Medicare DMEPOS Supplier Standards

All Medicare DMEPOS suppliers must be in compliance with these Supplier Standards 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 went into effect December 11, 2000. A supplier must disclose these standards to all customers/patients who are Medicare beneficiaries (standard 16). A shortened version has been created to help suppliers comply with this requirement.

(1) Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements; Federal regulatory requirements that specify requirements for the provision of DMEPOS and ensure accessibility for the disabled. Licensed services cannot be contracted to an individual or entity, unless allowed by the State where the licensed services are being performed. The licensed professional can be a part-time or full- time employee.

(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 necessary 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 non-procurement 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.);

(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 copies 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; Except for State-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice, maintain a practice location that is at least 200 square feet; is accessible to the public, Medicare beneficiaries, CMS, the NSC, and its agents during posted hours of business. (The location must not be in a gated community or other area where access is restricted). 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.

(8) Permits CMS, or its agents to conduct on-site inspections to ascertain supplier compliance with the requirements of this section.

(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 during posted hours of operation 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.
This rule prohibits a DMEPOS supplier from contacting a Medicare beneficiary based on a physician’s oral order unless an exception applies.

(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 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.

(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.

(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.

(25) All DMEPOS suppliers 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.

(26) Must meet the surety bond requirements specified in paragraph (d) of this section.

d) *Surety bonds requirements* —(1) *Effective date of surety bond requirements* . (i) *DMEPOS suppliers seeking enrollment or with a change in ownership* . Except as provided in paragraph (d)(15) of this section, beginning May 4, 2009, DMEPOS suppliers seeking to enroll or to change the ownership of a supplier of DMEPOS must meet the requirements of paragraph (d) of this section for each assigned NPI for which the DMEPOS supplier is seeking to obtain Medicare billing privileges.

(ii) *Existing DMEPOS suppliers,* Except as provided in paragraph (d)(15) of this section, beginning October 2, 2009, each Medicare-enrolled DMEPOS supplier must meet the requirements of paragraph (d) of this section for each assigned NPI to which Medicare has granted billing privileges.

(27) All DMEPOS suppliers must obtain oxygen from a State-licensed oxygen supplier (applicable only to those suppliers in States that require oxygen licensure (42 C.F.R. 424.57(c)).

(28) DMEPOS Suppliers must maintain ordering and referring documentation consistent with the provisions found in 42 CFR 424.57 (c). DMEPOS suppliers will be required to maintain written orders from a physician or eligible professional.

(29) DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers except physicians, licensed non-physician practitioners furnishing services to his or her own patient(s) as a part of his or her professional service or a physical or occupational therapist providing services to his or her own patients as part of his or her professional service.

(30) DMEPOS suppliers must remain open to the public for at least 30 hours a week, except physicians, licensed non-physician practitioners furnishing services to his or her own patient(s) as a part of his or her professional service or a DMEPOS supplier working with custom made orthotics and prosthetics.