



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS-6006-F3]

Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Technical Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; technical amendment.

SUMMARY: This technical amendment corrects codification, terminology, and technical errors in the requirements for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) at 42 CFR 424.57.

DATES: This technical amendment is effective [OFR: Insert date of publication in the Federal Register.]

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

For purposes of the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) supplier standards, the term "DMEPOS supplier" is defined in § 424.57(a) as an entity or individual, including a physician or Part A provider, that sells or rents Part B covered DMEPOS items to Medicare beneficiaries and that meet the DMEPOS supplier

standards. The term "DMEPOS" encompasses the types of items included in the definition of medical equipment and supplies in section 1834(j)(5) of the Act.

The term durable medical equipment is defined at section 1861(n) of the Act. Prosthetic devices are defined in section 1861(s)(8) of the Act as "devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens."

II. Summary of Technical Errors in the Regulations Text at § 424.57

In the January 2, 2009 **Federal Register** (74 FR 166), we published a final rule that implemented section 1834(a)(16) of the Act by requiring certain Medicare DMEPOS suppliers to furnish CMS with a surety bond. In codifying the regulatory changes included in the January 2, 2009 final rule, the Office of the Federal Register (OFR) found an inaccurate amendatory instruction for the amendments to § 424.57(d) and (e). OFR therefore, added the regulatory text via an editorial note in Code of Federal Regulations (CFR). Subsequently, we published a correcting amendment in the March 27, 2009 **Federal Register** (74 FR 13345) to correct the amendatory instruction errors made in the January 2, 2009 final rule. The correcting amendment redesignated § 424.57(d) and (e) as § 424.57(e) and (g). However, the provisions of the correcting amendment were inadvertently omitted in OFR's revisions to the CFR; therefore, the editorial note was retained.

In the August 27, 2010 **Federal Register** (75 FR 52629), we published a final rule that clarified, expanded, and added to the existing enrollment requirements that

DMEPOS suppliers must meet to establish and maintain billing privileges in the Medicare program. In the August 27, 2010 final rule, we included an amendment for § 424.57(e). This amendment revised the "failure to meet standards" provision which was redesignated as paragraph (e) in the March 27, 2009 correcting amendment. The revisions to § 424.57(e) specified the revocation and overpayment requirements associated with the failure of a supplier to meet the standards in § 424.57(b) and (c). (For more detailed information, see the August 27, 2010 final rule (75 FR 52649).) However, the amendment to paragraph (e) was inadvertently omitted from OFR's revisions to § 424.57 in the CFR.

In the February 2, 2011 **Federal Register** (76 FR 5862), we published a final rule with comment period that, among other things, stated our policy for revalidation of billing privileges. This final rule included an amendment to the provision regarding revalidation of billing privileges which is currently printed in the CFR at § 424.57(e). The revisions were incorporated for the correct provision. However, § 424.57(e) should have been redesignated as § 424.57(g) in accordance with the provision included in our March 27, 2009 correcting amendment.

As a result of the codification and technical errors for § 424.57(d) and (e) specified previously, the regulations text of this technical amendment sets forth the following:

- The surety bond requirements specified in the January 2, 2009 final rule as § 424.57(d).
- The "failure to meet standards" requirement specified in the August 27, 2010 final rule as § 424.57(e).

- The "revalidation of billing privileges" language specified in the February 2, 2011 final rule as § 424.57(g).

In our review of § 424.57(d) and (e), we also determined that there were other terminology and technical errors that needed to be addressed. Therefore, we are including the following additional changes in the regulations text of this technical amendment:

- Removal of the term "National Supplier Clearinghouse (NSC)" from the definitions in §424.57(a). We are also replacing term "NSC" with "CMS contractor" in § 424.57(d). Removing the name of the contractor and using the term "CMS contractor" more accurately reflects the possibility that different CMS contractors may handle these issues and eliminates the need to make regulatory text changes when we make contractual changes.

- Changing the terms "supplier" and "DME supplier" to "DMEPOS supplier." We note that throughout § 424.57(d), the terms "supplier," "DME supplier," and "DMEPOS supplier" are used interchangeably, though they have the same meaning for purposes of the applicability of §424.57(d). However, we are making the change to ensure consistent terminology and accuracy. We believe that this terminology change would clarify that § 424.57(d) does not apply to all Medicare suppliers but does apply to all Medicare DMEPOS suppliers.

- Updating Office of Management and Budget (OMB) number for the Medicare enrollment application form referenced in §424.57(d)(2)(i) from OMB number 0938-0685 to OMB control number 0938-1056. The OMB control number is out of date and at our request given a separate new control number.

- Revising the cross-references in § 424.515 (introductory text and paragraph (d)(3)).

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

This action merely corrects codification, terminology, and technical errors in 42 CFR 424.57. We are correcting regulatory paragraph designations, an omission, and a technical correction to previously published regulatory text as well as making terminology and cross-references changes. These revisions in no way change the policies or substantive regulatory text finalized in the January 2, 2009, August 27, 2010, and February 2, 2011 final rules. Since this technical amendment corrects codification and other technical errors and incorporates regulatory text that was inadvertently omitted, we find that both public comment and a delay in effective date of this technical amendment

CMS-6006-F3

is unnecessary. Therefore, we find there is good cause to waive notice and comment procedures and the 30-day delay in effective date for this action.

List of Subjects in 42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 424 as set forth below:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Amend § 424.57 by--

A. In paragraph (a) by removing the definition of "National Supplier Clearinghouse" (NSC).

B. Revising paragraphs (d) and (e).

C. Adding paragraph (g).

The revisions and addition read as follows:

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

* * * * *

(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 reenrollment 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 — (i) 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.

* * * * *

(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.)

§424.515 [Amended]

3. In § 424.515, the introductory text and in paragraph (d)(3), the cross-reference "§ 424.57(e)" is removed and the cross-reference "§ 424.57(g)" is added in its place.

Dated: November 14, 2014

C'Reda Weeden,

Executive Secretary to the Department,

Department of Health and Human Services.

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