

for services furnished to that beneficiary on an outpatient basis—

- (i) By the provider or facility;
- (ii) By physicians whose services are billed by the provider or facility in its name; or
- (iii) By physicians who bill separately, if the services were furnished in the provider or facility.

(3) *Services to outpatients: Independent rural health clinics and Federally qualified health centers.* A signed request for payment statement retained in the clinic's or center's files may be effective indefinitely for all claims for services furnished to that beneficiary by the clinic.

(d) *Signed statement in the supplier's record.* A signed request for payment statement retained in the supplier's file may be effective indefinitely subject to the following restrictions:

- (1) This policy does not apply to unassigned claims for rental of durable medical equipment (DME).
- (2) With respect to assigned claims for rental or purchase of DME, a new statement is required if another item of equipment is rented or purchased.

[53 FR 6634, Mar. 2, 1988, as amended at 57 FR 24982, June 12, 1992]

#### § 424.44 Time limits for filing claims.

(a) *Time limits.* (1) Except as provided in paragraphs (b) and (e) of this section, for services furnished on or after January 1, 2010, the claim must be filed no later than the close of the period ending 1 calendar year after the date of service.

(2) Except as provided in paragraphs (b) and (e) of this section and except for services furnished during the last 3 months of 2009, for services furnished before January 1, 2010, the claim must be filed—

- (i) On or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and
- (ii) On or before December 31st of the second following year for services that were furnished during the last 3 months of the calendar year.

(3) For services furnished during the last 3 months of CY 2009 all claims must be filed no later than December 31, 2010.

(b) *Exceptions to time limits.* Exceptions to the time limits for filing claims include the following:

(1) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section was caused by error or misrepresentation of an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of HHS that was performing Medicare functions and acting within the scope of its authority.

(2) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was not entitled to Medicare.

(ii) The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(3) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was not entitled to Medicare.

(ii) The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) A State Medicaid agency recovered the Medicaid payment for the furnished service from a provider or supplier 6 months or more after the service was furnished.

(4) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was enrolled in a Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization.

(ii) The beneficiary was subsequently disenrolled from the Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization effective retroactively to or before the date of the furnished service.

(iii) The Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization recovered its payment for the furnished service from a provider or supplier 6 months or more after the service was furnished.

(5) *Extension of time.* (i) If CMS or one of its contractors determines that a failure to meet the deadline specified in paragraph (a) of this section was caused by error or misrepresentation of an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of HHS that was performing Medicare functions and acting within the scope of its authority, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which either the beneficiary or the provider or supplier received notification that the error or misrepresentation referenced in paragraph (b)(1) of this section was corrected. No extension of time will be granted for paragraph (b)(1) when the request for that exception is made to CMS or one of its contractors more than 4 years after the date of service.

(ii) If CMS or one of its contractors determines that both of the conditions are met in paragraph (b)(2) of this section but that all of the conditions in paragraph (b)(3) are not satisfied, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which either the beneficiary or the provider or supplier received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) If CMS or one of its contractors determines that all of the conditions are met in paragraph (b)(3) of this section, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which the State Medicaid agency recovered the Medicaid pay-

ment for the furnished service from the provider or supplier.

(iv) If CMS or one of its contractors determines that all of the conditions are met in paragraph (b)(4) of this section, the time to file a claim will be extended through the last day of the sixth calendar month following the month in which the Medicare Advantage plan or Program of All-inclusive Care for the Elderly (PACE) provider organization recovered its payment for the furnished service from the provider or supplier.

(c) *Extension of period ending on a nonworkday.* If the last day of the period allowed under paragraph (a) or (b) of this section falls on a Federal nonworkday (a Saturday, Sunday, legal holiday, or a day which by statute or Executive Order is declared to be a nonworkday for Federal employees), the time is extended to the next succeeding workday.

(d) *Outpatient diabetes self-management training.* CMS makes payment in half-hour increments to an entity for the furnishing of outpatient diabetes self-management training on or after the approval date CMS approves the entity to furnish the services under part 410, subpart H of this chapter.

(e) As specified in §§ 424.520 and 424.521 of this subpart, there are restrictions on the ability of the following newly-enrolled suppliers to submit claims for items or services furnished prior to the effective date of their Medicare billing privileges:

- (1) Physician or nonphysician practitioner organizations.
- (2) Physicians.
- (3) Nonphysician practitioners.
- (4) Independent diagnostic testing facilities.

[53 FR 6634, Mar. 2, 1988, as amended at 65 FR 83153, Dec. 29, 2000; 73 FR 69939, Nov. 19, 2008; 75 FR 73627, Nov. 29, 2010]

## Subpart D—To Whom Payment Is Ordinarily Made

### § 424.50 Scope.

(a) This subpart specifies to whom Medicare payment is ordinarily made for different kinds of services.

