

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 Oblige, 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