(c) Payment to the beneficiary. Any part of the Part B benefit which, on the basis of paragraph (b) of this section, is not payable to the supplier, is paid to the beneficiary.

(d) Examples.

Example 1. An assigned bill of $300 on which partial payment of $100 has been made is submitted to the carrier. The carrier determines that $300 is the reasonable charge for the service furnished. Total payment due is 80 percent of $300 or $240. Of this amount, $200 (the difference between the $100 partial payment and the $300 reasonable charge) is paid to the supplier. The remaining $40 is paid to the beneficiary.

Example 2. An assigned bill of $275 has been made is submitted to the carrier. The carrier determines that $275 is the reasonable charge for the services. Total payment due is 80 percent of $275 or $220. The $220 is paid to the beneficiary, since any payment to the supplier, when added to the $275 partial payment, would exceed the reasonable charge for the services furnished.

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) Definitions. As used in this section, the following definitions apply:

Accredited DMEPOS suppliers means suppliers that have been accredited by a recognized independent accreditation organization approved by CMS in accordance with the requirements at § 424.58.

Affiliate means a person or organization that is related to another person or organization through a compensation arrangement or ownership.

Assessment means a sum certain that CMS or the Office of Inspector General (OIG) may assess against a DMEPOS supplier under Titles XI, XVIII, or XXI of the Social Security Act or as specified in this chapter.

Attended facility-based polysomnogram means a comprehensive diagnostic sleep test, including at least electroencephalography, electrooculography, electromyography, heart rate or electrocardiography, airflow, breathing effort, and arterial oxygen saturation furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed.

Authorized surety means a surety that has been issued a Certificate of Authority by the U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.

Civil money penalty (CMP) means a sum that CMS has the authority, as implemented by 42 CFR 402.1(c); or OIG has the authority, under section 1128A of the Act or 42 CFR part 1003, to impose on a supplier as a penalty.

CMS approved accreditation organization means a recognized independent accreditation organization approved by CMS under § 424.58.

Continuous positive airway pressure (CPAP) device means a machine that introduces air into the breathing passages at pressures high enough to overcome obstructions in the airway in order to improve airflow. The airway pressure delivered into the upper airway is continuous during both inspiration and expiration.

Direct solicitation means direct contact, which includes, but is not limited to, telephone, computer, e-mail, instant messaging or in-person contact, by a DMEPOS supplier or its agents to a Medicare beneficiary without his or her consent for the purpose of marketing the DMEPOS supplier’s health care products or services or both.

DMEPOS stands for durable medical equipment, prosthetics, orthotics and supplies.

DMEPOS supplier means an entity or individual, including a physician or a Part A provider, which sells or rents Part B covered items to Medicare beneficiaries and which meets the standards in paragraphs (c) and (d) of this section.

Final adverse action means one or more of the following actions:

(i) A Medicare-imposed revocation of any Medicare billing privileges.

(ii) Suspension or revocation of a license to provide health care by any State licensing authority.

(iii) Revocation for failure to meet DMEPOS quality standards.

(iv) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i) within the last 10 years.
preceding enrollment, revalidation, or re-enrollment.

(v) An exclusion or debarment from participation in a Federal or State health care program.

Government-operated supplier is a DMEPOS supplier owned or operated by a Federal, State, or Tribal entity.

Independent accreditation organization means an accreditation organization that accredits a supplier of DMEPOS and other items and services for a specific DMEPOS product category or a full line of DMEPOS product categories.

Medicare covered items means medical equipment and supplies as defined in section 1834(j)(5) of the Act.

National Supplier Clearinghouse (NSC) is the contractor that is responsible for the enrollment and re-enrollment process for DMEPOS suppliers.

Penal sum is the maximum obligation of the surety if a loss occurs.

Rider means a notice issued by a surety that a change in the bond has occurred or will occur.

Sleep test means an attended or unattended diagnostic test for a sleep disorder whether performed in or out of a sleep laboratory. The ‘provider of the sleep test’ is the individual or entity that directly or indirectly administers and/or interprets the sleep test and/or furnishes the sleep test device used to administer the sleep test.

Sufficient evidence means documents CMS may supply to the surety in order to establish that a DMEPOS supplier had received Medicare funds in excess of the amount due and payable under the statute and regulations, the amount of a CMP, or the amount of some other assessment against the DMEPOS supplier.

Surety bond means a bond issued by one or more sureties under 31 U.S.C. 9304 through 9308 and 31 CFR parts 223, 224, and 225.

Unpaid claim means an overpayment made by the Medicare program to the DMEPOS supplier for which the DMEPOS supplier is responsible, plus accrued interest that is effective 90 days after the date of the notice sent to the DMEPOS supplier of the overpayment. If a written agreement for payment, acceptable to CMS, is made, an unpaid claim also means a Medicare overpayment for which the DMEPOS supplier is responsible, plus accrued interest after the DME supplier’s default on the arrangement.

