CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 618	**Date: October 9, 2015**
	Change Request 9364

SUBJECT: Written Orders Prior to Delivery (WOPD)

I. SUMMARY OF CHANGES: This Change Request (CR) provides new instructions for WOPD for power operated vehicles, power wheelchairs, and certain covered durable medical equipment (DME) items. The CR also provides specific date and timing requirements.

EFFECTIVE DATE: November 10, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: November 10, 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	TOC Chapter 5 - Items and Services Having Special DME Review Considerations
R	5/5.2.2 - Verbal and Preliminary Written Orders
R	5/5.2.3 - Detailed Written Orders
R	5/5.2.4 - Written Orders Prior to Delivery
R	5/5.2.5 - Face-to-Face Encounter Requirements
N	5/5.2.5.1 - Face-to-Face Encounter Conducted by the Physician
N	5/5.2.5.2 - Face-to-Face Encounter Conducted by a Nurse Practitioner, Physician Assistant or Clinical Nurse Specialist
R	5/5.2.6 - Date and Timing Requirements
N	5/5.2.7 - Requirements of New Orders
N	5/5.2.8 - Billing for Refills of DMEPOS Items Provided on a Recurring Basis
N	5/5.2.9 - Refills of DMEPOS Items Provided on a Recurring Basis

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

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I. GENERAL INFORMATION

A. Background: A WOPD is required for certain durable medical equipment prosthetic, orthotic and supplies as specified in 42 CFR 410.38(c)(4) and 410.38(g)(2). For these items, the supplier must have received a written order that has been both signed and dated by the treating physician/practitioner before dispensing the item.

B. Policy: There are no statutory or regulatory policies that impact this CR.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9364.1	Contractors shall follow these requirements when reviewing claims for certain DMEPOS items.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

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): Charlene Harven, 410-786-8228 or charlene.harven@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

Medicare Program Integrity Manual

Chapter 5 – Items and Services Having Special DME Review Considerations

Table of Contents
(Rev.617, Issued: 10-09-15)

Transmittals for Chapter 5

5.2.2 - Verbal and Preliminary Written Orders

(Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

Except as noted in chapter 5 section 5.2.4 suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician. This order must include: a description of the item, the beneficiary's name, the physician's name and the start date of the order. Suppliers must maintain the preliminary written order or written documentation of the verbal order and this documentation must be available to the DME MACs, Zone Program Integrity Contractors (ZPICs) *or other CMS review contractor* upon request. If the supplier does not have an order from the treating physician before dispensing an item, the contractor shall consider the item as noncovered.

For items that are dispensed based on a verbal order or preliminary written order, the supplier must obtain a detailed written order that meets the requirements of section 5.2.3 before submitting the claim.

5.2.3 – Detailed Written Orders

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

All DMEPOS items other than those referenced in 42 CFR 410.38(c)(4) and 410.38(g)(2) require detailed written orders prior to billing. Detailed written orders may take the form of a photocopy, facsimile image, electronically maintained, or original "pen-and-ink" document. (See chapter 3, section *3.3.2.4*).

The written order must be sufficiently detailed, including all options or additional features that will be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number. All orders must clearly specify the start date of the order.

If the written order is for supplies that will be provided on a periodic basis, the written order should include appropriate information on the quantity used, frequency of change, and duration of need. For example, an order for surgical dressing might specify one 4 x 4 hydrocolloid dressing that is changed 1-2 times per week for 1 month or until the ulcer heals.

If the supply is a drug, the order must specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable).

Someone other than the physician may complete the detailed description of the item. However, the treating physician/*practitioner* must review the detailed description and personally sign and date the order to indicate agreement.

The supplier must have a detailed written order prior to submitting a claim. If a supplier does not have a faxed, photocopied, electronic or pen and ink detailed written order signed *and dated by the treating physician/practitioner* in their records before they submit a claim to Medicare (i.e., if there is no order or only a verbal order), the claim will be denied. If the claim is for an item for which an order is required by statute (e.g., therapeutic shoes for diabetics, oral anticancer drugs, oral antiemetic drugs which are a replacement for intravenous antiemetic drugs), the claim will be denied as not meeting the benefit category and is therefore not appealable by the supplier (see Pub. 100-04, chapter 29, for more information on appeals). For all other items (except those listed in section 5.2.4), if the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary.

Medical necessity information (e.g., *applicable* diagnosis code, narrative description of the patient's condition, abilities *and* limitations) is NOT in itself considered to be part of the order although it may be put on the same document as the order.

5.2.4 *– Written Orders Prior to Delivery*

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

A. General

A written order prior to delivery is required for *certain DMEPOS items as specified in 42 CFR 410.38(c)(4) and 410.38(g)(2). For these items, the supplier must have received a written order that has been both signed and dated by the treating physician/practitioner before dispensing the item.*

If a supplier bills for an item without a written order prior to delivery, the item will be denied. (see Pub. 100-04, chapter 29, §10, 30.3, 60 for more information on appeals).

B. Written Orders Prior to Delivery for Power Operated Vehicles and Power Wheelchairs

For power operated vehicles and power wheelchairs, the supplier must have received a written order that has been both signed and dated by the treating physician/practitioner and meets the requirements in 42 CFR.410.38(c)(1)and (2) before dispensing the item. This order referred to as the "7 element order" must include the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that the PMD is expected to modify, a description of the item (for example, a narrative description of the specific type of PMD), the length of need, and the treating physician/practitioner's signature and the date the prescription was written. For power operated vehicles and power wheelchairs, the treating physician/practitioner completing the face-to-face requirements must write the 7-element order.

