TABLE 3.—SITES WHERE ACTION OCCURRED—Continued

| | | |
|---|---|---|
| CS–3 (CG)* | CS–16/CS–17/DDOU* | FS–20* |
| CS–4* | CS–22 | FS–23 |
| CS–4 (CG)/FS–1 (CG)* | FS–2 | FS–25* |
| CS–5* | FS–4 | FS–26 (CG) |
| CS–6*/FS–22 | FS–7 | LF–4 |
| CS–6 (CG)* | FS–9* | SD–2/FS–6/FS–8 |
| CS–8/FS–21* | FS–13 | SD–3/FTA–3/CY–4 |

Key: CS = Chemical Spill.
CY = Coal Yard.
DDOU = Drum Disposal Operable Unit.
FS = Fuel Spill.
FTA = Fire Training Area.
LF = Landfill.
SD = Storm Drain.
USCG = U.S. Coast Guard.
* Includes structure(s)

[FR Doc. E7–14677 Filed 7–31–07; 8:45 am]
BILLING CODE 6560–50–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

### 42 CFR Part 424

**[CMS–6006–P]**

**RIN 0938–AO84**

## 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:** Proposed rule.

**SUMMARY:** Consistent with section 4312(a) of the Balanced Budget Act of 1997 (BBA), this proposed rule implements section 1834(a)(16)(B) of the Social Security Act (the Act) by requiring all Medicare suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to furnish CMS with a surety bond. We believe that this requirement would limit the Medicare program risk to fraudulent DME suppliers; 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 its 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.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 1, 2007.

**ADDRESSES:** In commenting, please refer to file code CMS–6006–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6006–P, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6006-P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

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

**SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–6006–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential

business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

**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).

A supplier that furnishes durable medical equipment, prosthetics, orthotics, and suppliers (DMEPOS) is one category of supplier. Other supplier categories may include, for example, physicians, nurse practitioners, 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.

For purposes of the DMEPOS supplier standards, the term ''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. This proposed rule would apply to all DMEPOS suppliers. Those individuals or entities that do not furnish DMEPOS items but furnish other types of health care services only (for example, physician services or nurse practitioner 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 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), 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 replacement of required because of a change in 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.

## II. General Overview of the Proposed Rule

In the January 20, 1998 **Federal Register** (63 FR 2926), we published a proposed rule 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 DMEPOS supplier to provide us, on a continuing basis, with a surety bond of at least $65,000, as a condition of the issuance or renewal of a provider number. Section 1834(a)(16), 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. However, since section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (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, this rule was never finalized.

As a result, we are proposing this rule at this time to implement the statutory

surety bond requirement set forth in section 1834(a)(16)(B) of the Act. However, given the lapse in time between the statutory effective date and date of this proposed rule, we believe that it appropriate to adjust the amount of the surety bond from $50,000 in 1997 by the Consumer Price Index (CPI) and calculate a higher surety bond amount. In doing so, we have adjusted the initial surety bond amount of $50,000 by the CPI and have calculated that a $50,000 surety bond in 1997 would equate to a surety bond value of $64,907.17 in 2007. Further, we have rounded the calculated value of $64,907.17 to the nearest thousand to derive a surety bond amount of $65,000. We believe 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.

**III. Provisions of the Proposed Rule**

[If you choose to comment on issues in this section, please include the caption ''PROVISIONS'' at the beginning of your comments.]

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

In § 424.57, we are proposing to define the following terms as they are used throughout this 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 are proposing to define ''unauthorized surety'', we clarify that we do 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 propose to add new (c)(26). Specifically, we propose that—

- § 424.57(c)(26) would specify the requirements for a DMEPOS supplier seeking to become a Medicare-enrolled DMEPOS supplier.
- § 424.57(c)(26)(i) would clarify the minimum requirements for a DMEPOS supplier. We specify 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 must be in the amount of $65,000 and in the form specified by the Secretary. While we are proposing 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 are not proposing to adjust the base surety bond amount by the CPI annually thereafter. However, we will consider whether any additional adjustments (increase or decrease) in the base surety amount are necessary in through a future rulemaking effort.
- § 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.
- § 424.57(c)(26)(i)(B) specifies how a change of ownership interest affects the DMEPOS supplier.
- § 424.57(c)(26)(i)(C) specifies 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.
- § 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 does not qualify for an exception must submit a surety bond. We have determined that an exception of 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 the 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.