(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.)

(5) The supplier has furnished to CMS all information or documentation required to process the claim.

(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:

(1) Operates its business and furnishes Medicare-covered items in compliance with the following applicable laws:

(a) Federal regulatory requirements that specify requirements for the provision of DMEPOS and ensure accessibility for the disabled.
(ii) State licensure and regulatory requirements. If a State requires licensure to furnish certain items or services, a DMEPOS supplier—
   (A) Must be licensed to provide the item or service;
   (B) Must employ the licensed professional on a full-time or part-time basis, except for DMEPOS suppliers who are—
      (1) Awarded competitive bid contracts using subcontractors to meet this standard; or
      (2) Allowed by the State to contract licensed services as described in paragraph (c)(1)(ii)(C) of this section.
   (C) Must not contract with an individual or other entity to provide the licensed services, unless allowed by the State where the licensed services are being performed; and
   (iii) Local zoning 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 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 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 §414.229 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. An appropriate site must meet all of the following:
      (i) Must meet the following criteria:
         (A) Except for State-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice, maintains a practice location that is at least 200 square feet beginning—
         (1) September 27, 2010 for a prospective DMEPOS supplier;
         (2) The first day after termination of an expiring lease for an existing DMEPOS supplier with a lease that expires on or after September 27, 2010 and before September 27, 2013; or
         (3) September 27, 2013, for an existing DMEPOS supplier with a lease that expires on or after September 27, 2013.
         (B) Is in a location that is accessible to the public, Medicare beneficiaries, CMS, NSC, and its agents. (The location must not be in a gated community or other area where access is restricted.)
         (C) Is accessible and staffed during posted hours of operation.
         (D) Maintains a permanent visible sign in plain view and posts hours of operation. If the supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the supplier.
         (E) Except for business records that are stored in centralized location as described in paragraph (c)(7)(ii) of this
section, is in a location that contains space for storing business records (including the supplier’s delivery, maintenance, and beneficiary communication records).

(F) Is in a location that contains space for retaining the necessary ordering and referring documentation specified in §424.516(f).

(ii) May be the centralized location for all of the business records and the ordering and referring documentation of a multisite supplier.

(iii) May be a “closed door” business, such as a pharmacy or supplier providing services only to beneficiaries residing in a nursing home, that complies with all applicable Federal, State, and local laws and regulations. “Closed door” businesses must comply with all the requirements in this paragraph.

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

(9) Maintains a primary business telephone that is operating at the appropriate site listed under the name of the business locally or toll-free for beneficiaries.

(i) Cellular phones, beepers, or pagers must not be used as the primary business telephone.

(ii) Calls must not be exclusively forwarded from the primary business telephone listed under the name of the business to a cellular phone, beeper, or pager.

(iii) Answering machines, answering services, facsimile machines or combination of these options must not be used exclusively as the primary business telephone during posted operating hours.

(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) Agree not to make a direct solicitation (as defined in §424.57(a)) of a Medicare beneficiary unless one or more of the following applies:

(i) The individual has given written permission to the supplier or the ordering physician or non-physician practitioner to contact them 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 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.
(27) Must obtain oxygen from a State-licensed oxygen supplier (applicable only to those suppliers in States that require oxygen licensure.)
(28) Is required to maintain ordering and referring documentation consistent with the provisions found in §424.516(f)
(29)(i) Except as specified in paragraph (c)(29)(ii) of this section, is prohibited from sharing a practice location with any other Medicare supplier or provider.
(ii) The prohibition specified in paragraph (c)(29)(i) of this section is not applicable at a practice location that meets one of the following:
(A) Where a physician whose services are defined in section 1848(j)(3) of the Act or a nonphysician practitioner, as described in section 1842(b)(18)(C) of the Act, furnishes items to his or her own patient as part of his or her professional service.
(B) Where a physical or occupational therapist whose services are defined in sections 1861(p) and 1861(g) of the Act, furnishes items to his or her own patient as part of his or her professional service.
(C) Where a DMEPOS supplier is co-located with and owned by an enrolled Medicare provider (as described in §489.2(b) of this chapter). The DMEPOS supplier—
(1) Must operate as a separate unit; and
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(2) Meet all other DMEPOS supplier standards.

(30)(i) Except as specified in paragraph (c)(30)(ii) of this section, is open to the public a minimum of 30 hours per week.

(ii) The provision of paragraph (c)(30)(i) of this section is not applicable at a practice location where a—

(A) Physician whose services are defined in section 1848(j)(3) of the Act furnishes items to his or her own patient(s) as part of his or her professional service;

(B) Licensed non-physician practitioners whose services are defined in sections 1861(p) and 1861(g) of the Act furnishes items to his or her own patient(s) as part of his or her professional service; or

(C) DMEPOS supplier is working with custom made orthotics and prosthetics.

