CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 460	**Date: April 19, 2013**
	Change Request 8194

SUBJECT: Clarify the definition of customized durable medical equipment (DME) items

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to clarify the definition of customized DME items set forth at 42 CFR Section 414.224.

EFFECTIVE DATE: January 1, 1992
IMPLEMENTATION DATE: July 19, 2013

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	Chapter 5/5.15/Definition of Customized DME

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor's activities are to be carried out within their operating budgets.

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 obliged 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

Pub. 100-08	Transmittal: 460	Date: April 19, 2013	Change Request: 8194

SUBJECT: Clarify the definition of customized durable medical equipment (DME) items

EFFECTIVE DATE: January 1, 1992
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I. GENERAL INFORMATION

A. Background:

The definition of customized DME set forth in regulations at 42 CFR Section 414.224 is based on the longstanding definition of customized DME used in making decisions regarding when to make individual payment determinations outside the normal process for calculating customary and prevailing charges under the reasonable charge payment methodology used for DME prior to 1989. Public Law 101-508, Omnibus Budget Reconciliation Act (OBRA), November 5, 1990 (104 Stat. 1388-79) amended the criteria for treatment of wheelchair as a customized item at section 1834 (a) (4) of the Social Security Act by adding a clause that in case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modification or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician. The amendment further noted that this clause applied only to items furnished on or after January 1, 1992, unless the Secretary developed specific criteria before that date for the treatment of wheelchairs as customized items for purposes of section 1834(a) (4) of the Social Security Act (in which case the amendment made by such clause would not become effective. CMS issued an interim final rule on December 20, 1991 (56 FR 65995) to announce the decision not to use the optional definition of customized wheelchairs in section 1834 (a) (4) of the Act and add a new section 414.224 to 42 CFR to provide in regulation criteria that must be met for a covered item to be considered a customized item for payment purposes. The final rule (58 FR 34919) was published on June 30, 1993.

NOTE: Contractors must observe that the alternative definition of customized wheelchairs found in section 1834(a)(4) of the Act was never adopted for Medicare payment purposes and should not be confused with the definition of customized items at 42 CFR 414.224.

B. Policy: In accordance with 42 CFR Section 414.224, in order to be considered a customized item, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8194.1	Contractors shall recognize the revised definition of customized DME items in accordance with new information provided in the Manual (Section 5.15 of Chapter 5 - Medicare Program Integrity Manual) and per the regulatory definition for customized DME Items set forth at Section 414.224.			X			X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Other
		Part A	Part B					
8194.2	MLN Article : A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.							

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Sandhya Gilkerson, sandhya.gilkerson@cms.hhs.gov , Karen Jacobs, karen.jacobs@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:

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Section B: For Medicare Administrative Contractors (MACs):

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Medicare Program Integrity Manual
Chapter 5 – Items and Services Having Special DME Review Considerations

5.15 – Definition of Customized DME
(Rev.460, Issued; 04-19-13, Effective: 01-01-92, Implementation: 07-19-13)

42 CFR 414.224 defines customized DME as being items of DME which have been uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of the beneficiary's treating physician. See Pub. 100-04, Chapter 20, Section 30.3 for information on customized DME.