CMS Manual System	Department of Health & Human Services (DHHS)					
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)					
Transmittal 587	Date: April 17, 2015					
	Change Request 9112					

SUBJECT: Clarification of Ordering and Certifying Documentation Maintenance Requirements

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to clarify the term "access to documentation" in chapter 15, section 15.18, of Pub. 100-08.

EFFECTIVE DATE: July 20, 2015

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

IMPLEMENTATION DATE: July 20, 2015

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	15/15.18/Ordering and Certifying Documentation - Maintenance Requirements			

III. FUNDING:

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

Attachment - Business Requirements

SUBJECT: Clarification of Ordering and Certifying Documentation Maintenance Requirements

EFFECTIVE DATE: July 20, 2015

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I. GENERAL INFORMATION

- **A. Background:** This CR clarifies the term "access to documentation" in chapter 15, section 15.18 of Pub. 100-08. Under 42 CFR §424.516(f)(1), a provider or supplier that furnishes covered ordered items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), clinical laboratory, imaging services, or covered ordered/certified home health services is required to:
- Maintain documentation for seven years from the date of service, and
- Upon the request of the Centers for Medicare and Medicaid Services or a Medicare contractor, provide access to that documentation.
- **B.** Policy: As described in this CR, the term "access to documentation" means that the documentation is actually provided or made available in the manner requested by CMS or a Medicare contractor. Examples of sufficient and deficient access to documentation are described in this CR.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC		D	Shared-			Other		
				M	System					
				Е	Maintainers					
		A	В	Н		F	M	V	C	
				Н	M	I	C	M	W	
				Н	Α	S	S	S	F	
					С	S				
9112.1	The contractor shall be advised of the clarification	X	X	X						Providers
	of the term "access to documentation" contained									
	in this CR.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC		DME MAC	CEDI	
		A	В	ННН		
9112.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 5 business days after receipt of the notification from CMS announcing the availability of the 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.	X	X	X		

IV. SUPPORTING INFORMATION

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

[&]quot;Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

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

V. CONTACTS

Pre-Implementation Contact(s): Frank Whelan, 410-786-1302 or frank.whelan@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

15.18 - Ordering and Certifying Documentation - Maintenance Requirements

(Rev. 587, Issued: 04-17-15, Effective: 07-20-15, Implementation: 07-20-15)

A. Background

Under 42 CFR §424.516(f)(1), a provider or supplier that furnishes covered ordered items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), clinical laboratory, imaging services, or covered ordered/certified home health services is required to:

- Maintain documentation (see next paragraph) for 7 years from the date of service, and
- Upon the request of CMS or a Medicare contractor, provide access to that documentation.

The documentation to be maintained includes written and electronic documents (including the National Provider Identifier (NPI) of the physician who ordered/certified the home health services and the NPI of the physician - or, when permitted, other eligible professional - who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

In addition, under §424.516(f)(2), a physician who orders/certifies home health services and the physician - or, when permitted, other eligible professional - who orders items of DMEPOS or clinical laboratory or imaging services is required to maintain the documentation described in the previous paragraph for 7 years from the date of service and to provide access to that documentation pursuant to a CMS or Medicare contractor request.

If the provider, supplier, physician or eligible professional (as applicable) fails to maintain this documentation or to furnish this documentation upon request, the contractor may revoke *enrollment* under §424.535(a)(10).

B. Justification for Request for Documentation

Absent a CMS directive to the contrary, the contractor shall request the documentation described in subsection (A) if it has reason to believe that the provider, supplier, physician or eligible professional (hereinafter collectively referred to as "provider") is not maintaining the documentation in accordance with §424.516(f)(1) or (2). Examples of when a request might be appropriate include, but are not limited to:

- The contractor has detected an unusually high number of denied claims involving the provider, or the Fraud Prevention System has generated an alert with respect to the provider.
- The provider has been the subject of a recent Zone Program Integrity Contractor referral.
- The provider maintains an elevated surety bond amount.

These are, of course, only examples of when a request could perhaps be warranted. Ultimately, the contractor would have to consider the surrounding circumstances of each case, including those involving situations not addressed in the aforementioned examples. The contractor may always contact its *CMS* Provider Enrollment Business Function Lead (*PEBFL*) if it is uncertain as to whether a particular documentation request should be made.

NOTE: Documentation cannot be requested for written orders and certifications dated prior to July 6, 2010.

C. Maintaining and Providing Access to Documentation

Under §424.516(f), CMS or a Medicare contractor may request access to documentation described in §424.516(f). The term "access to documentation" means that the documentation is actually provided or made available in the manner requested by CMS or a Medicare contractor. All providers and suppliers who either furnish, order, or certify the items described in section A above are subject to this requirement and are individually responsible for maintaining these records and providing them upon request.

For example, if a Medicare contractor requests copies of all orders for wheelchairs from an ordering physician for all beneficiaries with dates of service from November 1, 2014 through November 10, 2014, the ordering physician must provide the copies, in full, according to the specific request. If copies cannot be provided because the physician or eligible professional did not personally maintain the records or can only be partially provided, then the requirement to maintain this documentation and provide access to it will not have been met and the provider, supplier, physician, or eligible professional may be subject to the revocation basis set forth in §424.535(a)(10).

