

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS-6006-F]

RIN 0938-A084

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

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

ACTION: Final rule.

SUMMARY: Consistent with section 4312(a) of the Balanced Budget Act of 1997 (BBA), this final rule implements section 1834(a)(16) of the Social Security Act (the Act) by requiring certain Medicare suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to furnish CMS with a surety bond.

DATES: *Effective Date:* These regulations are effective on March 3, 2009.

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786-1302.

SUPPLEMENTARY INFORMATION:

I. Background

A. General and Legislative History

Medicare services are furnished by two types of entities—providers and suppliers. At § 400.202, “provider” is defined as a hospital, a critical access hospital (CAH), a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency (HHA), or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services. The term “provider” is also defined in sections 1861(u) and 1866(e) of the Social Security Act (the Act).

The term “supplier” is defined at section 1861(d) of the Act and includes an entity that furnishes durable medical equipment, prosthetics, orthotics, and suppliers (DMEPOS). Other supplier categories may include, for example, physicians, nurse practitioners (NPs), and physical therapists. The term “DMEPOS” encompasses the types of items included in the definition of medical equipment and supplies found

at section 1834(j)(5) of the Act. As used in this final rule, the term “supplier” refers only to a supplier of DMEPOS.

For purposes of the 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 meets the DMEPOS supplier standards. Those individuals or entities that do not furnish DMEPOS items but furnish other types of health care services only (for example, physician services or NP services) would not be subject to this requirement.

B. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

1. Durable Medical Equipment

The term DME is defined at section 1861(n) of the Act. This definition, in part, excludes from coverage as DME those items furnished in skilled nursing facilities and hospitals (equipment furnished in those facilities is paid for as part of their routine or ancillary costs). Also, the term “DME” is included in the definition of “medical and other health services” found at section 1861(s)(6) of the Act. Furthermore, the term is defined in § 414.202 as equipment furnished by a supplier or a HHA that—

- (1) Can withstand repeated use;
- (2) Is primarily and customarily used to serve a medical purpose;
- (3) Generally is not useful to an individual in the absence of an illness or injury; and
- (4) Is appropriate for use in the home.

Examples of DMEPOS supplies include items such as blood glucose monitors, hospital beds, nebulizers, oxygen delivery systems, and wheelchairs.

2. Prosthetic Devices

Prosthetic devices are included in the definition of “medical and other health services” under section 1861(s)(8) of the Act. Prosthetic devices are defined in this section 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.” Other examples of prosthetic devices include cardiac pacemakers, cochlear implants, electrical continence aids, electrical nerve stimulators, and tracheostomy speaking valves. Under section

1834(h)(4)(B) of the Act, prosthetic devices do not include parenteral and enteral nutrition nutrients and implantable items payable under section 1833(t) of the Act.

3. Orthotics and Prosthetics

Section 1861(s)(9) of the Act provides for the coverage of “leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient’s physical condition.” As indicated by section 1834(h)(4)(C) of the Act, these items are often referred to as “orthotics and prosthetics.”

4. Supplies

Section 1861(s)(5) of the Act includes “surgical dressings, splints, casts, and other devices used for reduction of fractures and dislocation” as one of the “medical and other health services” that is covered by Medicare. Other items that may be furnished by suppliers would include (among others):

- Prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under this title, and that are furnished within a certain time period after the date of the transplant procedure as noted at section 1861(s)(2)(j) of the Act.
- Extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes as listed at section 1861(s)(12) of the Act.
- Home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies included at section 1861(s)(2)(F) of the Act.
- Oral drugs prescribed for use as an anticancer therapeutic agent as specified in section 1861(s)(2)(Q) of the Act.
- Self-administered erythropoietin as described in section 1861(s)(2)(O) of the Act.

C. The January 20, 1998 Proposed Rule

In the Medicare Program; Additional Supplier Standards proposed rule published in the January 20, 1998 **Federal Register** (63 FR 2926), we proposed to reflect the changes made to section 1834 of the Act by section 4312(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33). (Section 4312(a) of the BBA amended section 1834(a) of the Act by adding paragraph (a)(16)(B), which requires a DME supplier to provide us, on a continuing basis, with a surety bond of at least \$50,000, as a condition of the issuance or renewal of a provider number. Section 1834(a)(16) of the Act, as amended by section 4312(c) of the BBA, further provides that we may also

require a surety bond from some or all providers or suppliers who furnish items or services under Medicare Part A or Part B.) In the January 20, 1998 proposed rule, we also proposed that for each tax identification number (TIN) for which a supplier billing number is issued, a DMEPOS supplier must obtain a surety bond in an amount not less than \$50,000.

On October 11, 2000, we published a final rule titled, "Medicare Program; Additional Supplier Standards (HCFA-6004-FC)" in the **Federal Register** (65 FR 60366). However, as we stated in the October 11, 2000 final rule with comment that we decided not to incorporate the provisions related to surety bonds into this final rule with comment, but rather issue the surety bond provisions as a proposed rule at a future date.

In 2003, the Congress enacted section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) which prohibits the Secretary from finalizing a proposed rule related to Title 18 that was published more than 3 years earlier except under exceptional circumstances. In light of section 902 of MMA and our previous decision to issue a proposed rule, we published a proposed rule titled, "Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (DMEPOS) (CMS-6006-P) in the **Federal Register** (72 FR 42001) on August 1, 2007.

II. Provisions of the Proposed Regulations

In the August 1, 2007 **Federal Register** (72 FR 42001), we proposed to implement the statutory surety bond requirement set forth in section 1834(a)(16)(B) of the Act.

Given the lapse in time between the statutory effective date (that is, section 1834 of the Act was amended by section 4312(a) of the BBA enacted on August 5, 1997) and the date of the proposed rule, we proposed to adjust the amount of the surety bond from \$50,000 in 1997 by the Consumer Price Index (CPI) resulting in a higher surety bond amount. In doing so, we proposed to adjust the initial surety bond amount of \$50,000 by the CPI and calculated that a \$50,000 surety bond in 1997 would equate to a surety bond value of \$64,907.17 in 2007. Further, we rounded the calculated value of \$64,907.17 to the nearest thousand to derive a surety bond amount of \$65,000. We proposed that establishing a \$65,000 surety bond for DMEPOS suppliers would: (1) Limit the Medicare program

risk to fraudulent DME suppliers; (2) enhance the Medicare enrollment process to help ensure that only legitimate DME suppliers are enrolled or are allowed to remain enrolled in the Medicare program; (3) ensure that the Medicare program recoups erroneous payments that result from fraudulent or abusive billing practices by allowing CMS or its designated contractor to seek payments from a surety up to the penal sum; and (4) help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers.

In § 424.57(a), we proposed to define the following terms as they are used throughout the regulation in the context of the surety bond requirements:

- Assessment.
- Authorized Surety.
- Civil money penalty.
- Government-Operated Suppliers.
- National Supplier Clearinghouse (NSC).
- Penal Sum.
- Rider.
- Sufficient evidence.
- Surety bond.
- Unauthorized Surety.
- Unpaid claim.

Although we proposed to define "unauthorized surety", we clarified that we did not envision that we would need to declare a surety to be unauthorized except on rare occasions. We anticipate that virtually every surety would provide us, upon written request, information needed to verify the identity of a bondholder, the effective date of the bond, and proof that the surety issued the bond as represented by the supplier. However, if a surety fails to comply with our request for this information, we would consider that surety as unauthorized to provide bonds to DMEPOS suppliers seeking enrollment in the Medicare program. We believe that without this provision, some sureties may not be inclined to provide information we need on a timely basis.

Furthermore, a surety is unauthorized if it had previously failed to comply with a reasonable request from us for payment against a bond. An example of a reasonable request would be a request in writing, signed by an official of CMS or its representatives, or documentation about the amount payable by the supplier. This provision would allow us to take action to prevent a surety from issuing a bond to a Medicare DMEPOS supplier in cases where we have determined that the surety failed to meet its obligations to the Medicare program.

In § 424.57, we proposed to add new (c)(26). Specifically, we proposed that—

- Section 424.57(c)(26) would specify the requirements for a DMEPOS supplier seeking to become a Medicare-enrolled DMEPOS supplier.
- Section 424.57(c)(26)(i) would clarify the minimum requirements for a DMEPOS supplier. We specified that each Medicare-enrolled DMEPOS supplier must obtain a surety bond for each National Provider Identifier (NPI) from an authorized surety. The surety bond or government security would have had to be in the amount of \$65,000 and in the form specified by the Secretary. While we proposed to adjust the amount of the surety bond from \$50,000 in 1997 by the CPI and calculate a higher surety bond amount of \$65,000 in 2007, we did not propose to adjust the base surety bond amount by the CPI annually thereafter. However, we would consider whether any additional adjustments (increase or decrease) in the base bond amount are necessary through a future rulemaking effort.

- Section 424.57(c)(26)(i)(A) would specify that a DMEPOS supplier must submit a surety bond with its initial paper or electronic Medicare enrollment application (CMS-855S, OMB Number 0938-0685) or with its paper or electronic revalidation or reenrollment application.

- Section 424.57(c)(26)(i)(B) would specify how a change of ownership interest affects the DMEPOS supplier.

- Section 424.57(c)(26)(i)(C) would specify that a DMEPOS supplier seeking to enroll a new location must obtain a new surety bond for this new location since this new location is also required to be enumerated with a unique NPI.

- Section 457.57(c)(26)(ii) would establish an exception to the bond requirement for a DMEPOS supplier operated by a Federal, State, local, or tribal government agency if the DME supplier has provided CMS with a comparable surety bond required under State law and if the supplier does not have any unpaid claims, civil money penalties (CMPs), or assessments. However, a government-operated supplier that did not qualify for an exception would have to submit a surety bond. We have determined that an exception to the surety bond requirement for government-operated suppliers extends only to those suppliers that have a good history of paying their Medicare debts. The basis for this exception is principally that government-operated suppliers have the power to tax; therefore, it is unlikely that these DMEPOS suppliers will be

unable to pay their Medicare debts. Thus, government-operated DMEPOS suppliers, by their public nature, furnish a comparable or greater guarantee of payment than would be afforded us by a surety bond issued by a private surety.

Also, a supplier operating under a contract with a government agency but not owned and staffed by the government would not qualify for this exception. Our experience with previously published rules suggests that a government-operated entity would timely pay their Medicare debts (see the HHA surety bond final rule published in the **Federal Register** on January 5, 1998 (63 FR 315); amended by a final rule published in the **Federal Register** on March 4, 1998 (63 FR 10731); a final rule published in the **Federal Register** on June 1, 1998 (63 FR 29656); and a final rule published in the **Federal Register** on July 21, 1998 (63 FR 41171)).

• We solicited comments on whether to establish exceptions for certain types of suppliers. Specifically, we solicited the following comments:

+ Whether we should consider establishing an exception to the surety bond requirement for certain physicians and nonphysician practitioners (NPPs), such as those that occasionally furnish DMEPOS items for the convenience of their patients. While we sought comments about establishing an exception for physicians and NPPs, we were not certain about the scope of the exception that should be established for physicians and NPPs. As such, we solicited comments on how to identify whether a physician or NPP should be given an exception to the surety bond requirement. We also solicited comments on any other appropriate criteria that we should use when considering the establishment of an exception to this requirement for certain physicians and NPPs.

+ Whether we should establish an exception to the surety bond requirement for licensed pharmacists who furnish DMEPOS items for the convenience of their patients and any other appropriate criteria that we should consider in establishing an exception to this requirement for licensed pharmacists.

+ Any other appropriate criteria that we should consider in establishing an exception to this requirement for these types of suppliers.

+ Whether we should establish an exception to the surety bond requirement for large, publicly traded chain suppliers of DMEPOS and on any appropriate criteria that we should

consider in waiving this requirement for these types of suppliers.

+ The appropriate criteria that we may use for establishing exceptions for other types of DMEPOS suppliers from the requirement to purchase a surety bond.

• Section 424.57(c)(26)(iii) would specify the terms of a bond submitted by a DMEPOS supplier.

• Section 424.57(c)(26)(iv) would specify additional DMEPOS supplier bond requirements and would specify the surety's liability under the bond for unpaid claims, CMPs, or assessments that the surety is liable to us, up to a total of the full penal amount of the bond. Thus, since we proposed that surety bonds be issued in an amount equal to \$65,000, the surety is liable to us for up to \$65,000.

• Section 424.57(c)(26)(v) would specify the requirements to cancel a surety bond. Specifically, this section would allow a DMEPOS supplier to terminate or cancel a bond upon proper notice to the NSC. If another bond is submitted and there is a lapse in bond coverage, Medicare would not pay for items or services furnished during the gap in coverage, and the DMEPOS supplier would be 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). Failure by the DMEPOS supplier to submit another bond would result in the revocation of the DMEPOS supplier's Medicare billing privileges. The supplier would be required to refund the beneficiary any amounts collected for services or supplies furnished during the gap in the surety bond coverage. Finally, a supplier or surety may not make amendment to a conforming bond that will limit the scope or term of the bond in a manner resulting in the bond no longer conforming to the provisions of this regulation. Any attempt to do so may result in the revocation of the DMEPOS supplier's billing privileges and a determination that the surety is an unauthorized surety.

• Section 424.57(c)(26)(vi) would specify that the bond must provide that actions under the surety bond may be brought by our contractors or us.

• Section 424.57(c)(26)(vii) would specify that the surety must provide information regarding its physical location including its name, street address, city, state, and zip code and, if different, its mailing address, including name, post office box, city, state, and zip code.

• Section 424.57(c)(26)(viii) would specify the submission date and the term of the DMEPOS supplier bond.

• Section 424.57(c)(26)(viii)(A) would specify that each enrolled DMEPOS supplier that does not meet the criteria for an exception must submit to the NSC an initial surety bond before (60 days following the publication date of the final rule).

• Section 424.57(c)(26)(viii)(B) would specify the type of bond required to be submitted by a DMEPOS supplier under this subpart must be either a continuous bond or an annual bond, with the exception of the initial bond which may differ as specified in this section.

• Section 424.57(c)(26)(ix) would specify the loss of a DMEPOS supplier exception. A DMEPOS supplier that no longer qualifies for an exception as a government-operated DMEPOS supplier must submit a surety bond to the NSC within 60 days after it receives notice that it no longer meets the criteria for an exception.

• Section 424.57(c)(26)(x) would specify the conditions under which a DMEPOS supplier changes a surety.

• Section 424.57(c)(26)(xi) would specify who the parties are to the bond.

• Section 424.57(c)(26)(xii) would specify the effect of a DMEPOS supplier's failure to obtain and maintain a surety bond.

• Section 424.57(c)(26)(xii)(A) would specify that we may revoke the DMEPOS supplier's billing privileges if an enrolled supplier fails to obtain, file timely, and maintain a surety bond as specified in this subpart and as instructed by us. The revocation is effective with the date the bond lapsed, and any payments for items or services furnished on or after that date must be repaid to us by the DMEPOS supplier.

• Section 424.57(c)(26)(xii)(B) would specify that we refuse to issue billing privileges to the DMEPOS supplier if a DMEPOS supplier seeking to become an enrolled DMEPOS supplier fails to obtain and file timely a surety bond as specified in this subpart and our instructions.

• Section 424.57(c)(26)(xiii) would specify the documentation that a DMEPOS supplier must have to be in compliance with these requirements and that we may require a supplier to produce documentation demonstrating that it has a bond and that it meets the requirements of this section.

• Section 424.57(c)(26)(xiv) would specify the effect of subsequent DMEPOS supplier payments paid to us. If a surety has paid an amount to us on the basis of liability incurred under a bond and we subsequently collect from the DMEPOS supplier, in whole or in part, on the unpaid claims, CMPs, or assessments that were the basis for the surety's liability, we would reimburse

the surety the amount that we collected from the DMEPOS supplier, up to the amount paid by the surety to us, provided the surety has no other liability to us under the bond.

- Section 424.57(c)(26)(xv) would specify the effect of a review reversing an appealed determination. We would refund to the DMEPOS supplier the amount that the DMEPOS supplier paid us, 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.

In addition, DMEPOS suppliers have the right to appeal any adverse decisions with respect to unpaid claims, CMPs or assessments. DMEPOS suppliers must use the following applicable appeals provisions specified in 42 CFR associated with each adverse determination: Part 405, subpart I (claims appeals); Part 1003 (civil money penalties); and Part 498 (Medicare participation and enrollment).

We believe that the appeals processes as they apply to DMEPOS suppliers and sureties should be addressed through a private contract between the parties. Specifically, we believe that sureties should consider requiring DMEPOS suppliers to agree to repay the surety any payments made by a Medicare contractor resulting from a DMEPOS supplier's appeal of any adverse decisions with respect to unpaid claims, CMPs, or assessments. Any such contract must be consistent with the applicable appeals processes referenced above. In determining whether a private contract is necessary, we suggest that the sureties and DMEPOS suppliers consider the following types of provisions: Appointment of representative, repayment of any bonding amounts paid to the DMEPOS supplier that were already paid by the surety and the potential cost of pursuing administrative appeals.

Furthermore, we solicited comments on requiring DMEPOS suppliers to obtain a surety bond of more than \$65,000 if the DMEPOS supplier poses a significantly higher than average risk to the Medicare Trust Funds. Specifically, we solicited comments on how to establish elevated amounts of

surety bonds for higher risk DMEPOS suppliers. We proposed to consider the option of establishing elevated amounts of the surety bond at a rate of \$65,000 per high risk factor. Also, we solicited comments on determining the high risk factors that should be used. We suggested several potential high risk factors, and solicited comments on these factors, as well as suggestions for additional factors.

We proposed to consider a \$65,000 increase in the surety bond amount for each occurrence when a DMEPOS supplier has an adverse action as specified in section 221(g)(1)(A) of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA). Examples of adverse actions include, but are not limited to, Federal and State criminal convictions related to the delivery of a health care item or service; formal or official actions, such as the revocation or suspension of a license; and exclusion from participation in Federal or State health care programs. The following is an example of how high-risk criteria would be used to increase the bond amount by \$65,000 per occurrence.

- We proposed, for example, a DMEPOS supplier would be required to obtain a surety bond in the amount of \$130,000, an increase of \$65,000 from the base surety bond amount of \$65,000, if the DMEPOS supplier or any of its owners, authorized officials, or delegated officials had their billing privileges revoked within the last 10 years. If the DMEPOS supplier or any of its owners, authorized officials, or delegated officials had more than one revocation in the last 10 years, then the amount of the surety bond the DMEPOS supplier would be required to obtain would increase \$65,000 per occurrence. We proposed, for example, that a DMEPOS supplier with three different revocations during the preceding 10 years would be required to obtain a surety bond in the amount of \$260,000; \$65,000 for the base surety amount and \$195,000 (3 × \$65,000) for the multiple revocations.

In addition to the elevated risk-based model described above, we solicited comments regarding the establishment of elevated bond amounts by classifying

DMEPOS suppliers into two or three general categories such as—

- New DMEPOS supplier applicants that have no prior billing history with the Medicare program that also would be required to secure a surety bond;
- Current Medicare enrolled DMEPOS suppliers that do not have any prior history of criminal, civil or administrative sanctions for billing-related problems; and,
- Current Medicare enrolled DMEPOS supplier with a prior “adverse history” of criminal, civil or administrative sanctions for billing-related problems for which the regulation would elevate the amount of the required bond by an appropriate amount per prior sanction.

We solicited comments regarding the appropriate elevated amounts of the surety bond using this categorical approach.

We also solicited comments on whether we should establish an exception for rural DMEPOS suppliers and the appropriate criteria that we should consider in establishing an exception for rural DMEPOS suppliers.

Finally, we solicited comments on the appropriate period of time for which a DMEPOS supplier should be required to maintain a higher surety bond amount. Given the higher level of risk associated with DMEPOS suppliers that have one or more risk factors, we proposed to establish a timeframe of 5 years.

III. Analysis of and Responses to Public Comments

We received approximately 200 timely public comments in response to the August 1, 2007 proposed rule. The following is a summary of the comments received and our responses.

(Note: In order to clarify the regulations regarding surety bonds, we have made some technical changes to our proposals.)

Table 1 is provided to assist the reader in cross-referencing the proposed provision with its revised section. (For a more detailed explanation of the technical changes made to this final rule, please see section IV. of this final rule.)

TABLE 1—REDESIGNATIONS FROM PROPOSED RULE TO FINAL RULE

Subject heading	Proposed rule	Final rule
Definitions	§ 424.57(a)	§ 424.57(a)
Effective date	§ 424.57(c)(26)	§ 424.57(d)(1)
Minimum requirements for a DMEPOS supplier	§ 424.57(c)(26)(i)	§ 424.57(d)(2)
Exception to the surety bond requirement	§ 424.57(c)(26)(ii)	§ 424.57(d)(15)
Terms of the surety bond	§ 424.57(c)(26)(iii)	§ 424.57(d)(4)
Specific surety bond requirements	§ 424.57(c)(26)(iv)	§ 424.57(d)(5)
Cancellation of a bond and lapse of surety bond coverage	§ 424.57(c)(26)(v)	§ 424.57(d)(6)

TABLE 1—REDESIGNATIONS FROM PROPOSED RULE TO FINAL RULE—Continued

Subject heading	Proposed rule	Final rule
Actions under the surety bond	§ 424.57(c)(26)(vi)	§ 424.57(d)(7)
Required surety information on the surety bond	§ 424.57(c)(26)(vii)	§ 424.57(d)(8)
Submission date	§ 424.57(c)(26)(viii)	§ 424.57(d)(1)
Type of bond	§ 424.57(c)(26)(viii)	§ 424.57(d)(4)
Loss of DMEPOS supplier exception	§ 424.57(c)(26)(ix)	§ 424.57(d)(15)(ii)
Change of surety	§ 424.57(c)(26)(x)	§ 424.57(d)(9)
Parties to the bond	§ 424.57(c)(26)(xi)	§ 424.57(d)(10)
Effect of DMEPOS supplier's failure to obtain, maintain, and timely file a surety bond	§ 424.57(c)(26)(xii)	§ 424.57(d)(11)
Evidence of DMEPOS supplier's compliance	§ 424.57(c)(26)(xiii)	§ 424.57(d)(12)
Effect of subsequent DMEPOS supplier payment	§ 424.57(c)(26)(xiv)	§ 424.57(d)(13)
Effect of review reversing determination	§ 424.57(c)(26)(xv)	§ 424.57(d)(14)

A. General Comments

Comment: Numerous commenters opposed the surety bond requirement. Commenters stated that the surety bond requirement would create an additional and unnecessary burden on DMEPOS suppliers. Commenters indicated that DMEPOS suppliers have already been burdened with, among other things, continued reductions in Medicare reimbursement, competitive bidding, and accreditation. In addition, commenters stated that there is no need to impose the surety bond requirement on DMEPOS suppliers since these suppliers represent a small fraction of Medicare spending.