(b) Subpart E of this part sets forth provisions applicable in special situations.

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(c) Subpart F of this part specifies the exceptional circumstances under which payment may be made to an assignee or reassignee.

### § 424.51 Payment to the provider.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare pays the provider for services furnished by a provider.

(b) *Exception.* Medicare pays the beneficiary for outpatient hospital services if the hospital has collected an amount in excess of the unmet deductible and coinsurance, as specified in § 489.30(b)(4) of this chapter.

### § 424.52 Payment to a nonparticipating hospital.

Medicare pays a nonparticipating hospital for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a U.S. hospital, if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a U.S. hospital, if the hospital meets the requirements of § 424.55 for payment as a supplier.

(c) Emergency or nonemergency inpatient services furnished by a foreign hospital if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

### § 424.53 Payment to the beneficiary.

Medicare pays the beneficiary for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a nonparticipating U.S. hospital that has not elected to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a nonparticipating U.S. hospital, if the hospital does not receive assigned payment as a supplier under § 424.55.

(c) Emergency or nonemergency services furnished by a foreign hospital if the hospital does not have in effect an election to claim payment in accordance with subpart H of this part.

(d) Physician and ambulance services furnished outside the United States.

(e) Services furnished by a supplier if the claim has not been assigned to the supplier.

### § 424.54 Payment to the beneficiary's legal guardian or representative payee.

Medicare may pay amounts due a beneficiary to the beneficiary's legal guardian or representative payee.

### § 424.55 Payment to the supplier.

(a) Medicare pays the supplier for covered services if the beneficiary (or the person authorized to request payment on the beneficiary's behalf) assigns the claim to the supplier and the supplier accepts assignment.

(b) In accepting assignment, the supplier agrees to the following:

(1) To accept, as full charge for the service, the amount approved by the carrier as the basis for determining the Medicare Part B payment (the reasonable charge or the lesser of the fee schedule amount and the actual charge).

(2) To limit charges to the beneficiary or any other source as follows:

(i) To collect nothing for those services for which Medicare pays 100 percent of the Medicare approved amount.

(ii) To collect only the difference between the Medicare approved amount and the Medicare Part B payment (for example, the amount of any reduction in incurred expenses under § 410.155(c), any applicable deductible amount, and any applicable coinsurance amount) for services for which Medicare pays less than 100 percent of the approved amount.

(3) Not to charge the beneficiary when Medicare paid for services determined to be "not reasonable or necessary" if—

(i) The beneficiary was without fault in the overpayment; and

(ii) The determination that the payment was incorrect was made by the carrier after the third year following the year in which the carrier sent notice to the beneficiary that it approved the payment.

(c) *Exception.* In situations when payment under the Act can only be made on an assignment-related basis or when

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payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

(d) For purposes of claims for services submitted by an MDPP supplier (as defined at §410.79(b) of this chapter), Medicare deems such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDPP supplier.

[53 FR 6634, Mar. 2, 1988, as amended at 63 FR 20130, Apr. 23, 1998; 69 FR 66426, Nov. 15, 2004; 82 FR 53364, Nov. 15, 2017]

## § 424.56 Payment to a beneficiary and to a supplier.

(a) *Conditions for split payment.* If the beneficiary assigns the claim after paying part of the bill, payment may be made partly to the beneficiary and partly to the supplier.

(b) *Payment to the supplier.* Payment to the supplier who submits the assigned claim is for whichever of the following amounts is less:

(1) The reasonable charge minus the amount the beneficiary had already paid to the supplier; or

(2) The full Part B benefit due for the services furnished.

(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 \$325 on which partial payment 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

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would exceed the reasonable charge for the services furnished.

[53 FR 6641, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

## § 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:

(i) 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; and

(B) May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

(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 § 414.220(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. An appropriate site must meet all of the following:

(i) Must meet the following criteria:

(A)(1) Except for orthotic and prosthetic personnel described in paragraph (c)(7)(i)(A)(2) of this section, maintains a practice location that is at least 200 square feet beginning—

(i) September 27, 2010 for a prospective DMEPOS supplier;

(ii) 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

(iii) September 27, 2013, for an existing DMEPOS supplier with a lease that expires on or after September 27, 2013.

(2) Orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice do not have to meet the practice location requirements in paragraph (c)(7)(i)(A)(I) of this section if the orthotic and prosthetic personnel are—

- (i) State-licensed; or
- (ii) Practicing in a State that does not offer State licensure for orthotic and prosthetic personnel.

(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.

(8) 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) 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

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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

(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) 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(s) as part of his or her professional service; or

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

(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.