(d) Failure to meet standards. CMS will revoke a supplier’s billing privileges if it is found not to meet the standards in paragraphs (b) and (c) 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.)

(e) Revalidation of billing privileges. A supplier must revalidate 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 revalidation.)

(f) 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.


Editorial Note: At 74 FR 198, Jan. 2, 2009, §424.57 was amended by redesignating paragraphs (d) and (e) as paragraphs (e) and (f), adding a new paragraph (d) and in newly redesignated paragraph (e), by removing the cross-reference “paragraphs (b) and (c)” and adding the cross-reference “paragraphs (b), (c), and (d)”; however, these amendments could not be incorporated due to inaccurate amendatory instruction. For the convenience of the user, the added text is set forth as follows:

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(3) Elevated surety bond amounts. (1) If required, a DMEPOS supplier must obtain and maintain a base surety bond in the amount of $50,000 as specified in paragraph (d)(2) of this section and an elevated surety bond in the amount prescribed by the NSC as described in paragraph (d)(3)(i) of this section.  

(i) The NSC prescribes an elevated surety bond amount of $50,000 per occurrence of an adverse legal action within the 10 years preceding enrollment, revalidation, or reenrollment, as defined in paragraph (a) of this section.  

(ii) The bond must provide the following:  

(A) The amount of any unpaid claim, plus interest.  

(B) The amount of any unpaid claims, CMPs, or assessments imposed by CMS or OIG on the DMEPOS supplier, plus accrued interest.  

(ii) The bond must provide the following:  

(A) CMS or the OIG imposes or asserts against the DMEPOS supplier based on overpayments or other events that took place during the term of the bond or rider; and  

(B) Were imposed or assessed by CMS or the OIG during the 2 years following the date that the DMEPOS supplier failed to submit a bond or required rider, or the date the DMEPOS supplier’s billing privileges were terminated, whichever is later.  

(6) Cancellation of a bond and lapse of surety bond coverage. (1) A DMEPOS supplier may cancel its surety bond and must provide written notice at least 30 days before the effective date of the cancellation to the NSC and the surety.  

(ii) Cancellation of a surety bond is grounds for revocation of the DMEPOS supplier’s Medicare billing privileges unless the DMEPOS supplier provides a new bond before the effective date of the cancellation. The liability of the surety continues through the termination effective date.  

(iii) If CMS receives notification of a lapse in bond coverage from the surety, the DMEPOS supplier’s billing privileges are revoked. During this lapse, Medicare does not pay for items or services furnished during the gap in coverage, and the DMEPOS supplier is held liable for the items or services (that is, the DMEPOS supplier would not be permitted to charge the beneficiary for the items or services).  

(iv) The surety must immediately notify the NSC if there is a lapse in the surety’s coverage of the DMEPOS supplier’s coverage.  

(7) Actions under the surety bond. The bond must provide that actions under the bond may be brought by CMS or by CMS contractors.  

(8) Required surety information on the surety bond. The bond must provide the surety’s name, street address or post office box number, city, state, and zip code.  

(9) Change of surety. A DMEPOS supplier that obtains a replacement surety bond from a different surety to cover the remaining term of a previously obtained bond must submit the new surety bond to the NSC at least 30 days prior to the expiration of the previous surety bond. There must be no gap in the coverage of the surety bond periods. If a gap in coverage exists, the NSC revokes the supplier’s billing privileges and does not pay for any items or services furnished by the DMEPOS supplier during the period for which no bond coverage was available. If a DMEPOS supplier changes its surety during the term of the bond, the new surety is responsible for any overpayments, CMPs, or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond. The previous surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety.  

(10) Parties to the surety bond. The surety bond must name the DMEPOS supplier as Principal, CMS as Obligee, and the surety (and its heirs, executors, administrators, successors and assignees, jointly and severally) as surety.
§ 424.58 Accreditation.

(a) Scope and purpose. This part implements section 1834(a)(20)(B) of the Act, which requires the Secretary to designate and approve one or more independent accreditation organizations for purposes of enforcing the DMEPOS quality standards for suppliers of DMEPOS and other items or services. Section 1847(b)(2)(A)(i) of the Act requires a DMEPOS supplier to meet the DMEPOS quality standards under section 1834(a)(20) of the Act before being awarded a contract.

(b) Application and reapplication procedures for accreditation organizations. (1) An independent accreditation organization applying for approval or re-approval of authority to survey suppliers for compliance with the DMEPOS quality standards is required to furnish the following to CMS:

   (i) A list of the types of DMEPOS supplies, and a list of products and services for which the organization is requesting approval.

   (ii) A detailed comparison of the organization’s accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.

   (iii) A detailed description of the organization’s operational processes, including procedures for performing unannounced surveys, frequency of the