Response: We recognize that we have recently implemented a number of program integrity measures designed to strengthen the enrollment process and improve quality of products and services. As the commenter notes, one such initiative is accreditation. Section 302 of the MMA added section 1834(a)(20) to the Act, which mandates the establishment and implementation of quality standards for DMEPOS suppliers. All suppliers that furnish such items or services under section 1834(a)(20)(D) of the Act, as the Secretary determines appropriate, must comply with the quality standards in order to obtain and maintain Medicare billing privileges. The Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) required all DMEPOS suppliers to meet quality standards for Medicare accreditation by October 1, 2009. In addition, section 154 of the MIPPA stated that certain professionals and persons do not have to meet this deadline unless quality standards are developed specific to these professionals and persons. Section 154(b) of the MIPPA, added a new subparagraph (F) to section 1834(a)(20) of the Act. This subparagraph states that eligible professionals and other persons are exempt from meeting the October 1, 2009 accreditation deadline unless CMS

determines that the quality standards are specifically designed to apply to such professionals and persons. Eligible professionals under section 1834(a)(20)(F) of the Act include physicians (as defined in section 1861(r) of the Act), physical therapists, occupational therapists, qualified speech-language pathologists, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, registered dietitians, and nutritional professionals. We have designated certain individuals as falling within the category of “other persons” under the statute; these individuals include orthotists, prosthetists, opticians, and audiologists. We will work in collaboration with the medical and professional groups to develop specific quality standards.

We believe that the accreditation process will assure that Medicare beneficiaries receive quality supplies and services from eligible suppliers.

Nevertheless, we do not believe that the implementation of accreditation and other program integrity initiatives obviates the need to establish a surety bond requirement for DMEPOS suppliers, something that will help ensure that DMEPOS suppliers meet minimum financial requirements in order to participate in Medicare.

Comment: Many commenters stated that a surety bond would offer little or no additional protection to CMS since the accreditation process for DMEPOS suppliers is already providing a greater level of security. The commenters indicated that the quality standards in the accreditation process include stringent provisions that limit the risk of Medicare fraud. As a result, some of the commenters described the surety bond requirement as redundant, duplicative, unnecessary, costly, and extreme. Another commenter stated that it believes its licensure and certification status as a hand therapist and our

accreditation process are sufficient evidence of both its competence and ethical behavior. Yet another commenter stated that both initiatives should be analyzed, coordinated, and reconciled before implementation.

Response: We disagree with the commenters that a surety bond would offer little or no protection because we are in the process of implementing the accreditation requirements for DMEPOS suppliers. As already indicated, while accreditation will ensure that a DMEPOS supplier meets certain quality standards, a surety bond will ensure that DMEPOS suppliers that do not qualify for an exception to the bonding requirement meet enhanced financial requirements. Moreover, only surety bonds can be used to repay any incurred overpayments. We believe that these efforts, when combined, will have a significant impact on both the quality of products and services provided to Medicare beneficiaries, but also increase our efforts to ensure that only qualified suppliers are eligible to enroll or remain enrolled in the Medicare program.

We understand that many DMEPOS suppliers are concerned with the cumulative effect that several different statutory changes will have on suppliers of DMEPOS. We have taken this effect into consideration, and the revised impact analysis contained in this final rule accounts for the cumulative impact.

Comment: A commenter stated that it is a waste of American citizens' money to require DMEPOS suppliers that bill \$25,000 a year or less to obtain surety bonds.

Response: We disagree with the commenter. The surety bond for DMEPOS suppliers is designed to reduce the amount of money that is lost due to fraudulent or abusive billing schemes perpetrated by individuals and organizations. In addition, we do not believe that prior billing is necessarily proof of future actions.

Comment: One commenter believes that the surety bond requirement will not substantively strengthen program

integrity. The commenter stated that, although requiring suppliers to obtain a surety bond as a condition of Medicare enrollment may deter some of the more simplistic criminal fraud schemes, it is unrealistic for CMS to expect that the requirement will eliminate the most insidious type of fraudulent supplier, which is the DMEPOS supplier that initially appears to meet the minimum indicia of a legitimate business. The commenter stated that this is the type of criminal element that has consistently evaded our oversight and enforcement initiatives. Other commenters stated that the surety bond requirement is only a repayment mechanism for the Medicare program and not a true deterrent to criminal or abusive billing practices. The commenters also stated that anyone with a criminal intent, and the means to effectuate it, can bill and get paid for fraudulent claims before we have identified the fraud.

Response: We believe that the surety bond requirement is an important tool that, when used in conjunction with other efforts to reduce fraudulent or abusive behavior, will assist us in protecting the Medicare Trust Funds. While we recognize that implementing a surety bond requirement for certain DMEPOS suppliers will not deter all types of fraud and abuse perpetrated by individuals and organizations intent on committing such actions, we believe that this statutorily mandated requirement will greatly assist us in our efforts to reduce fraud and abuse by some suppliers of DMEPOS and to identify more sophisticated instances of fraudulent behavior.

Comment: One commenter stated that if fraud is located primarily in urban areas, such as Miami, Florida, and involves DMEPOS suppliers that conduct a large volume of business, then the August 1, 2007 proposed rule is misdirected because it penalizes suppliers that conduct a small volume of business in other parts of the country, such as the Midwest.

Response: We understand the concerns of the commenter, but we also recognize that fraudulent schemes are portable and can be perpetuated in any part of the country, not just urban areas. The surety bond requirement will help to ensure that certain newly enrolling DMEPOS suppliers meet financial solvency standards, as well as our established conditions for enrollment and payment.

Comment: One commenter stated that we should not impose additional costs through the surety bond requirement but should instead focus our resources on those suppliers it can readily find committing Medicare fraud and abuse.

Response: We are expanding our effort to identify, detect, and revoke the billing privileges of those DMEPOS suppliers who fail to meet the supplier standards found at § 424.57. By establishing a surety bond requirement for newly enrolling DMEPOS suppliers as well as existing DMEPOS suppliers, we believe that we will improve the quality of services received by Medicare beneficiaries, as well as establish additional program safeguards for the Medicare program.

B. Legislative Authority

Comment: One commenter stated that we have no legislative authority to implement the surety bond requirement. The commenter noted that section 902 of the MMA prohibits the Secretary from finalizing a proposed rule related to Title 18 that was published more than 3 years earlier except under exceptional circumstances. The commenter indicated that we did not finalize the January 20, 1998 proposed rule within the prescribed timeframe. As a result, the commenter believes that we have no specific statutory authority to implement the surety bond requirement.

Response: While the commenter is correct that we did not finalize the January 20, 1998 proposed rule in the allotted amount of time as required by section 902 of the MMA, we did repropose the surety bond provisions in the August 1, 2007 proposed rule and have 3 years from that date to finalize the regulation as required by the MMA. Therefore, we believe that we are within our statutory authority for finalizing this rule.

Comment: Some commenters questioned the need for the surety bond requirement by noting that the surety bond requirement specified in the BBA of 1997 reflected a different era when there were fewer requirements to become a DMEPOS supplier. For example, one commenter observed that DMEPOS suppliers are now required to become accredited, and most are about to be subject to additional scrutiny and cost controls via the DMEPOS competitive bidding program. Another commenter stated that the NSC did not routinely perform onsite inspections before issuing billing numbers. Commenters stated the NSC is now required to perform an onsite inspection for every DMEPOS supplier that seeks to obtain a Medicare billing number.

Response: While these commenters are correct in that we have implemented significant programmatic changes—such as the routine performance of onsite visits—we note that the problems that led to the enactment of section 4312 of the BBA are still prevalent in the

DMEPOS industry now. Indeed, the Office of Inspector General (OIG) continues to identify questionable conduct in the DMEPOS arena, as reflected in its recent report entitled, “Los Angeles County Suppliers’ Compliance with Medicare Standards: Results from Unannounced Visits; OEI–09–07–00550.”

We further note that on July 15, 2008, the Congress enacted the MIPPA which delayed the implementation of the DMEPOS Competitive Bidding Program. This, in our view, enhances the importance of the implementation of the surety bond requirement; with the delay in competitive bidding, we need to utilize the remaining tools at our disposal to prevent fraudulent activity in the DMEPOS arena. The onsite audits of every DMEPOS supplier serves as an important tool in ensuring that the NSC grants billing privileges to legitimate suppliers.

C. Bond Amount

Comment: Several commenters disagreed with our proposal to increase the amount of the surety bond from \$50,000 to \$65,000 based on the Consumer Price Index (CPI). One commenter stated that the proposal is flawed because it is not based on risk to the Medicare program or Medicare reimbursement levels, and that the amount should be adjusted downward to reflect reduced Medicare reimbursement to DMEPOS suppliers (that is, commenters noted that Medicare reimbursement to many DMEPOS suppliers has decreased, remained the same, or only minimally increased since 1997.) In addition, several commenters believe that we should assess whether our proposal to increase the surety bond amount, which would raise the annual cost of the surety bond requirement from \$150 million to approximately \$198 million, would have any appreciable increase in benefit. Other commenters stated that nothing in the surety bond requirement set forth in section 1834(a)(16)(B) of the Act or its history indicates that Congress ever contemplated inflation adjustments, or that the surety bond amount should be higher than \$50,000.

Response: We disagree with these comments for the following reasons. First, section 4312(a)(16)(B) of the BBA states that the bond amount must be “in an amount that is not less than \$50,000.” The phrase “not less than” makes it clear that we have the authority to impose a bond amount higher than \$50,000. Second, nowhere in the statute or the legislative history did the Congress indicate that the bond amount should be tied to the reimbursement

levels of the provider or supplier type in question. To the contrary, we believe that the Congress intended for the key factor in determining the bond amount to be the risk of fraudulent activity posed by that class of provider or supplier.

Having said this, we nevertheless have elected to reduce the base surety bond amount from \$65,000 to \$50,000 for two reasons. First, we wish to preclude an additional regulatory impact associated with implementing section 4312(a) of the BBA. This is especially true with respect to small, rural DMEPOS suppliers, as discussed in section G of the Regulatory Impact Analysis. Second, we believe that \$50,000 is an appropriate starting point for the bond requirement. Using the statutory minimum amount will, in our view, allow us to better gauge whether a higher surety bond amount is needed to protect the Medicare Trust Funds.

However, we are establishing a surety bond amount higher than \$50,000 for those DMEPOS suppliers that pose a significantly higher risk to the Medicare program. In addition, we will evaluate the impact of this \$50,000 surety bond amount requirement for certain DMEPOS suppliers before considering any increase in the base surety bond amount.

Comment: Commenters stated there was no need to impose a tiered approach to determine what bond amount to impose on a DMEPOS supplier based on past conduct. For established DMEPOS suppliers, commenters believed that CMS and the OIG have significant administrative remedies to address misconduct, including excluding the supplier from the Medicare program. Commenters maintained that we should limit the bond requirement to new suppliers, which is consistent with the Congress' original intent under the BBA.

Response: We do not agree with the commenters that there is no need to establish elevated surety bond amounts for DMEPOS suppliers that pose additional risk to the Medicare program, nor do we agree with the commenters' statement that the Congress intended to limit the surety bond requirement to only new DMEPOS suppliers. As for the former comment, we believe that elevated bond amounts are necessary to protect the Medicare Trust Fund and Medicare beneficiaries. Furthermore, we note that section 4312(a) of the BBA expressly states that "the Secretary shall not provide for the issuance (or renewal) of a provider number * * *" unless the supplier furnishes a surety bond of not less than \$50,000. (Emphasis added.) Use of the term "renewal" evidences a

congressional intention to apply the surety bond requirement to those DMEPOS suppliers already in the Medicare program.

It is true that CMS and the OIG have various administrative remedies to address fraudulent or abusive conduct by DMEPOS suppliers after they have enrolled to participate in Medicare; however, we believe that the Congress intended to require that suppliers of DMEPOS meet financial solvency requirements and to ensure that Medicare could recoup some, if not all, of the improper payments made to suppliers of DMEPOS.

Comment: One commenter stated that the preamble to the August 1, 2007 proposed rule factually "misdescribes" the January 20, 1998 proposed rule. The commenter indicated that the January 20, 1998 proposed rule did not propose a \$65,000 surety bond level, but instead proposed a sliding scale approach starting at \$50,000 and rising to 15 percent of reimbursement.

Response: We agree that the January 20, 1998 proposed rule included a minimum \$50,000 surety bond amount. We note that the \$65,000 figure in the August 1, 2007 proposed rule has been reduced in this final rule to \$50,000, except in the case of high-risk suppliers. We consider any DMEPOS supplier with at least one adverse legal action within the 10 years preceding enrollment, revalidation, or reenrollment to be a "high-risk" supplier.

Comment: Several commenters maintained that we should have sought public comment on the reasonableness of increasing the surety bond amount from \$50,000 to \$65,000. The commenters stated that this change represents an increase of 25 percent over the original \$50,000 surety bond requirement proposed in the January 20, 1998 proposed rule.

Response: In the August 1, 2007 proposed rule, we solicited public comments on the amount of the surety bond for DMEPOS suppliers and, as already noted, we have chosen to reduce the minimum surety bond amount to \$50,000.

Comment: One commenter stated that, although we justified our proposal to increase the amount of the surety bond from \$50,000 to \$65,000 based on the CPI, expecting a DMEPOS supplier to obtain a surety bond that far exceeds the value of the supplier's annual claims seems unreasonable.

Response: As already discussed, neither section 4312(a) of the BBA nor its legislative history indicate that the Congress intended for the bond amount to be tied to the level of reimbursement

a supplier receives from the Medicare program. The regulatory impact section of the proposed rule (72 FR 42008) stated that, "We estimate that as many as 15,000 DMEPOS suppliers, or 23 percent of the 65,984 entities and 15 percent (or 17,471) of the 116,471 individual suppliers currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries if this proposed rule is implemented." While we are reducing the amount of the surety bond from \$65,000 to \$50,000, the lowest amount allowable under section 4312(a)(16)(B) of the BBA, and limiting its impact to certain DMEPOS suppliers, we understand that the implementation of this rule will require some DMEPOS suppliers to reconsider their participation in the Medicare program because of the added cost of the bond.

Comment: A commenter stated that the surety bond requirement may increase costs for small DMEPOS suppliers and reduce costs for large DMEPOS suppliers. The commenter stated that the January 20, 1998 proposed rule provided for a sliding scale approach to the bond requirement for DMEPOS suppliers in that the surety bond started at \$50,000 and rose to 15 percent of Medicare reimbursement (capped at \$3 million). Many commenters stated that a tiered system would be more equitable.

Response: We do not believe that establishing a sliding scale approach is appropriate because of the operational complexity associated with establishing and maintaining this approach. Moreover, it is important to note that 4312(a) of the BBA requires that we establish a surety bond in an amount of not less than \$50,000. Accordingly, by statute, the lowest amount that we can establish for a DMEPOS surety bond is \$50,000, and based on the public concerns about higher bond amounts, we have decided to implement higher surety bond amounts only for those individuals or organizations that pose a higher risk to the Medicare program.

Comment: A commenter stated that the financial soundness of DMEPOS suppliers will be a factor in the price of surety bonds. The commenter maintained that the financial soundness of a DMEPOS may result in DMEPOS suppliers not being able to obtain surety bonds. The commenter stated that this is one reason for keeping the amount of the surety bond low and for allowing sufficient time for a competitive market to be formed for surety bonds.

Response: We agree that financial soundness will be a key determinant in whether a DMEPOS supplier will be able to secure a surety bond and the

amount that the DMEPOS supplier will have to pay for the bond. To reduce cost associated with obtaining a bond, we have reduced the amount of surety bond from \$65,000 bond to \$50,000. In addition, we have delayed the implementation of this regulation.

Comment: One commenter maintained that we did not adequately outline the rationale for adjusting the amount of the surety bond in the August 1, 2007 proposed rule. The commenter noted that the inflation adjusted bond will be 25 percent higher than the \$50,000 bond originally contemplated by the Congress. The commenter stated that, since it appears that our only rationale for increasing the bond amount is based on the passage of time, imposing this additional financial and administrative burden on suppliers is arbitrary.

Response: We note that this final rule has been revised to reduce the proposed \$65,000 surety bond amount to \$50,000, the minimum allowable under the statute.

Comment: One commenter stated that the proposed surety bond amount of \$65,000 is realistic, and that establishing a bond requirement for the majority of DMEPOS suppliers is consistent with standard suretyship.

Response: We appreciate this comment. However, this final rule has been revised to require a \$50,000 surety bond (the minimum allowable under the statute) for certain DMEPOS suppliers.

D. Timeframe for Implementation

Comment: Several commenters requested that we give DMEPOS suppliers at least 120 days to comply with this final rule instead of 60 days following publication of this rule.

Response: We agree with the commenters and have revised § 424.57(d)(1) (proposed § 424.57(c)(26)) to require existing suppliers (that is, DMEPOS suppliers already enrolled in the Medicare as of the publication date of this final rule in the **Federal Register**) of DMEPOS to obtain a surety bond no later than 9 months after the effective date of this final rule. Moreover, beginning 120 days after the effective date of this final rule, DMEPOS suppliers, who are seeking to enroll in the Medicare program and are subject to the provisions of this final rule, are required to furnish to the NSC a surety bond of at least \$50,000 from an authorized surety for each assigned NPI for which the DMEPOS supplier is seeking to obtain Medicare billing privileges. Accordingly, any DMEPOS supplier, except those specified in § 424.57(d)(15) (proposed § 424.57(c)(26)(ii)), seeking to enroll a

new practice location or to change the ownership of an existing DMEPOS supplier after the publication date of this rule is required to submit to the NSC a surety bond of at least \$50,000 beginning 120 days after the effective date of this final rule. The DMEPOS supplier must submit a surety bond of at least \$50,000 with its enrollment application on the date of filing.

Comment: Several commenters suggested that we delay implementing this final rule. The commenters stated that we should wait to see if our accreditation process reduces the level of Medicare fraud in the DMEPOS industry. Another commenter stated that we should consider granting a transition or “grace period” that gives suppliers an opportunity to, among other things, assess the availability of surety bonds and learn how to obtain surety bonds before requiring them to comply with any surety bond requirement. The commenter also urged us to grant this transition or “grace period” to allow time for a robust market for DMEPOS supplier surety bonds to develop.

Response: We agree with the commenters and we have delayed the requirement of a surety bond for certain existing DMEPOS suppliers until 9 months after the effective date of this final rule, and 120 days after the effective date of this final rule for certain new DMEPOS suppliers. These delays will give existing suppliers an opportunity to assess and determine whether they will continue to participate in the Medicare program during the accreditation implementation without incurring additional costs associated with a surety bond.

E. Definitions

Comment: Several commenters noted that § 424.57(a) of the August 1, 2007 proposed rule stated that paragraph (3) of the proposed definition of “unauthorized surety” means, among other things, a surety that “[f]ails to pay CMS in full the amount requested, up to the penal sum of the bond when presented with a request for payment within 30 days of written notification.” The commenters stated that there is no requirement that the request for payment be supported by sufficient evidence, and recommended that we revise paragraph (3) as follows: “Fails to pay CMS any amount owed, up to the penal sum of the bond, within 30 days of receipt of a request for payment and sufficient evidence to support the request.”

Response: We have removed the proposed definition of an “unauthorized surety” from this final rule.

Comment: One commenter stated that it is unclear whether there will be any ramifications if a DMEPOS supplier purchases a bond from a surety that becomes an “unauthorized surety.” The commenter believes that requiring the supplier to obtain a replacement bond without receiving a refund of the premium would penalize the wrong party.

Response: We believe it is essential that DMEPOS suppliers select surety bond companies that will honor their commitments to pay the bond amount when presented with sufficient evidence by CMS or the NSC that a debt is owed by the DMEPOS supplier.

Comment: One commenter suggested that we revise the definition of a “penal sum” from, “a sum to be paid (up to the value of the bond) by the surety as a penalty under the terms of the surety bond when a loss has occurred” to “a sum in the amount of the bond and the maximum obligation of the surety if a loss occurs.” The commenter stated that the penal sum is not a penalty to be paid; rather, it represents the surety’s obligation to pay what the principal owes up to the penal sum.

Another commenter suggested that we revise the definition of “sufficient evidence” from “means the documentation that CMS may supply to the surety in order to establish that a DMEPOS supplier had received Medicare funds in excess of amounts due and payable under the statute and regulations” to “means documents CMS supplied to the surety that established both the amount of Medicare funds a DMEPOS supplier received in excess of amounts due and payable under applicable statutes and regulations and that this amount was an obligation of the surety.”

Response: In response to these comments, we have revised the definitions of “penal sum” and “sufficient evidence” in § 424.57(a).

Comment: A commenter stated that the definition of “chain suppliers of DMEPOS” should include chain pharmacies.

Response: We agree that publicly traded chain suppliers of DMEPOS include chain pharmacies as long as there are 25 or more distinct practice locations under common ownership.

Comment: One commenter stated that our definition of a “small supplier” is inconsistent and problematic. The commenter maintained that we made an arbitrary decision in the Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Final Rule (April 10, 2007, 72 FR 17992) to define

a small supplier as a supplier that generates gross revenue of \$3.5 million or less in annual receipts, but did not discuss why it chose \$3.5 million as the ceiling as opposed to some other figure (for example, the commenter noted the SBA defines a small business as a business that has less than \$6.5 million in annual receipts). The commenter stated that we should adopt SBA's definition of a small business.

