

This letter is revised to update the criteria associated with the five-element written order prior to delivery (5EO) and face-to-face examination. While this document makes reference to "ACA 6407 requirements", technically these requirements are found in the Social Security Act Section 1843(a)(11)(B) and its implementing regulation at 42 CFR 410.38. The CMS regulation contains the details for the face-to-face examination, written order prior to delivery and the list of items subject to these requirements.

Dear Physician,

For certain specified items of durable medical equipment (listed on CMS's website, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.html>), the Affordable Care Act requires:

1. An in-person, face-to-face examination with the treating practitioner (Medical Doctor (MD), Doctor of Osteopathic Medicine (DO) or Doctor of Podiatric Medicine (DPM), physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS))* and,
2. The treating practitioner must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered; and,
3. The face-to-face examination must have occurred sometime during the six (6) months prior to the date of the order for the item.

* The Medicare Access and SCHIP Reauthorization Act of 2015 eliminated the ACA requirement that the NP, PA, or CNS face-to-face examination documentation be co-signed by an MD or DO.

The purpose of this letter is to provide additional details of these requirements.

Medicare rules stipulate that a face-to-face examination meeting the requirements discussed below be performed each time a new prescription (i.e., written order) for one of the specified items is written. A new prescription is required by Medicare:

- For all claims for purchases or initial rentals
- If 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
- When there is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order and documentation from the original supplier.

These requirements are effective for all new Medicare orders for the specified items created on or after July 1, 2013.

Prescription (order) Requirements

ACA 6407 requires a specific written order prior to delivery for the specified items. This ACA 6407-required prescription has five (5) mandatory elements. The ACA 6407- required order is referred to as a 5-element order (5EO). The 5EO must meet all of the requirements below:

- The 5EO must include all of the following elements:

- Beneficiary's name
- Item of DME ordered - this may be general – e.g., "hospital bed"– or may be more specific
- Signature of the prescribing practitioner
- Prescribing practitioner's National Practitioner Identifier (NPI)
- The date of the order
- The 5EO must be completed within six (6) months after the required ACA 6047 face-to-face examination; and,
- The date of the written order shall be on or before the date of delivery or date shipped if the shipping date is used as the date of service.

Note that a 5EO for these specified DME items require the National Provider Identifier to be included on the prescription. Prescriptions for other DME items do not have this NPI requirement.

Face-to-face Examination Requirements

For Medicare beneficiaries, the treating practitioner must have a face-to-face examination with the beneficiary in the six (6) months prior to the date of the written order for the specified items of DME.

This face-to-face requirement includes examinations conducted via the Centers for Medicare & Medicaid Services (CMS)-approved use of telehealth examinations (as described in Chapter 15 of the Medicare Benefit Policy Manual and Chapter 12 of the Medicare Claims Processing Manual - CMS Internet-Only Manuals, Publ. 100-02 and 100-04, respectively).

For the treating practitioner prescribing a specified DME item:

- The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.
- The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.
- Remember that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.

The treating practitioner that conducted the face-to-face examination does not need to be the prescriber for the DME item; however, the prescriber must:

- Verify that the in-person visit occurred within the six (6) months prior to the date of their prescription; and,
- Have documentation of the face-to-face examination that was conducted.

Date and Timing Requirements

There are specific date and timing issues:

- The date of the face-to-face examination must be on or before the date of the 5EO and maybe no older than 6 months prior to the 5EO 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 5EO (prescription) must be on or before the date of delivery or Date of Service (DOS).
- ALL DMEPOS suppliers must have the completed 5EO in their file BEFORE the delivery of these items.

All other date and timing requirements specified in the CMS Program Integrity Manual regarding specific items or services remain unchanged.

Upon request by the contractor, all DMEPOS suppliers must provide documentation from the qualifying face-to-face examination and the completed 5EO.

This letter is intended to be a general summary. It is not intended to take the place of the law, regulations, or national and local coverage determinations. Detailed information about these requirements can be found on the CMS website <http://www.cms.gov> or on the DME contractors' website.

Sincerely,

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PUBLICATION HISTORY

Publication Date: August 2017

Revised: Clarifies Date and Timing Requirements for documentation associated with 42 CFR 410.38(g)

Added: Link to CMS website in place of Table for items specified per 42 CFR 410.38(g)

Publication Date: April 2016

Update the criteria associated with the written order prior to delivery and face-to-face examination.

Original Publication Date: February and May 2014