
42 C.F.R. § 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, electro-oculography, 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U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.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.

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.

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.

(6) The supplier is in compliance with all conditions of payment in paragraph (b) of this section, as well as with paragraph (c)(1)(ii)(A) of this section, at the time the item or service is furnished.

(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:

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