

Supplier Standards for DMEPOS

Note: This list is an abbreviated version of the application certification standards that every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. pt. 424, sec 424.57(c) and were effective on December 11, 2000.

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or nonprocurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment. *[Note: Does not apply to optical dispensary]*
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare-covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, or cell phone is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from calling beneficiaries in order to solicit new business.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare-covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.

14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e. the supplier may not sell or allow another entity to use its Medicare Supplier Billing Number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals).
[Note: Unless exempt]
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened. [Note: unless exempt]
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. [Note: unless exempt]
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. [Note: unless exempt]
26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). Implementation date-May 4, 2009 [Note: unless exempt]

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Resource: Medicare Enrollment Application, DMEPOS, Form CMS-855S,
<http://www.cms.gov/cmsforms/downloads/cms855s.pdf> [PDF]

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Effective December 11, 2000.

Title 42: Public Health

Part 424 – CONDITIONS FOR MEDICARE PAYMENT

Subpart D – To Whom Payment is Ordinarily Made

§ 424.57(b) *General rule.* A DMEPOS supplier must meet the following conditions in order to be eligible to receive payment for a Medicare-covered item:

1. The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.)
2. The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.
3. CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished has not been revoked or excluded.
4. A supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs. (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.) [Note: Does not apply to optical dispensary]
5. The supplier has furnished to CMS all information or documentation required to process the claim.

§ 424.57(c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards. The supplier:

1. Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements.
2. Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.)
3. Must have the application for billing privileges signed by an individual whose signature binds a supplier.
4. Fills orders, fabricates, or fits items from its own inventory or by contracting with other companies for the purchase of items to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State

health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity.

5. Advises beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental durable medical equipment, as defined in §414.220(a) of this subchapter. (The supplier must provide, upon request, documentation that it has provided beneficiaries with this information, in the form of copies of letters, logs, or signed notices.) [*Note: Does not apply to optical dispensary*]
6. Honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in §414.229 of this subchapter. The supplier must provide, upon request, documentation that it has provided beneficiaries with information about Medicare covered items covered under warranty, in the form of letters, logs, or signed notices.
7. Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location.
8. Permits CMS, or its agents to conduct on-site inspections to ascertain supplier compliance with the requirements of this section. The supplier location must be accessible during reasonable business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation.
9. Maintains a primary business telephone listed under the name of the business locally or toll-free for beneficiaries. The supplier must furnish information to beneficiaries at the time of delivery of items on how the beneficiary can contact the supplier by telephone. The exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine may not be used as the primary business telephone for purposes of this regulation.
10. Has a comprehensive liability insurance policy in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.
11. Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:
 - i. The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.
 - ii. The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.
 - iii. If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

12. Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use the Medicare-covered items safely and effectively).
13. Must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions.
14. Must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced.
15. Must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold.)
16. Must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17. Must comply with the disclosure provisions in §420.206 of this subchapter.
18. Must not convey or reassign a supplier number.
19. Must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. (This information must be kept at its physical facility and made available to CMS, upon request.)
20. Must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:
 - i. The name, address, telephone number, and health insurance claim number of the beneficiary.
 - ii. A summary of the complaint, the date it was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.
 - iii. If an investigation was not conducted, the name of the person making the decision and the reason for the decision.
21. Provides to CMS, upon request, any information required by the Medicare statute and implementing regulations.
22. All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services. [Note: unless exempt]
23. All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the new supplier location for three months after it is operational without requiring a new site visit. [Note: unless exempt]

24. All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards. [*Note: unless exempt*]
25. All DMEPOS supplier must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products. [*Note: unless exempt*]
26. Must meet the surety bond requirements specified in paragraph (d) of this section.

§ 424.57(d)

1. *Failure to meet standards.* CMS will revoke a supplier's billing privileges if it is found not to meet the standards in paragraphs (b), (c), and (d) of this section. (The revocation is effective 15 days after the entity is sent notice of the revocation, as specified in §405.874 of this subchapter.)
2. *Renewal of billing privileges.* A supplier must renew its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last renewal of privileges.)
3. *Payment prohibition.* No Medicare payment will be made to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea. This prohibition does not apply if the sleep test is an attended facility-based polysomnogram. [*Note: does not apply to optical dispensary*]

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