C. Written Orders for Certain Covered Durable Medical Equipment (DME) Items

For items outlined in 42 CFR 410.38(g) the treating physician/ practitioner who conducted the face-to-face examination does not need to be the prescribing practitioner who writes the written order prior to delivery of the DME item. However, the prescribing physician/practitioner must have knowledge and documentation of the face-to-face examination that was conducted.

For a covered DME item, outlined in 42 CFR 410.38(g), the contractor shall ensure that the written order is consistent with requirements in 42 CFR 410.38(g)(4). This order must include, the beneficiary's name, the item of DME ordered, the NPI of the prescribing physician/practitioner, the signature of the prescribing physician/practitioner and the date of the order. If this information is not included on the written order, the claim will be denied. Medicare requires that the written order is completed after the face-to-face encounter. If the date of the written order is prior to the date of the face-to-face encounter, the contractor shall deny the claim.

5.2.5 – *Face-to-Face Encounter Requirements*

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

This section only applies to covered items as defined in 42 CFR 410.38(g). CMS will notify contractors of any annual updates to the list of covered items. CMS will notify the public of any updates in the list of covered items via the Federal Register. Contractors shall not apply this section to PMDs.

For covered items as defined in 42 CFR 410.38(g) a physician, a physician assistant (PA), a nurse practitioner (NP) or a clinical nurse specialist (CNS) must document that he/she has had a face-to-face encounter with the beneficiary within six (6) months prior to completing the written order. On claims selected for review if there is no documentation of a face-to-face encounter, contractors shall deny the claim when directed by CMS.

5.2.5.1 – Face-to-Face Encounter Conducted by the Physician

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

When conducting a review of a covered DME item, outlined in 42 CFR 410.38(g) ordered by a physician (MD or DO), the contractor shall ensure that the physician saw the beneficiary (including through the appropriate use of telehealth (see Pub 100-02, the Medicare Benefit Policy Manual, Chapter 15 and Pub 100-04, the Medicare Claims Processing Manual, Chapter 12) and conducted a face-to-face assessment.

The contractor shall verify that the face-to-face encounter documentation includes information supporting that the beneficiary was evaluated or treated for a condition that supports the DME item(s) ordered. If this information is not included, the contractor shall deny the claim. If the physician completed the written order before the face-to-face encounter, the contractor shall deny the claim.

5.2.5.2 – Face-to-Face Encounter Conducted by a Nurse Practitioner, Physician Assistant or Clinical Nurse Specialist

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

When conducting a review of a covered DME item, outlined in 42 CFR 410.38(g) ordered by a PA, NP, or CNS, the contractor must ensure that the practitioner who conducted the face-to-face encounter saw the beneficiary (including through the appropriate use of telehealth (see Pub 100-02, the Medicare Benefit Policy Manual, Chapter 15 and Pub 100-04, the Medicare Claims Processing Manual, Chapter 12). If the face-to-face encounter documentation does not include information supporting that the beneficiary was evaluated or treated for a condition that supports the DME item(s) ordered, the contractor shall deny the claim.

5.2.6- *Date and Timing Requirements*

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

For items outlined in 42 CFR 410.38 (g), the following specific date and timing requirements apply:

- *The date of the face-to-face examination must be on or before the date of the written order (prescription) and may be no older than 6 months prior to the prescription date.*
- *The date of the face-to-face examination must be on or before the date of delivery for the item (s) prescribed.*
- *The date of the written order must be on or before the date of delivery.*
- *The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.*

A date stamp (or similar) is required which clearly indicates the supplier's date of receipt of both the face-to-face record and the completed WOPD with the prescribing physician's signature and signature date. Both documents must be separately date-stamped to avoid any confusion regarding the receipt date of these documents.

5.2.7 – Requirement of New Orders

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

A new order is required in the following situations:

- *There is a change in the order for the accessory, supply, drug, etc.;*
- *On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy;*
- *When an item is replaced; and*
- *When there is a change in the supplier.*

5.2.8 - Billing for Refills of DMEPOS Items Provided on a Recurring Basis

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

This section applies to DME MACs, DME PSCs, and ZPICs.

For DMEPOS items and supplies that are provided on a recurring basis, billing must be based on prospective, not retrospective use. The following scenarios are illustrative of this concept:

Scenario 1: The treating physician writes an order for enteral nutrition which translates into the dispensing of 100 units of nutrient for one month. The supplier receives the order, delivers 100 units and bills the claim with a date of service as the date of delivery indicating 100 units. This is an example of prospective billing and is acceptable.

Scenario 2: The treating physician writes an order for enteral nutrition which translates into the dispensing of 100 units of nutrient for one month. The supplier receives the order and delivers 100 units. A claim is not billed. At the end of the month, the supplier determines that the beneficiary used 90 units for the month and delivers 90 units to replace the nutrient used. A claim is then submitted with a date of service as the date of delivery indicating 90 units of enteral nutrition. This is an example of retrospective billing and is not acceptable.

5.2.9 - Refills of DMEPOS Items Provided on a Recurring Basis

Rev. 617, Issued: 10-09-15: Effective: 11-10-15 Implementation: 11-10-15)

This section applies to DME MACs, DME PSCs, and ZPICs.

For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DME MACs shall allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.