Response: During the development of the April 10, 2007 final rule (72 FR 17992), we adopted a \$3.5 million revenue or less standard for DMEPOS suppliers. This standard was developed in consultation with the SBA during the development of the DMEPOS competitive bidding final regulation. To ensure consistency with both the April 10, 2007 rule and the guidance furnished by the SBA, we will continue to define a small supplier as a supplier that generates gross revenue of \$3.5 million or less in annual receipts, including Medicare and non-Medicare revenue.

F. Payment and Liability

Comment: A commenter stated that proposed § 424.57(c)(26)(iii) indicates that we will revoke or deny a DMEPOS supplier's billing privileges based on submission of a bond that does not reflect the requirements of that section. The commenter stated that because, in its view, DMEPOS suppliers may experience difficulty obtaining surety bonds in the marketplace, we should recognize situations where DMEPOS suppliers have made a good faith effort to secure a surety bond that meets our requirements if the market will not provide such a product. The commenter suggested that we add language to proposed § 424.57(c)(26)(iii) that recognizes a DMEPOS supplier's good faith effort to obtain a surety bond that satisfies the surety bond requirement.

Response: We believe that the delay in the implementation of this final rule will allow a surety bond market to develop for prospective DMEPOS suppliers as well as existing DMEPOS suppliers enrolled in the Medicare program. Therefore, we are not revising § 424.57(d)(4) (proposed § 424.57(c)(26)(iii)).

Comment: One commenter stated that proposed § 424.57(c)(26)(iv)(C) appears to conflict with § 424.57(c)(26)(iv)(B). The commenter noted that § 424.57(c)(26)(iv)(C) states that "the surety remains liable for unpaid claims, CMPs, or assessments that * * * took place during the term of the bond or rider * * *," and § 424.57(c)(26)(iv)(B) states that "[t]he surety is liable for unpaid claims, CMPs, or assessments

that are presented to the surety for payment when the surety bond is in effect, regardless of when the payment, overpayment, or other event giving rise to the claim, CMPs, or assessment occurred * * *." (Emphasis added.) The commenter suggested revising § 424.57(c)(26)(iv)(B) to place liability on the surety whose bond was in effect at the time of each respective default as provided by § 424.57(c)(26)(iv)(C).

Response: We agree that the provisions discussed above are in conflict and have revised § 424.57(d)(5) in this final rule (proposed § 424.57(c)(26)(iv)) accordingly.

Comment: A commenter stated that we need to clearly spell out the process and timeframes by which we would request payment from the surety.

Response: We believe that the provisions of this final rule contain sufficient information on both the process and the timeframes involved in our payment requests.

Comment: A commenter stated that it is unclear whether the original application and documentation for approval of the surety bond should be submitted to the NSC or the U.S. Department of Health and Human Services (HHS). The commenter maintained that the surety bond, all riders, and notices of cancellation should be filed with HHS to avoid any confusion or loss of data should HHS change contractors.

Response: Since the NSC is our designated contractor responsible for establishing DMEPOS billing privileges, all documentation (for example, bond approval, riders, and notices of cancellation) associated with the surety bond should be sent to the NSC.

Comment: Several commenters maintained that a default on the surety bond should be based on a finding of wrongdoing, not merely on the existence of debt, which may be disputed and subject to the Medicare appeals process. The commenters stated that a surety's liability should be triggered only when there has been a final determination of an assessment for fraud or other misconduct against a DMEPOS supplier and the time to file an appeal has expired. Commenters also stated that there is no valid rationale to impose liability under the bond before a final determination has been made because the bond, by its terms, guarantees payment of the assessment. Another commenter stated that underwriters should not be required to reimburse CMS for any overpayment until the DMEPOS supplier exercises its Medicare appeal rights, supplier liability for the claim is firmly

established, and the supplier is past due on repayment.

Response: We do not agree that we should be prohibited from seeking payment from a surety until all supplier appeals have been exhausted. In addition, we believe that it is appropriate for the surety to pay CMS a total of up to the full penal amount of the bond when sufficient evidence is presented. We note that in revised § 424.57(d)(14), 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.

Comment: In order to limit the surety's liability to the penal sum of the bond, one commenter recommended that proposed § 424.57(c)(26)(iv) and any required surety bond form should include the following language: "Regardless of the number of years the bond is in force, the number of premiums paid, or the number of claims made, the surety's aggregate liability shall not be more than the penal sum stated above."

Response: We agree with this commenter and have revised § 424.57(d)(5) (proposed § 424.57(c)(26)(iv)) accordingly.

Comment: A commenter stated that permitting the surety to cancel the bond as to future events will protect CMS and the surety. The commenter stated that a bond is an essential requirement for participation in the DMEPOS program. The commenter stated that if the surety learns that a DMEPOS supplier is violating Medicare rules or receiving Medicare overpayments, then the surety should be able to cancel the bond. The commenter observed that the surety would remain liable for overpayments and other debts already incurred, but it could avoid watching its obligations increase if the DMEPOS supplier violates Medicare rules or receives Medicare overpayments. Since the bond would no longer be in effect, the commenter noted that the supplier would be ineligible for reimbursement for supplies furnished after the effective date of cancellation. In effect, the commenter believes that the surety's cancellation of the bond would protect CMS from having to continue to do

business with violators. The commenter stated that a right to cancel protects the Medicare program from fraud and abuse. The commenter noted that, if the surety mistakenly cancels a DMEPOS supplier's surety bond, then the supplier can simply obtain a replacement bond. The commenter recommended that proposed § 424.57(c)(26)(iv) and any required surety bond form should include the following language: "The Surety may terminate its liability for future acts of the Principal at any time by giving thirty (30) days written notice of termination of the bond of the Obligee."

Response: We agree with this commenter and have revised § 424.57(d)(6) (proposed § 424.57(c)(26)(v)) accordingly.

Comment: One commenter stated that the success of the surety bond requirement depends on the reasonableness of the terms of the surety bond. The commenter stated that sureties have to be able to, based on the merits of each applicant, provide the bonds to qualified DMEPOS suppliers and decline to offer bonds to unqualified DMEPOS suppliers. If the terms of the bond alone place an unreasonable risk on the surety, then the bonds will be available only to the largest, best-capitalized DMEPOS suppliers. Therefore, the commenter maintained that it is important that we carefully consider the bond terms and make sure that they conform to reasonable standards. First, the commenter stated that the penal sum of the bond has to be the limit of the surety's obligations. If the surety cannot be sure of its maximum exposure, it cannot underwrite the risk. Second, the commenter stated that the surety should be able to cancel the bond on 30 days advance notice. The commenter stated that the surety would remain liable for any overpayments or other defaults that occur before the effective date of the cancellation but would be able to prevent future losses. Finally, the commenter maintained that there must be a reasonable time limit on the surety's exposure so that at the end of that period, if no claims have been made, the surety can close its books on the bond and return any security or collateral the principal provided.

Response: We have revised the relevant provisions, including the provisions pertaining to 30-day cancellations, and believe we have addressed the commenter's concerns in this final rule.

Comment: A commenter stated that proposed § 424.57(c)(26)(iv)(B) and (C) partially address the time limit of the surety's liability. The commenter

indicated that subparagraph (B) provides that the bond in force when the claim is made is responsible. The commenter stated that this implies that the earlier bond in force when the events giving rise to the claim occurred is not responsible. The commenter stated that, in effect, any bond is discharged from liability (except for claims already made) once the supplier furnishes a new bond that complies with the surety bond requirement. The commenter also stated that if at any point the DMEPOS supplier fails to furnish an acceptable bond, then for up to 2 years we can make claims on the existing bond based on overpayments or other events that took place during the bond term. However, the commenter observed that subparagraph (C)(2) starts the 2-year period from the date the supplier failed to submit a required bond or the date the DMEPOS supplier's billing privileges were terminated, whichever is later. The commenter stated that, in theory, there should not be much difference between either starting dates since the supplier's billing privileges should be terminated as soon as it fails to renew or submit a bond. Sureties will be concerned that, despite CMS oversight, we may not promptly terminate the supplier's billing privileges. The commenter stated that the surety could then face a liability period longer than the anticipated 2-year timeframe solely because of the neglect of CMS or one of its contractors. The commenter also stated that this issue would greatly concern sureties. Therefore, the commenter recommended that we amend subparagraph (C)(2) to read as follows: "Were imposed or assessed by CMS or the OIG during the 2 years following the date the bond terminated, expired or was cancelled."

Response: We agree, and have revised subparagraph § 424.57(d)(5)(iii)(B) (proposed § 424.57(c)(26)(iv)(C)(2)) accordingly.

Comment: A commenter states that proposed § 424.57(c)(26)(v)(G) provides that "[t]he liability of the DMEPOS supplier and the surety to CMS is not extinguished by * * * [t]he DMEPOS supplier's failure to exercise available appeal rights under Medicare or to assign the rights to the surety." (Emphasis added.) The commenter stated that, upon receiving notification of a default from CMS or the NSC, the surety should be provided the same right to the appeals process as the principal because to provide otherwise would result in unjust enrichment for CMS.

Response: We disagree with the commenter because our relationship is

primarily with the DMEPOS supplier, as opposed to the surety. Accordingly, we believe that only the DMEPOS supplier should be afforded appeal rights.

Comment: A commenter noted that proposed § 424.57(c)(26)(viii)(B) states that DMEPOS suppliers must submit either a continuous bond or an annual bond to the NSC. The commenter stated that requiring a continuous surety bond would be the most efficient approach and would require minimal maintenance in terms of recordkeeping.

Response: We agree with this comment and have revised § 424.57(d)(4) (proposed § 424.57(c)(26)(viii)(B)) to require a continuous bond. We believe that a continuous bond contains administrative benefits for the surety, the DMEPOS supplier, and CMS.

Comment: One commenter asserted that proposed § 424.57(c)(26)(x) appears to conflict with proposed § 424.57(c)(26)(iv)(B). The commenter noted that § 424.57(c)(26)(iv)(B) states that "[t]he surety is liable for unpaid claims, CMPs, or assessments that are presented to the surety for payment when the surety bond is in effect, regardless of when the payment, overpayment, or other event giving rise to the claim, CMPs, or assessment occurred * * *" (Emphasis added.) Section 424.57(c)(26)(x), the commenter observed, indicates that "[i]f a DMEPOS supplier changes its surety during the term of the bond, the new surety will be responsible for any overpayments, CMPs, or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond." (Emphasis added.) The commenter stated that the provision also indicates that "[t]he previous surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety." (Emphasis added.) The commenter suggested revising proposed § 424.57(c)(26)(iv)(B) to place liability on the surety whose bond was in effect at the time of each respective default as provided by proposed § 424.57(c)(26)(iv)(C), which states that "the surety remains liable for unpaid claims, CMPs, or assessments that * * * took place during the term of the bond or rider * * *"

Response: We agree and have revised the provisions of this final rule to ensure consistency.

Comment: A commenter stated that the surety bond requirement should cover only amounts of proven losses, and thus, should not include amounts for civil monetary penalties.

Response: We disagree because CMPs are debts owed to the Federal government.

G. Bond Cancellations and Lapses

Comment: Several commenters noted that proposed § 424.57(c)(26)(v) allows a DMEPOS supplier to terminate or cancel a surety bond upon proper notice to the NSC. The commenter maintained that the surety should also be allowed to terminate or cancel the bond. Another commenter agreed that it is important for the surety to be able to cancel the bond by providing advance written notice to the DMEPOS supplier, CMS, and the NSC. The commenter noted that the events listed in proposed subparagraphs (A) through (G) of § 424.57(c)(26)(v) do not extinguish any preexisting liability, but cancellation of the bond does prevent new liability from accruing. The commenter suggested that we revise the last sentence of the introductory text of paragraph (v), which immediately precedes subparagraphs (A) through (G), to read as follows: “The liability of the DMEPOS supplier and the surety to CMS arising out of the overpayments or other events that occurred prior to cancellation is not extinguished by any of the following * * *”

Response: While we believe that a surety has the right to cancel a bond and that it is purely a contractual matter between the two parties, we agree that a surety should notify the DMEPOS supplier and the NSC when a cancellation occurs. Therefore, we have revised § 424.57(d)(6) accordingly.

Comment: A commenter stated that we should not prohibit Medicare payments during any lapses in surety bond coverage as proposed in § 424.57(c)(26)(v). The commenter maintained that this prohibition would penalize suppliers by treating reimbursable Medicare payments during a lapse in surety bond coverage as overpayments. The commenter stated that this practice would, among other things, result in a windfall to the government. Another commenter stated that notice from CMS indicating that the surety bond is not in effect and that payments will cease in 30 days would be sufficient and fair. The commenter maintained that retroactively applying a denial is too great a penalty for “what could well be a simple administrative lapse.”

Response: We disagree with the commenter. If the bond coverage lapses, the supplier is immediately and automatically out of compliance with the requirement at § 424.57(d) (proposed § 424.57(c)(26)) that the bond coverage be maintained in order for the DMEPOS

supplier to receive payment from Medicare for its provision of DME.

Comment: A commenter noted that proposed § 424.57(c)(26)(v) requires a surety to immediately notify the NSC if there is a lapse in surety bond coverage. The commenter stated that this requirement is unreasonable because the surety with the expiring surety bond would not know whether the replacement surety bond has been issued or if the principal’s billing privileges have been revoked. The commenter believes that providing the surety with the right to cancel the bond and requiring the surety to notify CMS and NSC if the surety has received a notification of cancellation from the principal should be adequate.

Response: We agree with the commenter and have revised the language in § 424.57(d)(6)(iv) (proposed § 424.57(c)(26)(v)(D)) to read as follows: “The surety must immediately notify the NSC if there is a lapse in the surety’s coverage of the supplier.” The surety, in other words, will only be responsible for notifying the NSC if its coverage of the supplier has lapsed.

Comment: Several commenters believe that we should have provisions to protect a DMEPOS supplier if its surety bond is erroneously reported as lapsed or cancelled. The commenters stated that a DMEPOS supplier should have a reasonable, though limited, amount of time to prove that an error occurred, and that it has a valid surety bond.

Response: Section 424.57(e) (redesignated § 424.57(d)) specifies that a revocation of a DMEPOS supplier’s billing privileges does not become effective until 15 days after the date on the revocation notice letter. During that 15-day period, the supplier may submit a corrective action plan (CAP) as specified in § 424.535(a)(1).

Comment: A commenter stated that the last two sentences of proposed § 424.57(c)(26)(x) appear to contemplate that a bond will remain in force, but the surety would change. The commenter stated that this would be highly unlikely, even though it is arguably possible. The commenter stated that if a DMEPOS supplier wants to change sureties, then the typical way this would occur would be for it to execute a new bond with the new surety and substitute the new bond for the existing one. The commenter stated that the respective liabilities of the sureties would then be controlled by subparagraphs (B) and (C) in proposed § 424.57(c)(26)(iv). The commenter stated that if the DMEPOS supplier provides an acceptable bond from a different surety, then the new bond

should be liable for any claims made after its effective date “regardless of when the payment, overpayment or other event giving rise to the claim” occurred, and the replaced bond and its surety should have no further liability other than for claims already made. Therefore, the commenter suggested striking the last two sentences of proposed § 424.57(c)(26)(x).

Response: We agree and have revised § 424.57(d)(9) (proposed § 424.57(c)(26)(x)) by removing the last two sentences.

Comment: One commenter noted that proposed § 424.57(c)(26)(xii) would give CMS the ability to revoke a DMEPOS supplier’s billing privileges if the supplier fails to obtain, maintain, and timely file a surety bond. The commenter characterized this action as a penalty and stated that revoking a DMEPOS supplier’s billing privileges would be harsh. The commenter stated that revocation of billing privileges should be reserved for the most flagrantly noncompliant DMEPOS suppliers, that some DMEPOS suppliers may fail to comply with proposed § 424.57(c)(26)(xii) due to reasons outside of their control, and that first-time “simple negligence” should be addressed with a less punitive sanction.

Response: As stated previously, if the bond coverage lapses the supplier is immediately out of compliance. This provision is similar to the current requirement at § 424.57(c)(11) that a DMEPOS supplier maintain comprehensive liability insurance at all times.

H. Exceptions to the Bond Requirement

Comment: Several commenters urged us to establish an exception to the surety bond requirement for physicians and NPPs. The commenters stated, among other things, that the Congress did not intend for CMS to impose this requirement on physicians and NPPs; and referred to a conference report on the BBA of 1997 indicating that “the Conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals.” The commenters also noted that section 4312(c) of the BBA, which provides the Secretary with the authority to apply surety bond requirements to health care providers other than DME suppliers, explicitly states that the surety bond requirements may not be extended to physicians or other practitioners as defined in section 1842(b)(18)(C) of the Act. Commenters in support of an exception stated: (1) Physicians and NPPs are already licensed by the State; (2) large DMEPOS suppliers that generate significant

revenue may be able to absorb the cost of the surety bond more than a physician or NPP who occasionally furnishes DMEPOS items for the convenience of his or her patients; (3) government reports show that unscrupulous individuals and corporations, not physicians who primarily furnish DMEPOS only as an ancillary service to their patients, engage in fraudulent DMEPOS supplier conduct; (4) personal instruction in disease processes and prevention of injuries for most Medicare beneficiaries needs to come from a professionally trained clinician, not from a DMEPOS mail order catalogue; and (5) physicians who occasionally provide DMEPOS items for the convenience of his or her patients may choose not to renew their DMEPOS supplier numbers due to the costly burden of the surety bond requirement, and that this could impede the ability of Medicare beneficiaries to access immediate, safe, effective, and quality care.

Conversely, several commenters stated that physicians and NPPs should not be exempt from the surety bond requirement. One commenter stated that physicians have been implicated in large Medicare fraud prosecutions and that large, publicly-traded chain suppliers of DMEPOS have been at risk for bankruptcy. The commenter believed that requiring these suppliers to obtain a surety bond would provide an alternative means for CMS to recover overpayments. Another commenter stated that physicians are no less likely to cost the Federal program money than other DMEPOS suppliers, and a surety bond should not be difficult for them to obtain. Another commenter stated that we should not exempt physicians and NPPs that furnish DMEPOS as a convenience to their patients from the surety bond requirement unless they otherwise meet the criteria for an exception.

Response: In reviewing the statutory language and legislative history of section 4312(a) of the BBA, we believe that the Congress intended to create an exception for physicians and NPPs. Accordingly, we have revised this final rule to establish an exception to the surety bond requirement for physicians as defined in section 1861(r) of the Act and NPPs as defined in section 1842(b)(18) of the Act, provided that the items are furnished only to the physician or NPP's own patients as part of his or her professional service as defined at section 1861(q) of the Act and as described in section 1861(s)(2)(K) of the Act.

Comment: Several commenters recommended that we not require a

surety bond for accredited and State-licensed orthotic and prosthetic personnel. A commenter stated that State-licensed orthotic and prosthetic suppliers are highly clinical and service-oriented, and the training and expertise required to provide quality orthotic and prosthetic care differ greatly from the provision of DME, which typically requires little more than opening a store front and obtaining a Medicare supplier number.

Response: We agree with these commenters and have created an exception for State-licensed orthotic and prosthetic personnel operating in private practice and who are only providing custom-made orthotics and prosthetics and supplies related to custom-made orthotics and prosthetics.

It is important to note that we believe that there is a clear distinction between a DMEPOS supplier enrolled as a State-licensed orthotic and prosthetic supplier operating in private practice who is only providing custom made orthotics and prosthetics and supplies related to custom made orthotics and prosthetics, and orthotic and prosthetic personnel employed by a medical supply company or co-owned with another individual or entity or furnishing DME. Since a medical supply company can enroll as a DMEPOS supplier with or without employing State-licensed orthotic and prosthetic personnel, we do not believe that medical supply companies employing State-licensed orthotic and prosthetic personnel qualify for an exception because the owners of the medical supply company are responsible for the management and billing of products and services, not the licensed orthotic or prosthetic personnel. Similarly, we believe orthotic or prosthetic personnel are not operating in private practice when another individual or entity is a part owner of the enrolled orthotic or prosthetic personnel's practice location. Specifically, the business must be solely-owned and operated by orthotic or prosthetic personnel who are making custom made orthotics or prosthetics.

Finally, as with physicians and NPPs, State-licensed orthotic and prosthetic personnel operating in private practice risk their State license if they are found guilty of fraudulent or abusive behavior, whereas a medical supply company can reorganize under new ownership and reapply to participate in the Medicare program. Consequently, since all DMEPOS suppliers are required to be accredited to participate in the Medicare program by September 30, 2009, we do not believe that it is appropriate to establish an exception based solely on

whether State-licensed orthotic or prosthetic personnel are accredited.

Comment: One commenter stated that DME suppliers and non-accredited suppliers of orthotic and prosthetic services that bill Medicare for orthotic and prosthetic services should be subject to the surety bond requirement. The commenter stated that, to the extent that these providers submit claims for orthotic and prosthetic care when they do not possess "independent validation" (for example, orthotic and prosthetic accreditation certification or State orthotic and prosthetic licensure), the surety bond requirement is one way for us to provide a basic level of protection to the Medicare program.

Response: We agree with this commenter. As such, we are not establishing an exception to the surety bond requirement for medical supply companies that employ orthotic or prosthetic personnel.

Comment: Some commenters urged us to exempt physical therapists, occupational therapists, and physician assistants (PAs) from the surety bond requirement. The commenters stated that physical therapists, for instance, who work in private practice often specialize in treating certain conditions and provide DMEPOS supplies that are integral to their plan of care. The commenters also maintained that, given the small size of physical therapy practices and the scope of services they furnish, the potential for fraud and abuse is limited. Commenters also stated that the cost of the surety bond may force some physical and occupational therapists to not enroll or to discontinue their enrollment as a DMEPOS supplier, which may hinder patient access to their services. Commenters also expressed concern that the surety bond requirement will allow unqualified DMEPOS suppliers—rather than qualified NPPs—to fabricate custom splints because of their ability to pay to obtain a surety bond. Commenters stated that the fabrication of custom orthotics and the frequent adjustments they entail cannot be performed by a DMEPOS supplier that is not treating the Medicare beneficiary. Yet another commenter stated that suppliers of material for splints will be affected by the surety bond requirement if occupational therapists that provide DMEPOS services opt out of the DMEPOS program.