Examples of Sufficient and Deficient Access may include, but are not limited to:

Sufficient Access	Deficient Access
All documentation requested	• Providing none of the requested documentation
 Documentation specific to the order(s) or certification(s), as requested 	Providing only a portion of the requested documentation
Documentation for the dates of service or billing periods requested	 Providing similar documentation that does not contain the order or certification requested
	 Providing other documents NOT requested by CMS or a Medicare contractor and/or not specifically directing attention to the requested documentation

CMS recognizes that providers and suppliers often rely upon an employer or another entity to maintain these records on their behalf. However, it remains the responsibility of the individual or entity upon whom/which the request has been made to provide documentation. All individuals and entities subject to this documentation requirement are responsible for ensuring that documents are provided upon request and may ultimately be subject to the revocation basis associated with not complying with the documentation request.

D. Process

If the contractor believes that a request for documentation is warranted, it shall prepare and send a request letter to the provider via mail. If the provider:

- Fails to respond within 30 calendar days of the contractor's request (i.e., a complete non-response), the contractor shall revoke enrollment using §424.535(a)(10) as the basis. Prior approval from the contractor's PEOG BFL is not necessary. A 1-year re-enrollment bar shall be imposed.
- Timely furnishes documentation that the contractor nevertheless deems inadequate, the contractor shall send a developmental letter via mail, e-mail or fax to the provider that requests more sufficient documentation. If the provider fails to submit such documentation (either via a complete non-response or by submitting additional inadequate documentation), the contractor shall refer the matter (including the documentation submitted to

date) to its CMS PEBFL. CMS will determine whether a revocation is warranted and will notify the contractor via e-mail of its decision.

• Furnishes documentation that the contractor deems adequate, the contractor need not take further action other than to place the documentation and the documentation request letter(s) in the provider file.

E. Additional Guidance

The contractor shall also abide by the following:

- 1. When preparing the letter referred to in (C)(1) above, the contractor shall use the appropriate model language in (E) or (F) below. Note, however, that while the letters request copies of orders, the contractor has the discretion to ask for different or additional documentation (e.g., documentation that supports the legitimacy of a particular service or the payment of a particular claim). Copies of orders need not be requested in every situation. As alluded to in (B) above, the contractor would have to examine the facts of each case in determining the type(s) of documentation to be requested.
- 2. There may be situations in which CMS directs the contractor to request documentation in a particular case. The contractor shall follow the instructions in this section 15.18 with respect to doing so.
- 3. The contractor shall contact its CMS PEBFL if it has questions as to whether particular submitted documentation is adequate or legitimate specifically, whether it falls within the category of documentation described in section (A) above.
- F. Model Language for § 424.516(f)(1) Situations

The contractor shall use the model language below if it is requesting documentation from a provider or supplier furnishing the items or services addressed in \$424.516(f)(1).

"Dear Provider/Supplier:

Under 42 CFR §424.516(f)(1), a provider or supplier that furnishes covered ordered items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), clinical laboratory, imaging services, or covered ordered/certified home health services is required to:

- Maintain documentation for 7 years from the date of service, and
- Upon the request of CMS or a Medicare contractor, provide access to that documentation.

The documentation to be maintained includes written and electronic documents (including the National Provider Identifier (NPI) of the physician who ordered/certified the home health services and the NPI of the physician - or, when permitted, other eligible professional - who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

Consistent with $\S424.516(f)(1)$, please mail to us copies of the orders for the items or services that were furnished to the following beneficiaries on the dates specified:

(Contractors shall insert the beneficiaries' names (up to 5 may be listed, unless CMS specifies otherwise), appropriate identification information, and the dates on which the provider or supplier furnished the items/services in question. The contractor has the discretion to determine the cases/services that are included in this documentation request as well as the type(s) of documentation to be requested.)

The documentation must be received at the following address no later than 30 calendar days after the date of this letter:

(Cite appropriate address)

Failure to timely submit this documentation may result in the revocation of your enrollment pursuant to 42 CFR §424.535(a)(10)."

G. Model Language for §424.516(f)(2) Situations

The contractor shall use the model language below if it is requesting documentation from a provider or supplier furnishing the items or services addressed in $\S 424.516(f)(2)$.

"Dear Physician/Professional:

Under 42 CFR §424.516(f)(2), a physician who orders/certifies home health services and the physician - or, when permitted, other eligible professional - who orders items of DMEPOS or clinical laboratory or imaging services is required to maintain documentation for 7 years from the date of service and to provide access to that documentation pursuant to a CMS or Medicare contractor request. The documentation to be maintained includes written and electronic documents relating to written orders and certifications and requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

Consistent with $\S424.516(f)(2)$, please mail to us copies of the orders for items or services that you issued for the following beneficiaries on the dates specified:

(Contractors shall insert the beneficiaries' names (up to 5 may be listed, unless CMS specifies otherwise), appropriate identification information, and the dates on which the orders were made. The contractor has the discretion to determine the cases/services that are included in this documentation request as well as the type(s) of documentation to be requested.)

The documentation must be received at the following address no later than 30 calendar days after the date of this letter:

(Cite appropriate address)

Failure to timely submit this documentation may result in the revocation of your enrollment pursuant to 42 CFR §424.535(a)(10)." (For individuals enrolled via the Form CMS-855O, the contractor shall instead use the following language: "Failure to timely submit this documentation may result in the revocation of your Form CMS-855O enrollment.")