(2) *Minimum requirements for a DMEPOS supplier.* (i) A DMEPOS supplier enrolling in the Medicare program, making a change in ownership, or responding to a revalidation or re-enrollment request must submit to the CMS contractor a surety bond from an authorized surety of \$50,000 and, if required by the CMS contractor, an elevated bond amount as described in paragraph (d)(3) of this section with its paper or electronic Medicare enrollment application (CMS-855S, OMB number 0938-1056). The term of the initial surety bond must be effective on the date that the application is submitted to the CMS contractor.

(ii) A supplier that seeks to become an enrolled DMEPOS supplier through a purchase or transfer of assets or ownership interest must submit to the CMS contractor surety bond from an authorized surety of \$50,000 and, if required by the CMS contractor, an elevated bond amount as described in paragraph (d)(3) of this section that is effective from the date of the purchase or transfer in order to exercise billing privileges as of that date. If the bond is effective at a later date, the effective date of the new DMEPOS supplier billing privileges is the effective date of the surety bond as validated by the CMS contractor.

(iii) A DMEPOS supplier enrolling a new practice location must submit to the CMS contractor a new surety bond from an authorized surety or an amendment or rider to the existing bond, showing that the new practice location is covered by an additional base surety bond of \$50,000 or, as necessary, an elevated surety bond amount as described in paragraph (d)(3) of this section.

(3) *Elevated surety bond amounts.* (i) 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 CMS contractor as described in paragraph (d)(3)(ii) of this section.

(ii) The CMS contractor 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.

(4) *Type and terms of the surety bond—*

(i) *Type of bond.* A DMEPOS supplier must submit a bond that is continuous.

(ii) *Minimum requirements of liability coverage.* (A) The terms of the bond submitted by a DMEPOS supplier for the purpose of complying with this section must meet the minimum requirements of liability coverage (\$50,000) and surety and DMEPOS supplier responsibility as set forth in this section.

(B) CMS requires a DMEPOS supplier to submit a bond that on its face reflects the requirements of this section. CMS revokes or denies a DMEPOS supplier's billing privileges based upon the submission of a bond that does not reflect the requirements of paragraph (d) of this section.

(5) *Specific surety bond requirements.*

(i) The bond must guarantee that the surety will, within 30 days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond of unpaid claims, CMPs, or assessments, pay CMS a total of up to the full penal amount of the bond in the following amounts:

(A) The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible.

(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: The surety is liable for unpaid claims, CMPs, or assessments that occur during the term of the bond.

(iii) If the DMEPOS supplier fails to furnish a bond meeting the requirements of paragraph (d) of this section,

fails to submit a rider when required, or if the DMEPOS supplier's billing privileges are revoked, the last bond or rider submitted by the DMEPOS supplier remains in effect until the last day of the surety bond coverage period and the surety remains liable for unpaid claims, CMPs, or assessments that—

(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.* (i) 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 CMS contractor 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 CMS contractor 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 CMS contractor 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 CMS contractor revokes the DMEPOS 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.

(11) *Effect of DMEPOS supplier's failure to obtain, maintain, and timely file a surety bond.*

(i) CMS revokes the DMEPOS supplier's billing privileges if an enrolled DMEPOS supplier fails to obtain, file timely, or maintain a surety bond as specified in this subpart and CMS instructions. Notwithstanding paragraph (e) of this section, the revocation is effective the date the bond lapsed and any payments for items furnished on or after that date must be repaid to CMS by the DMEPOS supplier.

(ii) CMS denies billing privileges to a DMEPOS supplier if the supplier seeking to become an enrolled DMEPOS supplier fails to obtain and file timely a surety bond as specified with this subpart and CMS instructions.

(12) *Evidence of DMEPOS supplier's compliance.* CMS may at any time require a DMEPOS supplier to show compliance with the requirements of paragraph (d) of this section.

(13) *Effect of subsequent DMEPOS supplier payment.* If a surety has paid an amount to CMS on the basis of liability incurred under a bond and CMS subsequently collects from the DMEPOS supplier, in whole or in part, on the unpaid claim, CMPs, or assessment that was the basis for the surety's liability, CMS reimburses the surety the amount that it collected from the DMEPOS supplier, up to the amount paid by the surety to CMS, provided the surety has no other liability to CMS under the bond.

(14) *Effect of review reversing determination.* If a surety has paid CMS on the basis of liability incurred under a surety bond and to the extent the DMEPOS supplier that obtained the bond is subsequently successful in appealing the determination that was the basis of the unpaid claim, CMP, or assessment that caused the DMEPOS supplier to pay CMS under the bond, CMS refunds the DMEPOS supplier the amount the DMEPOS supplier paid to CMS to the extent that the amount relates to the matter that was successfully appealed, provided all review, including judicial review, has been completed on the matter.

(15) *Exception to the surety bond requirement—*(1) *Qualifying entities and requirements.* (A) Government-operated DMEPOS suppliers are provided an exception to the surety bond requirement if the DMEPOS supplier has provided CMS with a comparable surety bond under State law.