In addition, commenters stated that the surety bond requirement will have a negative impact on physical and occupational therapists, certified hand therapists, and PAs that work for small businesses, not-for-profit organizations, and minority-owned companies. The

commenter stated that small businesses that provide occupational therapy services, such as outpatient occupational therapy clinics, are already burdened with the DMEPOS application and reoccurring certification requirement and accompanying expense.

Response: While PAs are included in the definition of “nonphysician practitioner” in accordance with section 1842(b)(18)(C) of the Act, physical therapists and occupational therapists are not included. However, we believe that physical therapists in private practice and occupational therapists in private practice should be exempt from the surety bond requirements, provided that the therapist furnishes orthotics, prosthetics and supplies to the therapist’s own patients as part of the physical or occupational therapy service.

We believe that this approach is consistent with both the provisions that had been established in the DMEPOS competitive bidding program prior to the enactment of the MIPPA, as well as the intention of section 4312(a) of the BBA. As with prosthetic and orthotic personnel, we believe that there is a clear distinction between a DMEPOS supplier enrolled as a physical or occupational therapist in private practice and physical or occupational therapists employed by a medical supply company or co-owned with another individual or entity. Since medical supply companies can enroll as a DMEPOS supplier with or without employing State-licensed physical or occupational therapists, we do not believe that medical supply companies employing State-licensed physical or occupational therapists qualify for an exception because the owners of the medical supply company are responsible for the management and billing of products and services, not the licensed physical or occupational therapist. In addition, we believe that a physical or occupational therapist is not operating in private practice when another individual or entity is a part owner of the enrolled therapist’s practice location. Specifically, the business must be solely-owned and operated by the physical or occupational therapist.

Finally, as with physicians and NPPs, and State-licensed orthotic and prosthetic personnel operating in private practice, physical and occupational therapists risk their State license if they are found guilty of fraudulent or abusive behavior. Nonphysician practitioners, physical therapists in private practice and occupational therapists in private

practice who furnish DMEPOS products or services that are not incident to a physician’s order, or who enroll to provide DMEPOS to the general public, must separately enroll and are subject to the bonding requirement. Finally, we recognize that although physical and occupational therapists, certified hand therapists, and PAs work for small businesses, not-for-profit organizations, and minority-owned companies, the bonding requirement is the responsibility of the owner(s) of the DMEPOS supplier, regardless of the size of the business.

Comment: A commenter stated that we should require DMEPOS suppliers that have a history of committing Medicare fraud and abuse to obtain a surety bond.

Response: We appreciate this comment and are establishing an increased surety bond amount for those DMEPOS suppliers that have significantly higher risk.

Comment: Some commenters asked us to waive the surety bond requirement for nursing facilities that provide DMEPOS services and bill Medicare for those services for their own residents. The commenters stated that the surety bond requirement aims to deter fraudulent conduct that is primarily and historically associated with small, independent, and commercial DMEPOS suppliers, not with nursing facilities that provide DMEPOS to their own residents. The commenters also stated that nursing facilities are subject to other legal and regulatory requirements that ensure that they are qualified to provide DMEPOS services to their residents. The commenters also stated that we did not demonstrate in the August 1, 2007 proposed rule that DMEPOS fraud in nursing homes is a bona fide problem.

Response: We disagree with the commenters and note that nothing in the statute or section 4312(a) of the BBA indicates a Congressional intent to exempt nursing facilities from the surety bond requirement. Indeed, the statute requires all suppliers of DME, except for physicians and NPPs who provide DME to their patients, to provide the Secretary with a surety bond.

Comment: Some commenters stated that we should develop an exception to the surety bond requirement for pharmacies that provide DMEPOS only when necessary for the administration of a drug and that furnish DMEPOS as a convenience to their patients. The commenters believe that requiring pharmacies to obtain a surety bond may prevent or discourage them from providing DMEPOS services to Medicare beneficiaries, who benefit

from being able to obtain all of their medications, including those that must be administered via a medical device, from a single pharmacy.

One commenter stated that we should exempt pharmacies that furnish home infusion DMEPOS services (in other words, services that require medications to be administered intravenously in a patient’s home) and pharmacies that provide a small volume of DMEPOS from the surety bond requirement unless they have had a prior adverse history.

Response: In reviewing the legislative history of section 4312(a) of the BBA and the overall purpose of the surety bond requirement, we do not believe that there was a congressional intention to exempt pharmacies—regardless of size or setting—from the surety bond requirement.

Comment: Several commenters stated that we should develop an exception to the surety bond requirement for large, publicly-traded chain DMEPOS suppliers. Some commenters stated that these companies are subject to laws such as the Sarbanes-Oxley Act, which targets corporate fraud by requiring public companies to implement internal controls, enhances financial disclosures, and imposes penalties for noncompliance. This indicates that large, publicly-traded companies are not the type of businesses that the Congress intended to target with the surety bond requirement. The commenters maintained that the Congress supported the surety bond requirement because it was concerned about “fly-by-night” companies that can quickly and inexpensively set up sham businesses to fraudulently receive Medicare reimbursement. Other commenters stated that large, publicly-traded companies tend to have established relationships with the Medicare program and significant assets. As a result, they pose less risk of nonpayment to the Medicare program than other DMEPOS suppliers, which may have less established relationships with the Medicare program and fewer assets.

One commenter suggested criteria that we could use to exempt large, publicly-traded chain suppliers of DMEPOS from the surety bond requirement. The commenter suggested that in order for a large, publicly traded DMEPOS supplier to be exempt from the surety bond requirement, we could require the DMEPOS supplier to have a minimum net worth for the chain (as set by CMS) and be publicly-traded. The commenter recommended that the supplier’s net worth should be \$5 million. The commenter also stated that we might

also consider the following factors: Prior history of paying Medicare debts; revocation or suspension of a license to provide health care products or services; Federal or State criminal convictions related to the delivery of health care products or services; and exclusion(s) from Federal or State health care programs. Yet, another commenter stated that we may wish to adopt criteria for what would constitute a "large, publicly-traded company," such as a dollar threshold for capitalization and annual gross sales volume.

Conversely, many commenters urged us not to establish an exception to the surety bond requirement for large, publicly-traded chain suppliers of DMEPOS. One commenter stated that the exception should not be granted because large, publicly-traded chain suppliers of DMEPOS represent the same level of risk for inappropriate Medicare billing as other DMEPOS suppliers. Another commenter stated that such high volume suppliers pose significant risk exposure, particularly if they become bankrupt. Yet another commenter stated that there is no legitimate basis to exempt larger DMEPOS suppliers from the surety bond requirement.

Response: In reviewing the statutory language and legislative history of section 4312(a) of the BBA and the overall purpose of the surety bond requirement, there is nothing to indicate that the Congress intended to exempt publicly-traded chain DMEPOS suppliers from the surety bond requirement. Accordingly, we are not able to establish such an exemption for publicly-traded chain DMEPOS suppliers.

Comment: Some commenters urged us to exempt all State-licensed chain pharmacies from the surety bond requirement without regard to whether they are "large" or "publicly-traded." Some commenters stated that, unlike other DMEPOS suppliers, community pharmacies are subject to numerous and rigorous Federal and State standards. Other commenters stated that staff pharmacists, technicians, and other employees at the community chain pharmacies have no financial incentive to engage in Medicare fraud because their compensation is not tied to the volume of Medicare prescriptions filled or DMEPOS items.

Response: While it may be true that staff pharmacists at pharmacies do not have an incentive to perpetuate schemes that may increase reimbursement levels for the pharmacy, there is nothing in section 4312(a) of the BBA or its legislative history to indicate that the Congress intended to exempt these

suppliers from the surety bond requirement. As such, we disagree that we should establish a broad based exception for all State-licensed chain pharmacies.

Comment: A commenter stated that there should be a monetary cap on the amount of the surety bond required for DMEPOS suppliers that belong to a chain. The commenter believed that this cap should not be limited only to publicly traded DMEPOS suppliers.

Response: We disagree that such a cap should be established, since DMEPOS suppliers are enrolled separately and are required to obtain a distinct NPI for each practice location if the DMEPOS supplier is operating as an organizational entity.

Comment: Several commenters stated that businesses falling under the Small Business Administration's (SBA) definition of "small business" should be exempt from the surety bond requirement.

Commenters stated that criteria for an exception to the surety bond requirement for small businesses could be based on a percentage of Medicare revenue and/or a percentage of revenue from Medicare DMEPOS.

Response: We disagree that we should establish an exception for small businesses based solely on the fact they are defined as a small business by the SBA. This would create an exception for nearly all DMEPOS suppliers and would effectively nullify the provisions contained in section 4312(a) of the BBA. Moreover, we believe that this requirement will limit the Medicare program's exposure to fraudulent DMEPOS activity; enhance the Medicare enrollment process to help ensure that only legitimate DME suppliers are enrolled or are allowed to remain enrolled in the Medicare program; ensure that the Medicare program recoups erroneous payments that result from fraudulent or abusive billing practices by allowing CMS or our designated contractor to seek payments from a surety up to the penal sum; and help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers.

Comment: Several commenters stated that if we implement the surety bond requirement, it should hold all DMEPOS suppliers to the same standard and no exceptions to the requirement should be granted.

Response: We disagree with the commenters because, as previously explained in this final rule, the Congress intended for some categories of DMEPOS suppliers to be exempt from the surety bond requirement.

Comment: Several commenters stated that if a DMEPOS supplier is in "good standing" with Medicare or has operated for a number of years (for example, 5 years) without committing Medicare fraud or abuse, then we should exempt the supplier from the surety bond requirement. Other commenters stated that we should exempt from the surety bond requirement those DMEPOS suppliers that have no prior adverse history with Medicare. The commenters maintained that we should exempt from the surety bond requirement all DMEPOS suppliers that: (1) Have been enrolled in the DMEPOS program for at least 10 years; (2) have never had their Medicare billing privileges revoked; (3) pose no increased risk to the Medicare program; (4) have not engaged in materially questionable billing practices in the past; and (5) have never had any history of criminal, civil, or administrative sanctions imposed against them.

Response: We disagree with the commenters. We do not believe that anything in section 4312(a) of the BBA indicates that the Congress intended for us to establish such a broad based exception for DMEPOS suppliers participating in the Medicare program. In addition, we do not believe that a broad based exception would address systemic problems with fraud and abuse perpetuated by significant numbers of newly enrolling DMEPOS suppliers each year.

Comment: Several commenters maintained that established DMEPOS suppliers that open new locations or that acquire established DMEPOS suppliers should be exempt from the surety bond requirement. The commenters stated that the value of the surety bond in these instances would be small compared to the financial and administrative burden imposed on the DMEPOS suppliers.

Response: We disagree with the commenters. While we are establishing an exception to the surety bond requirement for certain DMEPOS suppliers, for reasons discussed in the preamble to this final rule we do not believe that it is appropriate to establish a broad based exception for new DMEPOS practice locations or changes of ownership for existing DMEPOS suppliers.

Comment: Many commenters stated that we should consider establishing an exception to the surety bond requirement for suppliers that provide DMEPOS services on an occasional basis or in a low volume. For example, one commenter stated that a DMEPOS supplier with annual payments of less than a specified dollar amount would be

exempt from the surety bond requirement.

Response: We disagree with the commenters. It is not possible for us to determine whether a newly enrolling DMEPOS supplier will only bill on an occasional basis or in low volumes on a prospective basis. In addition, we believe that newly enrolling DMEPOS suppliers should develop a business case and market analysis to determine whether it makes business sense to open and establish a new DMEPOS supplier business. Moreover, with the delay in implementation of the surety bond requirement for existing DMEPOS suppliers until 9 months after the effective date of this final rule, we believe that existing DMEPOS suppliers will need to make the business decision as to whether to participate in the Medicare program after the full implementation of accreditation in September 2009.

Comment: Several commenters stated that we should establish an exception to the surety bond requirement for home health agencies and hospices that provide DMEPOS items as a convenience to their patients. One commenter stated that in a 1999 report by the Government Accounting Office (GAO) entitled "Medicare Home Health Agencies: Role of Surety Bonds in Increasing Scrutiny and Reducing Overpayments," the GAO indicated that the primary benefit of a surety bond is the scrutiny a surety provides as it reviews an applicant. The commenter stated that the GAO recommended that home health agencies with a proven track record in returning overpayments be exempt from the surety bond requirement. The commenter also stated that we did not explain why we ignored this information in the August 1, 2007 proposed rule.

Response: While we are aware of this report, we do not believe that it is appropriate to establish an exception to the bonding requirement for home health agencies and hospices. To the extent that HHAs provide DME to their patients, the statute requires that they submit a surety bond to the Secretary. We also note that we continue to experience systemic problems with fraud and abuse perpetuated by significant numbers of home health agencies. To address this specific concern of home health fraud, we initiated a provider enrollment home health demonstration in FY 2008 in Harris County, Texas and in select counties in California. Based on the results of these demonstrations, we will consider expanding these demonstrations into other parts of the country.

Comment: Several commenters believe that we should exempt rural DMEPOS suppliers from the surety bond requirement. The commenters stated that exempting rural DMEPOS suppliers that are in good standing with Medicare and that do not otherwise pose a risk to the Medicare program (for example, meet our accreditation standards) will ensure appropriate access to DMEPOS items for rural beneficiaries.

Conversely, another commenter stated that we should not exempt rural DMEPOS suppliers from the surety bond requirement unless they otherwise meet the criteria for an exception.

Response: While we understand the commenter's concerns, we do not believe that it is appropriate to establish a broad-based exception for rural DMEPOS suppliers based solely on the fact that they are located in a rural area. As stated above, we believe that rural DMEPOS suppliers should only receive an exception if they meet other criteria for an exemption.

Comment: Several commenters believe that holding all suppliers to the same surety bond requirement would place a disproportionate burden on smaller suppliers, give an unfair advantage to larger suppliers that may have more financial resources, and would not appropriately safeguard the Medicare Trust Fund from fraud. The commenters stated that small DMEPOS suppliers, particularly those located in rural areas, may not be able to remain in business if they are subject to the surety bond requirement because the cost of the bond would exceed their annual Medicare reimbursement for DMEPOS items.

Response: As stated previously, we do not believe that it is appropriate to establish a broad-based exception for small or rural suppliers of DMEPOS unless they meet other criteria for an exception.

Comment: A commenter stated that the surety bond requirement will not stop fraud committed by pharmacies that furnish home infusion DMEPOS services or home infusion pharmacies because there will always be a means to fraudulently bill Medicare for services. However, the commenter maintained that the surety bond requirement will decrease the availability of DMEPOS services for patients that need home infusion DMEPOS services. Another commenter stated that we should not exempt from the surety bond requirement those pharmacies that provide DMEPOS as a convenience to their patients unless they otherwise meet the criteria for an exception.

Response: As stated above, the purpose of a surety bond is to: (1) Limit the Medicare program risk to fraudulent DME suppliers; (2) enhance the Medicare enrollment process to help ensure that only legitimate DME suppliers are enrolled or are allowed to remain enrolled in the Medicare program; (3) ensure that the Medicare program recoups erroneous payments that result from fraudulent or abusive billing practices by allowing CMS or our designated contractor to seek payments from a surety up to the penal sum; and (4) help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers. In addition, while we believe that some DMEPOS suppliers will make the decision to withdraw from the Medicare program due to the additional costs associated with the surety bond, we believe that Medicare beneficiaries will not encounter barriers to care.

Comment: One commenter stated that it is a community pharmacy that receives Medicare reimbursement for selling diabetic supplies to patients. The commenter indicated that it has neither rented any equipment nor bid on any Medicare contracts. If this final rule is implemented, the commenter asked whether it would be subject to the surety bond requirement.

Response: We are not adopting an exception to the surety bond requirement for community pharmacies because the requirement is designed to ensure that owners of community pharmacies maintain basic financial solvency requirements to continue participation in the Medicare program.

Comment: One commenter stated that nothing prevents us from creating exceptions to the surety bond requirement based on the reasonableness of the exceptions.

Response: We agree that the Secretary has the authority to establish exceptions to the surety bond requirement for, among other entities, providers of services and suppliers of orthotics, prosthetics, and supplies. In response to public comments, we have established several exceptions to the bonding requirement for certain suppliers of DMEPOS, specifically certain suppliers of orthotics, prosthetics, and supplies in this final rule.

Comment: One commenter recommended that we delay publishing this final rule until we receive explicit guidance from the Congress on the types of exemptions that should be provided to the surety bond requirement. The commenter stated that, since 10 years have passed since the BBA was enacted, there appears to be no particular sense

of urgency to publish this final rule. Another commenter stated that neither the BBA nor its accompanying conference report gives us the authority to grant surety bond exceptions for certain classes of suppliers. Several other commenters questioned the need for the surety bond requirement at all stating that the bond requirement specified in the BBA of 1997 reflected a different era. For example, one commenter observed that DMEPOS suppliers are now required to become accredited; another commenter stated that the NSC now performs on-site inspections before issuing billing numbers.

Response: We continue to believe that section 4312(a) of the BBA permits us to establish an exception to the final rule's surety bond requirement. Moreover, in developing this final rule, we have considered the impact that accreditation will have on the suppliers of DMEPOS.

Comment: Commenters recommended that we implement a risk-based system that would require only DMEPOS suppliers that are likely to submit inappropriate billings to Medicare to comply with the surety bond requirement. Specifically, commenters stated that the requirement should apply only to DMEPOS suppliers that—(1) Have no prior history with the Medicare program unless they are part of an existing large, publicly-traded Medicare-enrolled DMEPOS suppliers that is opening a new pharmacy or taking ownership of another pharmacy; (2) suppliers that have engaged in materially questionable billing practices in the past; and (3) suppliers that have had any history of criminal, civil, or administrative sanctions involving the Medicare program. One commenter believed that DMEPOS suppliers that fall into category 1 above should not be treated as new suppliers because they would be subject to the large DMEPOS supplier's policies and procedures. In addition, a commenter stated that, in determining the materiality of any billing practice under category 2 above, we should take into account the overall size of the DMEPOS supplier and its number of locations. Finally, a commenter stated that the surety bond requirement should only be applied based on the number of locations that might be involved in Medicare fraud and abuse unless there is evidence of corporate-wide efforts to engage in fraudulent activity.

Response: Consistent with section 4312(a) of the Balanced Budget Act of 1997 (BBA), this final rule implements section 1834(a)(16) of the Act by requiring certain Medicare suppliers of DMEPOS to furnish CMS with a surety

bond. In addition, by establishing an elevated surety bond for those DMEPOS with increased risk, we believe that we are implementing a risk-based system for those suppliers that are considered high-risk.

I. High-Risk Suppliers

Comment: One commenter disagreed with increasing the bond amount based on a supplier's elevated risk. The commenter maintained that additional risk is addressed by sureties in the underwriting process and that a surety evaluates whether to write a bond based on whether the surety believes the principal will perform its obligations. In addition, the commenter observed that high risk criteria are taken into account in the decision whether to write the bond and whether collateral is required from the principal.

Response: While we agree that sureties consider additional risk when determining whether to issue a bond, sureties may not know that a particular supplier poses additional risk to the Medicare program based on past practices. In order for Medicare to easily convey to the surety that a particular individual or organization poses an elevated risk level, we believe that it is appropriate for Medicare to require a higher surety bond amount for certain DMEPOS suppliers participating in the Medicare program or for those DMEPOS suppliers that may be seeking to re-enroll in the Medicare program. Accordingly, we believe that we are in a unique position to inform sureties that certain DMEPOS suppliers pose a higher-than-normal risk to the Medicare program.

Comment: One commenter stated that we should apply the surety bond requirement in a manner designed to exact the higher surety amount from DMEPOS suppliers that pose the greatest risk to the Medicare Trust Funds.

Response: We agree with the commenter that a higher surety amount should be required from DMEPOS suppliers that pose an elevated risk and have revised the provisions of this final rule accordingly.

Comment: A commenter recommended that we keep the initial surety bond to a single amount because CMS may need to gain some experience with implementing a base surety amount before it undertakes a more complicated approach that involves elevated amounts of surety bonds for higher risk DMEPOS suppliers.

Response: While we appreciate this commenter's recommendation, we do not believe that the implementation of varying surety bond amounts for high

risk suppliers will pose an undue administrative burden on CMS or our contractor, the NSC. In fact, no later than 120 days after the publication of this final rule, we will notify each existing DMEPOS supplier by mail of the need to obtain with an elevated bond to maintain its enrollment in the Medicare program. In addition, we will work with the NSC to conduct outreach to all DMEPOS suppliers regarding the need to obtain a surety bond. Our outreach efforts will include discussing the implementation of the surety bond rule during Open Door Forums, issuing listserv announcements from CMS and the NSC, and posting information regarding this new requirement on our Web site.

Comment: Several commenters stated that new DMEPOS suppliers that have no prior billing history with the Medicare program should be required to obtain a surety bond for 5 years to establish a pattern of compliance with Medicare rules and regulations. One commenter stated that, if no sanctions are imposed against these suppliers during this timeframe, then we should no longer require them to obtain a surety bond. The commenter stated that new DMEPOS suppliers should not include locations that are opened by DMEPOS suppliers that are exempt from the surety bond requirement.

Response: We disagree with the commenters because section 4312(a) of the BBA did not specify nor did we propose a limitation on the base bonding period. Accordingly, we are not adopting this recommendation to establish a minimum bonding period for existing or newly enrolling suppliers of DMEPOS. Nevertheless, we believe that the duration of the elevated surety bond amount should be limited. Accordingly, in this final rule, we have established a 3-year duration on elevated surety bond amounts. We believe that this affords the appropriate protections to the Medicare program, establishes a reasonable period of time for submission of an elevated surety bond amount, and is consistent with our established reenrollment period for DMEPOS suppliers found in § 424.57(f) (redesignated § 424.57(e)).