Nevertheless, government-operated DMEPOS suppliers with a poor history of paying their Medicare debts are subject to the surety bond requirement. While the Medicare contractors collect overpayments in full or as part of a predetermined payment schedule, such as an extended repayment schedule, some DMEPOS suppliers default on their scheduled repayment plan. When this occurs and the repayment schedule cannot be extended, we will place the DMEPOS supplier on 100 percent payment withholding. In the event that a government-operated DMEPOS supplier is placed on 100 percent payment withholding due to non-payment of an overpayment, the DMEPOS supplier will also be required to obtain a surety bond. 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 anecdotal 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 are soliciting comments on whether we should consider establishing an exception to the surety bond requirement for certain physicians and non-physician practitioners, such as those that occasionally furnish DMEPOS items for the convenience of their patients. While we are seeking comments about establishing an exception for physicians and non-physician practitioners, we are not certain about the scope of the exception that should be established for physicians and non-physician practitioners. As such, we are soliciting comments on how to identify whether a physician or non-physician practitioner should be given an exception to the surety bond requirement. We also are soliciting comments on any other appropriate criteria that we should use when considering the establishment of an exception to this requirement for certain physicians and non-physician practitioners.
- We are soliciting comments on whether we should establish an exception to the surety bond requirement for licensed pharmacists who furnish DMEPOS items for the convenience of their patients. We also are soliciting comments on any other appropriate criteria that we should consider in establishing an exception to this requirement for licensed pharmacists.
- We are also soliciting comments on any other appropriate criteria that we should consider in establishing an exception to this requirement as to these types of suppliers.
- We are also soliciting comment on whether we should establish an exception to the surety bond requirement for large, publicly traded chain suppliers of DMEPOS. We are soliciting comments on any appropriate criteria that we should consider in waiving this requirement as to these types of suppliers.
- We are also soliciting comments on the appropriate criteria that we may use for establishing exceptions for other types of DMEPOS suppliers from the requirement to purchase a surety bond.
- § 424.57(c)(26)(iii) would specify the terms of a bond submitted by a DMEPOS supplier.
- § 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 are proposing that surety bonds be issued in an amount equal to $65,000, the surety is liable to us for up to $65,000.
- § 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 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.

Also, a supplier or surety may not place any limitations on the surety bond except as 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.

- § 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.
- § 424.57(c)(26)(vii) would specify that the surety must provide information regarding their physical location including their name, street address, city, state, and zip code and, if different, their mailing address, including name, post office box, city, state, and zip code.
- § 424.57(c)(26)(viii) would specify the submission date and the term of the DMEPOS supplier bond.
- § 424.57(c)(26)(viii)(A) would specify that each enrolled DMEPOS supplier that does not meet the criteria for exception must submit to the NSC an initial surety bond before (60 days following the publication date of the final rule).
- § 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.
- § 424.57(c)(26)(ix) would specify the loss of a DMEPOS supplier exception. A DMEPOS supplier that no longer qualifies for a 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 and exception.
- § 424.57(c)(26)(x) would specify the conditions under which a DMEPOS supplier changes a surety.
- § 424.57(c)(26)(xi) would specify who the parties are to the bond.
- § 424.57(c)(26)(xii) would specify the effect of a DMEPOS supplier's failure to obtain, maintain, and timely file a surety bond.
- § 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.
- § 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.
- § 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 that it has a bond and that it meets the requirements of this 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 it 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.
- § 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 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 are soliciting 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 are soliciting comments on how to establish elevated amounts of surety bonds for higher risk DMEPOS suppliers. We are considering the option of establishing elevated amounts of the surety bond at a rate of $65,000 per high risk factor. Also, we are soliciting comments on determining the high risk factors that should be used. We suggest several potential high risk factors below, but would consider any comments on these factors, as well as suggestions for additional factors.

