LCD record to the DME MACs.											X
5410.16	Contractors shall retain the retired LCD record for 6 years and 3 months.	X	X	X	X	X	X					
5410.17	Contractors shall have a mechanism for archiving retired LCDs.	X	X	X	X	X	X					
5410.18	The contractors' mechanism for archiving retired LCDs shall also allow the contractors to respond to requests and retrieve the LCD record.	X	X	X	X	X	X					
5410.19	Contractors shall post on their Web site information regarding how to obtain retired LCDs.	X	X	X	X	X	X					
5410.20	Contractors shall provide an Internet link on their contractor Web site to the MCD to provide access to the retired LCD.	X	X	X	X	X	X					
5410.21	Contractors 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 over-utilization of services.	X	X	X	X	X	X					
5410.22	The DME MACs shall provide the LCD record, received from the DME PSCs, to the		X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I I E R	C A R R I E R	D M R R I C	R E H I C	Shared-System Maintainers			
							F I S S	M C S	V M S	C W F	
	ALJ when an LCD is challenged as outlined in Pub. 100-08, Chapter 13, section 13.13.2.										
5410.23	The DME PSCs shall ensure that the LCDs they recommend to the DME MACs are developed and revised in accordance with Pub. 100-08, Chapter 13.		X			X					X
5410.24	As outlined in Pub. 100-08, Chapter 4, section 4.28, the Joint Operating Agreement (JOA) 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.		X			X					X

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I I E R	C A R R I E R	D M R R I C	R E H I C	Shared-System Maintainers			
							F I S S	M C S	V M S	C W F	
	None.										

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s):

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Post-Implementation Contact(s):

Regional offices

VI. FUNDING

A. For TITLE XVIII Contractors, use only one of the following statements:

Funding for implementation activities will be provided to contractors through the regular budget process.

B. For Medicare Administrative Contractors (MAC), use only one of the following statements:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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.

Medicare Program Integrity Manual

Chapter 13 – Local Coverage Determinations

Table of Contents *(Rev.186, 01-26-07)*

13.12 - Retired LCDs *and The LCD Record*

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

(Rev. 186, Issued: 01-26-07, Effective: DMERCs 09-11-06/DME MACs Upon Release of Contract Modification, Implementation: 02-26-07)

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.

13.12 - Retired LCDs *and The LCD Record*

(Rev. 186, Issued: 01-26-07, Effective: DMERCs 09-11-06/DME MACs Upon Release of Contract Modification, Implementation: 02-26-07)

Contractors shall list the retired date on all retired LCDs. *The active LCD record shall be maintained by contractors until the LCD is retired. Contractors shall retain the retired LCD record for 6 years and 3 months.* Contractors shall have a mechanism for archiving retired LCDs. This mechanism shall also allow the contractor to respond to requests and retrieve the LCD *record*. Contractors shall post on their Web site information regarding how to obtain retired LCD. *The LCD record shall be destroyed 6 years and 3 months from the date the LCD is retired.*

However, contractors shall not destroy the 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.