Comment: A commenter stated that, in general, surety bonds should be required for an entire category of licensees rather than exempting certain lower risk licensees. The commenter stated that requiring a bond from only a small segment of the group because that segment represents a higher risk and will likely cause future losses is a selection against the surety. According to the commenter, this is called adverse selection. The commenter stated that a

surety needs to underwrite the entire group in order to adequately price and spread the risk of exposure. The commenter stressed that adverse selection would discourage sureties from participating in a market and would make obtaining the bond more difficult for those subject to the surety bond requirement.

Response: While this final rule establishes exceptions for certain suppliers of DMEPOS, we believe that a sufficiently large number of other types of DMEPOS suppliers will remain in order for sureties to calculate and adjust for any adverse selection.

Comment: A commenter stated that many DMEPOS suppliers have "billing-related problems" with CMS, and that the vague proposed criteria (see 72 FR 42005) is not useful. The commenter believed that it would be difficult, if not impossible, for DMEPOS suppliers to obtain a bond from any surety if this type of criteria is used. The commenter recommended that only an "unpaid final action" that is not satisfied at the time a DMEPOS supplier applies for a surety bond be used to identify a DMEPOS supplier that would be subject to an elevated surety bond.

Response: We have clarified § 424.57(d)(4) (proposed § 424.57(c)(26)(iii)) to address this concern.

Comment: A commenter suggested that the surety bond requirement be eliminated after a business has had satisfactory relations with CMS for a 3-year time period. The commenter stated that this should apply to any surety bond. If CMS cannot adopt this recommendation due to a statutory restriction, then the commenter suggested that we reduce the bond level by \$10,000 for each successful year of relationship with CMS until the bond level amount reaches a minimum threshold of \$10,000. The commenter stated that this amount would then be in effect "until there is a problem of some kind."

Response: We do not have the statutory authority to lower the surety bond amount below \$50,000 and, as stated previously, section 4312(a) of the BBA did not specify nor did we propose a limitation on the base bonding period. Accordingly, we are not adopting this recommendation to establish a minimum bonding period for existing or newly enrolling suppliers of DMEPOS.

Comment: A number of commenters stated that we should require current Medicare-enrolled DMEPOS suppliers with a prior "adverse history" of criminal, civil, or administrative sanctions for billing-related problems to obtain a surety bond.

Response: We appreciate the commenters' support for surety bonds for those suppliers of DMEPOS that pose a significantly higher risk to the Medicare program and note that the provisions of this final rule cover such individuals.

Comment: One commenter observed that, according to the August 1, 2007 proposed rule, examples of final adverse actions include, but are not limited to, the following: Federal and State criminal convictions; formal or official actions such as a revocation of Medicare billing privileges; a revocation or suspension of a license; and an exclusion from participation in Federal or State health care programs. The commenter stated that our proposal to increase the bond amount by \$65,000 per occurrence if the DMEPOS supplier poses a significantly higher than average risk to the Medicare Trust Funds may penalize legitimate DMEPOS suppliers. The commenter stated that if the final rule imposes a surety bond requirement based on risk categories, then we need to create an exception to address honest mistakes by a DMEPOS supplier or the NSC. The commenter stated that we should limit such elevated costs to higher risk DMEPOS suppliers.

Another commenter stated that we need to specifically define the term "adverse actions." The commenter noted that even legitimate DMEPOS suppliers can be subject to overpayments, Federal investigation, or corporate integrity agreements. The commenter explained that, on their face, these actions could appear to be "adverse actions." To ensure that legitimate DMEPOS suppliers are not unfairly penalized by the surety bond requirement, the commenter maintained that we must list all "adverse actions" that would subject a supplier to elevated bond payments.

Response: We agree and have clarified what constitutes a final adverse action in § 424.57(c)(26)(a). A 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 or suspension by an accreditation organization;
- (iv) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(A)(i)) within the 10 years preceding enrollment, revalidation, or re-enrollment; or
- (v) An exclusion or debarment from participation in a Federal or State health care program.

Under the final adverse action as specified in section 221(g)(1)(A) of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA), we believe that a final adverse action occurs when the action is imposed, not when a DMEPOS supplier has exhausted all of its appeal rights associated with the final adverse action.

In addition, we believe that the provider enrollment appeals process affords existing suppliers of DMEPOS with an administrative avenue to challenge a revocation determination.

J. Access to Bonds

Comment: A commenter stated that our surety bond requirement may hinder DMEPOS suppliers' ability to obtain surety bonds. The commenter indicated that sureties may be unwilling to provide surety bonds to DMEPOS suppliers because the surety bond requirement imposes conditions that extend beyond the standards in the surety bond industry. The commenter stated that we failed in the August 1, 2007 proposed rule to discuss how this final rule will directly affect the surety industry as well as DMEPOS suppliers' ability to obtain surety bonds. The commenter urged us to provide this type of analysis in the final rule.

Response: We believe that we have clarified the obligations of sureties in this final rule. Moreover, based on information received from sureties as well as our independent research, we are confident that legitimate DMEPOS suppliers will be able to acquire a surety bond.

Comment: A commenter maintained that there must be real-time access to supplier information for sureties to evaluate risks. If this information is not available or is not provided to sureties, then the commenter believed that surety bonds may not be available for DMEPOS suppliers.

Response: We agree that sureties will require appropriate financial information in order to evaluate the risks associated with issuing a bond to a particular DMEPOS supplier, and believe that a surety should ensure that the supplier furnishes this information to it.

Comment: One commenter stated that we must meet with surety bond underwriters and vet surety bond requirements with the underwriters to ensure underwriter participation, and then make any necessary changes to the surety bond requirement prior to implementing this final rule.

Response: We have examined the role of underwriters in this process and have

made revisions to this final rule as necessary.

Comment: A commenter stated that it is uncertain as to whether the surety industry will be willing to issue surety bonds that comport with the surety bond requirement. The commenter stated that it contacted three sureties. Two of the sureties stated that they would not issue such bonds. The other surety stated that it might consider issuing such bonds to DMEPOS suppliers with established and unblemished records of participation in the DMEPOS program. The sureties stated that they would not issue bonds to DMEPOS suppliers that have their billing privileges revoked.

Response: While we appreciate the commenter's concerns, we believe that a reasonable number of sureties will offer to issue bonds to DMEPOS suppliers. Indeed, we believe that our implementation of this requirement will help create a market for sureties, as will the delay in the implementation of the bond requirement.

Comment: A commenter recalled that in the past we have experienced difficulty in attempting to implement a surety bond requirement in the home health industry, and that we abandoned that proposal as unworkable. The commenter believes that we would have difficulty implementing a surety bond requirement in the DMEPOS industry and speculated that it would be difficult to identify companies that would issue surety bonds for the DMEPOS industry.

Response: As stated above, we are confident that significant numbers of sureties will offer to issue bonds to DMEPOS suppliers; however, we have delayed the implementation for existing DMEPOS suppliers until 9 months after the effective date of this final rule.

K. Standard Bond Form

Comment: One commenter stated that, instead of leaving the actual terms of the bond up to each supplier or surety, we should require each DMEPOS supplier and surety use a standard bond form. Otherwise, the commenter stated, CMS will have to review each bond form submission to verify that it meets the terms of the surety bond requirement. The commenter stated that this proposal would make it easier for DMEPOS suppliers to obtain the surety bond, remove any uncertainty as to whether a particular bond complies with the surety bond requirement, and relieve CMS of a large volume of work reviewing the terms of each bond submission.

Response: While we appreciate the commenter's suggestion, we believe that this final rule will provide DMEPOS

suppliers with the guidance and flexibility necessary to obtain surety bonds that meet the requirements of the final rule.

L. Suggested Alternatives

Comment: Several commenters proposed alternatives to the surety bond requirement. One commenter stated that financial statements have been recently used by CMS to determine the financial stability of DMEPOS suppliers that apply for competitive bidding. The commenter indicated that these statements should be an acceptable alternative to a surety bond. Another commenter observed that we could require a bank letter of credit from a DMEPOS supplier or a DMEPOS supplier could provide us with a letter from an insurance broker that verifies the supplier's worth.

Response: We disagree with the comments that the alternatives proposed would offer as much protection to the Medicare Trust Funds as the proposed surety bond. Also, none of the alternatives offered above would allow Medicare to recoup any mistaken payments.

Comment: One commenter stated that large DMEPOS chain suppliers could be given the option to buy a \$50,000 surety bond for each site or to buy one surety bond that equals 5 percent of their total reimbursement at all of their sites.

Response: We do not believe it is appropriate to allow chain stores to purchase a single bond that equals 5 percent of their total reimbursement. Moreover and as already stated, there is nothing in section 4312(a) or its legislative history to indicate that the Congress intended for the bond amount to be tied to the supplier's level of reimbursement.

Comment: One commenter stated that instead of implementing this final rule, we should exclude from the Medicare program DMEPOS suppliers that have been investigated by law enforcement (for example, the Federal Bureau of Investigation) and that have repaid millions of dollars in restitution to the government.

Response: While we have the authority to revoke the billing privileges of a DMEPOS supplier, we do not have the authority to exclude a DMEPOS supplier from the Medicare program. This authority rests with the OIG.

Comment: Some commenters stated that instead of implementing this final rule, we should make accreditation mandatory for all Medicare DMEPOS suppliers. One commenter stated that mandatory accreditation would ensure that DMEPOS suppliers are legitimate before they are issued billing numbers

and allowed to bill the Medicare program. Another commenter stated that mandatory accreditation would be more effective at reducing Medicare fraud than this final rule.

Response: We believe that accreditation will improve the quality of products and services furnished to Medicare beneficiaries, accreditation does not offer as much protection to the Medicare Trust Fund as the proposed surety bond; accreditation does not allow Medicare to recoup any mistaken payments. In addition, section 154(b) of the MIPPA added a new subparagraph (F). This subparagraph states that eligible professionals and other persons (defined above) are exempt from meeting the October 1, 2009 accreditation deadline unless we determine that the quality standards are specifically designed to apply to such professionals and persons.

Comment: One commenter stated that DMEPOS suppliers should be recredentialed on an annual basis, whereby suppliers would be required to provide year-end financial statements, current information, and insurance renewals.

Response: We disagree with this commenter that an annual recredentialed process is necessary and whether an annual recredentialed process would afford the Medicare program with the type of protection afforded by implementing a surety bond.

Comment: Another commenter stated that we should either delay further expansion of the competitive bidding program or allow provisions so that bidders who have submitted bids before the implementation of the surety bond requirement may have their prices adjusted accordingly when the surety bond requirement is implemented.

Response: As previously stated in this final rule, on July 15, 2008 the Congress enacted the MIPPA delaying the implementation of the DMEPOS Competitive Bidding Program.

Comment: One commenter stated the following: "Collecting on a surety bond should involve adequate due process protections for a surety. While that process can start with a letter from CMS[,] the surety should have the ability to 'look behind the curtain' to be sure that the recoupment has not already been accomplished before sending in the bond funds. The same process should apply in reverse. If CMS recoups after asking the surety for funds[,] then the burden should be on CMS to automatically refund the payment to the source of the funds, [which would be] the surety."

Response: We disagree with the commenter. Since our primary relationship is with the DMEPOS supplier, we believe that only the DMEPOS supplier is eligible to appeal our decision.

Comment: One commenter stated that we are attempting through the surety bond requirement to encourage Medicare beneficiaries who need diabetes testing supplies to purchase these supplies through mail order instead of from retail pharmacy DMEPOS suppliers. The commenter stated that this could potentially further reduce declining revenues that retail pharmacies would receive from selling Medicare DMEPOS. The commenter also stated that, although it would like to continue to provide beneficiaries with access to DMEPOS, the increasing number of requirements that we impose on DMEPOS suppliers, coupled with a potential decrease in retail-based revenues, could cause it to reassess the economic feasibility of being a DMEPOS supplier.

Response: We are implementing statutory requirements to establish a surety bond requirement for DMEPOS suppliers. We are not attempting to steer Medicare beneficiaries to any particular individual DMEPOS supplier or type of DMEPOS supplier (for example, mail order).

Comment: A commenter stated that the general tone of the August 1, 2007 proposed rule shows that we do not understand the complexity of the surety bond market. The commenter predicted that, if DMEPOS suppliers are required to obtain a surety bond as a result of this final rule, most of them will have a difficult time obtaining one. The commenter noted that many DMEPOS suppliers will have to undergo a grueling application process and that many of the suppliers will be denied a surety bond by sureties. The commenter observed that there will be difficulty with accounting records, lack of audited statements, lack of liquidity, and general lack of financial ability. Therefore, the commenter stated that any bond requirements should be slowly phased-in, be as automated as possible, and that bond forms be carefully vetted and discussed with the surety industry before publication by CMS.

Response: While we believe that some DMEPOS suppliers will not be able to obtain surety bonds because they have not maintained accounting records, or lack audited financial statements, liquidity, or financial ability to repay obligations, we do not believe that most legitimate and financially secure suppliers will find it difficult to comply with the standards necessary to apply

for and meet a surety's bonding requirements. In addition, as mentioned previously, we are delaying the implementation of the surety bond requirement for existing DMEPOS suppliers until 9 months after the effective date of this final rule.

Comment: Several commenters stated that basic principles of administrative law require agencies to publish the factual basis for their proposed actions to encourage meaningful comments and argued that we have not provided any data requiring all DMEPOS suppliers to post a bond. Of particular relevance, according to the commenters, would be data to show the prevalence and demographics of suppliers that default on their Medicare debts inasmuch as the proposed rule would require suppliers to post a financial guarantee bond securing unpaid claims.

Response: We believe that the proposed rule was authorized by section 4312(a) of the BBA and published in accordance with the Administrative Procedures Act.

Comment: A commenter stated that it is not within the scope of this final rule to interfere with the private contractual rights of the surety and a DMEPOS supplier. The commenter observed that the terms of their contract are both negotiable and private, that due process in private insurance contracts is regulated at the State level, and that the parties to those contracts can take care of themselves.

Response: We agree that the specific language of a surety bond is not within the purview of this final rule. However, we believe that the Act grants us the authority to require DMEPOS suppliers to obtain a surety bond that satisfies certain minimum requirements as a prerequisite for participation in the Medicare program.

Comment: One commenter stated that we should not "bootstrap" the Federal surety approval list as the only source for surety bonds under the DMEPOS program. The commenter stated that the surety bond rule should allow for other less traditional bonding methods. The commenter noted that new surety bond providers need to emerge, which will take time. The commenter also stated that we should specify a system for approving new surety systems, which should adapt to the DMEPOS market and the risks of that market. According to the commenter, only by developing a number of surety bond providers and a competitive market will the DMEPOS program have a chance of keeping costs for surety bonds reasonable for suppliers.

Response: We disagree with this commenter because the use of the

Federal surety approval list will best ensure that sureties are legitimate firms. A link to this list, which is maintained by the Financial Management Service of the Department of the Treasury, will be posted on our Web site within 90 days after the publication date of this final rule.

Comment: One commenter stated that we gave commenters only 60 days to absorb and comment on the August 1, 2007 proposed rule, which consists of more than 60 pages. The commenter stated that this is unfair and will result in many people being unable to submit meaningful comments.

Response: The Administrative Procedures Act requires a 60-day comment period on proposed rules with a major impact. Therefore, we believe commenters were given adequate time to submit meaningful comments.

Comment: One commenter observed that in the August 1, 2007 proposed rule we indicated that we could conduct education and outreach efforts to help Medicare beneficiaries locate a replacement DMEPOS supplier if a significant number of DMEPOS suppliers leave the DMEPOS program as a result of the surety bond requirement.

Response: As stated above, by delaying the implementation of the surety bond requirement for existing DMEPOS suppliers until 9 months after the effective date of this final rule, and establishing exemptions for certain DMEPOS suppliers, CMS and the industry will have time to educate the public about their DMEPOS supplier alternatives.

M. Miscellaneous Comments

Comment: Some commenters stated that preexisting regulations (for example, the accreditation and liability insurance regulations) could be modified to prevent fraud in the program, rather than subjecting the DMEPOS industry to the surety bond requirement.

Response: We believe the comments are outside the scope of this final rule.

Comment: One commenter urged us to implement long-overdue regulations that would impose payment edits on practitioners and suppliers of orthotic and prosthetic care so that only qualified orthotic and prosthetic suppliers can be reimbursed under the Medicare program. The commenter stated that even though statutory directives require us to issue regulations within 1 year of enactment, we have never issued the regulations associated with section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554) (BIPA), a law

that limits payment of certain custom fabricated orthotics and all prosthetics to qualified practitioners and suppliers.

Response: We believe this comment is outside the scope of this final rule.

Comment: In order to more effectively protect Medicare beneficiaries and safeguard the Medicare Trust Fund, one commenter urged us to permanently expel DMEPOS suppliers that commit substantive fraud from the DMEPOS program.

Response: We do not have the statutory authority to permanently expel DMEPOS suppliers that commit substantive fraud from the DMEPOS program. This authority rests with the OIG. However, we are continuing to implement activities designed to protect the Medicare Trust Fund, including expanding onsite reviews of DMEPOS suppliers and revoking the billing privileges of DMEPOS suppliers that no longer meet the enrollment criteria found in § 424.57 and § 424.500 through § 424.555.

Comment: One commenter asked us to eliminate his copayment for DMEPOS items. He indicated that he is a diabetic and has a limited budget. He also stated that it is unfair that he must pay for his DMEPOS items when Medicare was paying for his DMEPOS items less than a year ago.

Response: While we understand this concern, we believe this comment is outside the scope of this final rule.

Comment: One commenter stated that, because we do not require home health agencies to obtain a surety bond, we should not require DMEPOS suppliers to obtain a surety bond.

Response: We believe this comment is outside the scope of this final rule.

Comment: The commenter maintained that if we enforced our own publication, Transmittal 656, and implemented existing laws, there would be no need to institute a surety bond requirement for orthotic and prosthetic suppliers.

Response: We believe this comment is outside the scope of this final rule.

Comment: A commenter found it difficult to believe that we cannot easily verify the legitimacy of home infusion services provided by pharmacies by crosschecking documentation (for example, medical procedures billed for services allegedly rendered to Medicare beneficiaries) in “the Medicare system.”

Response: While we appreciate this comment, we believe that this comment is outside the scope of this final rule.

Comment: Another commenter asked whether CMS realizes the impact the shortsighted implementation of Part D has had on independent pharmacies. The commenter stated that we refused

to acknowledge home infusion as a highly specialized service and “lumped” it with Part D.

Response: We believe this comment is outside the scope of this final rule.

Comment: Some commenters stated that we can reduce the risk of DMEPOS fraud and abuse by conducting credit checks on DMEPOS suppliers through established credit rating services, which can provide inexpensive and detailed credit reports on individuals and corporations. One commenter stated that we could require each supplier to provide evidence satisfactory to us that the supplier has a credit rating that will enable the supplier to pay 5 or 10 percent of its annual billings to Medicare if the supplier is not allowed to remain enrolled in the Medicare program.

Response: While we appreciate this suggestion, we believe it is outside the scope of this final rule.

Comment: Commenters stated that other measures, such as “real time” auditing and closely monitoring new DMEPOS suppliers, would more effectively deter fraud and abuse than the surety bond requirement.

Response: We believe this comment is outside the scope of this final rule.

Comment: One commenter stated that we underestimated the extent to which added DMEPOS costs will force independent pharmacists from the program, thus severely limiting patient access to DMEPOS and other medications. The commenter stated that it surveyed independent pharmacies after we issued the May 10, 2007 final rule (72 FR 17992), and that the survey targeted 10 Metropolitan Statistical Areas that were likely to be chosen to initiate our accreditation and competitive bidding program. The commenter reported that only 31 percent of independent pharmacists who responded to the survey indicated that they intended to submit bids to attempt to continue to sell DMEPOS supplies.

Response: We believe this comment is outside the scope of this final rule.

IV. Provisions of the Final Regulations

Based on public comments, we are adopting the provisions of the proposed rule with the following revisions:

In § 424.57(a), we are revising the definitions of “penal sum” and “sufficient evidence.” Based on public comments, we are adopting a change in the definition of the term, penal sum from “is a sum to be paid (up to the value of the bond) by the surety as a penalty under the terms of the surety bond when a loss has occurred.” to “is the amount of the bond and the

maximum obligation of the surety if a loss occurs.” We are also adopting a change in the definition of the term, sufficient evidence from “means the documentation that CMS may supply to the surety in order to establish that a DMEPOS supplier had received Medicare funds in excess of amounts due and payable under the statute and regulations” to “means documents CMS may supply to the surety that—(1) Establish both the amount of Medicare funds a DMEPOS supplier received in excess of amounts due, the amount of the CMP or the amount of some other assessment against the DMEPOS supplier; (2) is payable under applicable statutes and regulations; and (3) was an obligation of the surety.” We believe that these revisions will clarify the terms throughout the regulation and ensure that sureties understand the financial obligation that they are incurring when they issue a surety bond to a DMEPOS supplier.

We believe that the following technical changes to § 424.57(c)(26) will improve the clarity of the surety bond requirements:

- Redesignating existing § 424.57(d) and (e) as § 424.57(e) and (f).
- Redesignating the provisions of proposed § 424.57(c)(26) as § 424.57(d).
- Revising § 424.57(c)(26) to state “must meet the surety bond requirement in paragraph (d) of this section.”
- Making cross-reference changes in the definition of DMEPOS supplier § 424.57(a) and the newly redesignated § 424.57(e).

In the introductory text of § 424.57(d) (proposed § 424.57(c)(26)), we are revising this provision to reflect the \$50,000 surety bond amount and the delay in implementation: “Except as provided in paragraph (d)(15) of this section and no later than 9 months after the effective date of this final rule, each DMEPOS supplier that is a Medicare-enrolled DMEPOS supplier for each assigned NPI to which Medicare has granted billing privileges (DMEPOS suppliers seeking to enroll or to change the ownership of a supplier of DMEPOS after the effective date of this final rule are required to furnish to the NSC a surety bond of at least \$50,000 from an authorized surety for each assigned NPI for which the DMEPOS supplier is seeking to obtain billing privileges Medicare after 120 days following the effective date of this final rule.)