(B) State-licensed orthotic and prosthetic personnel in private practice making custom made orthotics and prosthetics are provided an exception to the surety bond requirement if—

(1) The business is solely-owned and operated by the orthotic and prosthetic personnel, and

(2) The business is only billing for orthotic, prosthetics, and supplies.

(C) Physicians and nonphysician practitioners as defined in section 1842(b)(18) of the Act are provided an exception to the surety bond requirement when items are furnished only to the physician or nonphysician practitioner's own patients as part of his or her physician service.

(D) Physical and occupational therapists in private practice are provided

an exception to the surety bond requirement if—

(1) The business is solely-owned and operated by the physical or occupational therapist;

(2) The items are furnished only to the physical or occupational therapist's own patients as part of his or her professional service; and

(3) The business is only billing for orthotics, prosthetics, and supplies.

(ii) *Loss of a DMEPOS supplier exception.* A DMEPOS supplier that no longer qualifies for an exception as described in paragraph (d)(15)(i) of this section must submit a surety bond to the CMS contractor in accordance with requirements of paragraph (d) of this section within 60 days after it knows or has reason to know that it no longer meets the criteria for an exception.

(e) *Failure to meet standards—(1) Revocation.* CMS revokes a supplier's billing privileges if it is found not to meet the standards in paragraphs (b) and (c) of this section. Except as otherwise provided in this section, the revocation is effective 30 days after the entity is sent notice of the revocation, as specified in § 405.874 of this subchapter.

(2) *Overpayments associated with final adverse actions.* CMS or a CMS contractor may reopen (in accordance with § 405.980 of this chapter) all Medicare claims paid on or after the date of a final adverse action (as defined in paragraph (a) of this section) in order to establish an overpayment determination.

(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.

(g) *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.)

[65 FR 60377, Oct. 11, 2000, as amended at 71 FR 48409, Aug. 18, 2006; 73 FR 69939, Nov. 19, 2008; 75 FR 52648, Aug. 27, 2010; 76 FR 5962, Feb. 2, 2011; 77 FR 14994, Mar. 14, 2012; 79 FR 69773, Nov. 24, 2014; 87 FR 70231, Nov. 18, 2022]

**§ 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 surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements, and dispute resolution processes and policies when there is a negative survey finding or decision.

(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(vii) Detailed professional information about the individuals who perform

surveys for the accreditation organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience requirements surveyors must meet. The information must include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the independent accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(viii) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(ix) Procedures for responding to, and investigating complaints against, accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the National Supplier Clearinghouse, and CMS.

(x) The organization's policies and procedures for notifying CMS of facilities that fail to meet the accreditation organization's requirements.

(xi) A description of all types, categories, and durations of accreditations offered by the organization.

(xii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types and categories of accreditation currently held by each supplier.

(C) The expiration date of each supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

(xiii) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xiv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.

(xv) An agreement that the accreditation organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(2) *Validation survey.* CMS surveys suppliers of DMEPOS and other items and services accredited under this section on a representative sample basis, or in response to substantial allegations of noncompliance, in order to validate the accreditation organization's survey process. When conducted—

(i) On a representative sample basis, the CMS survey may be comprehensive or focus on a specific standard;

(ii) In response to a substantial allegation, CMS surveys for any standard that CMS determines is related to the allegations.

(3) *Discovery of a deficiency.* If CMS discovers that a DMEPOS supplier was not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.

(4) *Authorization.* A supplier selected for a validation survey must authorize the—

(i) Validation survey to take place; and

(ii) CMS survey team to monitor the correction of any deficiencies found through the validation survey.

(5) *Refusal to cooperate with survey.* If a supplier selected for a validation survey fails to comply with the requirements specified at paragraph (b)(4) of this section, it is deemed to no longer meet the DMEPOS supplier quality standards and may have its supplier billing number revoked.

(6) *Validation survey findings.* If a validation survey results in a finding that the supplier was not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its supplier billing number revoked.

(c) *Ongoing responsibilities of a CMS-approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS all of the following in written format (either electronic or hard copy) and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers of DMEPOS and other items and services.

(iv) Information about any supplier of DMEPOS and other items and services against which the CMS-approved accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days of a change in CMS requirements, submit to CMS:

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised cross walk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 calendar days of identifying a deficiency of an accredited DMEPOS supplier that poses immediate jeopardy to a beneficiary or to the general public, provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS's notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, provide written notice of the withdrawal to all of the CMS-approved accreditation organization's accredited suppliers.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation survey.* CMS or its designated survey team may conduct a survey of an accredited DMEPOS supplier, examine the results of a CMS-approved accreditation organization's survey of a supplier, or observe a CMS-approved accreditation organization's onsite survey of a DMEPOS supplier, in order to validate the CMS-approved accreditation organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS or its designated survey team on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or