In § 424.57(d)(2) (proposed § 424.57(c)(26)(i)), we are clarifying the minimum requirements for a DMEPOS supplier. We specify that, unless a DMEPOS supplier meets the requirements for an exception in § 424.57(d)(15), the enrolling Medicare

DMEPOS supplier or the Medicare-enrolled DMEPOS supplier must obtain a surety bond for each National Provider Identifier (NPI) from an authorized surety. The surety bond must be in the amount prescribed by the NSC and in the form specified by the Secretary. We proposed to adjust the amount of the surety bond in the August 1, 2007 proposed rule from \$50,000 in 1997 by the CPI and calculate a higher surety bond amount to \$65,000. For reasons already stated, we have elected to require a base surety amount of \$50,000 for all individual and organizational suppliers of DMEPOS who do not meet the requirements for an exception in § 424.57(d)(15).

In § 424.57(d)(2)(i) (proposed § 424.57(c)(26)(i)(A)), we require a DMEPOS supplier to submit a surety bond with its initial paper or electronic Medicare enrollment application (CMS-855S, OMB Number 0938-0685), or with its paper or electronic revalidation, or reenrollment application. In addition, we are clarifying that for the purpose of meeting the surety bond requirement, a change of ownership constitutes an initial application and that suppliers of DMEPOS, except those with an exception in § 424.57(d)(15) (proposed § 424.57(c)(26)(ii)), are required to submit a surety bond in the amount prescribed by the NSC when a change of ownership occurs on or after the effective date of this final rule.

In § 424.57(d)(2)(iii) (proposed § 424.57(c)(26)(i)(C)), we are clarifying that we require a DMEPOS supplier seeking to enroll a new location to obtain a new surety bond for this new location since the location is also required to be enumerated with a unique NPI, unless the DMEPOS supplier is a sole proprietorship. With the implementation of the NPI as the standard health care identifier on May 23, 2008, we believe that the NPI, not the TIN, provides the best measure of program risk for the Medicare program. Moreover, we maintain that a DMEPOS supplier can obtain one TIN for many practice locations. However, these same DMEPOS suppliers can only obtain a single NPI per practice location (note that there is an exception for sole proprietorship). Accordingly, we are adopting a position that a separate surety bond be required for each NPI obtained for DMEPOS billing purposes. This will allow CMS, the NSC, and law enforcement an easy method to identify ownership, determine whether adverse legal actions have been previously imposed, and determine the value of the bond that each DMEPOS supplier must obtain and maintain in order to participate in the Medicare program.

Since each of these factors can enhance the overall risk to the Medicare Trust Fund, we have determined that the NPI, rather than the TIN, is more closely tied to the level of enrollment risk, and thus should be used in lieu of the TIN.

In § 424.57(d)(15) (proposed § 457.57(c)(26)(ii)), we are creating an exception to the bond requirement for a DMEPOS supplier operated by a Federal, State, local, or tribal government agency if the DME supplier has provided CMS with a comparable surety bond required under State law.

In the proposed rule, we stated that in order to satisfy this exception, a supplier must not have any unpaid claims, civil money penalties (CMPs), or assessments. We decided to remove this requirement from the final rule because we believe that the agency has adequate protection related to the financial status of government-operated DMEPOS supplier. Moreover, we want all of the exceptions to the surety bond requirement to be consistent for all supplier types.

As already discussed in section III of this final rule, we are also creating an exception to the bond requirement for physicians and NPPs, as defined in section 1842(b)(18)(C) of the Act provided that the items are furnished only to the physician or NPP's own patients as part of his or her professional service. We believe that requiring physicians and NPPs to obtain a surety bond for items furnished for patients other than the practitioner's own patients is appropriate and consistent with the provisions previously established in accreditation and the legislative history of section 4312(a) of the BBA. Nonphysician practitioners listed in section 1842(b)(18)(C) of the Act include the following: PAs, NPs, clinical nurse specialists, certified nurse anesthetists, certified clinical social workers, clinical psychologists, and registered dietitian or nutrition professionals.

We maintain that physicians and NPPs furnishing DMEPOS to someone other than the physician or NPP's own patients as part of his or her physician service are providing services as a medical supply company. Accordingly, we believe that physicians, including clinics and group practices, must obtain a surety bond if they are providing any DMEPOS items to someone other than the physician or NPP's own patient. This will ensure that physicians and NPPs meet the same quality and program safeguard standards as other DMEPOS suppliers who are not exempt from the bonding requirements found in § 424.57(d).

While it is true that the statutory exception identified in section 1834(a)(16) of the Act for physicians and NPPs does not specifically delineate between physicians and NPPs who provide DMEPOS supplies to their own patients and those who furnish such supplies in a different setting, we believe that there is a clear distinction between these two scenarios in terms of what the Congress intended in enacting section 1834(a)(16) of the Act. A physician or NPP who, for instance, furnishes DMEPOS supplies as part of her ownership of a DMEPOS supply company is not acting in her capacity as a practitioner who is providing ongoing care to a patient whom she is treating. Rather, the practitioner is operating his or her own side business. We do not believe that the Congress intended to allow a DMEPOS supply company to circumvent the surety bond requirement by hiring or contracting with a physician or NPP who can furnish DMEPOS supplies to the company's customers. To permit such a practice would be entirely inconsistent with the intent and spirit of section 1834(a)(16) of the Act. To ensure that this final rule conforms to the Congress's wishes, we have therefore limited the physician and NPP exception to those practitioners who furnish DMEPOS supplies only to their own patients.

We are also creating an exception to the bond requirement for State-licensed orthotic and prosthetic personnel operating in private practice and who furnish only orthotics, prosthetics, and supplies. Orthotic and prosthetic personnel are not operating in private practice when another individual or entity is a part owner of the enrolled practice location.

It is important to note that we believe that there is a clear distinction between a DMEPOS supplier enrolled as a State-licensed orthotic and prosthetic personnel operating in private practice and operating independently of a medical supply company or other DMEPOS supplier and orthotic and prosthetic personnel employed by medical supply company or co-owned with another individual or entity. Since medical supply companies can enroll as a DMEPOS supplier with or without employing State-licensed orthotic and prosthetic personnel, we do not believe that medical supply companies employing State-licensed orthotic and prosthetic personnel qualify for an exception because the owners of the medical supply company are responsible for the management and billing of products and services, not the State-licensed orthotic or prosthetic personnel. Similarly, we believe

orthotic or prosthetic personnel are not operating independently when other individual or entity is a part owner of an enrolled DMEPOS supplier's practice location. Finally, as with physicians and NPPs, State-licensed orthotic and prosthetic personnel operating as a sole owner and operating in private practice risk their State license if they are found guilty of fraudulent or abusive behavior; whereas, a medical supply company can reorganize under new ownership and reapply to participate in the Medicare program. Finally, since all DMEPOS suppliers are required to be accredited to participate in the Medicare program by September 30, 2009, we do not believe that it is appropriate to establish an exception based solely on whether State-licensed orthotic or prosthetic personnel are accredited.

As already discussed in section III of this final rule, we are also creating an exception to the bond requirement for State-licensed physical and occupational therapist operating in private practice provided that the therapist furnishes only orthotics, prosthetics and supplies and only to the therapist's own patients as part of the physical or occupational therapy service. State-licensed physical and occupational therapist are not operating in private practice when another individual or entity is a part owner of the enrolled practice location. Moreover, a State-licensed physical and occupational therapist furnishing DMEPOS to someone other than the therapist's own patients as part of the physical or occupational therapy service is not exempt from the surety bond requirement.

It is important to note that we believe that there is a clear distinction between a DMEPOS supplier enrolled as a State-licensed physical and occupational therapist operating in private practice and operating independently of a medical supply company or other DMEPOS supplier and a State-licensed physical and occupational therapist employed by a medical supply company or co-owned with another individual or entity. Since medical supply companies can enroll as a DMEPOS supplier with or without employing State-licensed physical and occupational therapists, we do not believe that medical supply companies employing State-licensed physical and occupational therapists qualify for an exception because the owners of the medical supply company are responsible for the management and billing of products and services, not the State-licensed physical and occupational therapists. Similarly, we believe State-licensed physical and occupational therapists are not

operating independently when another individual or entity is a part owner of an enrolled DMEPOS supplier's practice location. Finally, as with physicians and NPPs, State-licensed physical and occupational therapists operating as a sole owner and operating in private practice risk their State license if they are found guilty of fraudulent or abusive behavior; whereas, a medical supply company can reorganize under new ownership and reapply to participate in the Medicare program. Since all DMEPOS suppliers are required to be accredited to participate in the Medicare program by September 30, 2009, we do not believe that it is appropriate to establish an exception based solely on whether State-licensed physical and occupational therapists are accredited.

In § 424.57(d)(4)(ii) (proposed § 424.57(c)(26)(iii)(B)), we require that DMEPOS suppliers obtain a surety bond of more than \$50,000 if the DMEPOS supplier poses a significantly higher than average risk to the Medicare Trust Funds by establishing elevated amounts of surety bonds for higher risk DMEPOS suppliers. We are establishing elevated amounts of the surety bond at a rate of \$50,000 per occurrence when a DMEPOS supplier, has an adverse legal action. The term "adverse legal action" is defined in § 424.57 and means a Medicare-imposed revocation of any Medicare billing number; suspension of a license to provide health care by any State licensing authority; revocation or suspension of accreditation; a conviction of a Federal or State felony offense within the last 10 years preceding enrollment, revalidation, or re-enrollment; or an exclusion or debarment from participation in a Federal or State health care program.

We maintain that these adverse legal actions create a significantly higher level of risk to the Medicare Trust Fund. Moreover, these adverse legal actions are consistent with the denial and revocation reasons found in § 424.530 and § 424.535, respectively.

The following is an example of how high-risk criteria would be used to increase the bond amount by \$50,000 per occurrence. A DMEPOS supplier would be required to obtain a surety bond in the amount of \$100,000, an increase of \$50,000 from the base surety bond amount of \$50,000, if the DMEPOS supplier or any of its owners, authorized officials, or delegated officials (as the terms "owner," "authorized official," and "delegated official," are defined in § 424.502) had their Medicare billing privileges revoked within the 10 years preceding enrollment, revalidation, or reenrollment. If the DMEPOS supplier or any of its owners, authorized

officials, delegated officials had more than one revocation in the last 10 years, then the amount of the surety bond the DMEPOS supplier would be required to obtain would increase \$50,000 per occurrence. Thus, a DMEPOS supplier with three different revocations during the preceding 10 years would be required to obtain a surety bond in the amount of \$200,000; \$50,000 for the base surety amount and \$150,000 (3 × \$50,000) for the multiple revocations. We are also establishing a provision to require DMEPOS suppliers that have a significantly higher level of risk to maintain a higher surety bond amount for 3 years.

As explained earlier, we believe that a final adverse action, as specified in section 221(g)(1)(A) of the HIPAA, occurs when the action is imposed, not when a DMEPOS supplier has exhausted all of its appeal rights associated with the final adverse action.

In § 424.57(d)(5) (proposed § 424.57(c)(26)(iv)), we specify additional DMEPOS supplier bond requirements and the surety's liability under the bond for unpaid claims, CMPs, or assessments up to a total of the full penal amount of the bond. Regardless of the number of years the bond is in force, the number of premiums paid, or the number of claims made, the surety's aggregate liability shall not be more than the penal sum stated above. Thus, for instance, we proposed that surety bonds be issued in an amount equal to \$50,000; and the surety is liable to us for up to \$50,000.

In § 424.57(d)(6) (proposed § 424.57(c)(26)(v)), we are revising this provision to include that the surety may terminate its liability for future acts of the principal at any time by giving 30 days written notice of termination of the bond of the obligee. Also, a supplier or surety may not place any limitations on the surety bond that contradict or nullify the requirements for a surety bond specifically provided for in this section. Any attempt to do so may result in revocation of the DMEPOS supplier's billing privileges and a determination that the surety is an unauthorized surety.

In § 424.57(d)(4) (proposed § 424.57(c)(26)(viii)(B)), we are revising this provision to specify that the type of bond required to be submitted by a DMEPOS supplier under this subpart is a continuous bond. While we are not defining the term, "continuous", we believe that the term, "continuous" means that the surety bond will renew automatically from year to year unless the bond is cancelled by surety or the DMEPOS supplier or the DMEPOS supplier fails to pay the premium.

In § 424.57(d)(15) (proposed § 424.57(c)(26)(ix)), we specify the circumstances under which a supplier will no longer be exempt from the surety bond requirement and must submit a surety NSC within 60 days after it receives notice that it no longer meets the criteria for an exception. Specifically, we maintain that a government-operated supplier that ceases to be operated by a government does not qualify for an exception must submit a surety bond; a physician or NPP who provides DMEPOS to beneficiaries other than his or her own patients; State-licensed orthotic or prosthetic personnel in private practice or physical or occupational therapists in private practice have their State license suspended or revoked; or otherwise no longer qualify for the exceptions described in paragraph (d).

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the following issues pertaining to the information collection requirements discussed in this final rule.

Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Numbers (§ 424.57)

Section 424.57(d) outlines the surety bond requirements for DMEPOS suppliers. Specifically, § 424.57(d) states that each Medicare-enrolled DMEPOS supplier must obtain and furnish to the National Supplier Clearinghouse (NSC) a surety bond in the amount of \$50,000. The bond must be obtained from an authorized surety, and must be submitted for each NPI

obtained by a Medicare enrolled DMEPOS supplier.

Section 424.57(d)(2) outlines the minimum requirements for a DMEPOS supplier seeking to become a Medicare-enrolled DMEPOS supplier. Section 424.57(d)(2)(i) (proposed § 424.57(c)(26)(i)(A)) requires a DMEPOS supplier that seeks to become a Medicare-enrolled supplier, to make a change in ownership, or to respond to a revalidation or reenrollment request to submit a surety bond of \$50,000 with its paper or electronic Medicare enrollment application (Form CMS-855S). Section 424.57(d)(2)(ii) (proposed § 424.57(c)(26)(i)(B)) states that a DMEPOS supplier seeking to become an enrolled supplier through the purchase or transfer of assets must provide a surety bond 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 number will be effective no sooner than the effective date of the surety bond as validated by the NSC.

Section 424.57(d)(2)(iii) (proposed § 424.57(c)(26)(i)(C)) requires a DMEPOS supplier that is seeking to enroll a new location under a TIN for which it already has a DMEPOS surety bond in place to either obtain a new surety bond or to submit an amendment or rider to the existing surety bond.

Section 424.57(d)(4)(ii) (proposed § 424.57(c)(26)(iii)(B)) states that in addition to obtaining and maintaining a base surety bond in the amount of \$50,000, a DMEPOS supplier must also obtain and maintain an elevated surety bond in the amount prescribed by the NSC.

For those aforementioned requirements that are not already approved under OMB control number 0938-0685, we estimate the burden associated with the requirements in § 424.57(d)(2)(proposed § 424.57(c)(26)(i) and (iii)) to be 3 hours per DMEPOS supplier. In addition, we estimate that approximately 67,723 DMEPOS suppliers will comply with these requirements. Therefore, the estimated total annual burden is 203,169 hours.

Section 424.57(d)(6) (proposed § 424.57(c)(26)(v)) also states that a surety bond may be cancelled with written notice from the DMEPOS supplier to the NSC. The burden associated with this requirement is the time and effort necessary for either DMEPOS supplier to draft and submit the notice of cancellation to the NSC. We estimate the burden associated with this requirement to be 3 hours. In

addition, we anticipate that 250 suppliers will draft and submit the necessary documentation. We estimate the total annual burden to be 750 hours.

Section 424.57(d)(15)(ii) (proposed § 424.57(c)(26)(ix)) requires a DMEPOS supplier, other than physicians and NPPs, as defined in section 1842(b)(18)(C) of the Act, that no longer qualifies for an exception under this final rule to submit a surety bond to the NSC within 60 days of receiving notice that it no longer qualifies for an exception. The burden associated with this requirement is the time and effort necessary for the DMEPOS supplier to obtain and submit a surety bond to the NSC within 60 days of receiving notice that it no longer qualifies for an exception. We estimate the burden associated with this requirement to be 3 hours. In addition, we anticipate that 100 suppliers will draft and submit the necessary documentation. We estimate the total annual burden to be 300 hours.

Section 424.57(d)(9) (proposed § 424.57(c)(26)(x)) requires a DMEPOS supplier that obtains a replacement surety bond from a different surety to cover the remaining term of a previously obtained bond to submit the new surety bond to the NSC within 30 days of expiration of the previous bond. The burden associated with this requirement is the time and effort necessary to obtain and submit the new surety bond to the NSC. We estimate the burden associated with this requirement to be 3 hours. In addition, we anticipate that 250 suppliers will comply with this requirement. We estimate the total annual burden to be 750 hours.

Section 424.57(d)(12) (proposed § 424.57(c)(26)(xiii)) states that CMS may at any time require a DMEPOS supplier to show compliance with the requirements associated with 42 CFR part 424. The burden for this requirement is the time and effort associated with maintaining the necessary documentation on file. While this requirement is subject to the PRA, we believe the burden is exempt as stated in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

However, the burden associated with producing the documents upon request from CMS is estimated to be 30 minutes per DMEPOS supplier. We estimate that 500 DMEPOS suppliers will be asked to submit the requested documentation. The total annual burden associated with this requirement is estimated to be 250 hours.

The following is a summary of the comments received on the collection of information section and our responses.

Comment: A commenter stated that the suggested burden in the August 1, 2007 proposed rule for DMEPOS suppliers to obtain and keep a surety bond is too low in terms of hours and dollars. The commenter stated that obtaining all the information and attachments in an effort to obtain a bond will more than likely require 2 to 4 hours per application. The commenter also noted that a DMEPOS supplier may have to submit many applications in order to secure a surety bond, that it may have to deal with bankers and accountants to obtain the bond, and that it may have to borrow money in order to pay for the bond.

Response: We appreciate this comment and have revised our Collection of Information estimates accordingly.

Comment: A commenter stated that the surety bond requirement will

increase DMEPOS suppliers' cost and paperwork burden without accomplishing the Congress's and our goals. The commenter stated that sureties issuing financial guarantee bonds would be more likely to review a DMEPOS supplier's books and might request audited financial statements. Since most small suppliers do not have audited financial statements, the commenter stated that this requirement could pose a serious hurdle to their compliance. In addition, the commenter maintained that sureties would be more likely to ask for collateral to secure the issuance of a financial guarantee bond, and that sureties would likely favor highly liquid collateral such as letters of credit, which would require suppliers to incur an additional expense. Many commenters believe that this type of review is sensible when it is applied to DMEPOS suppliers that are new to the Medicare program, but not to established DMEPOS suppliers.

Response: We appreciate the concerns of the commenters, but continue to believe that surety bonds will serve as an effective deterrent to fraud and abuse, as well as provide the Medicare program with recourse when a supplier fails to pay claims against it, CMPs, or assessments.

Comment: A commenter stated that the cost and burden of the surety bond requirement will have a disproportionate impact on small DMEPOS suppliers. To ensure that small DMEPOS suppliers participate in the DMEPOS program if this final rule is implemented, the commenter stated that we should work with the SBA to extend low or no interest loans to qualified small DMEPOS suppliers for the express purpose of obtaining a surety bond.

Response: We do not have the authority to issue these types of loans to those DMEPOS suppliers that qualify as small businesses.

TABLE 2—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OCN	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden hours
§ 424.57(d)(2)(i)	0938–New ...	2,000	2,000	3.0	6,000
§ 424.57(d)(2)(ii)	0938–New ...	65,723	65,723	3.0	197,169
§ 424.57(d)(6)	0938–New ...	250	250	3.0	750
§ 424.57(d)(9)	0938–New ...	250	250	3.0	750
§ 424.57(d)(12)	0938–New ...	500	500	0.5	250
§ 424.57(d)(15)(ii)	0938–New ...	100	100	3.0	300
Total					205,219

We submitted a copy of this final rule to the OMB for its review of the information collection requirements. These information collection requirements are not effective until approved by OMB.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select

regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

The August 1, 2007 proposed rule was classified as economically significant, as the estimated annual cost of the surety bond requirement at that time was \$198 million. This was based largely on a preliminary estimation that 99,000 DMEPOS suppliers would need to obtain a surety bond in the amount of \$65,000, at an annual cost of \$2,000. As explained below, the establishment of a number of exceptions to the surety bond requirement, the reduction in both the bond amount and its cost, and the utilization of more current data in this final rule, has reduced the projected annual cost of the surety bond requirement from \$198 million to \$102.3 million. Accordingly, this final

rule is considered economically significant.

The RFA requires agencies to analyze the economic impacts of the regulation and alternatives for the regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year.

The RFA requires that a Regulatory Flexibility Analysis be conducted for all regulations that will have a “significant economic impact on a substantial number of small entities.” As already explained, we believe that the principal economic impact of this rule will fall on large, publicly traded chain pharmacies. Such organizations may have to expend several hundred thousand dollars to obtain surety bonds for each of their locations. However, even if we were to assume that each individual location—

if considered as a stand-alone business—qualifies as a small entity, we do not believe that the annual cost of a surety bond (\$1,500) would have an economic impact on it that rises to the level of qualifying as “significant.” The RFA generally defines “significant” as several percent; we do not believe that a \$1,500 cost would constitute more than one percent of a chain pharmacy location’s annual revenues. From that perspective, we do not believe that a Regulatory Flexibility Analysis is required.

We recognize that the cost of a surety bond may impact smaller pharmacies, such as single-site community pharmacies, as well as small medical supply companies in rural areas to a greater extent than large chain pharmacies. Though we do not believe that, at least in the case of community pharmacies, the bond requirement will have a significant economic impact on such businesses, we have elected to prepare a voluntary Final Regulatory Flexibility Analysis. As many of the requirements of the RFA are also contained in our Regulatory Impact Analysis, this Regulatory Impact Analysis section, taken together with the remainder of the preamble, constitutes the Final Regulatory Flexibility Analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing a rural impact statement since we have determined, and certify, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Our research has disclosed that well under 1 percent of a typical small rural hospital’s total annual reimbursement from Medicare would come from its enrollment as a DMEPOS supplier. Equipment furnished in hospitals is generally paid for as part of the facility’s direct or ancillary costs, rather than in the hospital’s capacity as a DMEPOS supplier. This is buttressed by the fact that less than four-tenths of one percent of all DMEPOS suppliers are hospitals.

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates

require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold is currently \$130 million. This final rule does not contain mandates that will impose spending costs on State, local, or tribal governments, in the aggregate, or on the private sector, of \$130 million or greater; as previously mentioned, we estimate that the maximum annual cost of this final rule will be \$102.3 million. Accordingly, we are furnishing the aforementioned assessment in this final rule.

Executive Order 13132 established certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this rule under the threshold criteria of Executive Order 13132 and have determined that it does not significantly affect the rights, roles, and responsibilities of States.

The following is a summary of the comments received on the proposed rule’s regulatory impact analysis and our responses.

Comment: Some commenters stated that the surety bond requirement would mandate each Medicare-enrolled DMEPOS supplier to obtain a surety bond for each National Provider Identifier (NPI) the supplier holds, and that, under the provisions of the August 1, 2007 proposed rule, this requirement would be applied to all DMEPOS suppliers to the same extent. Commenters maintained that large, publicly traded DMEPOS chain suppliers and community pharmacies have numerous locations and NPIs. As a result, commenters stated that our surety bond requirement is not only over-inclusive but also unnecessary and unduly burdensome on these types of suppliers. Some commenters describe this requirement as punitive. To ensure that large, publicly traded chain DMEPOS suppliers are not unduly burdened, another commenter urged us to consider establishing a maximum or cap on the aggregate dollar amount of the surety bonds required for these high volume suppliers. Yet another commenter maintained that, if we do not establish an exception to the surety bond regulation for large, publicly traded companies that provide DMEPOS services, then we should allow a company with multiple locations that provide DMEPOS services to obtain one surety bond. The commenters stated that requiring this type of company to obtain multiple bonds is redundant and greatly increases the cost of doing business with the Medicare program.

Response: As previously stated, we are not establishing an exception to the surety bond requirement for publicly traded chain DMEPOS suppliers or community pharmacies, for there is nothing in section 4312(a) of the BBA or its legislative history that evidences a congressional intent to do so. Moreover, we disagree with the comment that we should not establish the surety bond at the NPI level, since the NPI is established by practice location for all DMEPOS suppliers except for those operating as a sole proprietorship.

Comment: One commenter stated that one way to equalize the burden on large DMEPOS suppliers is to require them to pay us a specified amount in lieu of a surety bond. The commenter stated that the amount could be the average cost of the bond for the previous year. The commenter called this option a “bond waiver fee.” The commenter believes that this approach would, among other things, keep unnecessary funds from going to sureties rather than taxpayers.

Response: We do not have the statutory authority to establish a bond waiver fee.

Comment: Several commenters stated that the surety bond requirement could have a devastating impact on Medicare beneficiaries needing these DMEPOS supplies. The commenters urged us to ensure that beneficiary access to DMEPOS services is not jeopardized as a result of the potentially large number of DMEPOS suppliers that may not enroll or discontinue their enrollment due to the financial burden the surety bond requirement may impose.

Response: We believe that the exceptions established in this final rule will help ensure that beneficiary access to DMEPOS supplies continues unabated. In addition, while we expect some DMEPOS suppliers to exit the Medicare program due to the surety bond requirement, we expect that other suppliers will enter the Medicare program as suppliers become acquainted with the new accreditation and surety bond requirements.

Comment: One commenter stated that many small towns have only a few DMEPOS suppliers, and that a number of those suppliers will not find obtaining a surety bond economical.

Response: We understand the potential impact that this final rule may have on small DMEPOS suppliers and have revised the regulatory impact accordingly.

Comment: One commenter stated that our assumption that most, if not all, of the Medicare business conducted by DMEPOS suppliers that withdraw from the DMEPOS program due to this final rule would be assumed by other

DMEPOS suppliers remaining in the program (for example, by mail order or via the World Wide Web) is flawed. The commenter stated that, if DMEPOS suppliers in the power mobility industry withdraw from the DMEPOS program as a result of this final rule, the assumption that mail order DMEPOS suppliers would assume their Medicare business would be inappropriate. The commenter stated that DMEPOS suppliers in the power mobility industry are required to conduct an in-home assessment, which would make Internet or nationwide mail order DMEPOS suppliers a nonviable substitute for DMEPOS suppliers in the power mobility industry. Other commenters maintained that we should not assume that these suppliers can satisfactorily meet the needs of all Medicare beneficiaries.

Response: If DMEPOS suppliers of a particular type of DMEPOS indeed exit the Medicare program upon implementation of this final rule, we believe that the remaining DMEPOS suppliers would offer the products and services similar to those of the exiting DMEPOS suppliers. As stated above, by delaying the implementation of the surety bond requirement for existing DMEPOS suppliers until 9 months after the effective date of this final rule, and establishing exemptions for certain DMEPOS suppliers, we believe that remaining DMEPOS suppliers will adjust to meet an increased demand for products and services.

Comment: One commenter stated that the surety bond requirement would unfairly penalize home health or home infusion companies that provide DMEPOS. The commenter questioned why the surety bond requirement would extend to these companies since the commenter maintains that CMS has stated that “the problem is not with home infusion providers.”

Response: We disagree with this commenter because the intent of a surety bond is, among other goals, to make sure that all DMEPOS suppliers meet more stringent financial requirements before being permitted to participate in the Medicare program.

Comment: A commenter noted that we stated in the August 1, 2007 proposed rule that the surety bond requirement could cause approximately 15,000 DMEPOS suppliers to decide to cease providing items to Medicare beneficiaries. However, the commenter believes that this figure is likely underestimated.

Response: We have revised the regulatory impact to account for the changes incorporated into this final rule.

Comment: Some commenters stated that we need to improve the regulatory impact analysis from the August 1, 2007 proposed rule. The commenters stated that the August 1, 2007 proposed rule violates Executive Order 12866, which directs agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Commenters also maintained, among other things, that we did not design the proposed rule in the most cost effective manner to achieve the regulatory objective, and that the regulation failed to take into account the cost of cumulative regulations, such as the accreditation process for DMEPOS suppliers, and its impact on patient care.

Response: While we disagree that the regulatory impact analysis in the proposed rule was in violation of Executive Order 12866, we have revised the regulatory impact analysis to address the concerns expressed.

Comment: Several commenters stated that we did not provide an analysis of the percentage of the industry that is contributing to Medicare fraud. Commenters also indicated that we overlooked many of the Regulatory Flexibility Act (RFA) requirements because we failed to address obvious alternatives that would minimize any significant impact of the proposed rule on small entities, including discussion of significant alternatives, such as an exemption from coverage of the rule, or any part thereof, for these small entities. The commenters stated that it is not clear from the RFA whether we intended for information in the regulatory impact analysis to serve as an initial regulatory flexibility analysis for the purposes of the RFA. Commenters indicated that our intent should be made clear in this final rule.

Response: We have revised the regulatory impact analysis to address the concerns expressed.

Comment: Several commenters believed that our economic analysis is incomplete. Specifically, although we provided information on the number of small DMEPOS suppliers that would likely be impacted by the surety bond requirement, commenters observed that our regulatory impact analysis offers little analysis of how the rule will economically impact small DMEPOS suppliers. For example, commenters noted that the analysis does not provide any information on the cost of complying with the surety bond

requirement based on the size of the DMEPOS supplier.

Response: We have revised our economic analysis to address the concerns expressed.

Comment: One commenter stated that the August 1, 2007 proposed rule fails to conform to the Office of Management and Budget’s (OMB) standards for analyzing regulations, which are set forth in OMB Circular A–4. The commenter observed that OMB Circular A–4 indicates that a regulatory impact analysis should analyze a manageable number of alternatives, including different enforcement methods and different degrees of stringency. According to the commenter, the proposed rule does not present this type of analysis, and the “Alternatives Considered” section in the preamble under “Regulatory Impact Analysis” neither presents nor analyzes any alternatives whatsoever.

Response: We disagree with the commenter that the proposed rule does not comply with OMB Circular A–4. Nevertheless, as already stated, we have revised the impact analysis based on comments we received in response to the August 1, 2007 proposed rule.

Comment: One commenter believes that the cost/benefit analysis of the August 1, 2007 proposed rule appears heavily weighted on the cost side. The commenter stated that the August 1, 2007 proposed rule estimates that 1,000 suppliers would be asked for bond documentation. If all of these suppliers required payment to Medicare from the surety, this amounts only to \$65,000,000 even though suppliers are being asked to potentially pay almost \$200,000,000 per year.

Response: As previously stated, we have reviewed and revised our regulatory impact analysis in this final rule to address matters such as those raised by the commenter.

Comment: A commenter stated that the August 1, 2007 proposed rule provides a confusing array of data with respect to the number of DMEPOS suppliers that would be affected by the surety bond requirement. For example, in the impact analysis section, in estimating the costs of obtaining surety bonds, the commenter stated that we assume that approximately 99,000 suppliers will be involved and that the average annual cost of a bond will be \$2,000. However, in the section of the proposed rule summarizing the collection of information requirements, the commenter noted that we estimate that approximately 116,500 DMEPOS suppliers will comply with the surety bond requirement.

Response: As previously stated, we have reviewed and revised our regulatory impact analysis in this final rule to address matters such as those raised by the commenter.

Comment: One commenter stated that the August 1, 2007 proposed rule requires DMEPOS suppliers to have their financial statements audited each year. The commenter noted that many DMEPOS suppliers have external firms audit their annual financial statements. The commenter believed that the annual cost for DMEPOS suppliers to audit financial statements would be exorbitant and would exceed the original intent of the surety bond requirement.

Response: While we agree that a surety may require that a supplier provide audited financial statements as part of the surety's review and evaluation process, we did not propose, nor does this final rule adopt, provisions that require a DMEPOS supplier to have its financial statements audited on an annual basis.

Comment: Many commenters indicated that some DMEPOS suppliers are already required by State or Federal entities (for example, Medicaid) to obtain a surety bond at an approximate cost of \$2,000 annually in order to provide DMEPOS to consumers. The commenters stated that it would be a financial burden to pay for both their current surety bond and a surety bond that comports with this final rule.

Response: The non-Medicare surety bond to which the commenter refers covers financial losses associated with those other medical programs. We believe that by adopting a surety bond requirement, we will protect the Medicare program and its beneficiaries from unscrupulous suppliers or suppliers who lack the financial resources to operate a legitimate business organization. We note that we have already exempted government-operated DMEPOS suppliers who have a comparable surety bond under State law from the surety bond requirement. Besides already possessing a surety bond under State law, government-operated DMEPOS suppliers are financially more secure than other DMEPOS suppliers because of their ability to tax. Therefore, we have exempted them from the surety bond requirement.

Comment: Several commenters stated that although DMEPOS account for only a small part of Medicare spending, we are trying to reduce reimbursement to DMEPOS suppliers even further through this final rule. One commenter suggested that the surety bond requirement is another CMS rule that is

designed to put small DMEPOS suppliers out of business.

Response: We disagree with the assertion that the rule is designed to push small DMEPOS suppliers out of the Medicare program. It is true that we believe it is essential to implement the DMEPOS surety bond requirement to reduce fraud and abuse in the Medicare program and to protect Medicare beneficiaries from unscrupulous suppliers. However, we note that a number of the exceptions to the bond requirement will apply to small suppliers, such as physician offices. We believe this achieves an appropriate balance between the need to protect the Medicare Trust Fund and our interest in maintaining the presence of small suppliers in the Medicare program.

Comment: One commenter observed that the January 28, 1998 proposed rule sought to require a DMEPOS supplier to obtain a surety bond for every TIN under which a supplier billing number was issued. Under this proposal, a DMEPOS supplier with more than one location would have been required to obtain only a single surety bond. The commenter stated it would be unreasonable for us to now require a DMEPOS supplier with more than one location to obtain more than one surety bond. Therefore, the commenter urged us to require DMEPOS suppliers to obtain a surety bond for each TIN or "some comparable level of 'aggregation'" rather than for each supplier location or NPI. This would minimize the negative impact of the requirement.

Other commenters stated that we do not adequately provide the reasoning behind the transition from the TIN to the NPI and do not analyze the impact of the decision on the DMEPOS industry.

Response: We note that the NPI was not implemented back in 1998, which is why the TIN was used instead. In fact, the HIPAA Administrative Simplification Standard Unique Health Identifier for Health Care Providers; Final Rule, commonly referred to as the National Provider Identifier; Final Rule, was not published until January 23, 2004. With NPIs now the standard for identifying suppliers and their subparts, and in light of the fact that each DMEPOS practice location must enroll separately in the Medicare program (note there is an exception for sole proprietorships), we believe it is appropriate for a separate surety bond to be required for each practice location or NPI obtained for DMEPOS billing purposes. This will provide CMS, the NSC, and law enforcement an easy method to identify ownership, to

determine whether adverse legal actions have been previously imposed, and to determine the value of the bond that each DMEPOS supplier must obtain and maintain in order to participate in the Medicare program. It is also important to remember that the greater the number of NPIs a supplier organization has, the proportionately more practice locations the organization tends to have and, in turn, the larger the amount of Medicare funds for which it tends to bill. Since each of these factors can enhance the overall risk to the Medicare Trust Fund, we have determined that the NPI, rather than the TIN, is more closely tied to the level of enrollment risk, and thus, should be used in lieu of the TIN.

Comment: A commenter stated that the MMA makes clear that the Congress had great concerns about the impact of remedial legislation on small DMEPOS suppliers. For example, section 154 of the MMA required CMS to give special attention to developing a competitive bidding program to ensure that small suppliers are not driven from the market by a system that gives a competitive advantage to larger or national DMEPOS suppliers. The commenter also stated that the surety bond requirement undermines the Congressional intent, and thus places smaller DMEPOS suppliers at a competitive disadvantage.

Response: We disagree with the commenter. While our competitive bidding program for DMEPOS suppliers, which the implementation has been delayed by the MIPPA as previously noted in this final rule, did include protections for small businesses to participate in this program, we do not agree that the Congress intended that all small suppliers of DMEPOS be exempt from the surety bond requirement specified in section 4312(a) of the BBA. In addition, since almost all DMEPOS suppliers are considered small businesses by the Small Business Administration (SBA) definition, it is not practical to establish an exception for DMEPOS suppliers based on revenue alone.

B. Existing DMEPOS Suppliers

1. Number Participating

The National Supplier Clearinghouse (NSC) issues 10-digit NSC supplier numbers to suppliers that bill Medicare for DMEPOS items and services. Some DMEPOS suppliers operate at multiple locations while others operate at a single location. Suppliers that are part of a single firm share the first 6 digits of the 10-digit NSC supplier number, with the last 4 digits set equal to 0001, 0002, and so on, to denote individual locations. In the following discussion,

we will refer to the first 6 digits as the “6-digit NSC supplier number” to represent individual suppliers, while the 10-digit number represents individual supplier locations.

This distinction is important for the impact analysis because: (1) DMEPOS suppliers, except sole proprietorships, are required to obtain a distinct NPI for each enrolled DMEPOS practice location, and in this final rule we have adopted the NPI as the basis for obtaining a surety bond; and (2) accreditation organizations generally charge one fee for a supplier’s first location, and a lower fee for subsequent locations. Some of the accreditation organizations also offer lower accreditation fees to small suppliers, which typically have few locations.

In March 2008, there were 113,154 unique 10-digit NSC numbers and approximately 58,000 unique 6-digit NSC numbers. Our review indicates that there are approximately 50 Medicare-enrolled DMEPOS suppliers that are both sole proprietorships and have multiple locations. Therefore, we estimate that the total number of NPIs currently associated with Medicare-enrolled DMEPOS suppliers is only very slightly less than the total number of 10-digit NSC numbers. For purposes of this impact analysis, we will assume that there are 113,000 NPIs associated with Medicare-enrolled DMEPOS suppliers. Unless noted otherwise, this impact analysis will be based on the NPI, rather than the 6-digit or 10-digit NSC number.

In addition, unless otherwise stated, the term “supplier” refers to an

individually-enrolled location with its own NPI; for purposes of our discussion, therefore, we will assume that there are approximately 113,000 DMEPOS suppliers—one for each unique NPI.

Table 3 identifies the principal categories of DMEPOS suppliers and the number of suppliers within each category as of September 2008. Note that because a DMEPOS supplier may fall into multiple categories, the number of suppliers listed below significantly exceeds the actual number of suppliers—113,000—that are enrolled in Medicare. Hence, one should not assume, for instance, that there are 54,000 pharmacies enrolled in Medicare; we estimate that the actual figure is approximately 45,000.

TABLE 3—CATEGORIES OF DMEPOS SUPPLIERS AS OF SEPTEMBER 2008 (DENOTED BY NPI)

DMEPOS supplier type	Number of suppliers
Pharmacies	54,000
Physicians (including Podiatrists and Optometrists)	30,700
Medical Supply Companies with Orthotic Personnel, Prosthetic Personnel, Registered Pharmacist, or Respiratory Therapist	16,600
Medical Supply Companies without Orthotic Personnel, Prosthetic Personnel, Registered Pharmacist, or Respiratory Therapist ..	16,100
Opticians	13,500
Oxygen and Equipment Suppliers	12,400
Orthotic and Prosthetic Personnel	10,800
Grocery or Department Stores	7,000
Nursing Facilities	4,000
Independently Practicing/Billing Physical Therapists and Occupational Therapists	2,000
Other	1,500

2. Reimbursement

Table 4 contains information that identifies the amount of reimbursement allowed to DMEPOS suppliers in 2005. The statistics are based on the number of 6-digit NSC numbers at that time, or 65,984.

As explained in section H of this impact analysis, we recognize that the percentage breakdown of allowed charges in 2005 may not be precisely the same as that which exists today. For instance, Table 4 shows that approximately 10.8 percent of DMEPOS

suppliers in 2005 had allowed charges of between \$5,000–\$9,999. This does not necessarily mean that 10.8 percent of suppliers in 2007 or 2008 had allowed charges of this amount. We would, of course, prefer to have a table of NPI-allowed charge amounts over the past 12 months; however, this is not possible because use of the NPI was not mandatory until May 2008. Moreover, because we used the 2005 6-digit NSC number data in the proposed rule, we believe that—for purposes of consistency—it would be best to also use this information in the final rule. In

sum, while recognizing the potential for variations between the 6-digit number percentages and today’s NPI-based figures, we believe that such variations are modest at best and that the percentages shown in Table 4 are similar to those in 2008. Thus, if 10.1 percent of 6-digit NSC numbers received \$0 in reimbursement in 2005, this 10.1 percent figure is equally applicable to current levels of DMEPOS reimbursement; this means that 10.1 percent of the 113,000 Medicare-enrolled suppliers (based on the NPI) receive \$0 in reimbursement.

TABLE 4—TOTAL NUMBER OF SUPPLIERS LISTED BY ALLOWED CHARGES FOR DATES OF SERVICE IN CALENDAR YEAR 2005 ON 6-DIGIT UNIQUE BILLING NUMBERS

Allowed charge	Total number of DMEPOS suppliers	Percentage of total number of suppliers
\$0	6,671	10.1
\$0.01–\$999	9,168	13.9
\$1,000–\$2,499	7,092	10.7
\$2,500–\$4,999	6,744	10.2
\$5,000–\$9,999	7,117	10.8
\$10,000–\$24,999	8,896	13.5
\$25,000–\$49,999	5,478	8.3
\$50,000–\$99,999	4,026	6.1

TABLE 4—TOTAL NUMBER OF SUPPLIERS LISTED BY ALLOWED CHARGES FOR DATES OF SERVICE IN CALENDAR YEAR 2005 ON 6-DIGIT UNIQUE BILLING NUMBERS—Continued

Allowed charge	Total number of DMEPOS suppliers	Percentage of total number of suppliers
\$100,000–\$499,999	7,146	10.8
\$500,000–\$999,999	1,982	3.0
\$1,000,000–4,999,999	1,450	2.2
\$5,000,000 or more	215	0.3
Total	65,984

C. Anticipated Effects of Accreditation on DMEPOS Supplier Surety Bonding

Under this final rule, newly enrolling and existing DMEPOS suppliers not eligible for an exception will have to obtain and maintain a surety bond to enroll or maintain their billing privileges in the Medicare program. However, it is important to note that all existing DMEPOS suppliers are required to be accredited by an approved accreditation organization by September 30, 2009.

DMEPOS suppliers will incur costs for becoming accredited. Accreditation organizations will incur costs to accredit suppliers; we assume that these costs are approximately equal to the accreditation fees paid by suppliers. The cost and impact of accreditation on DMEPOS suppliers are described in a regulation titled, “Inpatient Rehabilitation Facility Prospective Payment System for Federal FY 2007; Provisions Concerning Competitive Acquisition for Durable Medical, Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Accreditation of DMEPOS Supplier” final rule (71 FR 47870) which was published in the **Federal Register** on August 18, 2006.

1. Factors Affecting the Cost Impact

As stated previously, in March 2008, there were 113,154 unique 10-digit NSC numbers. As of September 2008, there are approximately 113,000 NPIs. This total includes suppliers as well as providers and physicians that furnish items under Medicare Part B as suppliers. The distribution of locations by supplier type is very uneven across the industry. Over 90 percent of suppliers operate a single location, while some drug chains, grocery stores, optometry companies, and a few medical equipment companies have over a hundred locations.

2. Suppliers That Probably Will Not Seek a Surety Bond Due to Accreditation

Many currently-enrolled DMEPOS suppliers are small, receive relatively

little in Medicare payments, and do not specialize in DMEPOS. In 2005, as shown in Table 4, 10.1 percent of all suppliers received \$0 in allowed charges during the calendar year. This indicates that approximately 10.1 percent of DMEPOS suppliers—or, if based on the current number of NPIs, 11,413—are not actively participating and billing in the Medicare program. Based on our analysis, we believe that almost all of these DMEPOS suppliers will have their billing privileges deactivated for 12 consecutive months of nonbilling (see § 424.540) prior to the implementation of this final rule, will qualify for an exception, or will make the business decision to exit the Medicare program on or before September 30, 2009 due to the costs associated with accreditation.

Accordingly, we estimate that 60 percent (or approximately 6,848) of the approximately 11,413 suppliers that receive no payments from Medicare will exit the Medicare program due to the cost associated with accreditation and that the remaining DMEPOS suppliers who receive no annual reimbursement from Medicare will have their Medicare billing privileges deactivated or will qualify for an exception to the bonding requirement. Given that accreditation costs approximately \$3,000 for single location DMEPOS suppliers, we believe that approximately 60 percent of the DMEPOS suppliers that are participating in the Medicare program and not actively billing the program will voluntarily withdraw from the Medicare.

In addition, we believe that this estimate is consistent with the impact analysis contained in the August 18, 2006 final rule (71 FR 48406) which states that, “we assume that the 6,900 suppliers that currently receive \$0 in allowed charges will not seek accreditation.” As such, we believe that 6,848 suppliers will not seek a surety bond due to the implementation of accreditation.

3. Suppliers That Probably Will Not Seek a Surety Bond Due to Combined Costs Associated With Surety Bond and Accreditation

As stated above, many suppliers that currently have NSC supplier numbers are small, receive relatively little in Medicare payments, and do not specialize in DMEPOS. In 2005, approximately 45.6 percent of all DMEPOS suppliers received between \$1 and \$9,999, and an additional 13.5 percent of DMEPOS suppliers received between \$10,000 and \$24,999. Applying these percentages to the 113,000 current NPIs in the DMEPOS arena, we estimate that approximately 51,528 currently-enrolled DMEPOS suppliers receive annual reimbursement between \$1 and \$9,999 and approximately 15,255 DMEPOS suppliers receive annual reimbursement between \$10,000 and \$24,999. These suppliers will have to make a business decision on whether to pay for the costs associated with accreditation and a surety bond. Accreditation is for a 3-year period. The impact section of the August 18, 2006 final rule estimated that accreditation fees will be approximately \$3,000 for a DME supplier, or \$1,000 per year. The estimated average cost per year for a surety bond would be \$1,500. (Note that this is \$500 lower than the \$2,000 per year figure listed in the proposed rule. This is due to our decision to reduce the bond amount from \$65,000 to \$50,000.) We thus believe that combined costs for both accreditation and a surety bond would be approximately \$2,500 per year.

We estimate that approximately 40 percent (or 20,611) of the approximately 51,528 suppliers that receive between \$1 and \$9,999 annually from Medicare will exit the Medicare program because of the combined costs associated with the surety bond requirement and accreditation. The remaining 60 percent will consist of, naturally, suppliers that chose to remain in the program and suppliers that qualify for an exemption to the surety bond requirement. Indeed, a significant number of the physicians

and NPPs that qualify for such an exception are relatively small billers.

Furthermore, we estimate that approximately 30 percent (or 4,577) of the approximately 15,255 that receive between \$10,000 and \$24,999 annually from Medicare will exit the Medicare program because of the combined costs associated with the surety bond requirement and accreditation. The remaining 70 percent will consist of suppliers that chose to remain in the program and suppliers that would qualify for an exemption to the surety bond requirement.

4. Suppliers That Meet an Exception to the Surety Bond Requirement

Section 424.57(c)(26)(ii) establishes exceptions to the surety bond requirement for the following organizations and individuals:

- Government-operated DMEPOS suppliers are provided an exception to the surety bond requirement if the DME supplier has provided CMS with a comparable surety bond under State law, and if it does not have any unpaid claims, CMPs or assessments.
- State-licensed orthotic and prosthetic personnel operating in private practice and selling only orthotics, prosthetics and/or supplies if the supplier does not have any unpaid claims, CMPs, or assessments;
- Physicians and NPPs, as defined in section 1842(b)(18) of the Act, furnishing DMEPOS to the physician or NPP's own patients as part of his or her professional service; and
- State-licensed physical therapists and occupational therapists operating in private practice and furnishing prosthetics orthotics and/or supplies to the therapist's own patients as part of his or her professional service, and who does not have any unpaid claims, CMPs, or assessments.

As indicated in Table 3, there are approximately 10,800 orthotic and prosthetic personnel operating independently of a medical supply company, approximately 30,700 physicians (for example, podiatry and orthopedic/orthopedic surgery) and approximately 2,000 NPPs—specifically, physical and occupational therapists—who qualify for an exemption to the surety bond requirement. There are also approximately 35 government-operated DMEPOS suppliers. This means that 43,535 DMEPOS suppliers are eligible for an exemption from the surety bond requirement.

We recognize, however, that it is unlikely that all 43,545 of these suppliers will be exempt. As already indicated, the figures in Table 3 include

those suppliers that qualify as more than one supplier type. To illustrate, a physician who operates his or her own DMEPOS supply company may have indicated on his CMS-855S enrollment application that he is both a physician and a supply company. Clearly, such an individual would not qualify for the physician exemption. Furthermore, even those individual practitioners that only identified themselves as physicians, physical therapists, orthotic personnel, etc., may not meet the criteria for the exemption due to the composition of their practice. For instance, a physical therapist's practice may be one-half owned by a DMEPOS supply company, in which case the physical therapist would not qualify for an exemption.

For purposes of this impact analysis, we will assume that 35 percent of the 43,545 individual practitioners enrolled as DMEPOS suppliers—or 15,241—will not qualify for an exemption to the surety bond requirement. We believe that 35 percent is a high-end estimate and that, in all probability, more than 15,241 practitioners will meet an exception.

D. Surety Bond Costs for Currently Enrolled DMEPOS Suppliers

While the costs of a surety bond will vary by surety, we estimate that the surety bond requirement as specified in § 424.57(d) is \$106.2 million annually. This cost is based on the factors identified below.

1. Number of Currently Enrolled DMEPOS Suppliers That Must Obtain a Surety Bond

We derived the number of presently enrolled DMEPOS suppliers that must obtain a surety bond in the following manner:

Step A—Subtracted the number of DMEPOS suppliers (6,848) that we estimated would exit the program based on implementation of accreditation from the total number of NPIs associated with DMEPOS suppliers. The result was 106,152 suppliers.

Step B—Subtracted the estimated number of suppliers (25,188) that we believe will exit the Medicare program due to the combined costs associated with accreditation and a surety bond from the sum in Step A. The result was 80,964 suppliers.

Step C—Subtracted the estimated number of suppliers (15,241) eligible for an exemption to the surety bond amount from the sum in Step B. The result was 65,723 suppliers.

2. Number of New DMEPOS Suppliers That Will Need To Obtain a Surety Bond

Since any DMEPOS supplier seeking to enroll in the Medicare program on or after October 1, 2009 is required to meet all of supplier standards at § 424.57, including the accreditation standards at § 424.57(c)(22) through § 424.57(c)(25), we believe that a smaller number of applicants will apply to enroll in the Medicare program as a DMEPOS supplier after this date.

Before the implementation of accreditation, the NSC received approximately 12,000 initial enrollment applications per year, of which roughly one-half (or 6,000) were approved. After the full implementation of accreditation, we expect that the annual number of initial applications will fall to 6,000, of which approximately 2,000 will be approved. However, given the exceptions established in this final rule, it is likely that a number of these new suppliers will qualify for an exemption to the surety bond requirement. Nevertheless, for purposes of our analysis, we used the higher 2,000 figure to account for the possibility that the number of new DMEPOS suppliers in a given year may slightly exceed our expectations.

3. Cost of a Bond

Based on information received from the industry, we estimated that the average bond cost is approximately \$1,500, or 3 percent of the value of a \$50,000 bond. We multiplied the number of remaining suppliers (65,723) by \$1,500, which resulted in a figure of approximately \$98.6 million. We further estimated that no more than one-half of 1 percent of DMEPOS suppliers that are subject to the surety bond requirement (or 329 out of 65,723) have had a final adverse action imposed against them within the last 10 years and continue to participate in the Medicare program. For these suppliers, the average number of final adverse actions will be one, which will thus mandate a bond amount of \$100,000—or \$50,000 more than the base bond amount. Therefore, if we multiply 329 by the cost of the additional \$50,000 bond amount (or \$1,500), the total is \$493,500, which when added to the \$98.6 million amount identified above, results in \$99.1 million. We then add, as explained above, the estimated 2,000 new DMEPOS suppliers that will enroll in the Medicare program each year. With an average bond cost of \$1,500, this adds another \$3 million. Thus, the annual costs of the surety bond

increases from \$99.1 million to \$102.1 million.

A surety charges its underwriting fee based on the penal sum of the bond. We have determined that for this type of surety bond the industry usually has an underwriting charge of 2 to 3 percent. We believe that there is little variation of the charge based on geographical location or type of DMEPOS supplier although the DMEPOS supplier's financial average soundness probably will be a factor in the rate charged by the surety for the bond. We are unable to make an estimate of the range of financial soundness of DMEPOS suppliers, or its impact on the cost of surety bonds for Medicare.

4. Paperwork Costs for DMEPOS Suppliers

As already stated, we estimate that 65,723 currently-enrolled DMEPOS suppliers and 2,000 new DMEPOS suppliers per year will be subject to the surety bond requirement. We estimated that the year 1 implementation costs will be approximately \$4.1 million and that the annual implementation costs thereafter to be approximately \$180,000 per year.

To calculate the cost associated with the implementation of the surety bond in year 1, we calculated the cost of completing the revised Medicare enrollment application (CMS-855S) at \$20 per hour along with our estimate that it will take on average 3 hours to complete the information collection associated with surety bond.

Using this information, we multiplied 65,723 currently-enrolled DMEPOS suppliers by 3 hours to derive the time associated with completing this new information collection requirement. The result was 197,169 hours (65,723 × 3 hours). We then multiplied the result (197,169) hours times \$20 per hour to calculate the costs for existing DMEPOS suppliers subject to the bonding requirement to complete the information collection associated with the implementation of the surety bond requirement. The result equaled \$3,943,380. Similarly, we used the same calculation for newly enrolling DMEPOS suppliers and calculated a costs of \$120,000 (2,000 suppliers × 3 hours × \$20 per hour). Finally, we are assuming that a maximum of 1,000 suppliers will incur costs to update or change their surety. The resulting costs would equal \$60,000 (1,000 suppliers × 3 hours × \$20 per hour). Thus, we estimate that the paperwork burden associated with the surety bond is \$4,063,380 (\$3,943,380 + \$120,000) in year one and \$180,000 annually thereafter.

5. Total Costs

Based on the information identified in sections IV.D.1. through IV.D.4. of this final rule, we estimate that the total cost of the surety bond requirement in its first year will be approximately \$106.2 million. The cost in each subsequent year will be roughly \$102.3 million.

E. Impact on Beneficiary Access

As already discussed, we believe that 6,848 DMEPOS suppliers will exit the Medicare program as a result of the implementation of accreditation, irrespective of whether these suppliers qualify for a surety bond exemption. This will result in 106,152 suppliers remaining in the Medicare program. Starting from this figure, we will calculate the number of DMEPOS suppliers that will leave Medicare due to the surety bond requirement.

We previously estimated that 25,188 DMEPOS suppliers will exit the Medicare program due to the combined costs of the surety bond and accreditation requirements. This leaves 80,964 suppliers. If we were to assume that there are 15,241 suppliers that are eligible for an exception to the bonding requirement, 65,723 DMEPOS suppliers are left. We thus estimate that this many DMEPOS suppliers will remain in Medicare after the implementation of the surety bond requirement.

We believe that the majority of remaining DMEPOS suppliers will consist of three categories of suppliers: Pharmacies (whether large or small, chain or non-chain), physicians and NPPs who qualify for an exemption, and larger medical supply companies. Pharmacies and large medical supply companies are likely to remain in the Medicare program because, notwithstanding the cost of the bond, they have the revenues to more than offset said cost—including even those large chain pharmacies that will need to obtain a bond for each location. Those physicians and NPPs that qualify for an exemption, meanwhile, are likely to remain in Medicare for this very reason. We believe that many beneficiaries in non-rural areas, where there are a high number of chain pharmacies—and, of course, a high percentage of physician and NPP practices—will continue to have access to DMEPOS supplies offered by these suppliers.

We estimate that approximately 20 percent of all DMEPOS suppliers are located in rural areas. We believe that the majority of DMEPOS suppliers in these areas are physician and NPPs, community pharmacies, and small medical supply distributors. For reasons already stated, many physicians and

NPPs will be exempt from the surety bond requirement; as such, we do not foresee a significant decrease in the number of such rural practitioners who offer DMEPOS suppliers. Nor do we expect many community pharmacies to exit the program notwithstanding the need for them to obtain a bond. We do however recognize that a number of rural medical supply companies may withdraw from the Medicare program. However, we believe that much of the business conducted by these suppliers will be assumed by community pharmacies, physicians, NPPs, and mail-order medical supply companies; in fact, it is quite common for rural beneficiaries who are unable to access a local medical supply company to utilize mail-order services.

While we expect that some DMEPOS suppliers in rural areas will exit the Medicare program, we do not believe that this figure will be significant, nor do we believe that overall beneficiary access will be substantially curtailed. Nevertheless, to help Medicare beneficiaries in both rural and non-rural areas locate a qualified replacement DMEPOS supplier, we will conduct education and outreach efforts to ease the transition from a departing DMEPOS supplier to a DMEPOS supplier that will remain in the program.

The category of DMEPOS suppliers that will arguably be most affected by the imposition of the surety bond requirement, at least in terms of gross expenditures, is large, publicly-traded chain pharmacies. These suppliers, as already discussed, do not qualify for a surety bond exemption. Some chains have several hundred locations. Thus, for instance, a pharmacy chain that has 300 locations, each denoted by a separate NPI, will be required to obtain a bond for each site. With an annual bond cost of \$1,500, the yearly cost of the surety bond requirement for the chain organization would be \$450,000.

F. Alternatives Considered for DMEPOS Suppliers

The RFA requires agencies to analyze options for the regulatory relief of small entities. In compliance with section 604 of the RFA, therefore, we have incorporated several options designed to minimize the burden of the surety bond requirement—both a stand-alone requirement and when implemented in conjunction with the accreditation provisions found at § 424.58.

First, with respect to accreditation, we have approved multiple accreditation organizations that serve smaller suppliers, as well as accreditation organizations that will be responsible for only surveying the streamlined

quality standards for compliance and not providing any consultative services that may increase the time and cost of the survey process. Also, we believe that unannounced surveys will reduce the time and cost involved in suppliers' receiving and reviewing documents prior to the survey.

Second, we have reduced the surety bond amount from \$65,000 to \$50,000, in part to ease the economic impact on small, rural DMEPOS suppliers. Rather than a \$2,000 per year cost for a surety bond, the establishment of a \$50,000 bond amount will reduce the annual cost to \$1,500. This reduction will not, in our view, will help ensure that small, DMEPOS suppliers continue to participate in the Medicare program.

Finally, we have established several exceptions to the surety bond requirement. These exemptions apply almost exclusively to small businesses—specifically, physician and NPP practices—and will no doubt ease the economic impact on such businesses in both rural and non-rural areas.

For reasons already explained, we were unable to establish exceptions to the bond requirement for other types of small entities, such as single-site community pharmacies. Nevertheless, by reducing the bond amount to the statutory minimum and by creating those exceptions that were legally permissible, we believe that we have taken concrete steps to ease the economic burden on small business to the maximum extent permitted by section 4312(a) of the BBA.

G. Uncertainty

There are at least four important sources of uncertainty in estimating the impact of surety bonds on DMEPOS suppliers. First, our estimates assume that the vast majority of current DMEPOS suppliers with positive Medicare payments will obtain and maintain a surety bond. As noted previously, many suppliers that currently have NSC supplier numbers are small, receive relatively little in Medicare payments, and do not specialize in DMEPOS. We assume that suppliers that currently receive no Medicare allowed charges will choose not to seek accreditation and a surety bond, and that many of the suppliers with allowed charges between \$1 and \$10,000 may decide not to incur the costs of accreditation.

Second, it is unclear how high or low surety bond or accreditation fees will be in the future. With required

accreditation causing more suppliers to seek accreditation, fees may fall if the accreditation organizations can enjoy economies of scale as they expand. This would lessen the impact on DMEPOS suppliers.

Third, the timing of competitive bidding may impact some DMEPOS suppliers' decision to continue to participate in the Medicare program. With the delay in the implementation of the Competitive Bidding Program as mandated by the MIPPA, we cannot calculate the impact that competitive bidding will have on existing DMEPOS suppliers continuing to participate in Medicare.

Finally, as discussed in section B of this impact analysis, we recognize that the percentage breakdown of allowed charges in 2005, as described in Table 4, may not be precisely the same as that which currently exists. It is certainly possible that the use of allowed charge data based on the NPI, rather than the 6-digit NSC number, will lead to a greater percentage of suppliers falling into the category of "small billers," for a single location (that is, an NPI-specific site) is generally likely to receive less reimbursement than an entity with multiple locations (that is, an entity denoted by a 6-digit NSC number).

Yet we believe that any such increase in the percentage of small billers will be minor. Many of these NPI-specific sites are locations that are part of large chain pharmacy organizations; such pharmacy locations often receive significant levels of Medicare reimbursement. In other words, while the change from the 6-digit NSC number to the NPI as the primary supplier identifier greatly increased the number of DMEPOS suppliers, many of these "new" suppliers were chain pharmacy locations that could not be classified as "small billers." As such, we are not entirely convinced that the increase in DMEPOS suppliers will result in a concomitant rise in the overall percentage of small billers. Still, we cannot rule out this possibility and thus concede that this issue represented an element of uncertainty in our impact analysis.

H. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 6 we have prepared an accounting statement. This statement, it should be noted, addresses only the costs and monetary transfers

associated with the surety bond requirement. It does not address, from a strictly monetary standpoint, the prospective financial benefits of the bond requirement. While we, as explained in the preamble, expects the bond requirement to provide significant program integrity benefits for Medicare on the grounds that we will be able to recoup otherwise uncollectible overpayments, CMPs, and assessments and that unscrupulous DMEPOS suppliers will be deterred from entering the Medicare program, it is impossible for us to quantify these benefits in monetary terms. We cannot predict how many potentially fraudulent DMEPOS suppliers will be kept out of the Medicare program, nor can we determine for certain how much money Medicare will recoup from said overpayments, CMPs, and assessments.

The cost section addresses the data discussed in section IV.D. of this final rule. The monetary transfers section contains information on the transfer of Medicare reimbursement from those DMEPOS suppliers that will leave the Medicare program as a result of the surety bond requirement (as described in section IV.D.1. of this final rule) to those DMEPOS suppliers that will assume the DMEPOS business of these departing suppliers. As previously stated, we estimated that approximately 30 percent (or 4,577) of the approximately 15,255 DMEPOS suppliers that receive between \$10,000 and \$24,999 annually from Medicare will exit the Medicare program because of the combined costs associated with the surety bond requirement and accreditation. We further estimated that roughly 40 percent (or 20,611) of the approximately 51,528 suppliers that receive between \$1 and \$9,999 annually from Medicare will exit the Medicare program because of these combined costs. For purposes of this assessment statement, we used the midpoint of the two aforementioned categories (or \$17,500 and \$5,000, respectively) as the amount of annual reimbursement these suppliers receive. As such, we multiplied 20,611 by \$5,000 and arrived at \$103,055,000, and multiplied 4,577 by \$17,500 to obtain a figure of \$80,097,500. Therefore, we estimate that approximately \$183.2 million in annual Medicare reimbursement will be paid to existing or new DMEPOS suppliers in lieu of those suppliers exiting the Medicare program.

TABLE 6—CLASSIFICATION OF ESTIMATED EXPENDITURES AND COSTS

Category Surety bond requirement	In millions
COSTS	
Annualized Monetized Transfers Using the 7% Discount Rate	102.8.
Annualized Monetized Transfers Using the 3% Discount Rate	102.7.
Who is Affected?	DMEPOS Suppliers.
TRANSFERS	
Annualized Monetized Transfers Using the 7% Discount Rate	183.2.
Annualized Monetized Transfers Using the 3% Discount Rate	183.2.
From Who to Whom?	Departing DMEPOS Suppliers to Current or New DMEPOS Suppliers.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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 chapter IV, as set forth below:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority citation for part 424 is revised to read as follows:

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

Subpart D—To Whom Payment Is Ordinarily Made

■ 2. Section 424.57 is amended by—

■ A. Amending paragraph (a) by adding the following definitions in alphabetical order: “Assessment”, “Authorized surety”, “Civil money penalty”, “Final adverse action”, “Government-operated supplier”, “National Supplier Clearinghouse (NSC)”, “Penal sum”, “Rider”, “Sufficient evidence”, “Surety bond”, and “Unpaid claim”.

■ B. In paragraph (a), in the definition of “DMEPOS supplier”, the cross-reference “paragraph (c)” is removed and the cross-reference “paragraphs (c) and (d)” are added in its place.

■ C. Adding paragraph (c)(26).

■ D. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f).

■ D. Adding a new paragraph (d).

■ E. In newly redesignated paragraph (e), the cross-reference “paragraphs (b) and (c)” is removed and the cross-reference “paragraphs (b), (c), and (d)” is added in its place.

The additions read as follows:

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

(a) * * *

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.

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.

* * * * *

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 or suspension by an accreditation organization;

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

(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.

* * * * *

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

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

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

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.

* * * * *

(c) * * *

(26) Must meet the surety bond requirements specified in paragraph (d) of this section.

* * * * *

(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.

(i) *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 supplier enrolling in the Medicare program, making a change in ownership, or responding to a revalidation or reenrollment request must submit to the NSC a surety bond from an authorized surety of \$50,000 and if required by the NSC 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 0938-0685). The term of the initial surety bond must be effective on the date that the application is submitted to the NSC.

(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 NSC a surety bond from an authorized surety of \$50,000 and if required by the NSC 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 NSC.

(iii) A DMEPOS supplier enrolling a new practice location must submit to the NSC 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 NSC as described in paragraph (d)(3)(ii) of this section.

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

(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 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 NSC and the surety.

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

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

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

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

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

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

(10) *Parties to the surety bond.* The surety bond must name the DMEPOS supplier as Principal, CMS as 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 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 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 NSC 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.

* * * * *

Authority: Catalog of Federal Domestic Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: May 1, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: September 18, 2008.

Michael O. Leavitt,

Secretary.

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