We are considering a $65,000 increase in the surety amount for each occurrence when a DMEPOS supplier has a 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). Examples of final adverse actions include, but are not limited to, Federal and State criminal convictions related to the delivery of health care item or service, formal or official actions, such as 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.

- 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. For example, a DMEPOS supplier with three different revocations during the proceeding 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 x $65,000) for the multiple revocations.

In addition to the elevated risk-based model described above, we are soliciting 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 surety by an appropriate amount per prior sanction.

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

We are also soliciting 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 are soliciting comments on the appropriate period of time that 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 are proposing to establish a timeframe of 5 years.

## IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide a 60-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 are soliciting public comment on each of the following issues pertaining to the information collection requirements discussed in this proposed rule.

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

Section 424.57(c)(26) outlines the surety bond requirements for DMEPOS suppliers. Specifically, § 424.57(c)(26) states that each Medicare-enrolled DMEPOS supplier must obtain and furnish to the National Supplier Clearinghouse (NSC) a surety bond in the amount of $65,000. 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(c)(26)(i) outlines the minimum requirements for a DMEPOS supplier seeking to become a Medicare-enrolled DMEPOS supplier. Section 424.57(c)(26)(i)(A) requires a DMEPOS supplier seeking to become a Medicare-enrolled supplier to submit documentation verifying possession of a surety bond with its Medicare enrollment application. Section 424.57(c)(26)(i)(B) states that a DMEPOS supplier seeking to become an enrolled supplier through the purchase or transfer of assets or ownership interest of an enrolled or formerly enrolled DMEPOS supplier 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 the effective date of the surety bond as validated by the NSC rather than the date of the change of ownership.

Section 424.57(c)(26)(i)(C) requires a DMEPOS supplier that is seeking to enroll a new location to obtain a new surety bond for that new location since

that new location will also require a unique NPI.

Section 424.57(c)(26)(v) discusses the change of ownership process. DMEPOS suppliers are required to submit an updated enrollment application if they have undergone a change in ownership. As part of the updated application, the new owners are required to obtain and submit a surety bond to the NSC that is effective with the date of the change of ownership in order to obtain or retain billing privileges. If the bond is effective at a later date, the effective date of the change of ownership by the new DMEPOS supplier number is the date of the surety bond as validated by the NSC rather than the date of the transfer of ownership.

The burden associated with all of the requirements in § 424.57(c)(26)(i) through (iv) is the time and effort required for a DMEPOS supplier to obtain a surety bond and to submit the bond as part of its Medicare Enrollment Application.

A DMEPOS supplier is required to submit a Medicare enrollment application if it is:

- Enrolling in Medicare for the first time as a DMEPOS supplier.
- Currently enrolled in Medicare as a DMEPOS supplier and needs to report changes to its business, other than enrolling a new business location. Changes must be reported within 30 days of the effective date of the change.
- Currently enrolled in Medicare as a DMEPOS supplier but need to enroll a new business location. This is to add a new location to an organization with a TIN already listed with the NSC. (This differs from changing information on an already existing location.)
- Currently enrolled in Medicare as a DMEPOS supplier and has been asked to verify or update its information. This includes situations where it has been asked to attest that its organization is still eligible to receive Medicare payments.
- Reactivating its Medicare DMEPOS supplier billing number (for example, its Medicare supplier billing number was deactivated because of non-billing, and they wish to receive payment from Medicare for future claims).
- Voluntarily terminating its Medicare DMEPOS supplier billing number.

The burden associated with submitting an updated enrollment application is approved under OMB control number 0938–0685 with an expiration date of April 30, 2009. We believe the requirements in § 424.57(c)(26) impose a marginal increase in burden as DMEPOS suppliers are already required to submit the Medicare Enrollment Application.

We estimate the burden associated with the requirements in § 424.57(c)(26)(i) through (v) to be 60 minutes per DMEPOS supplier. In addition, we estimate that approximately 116,500 DMEPOS suppliers will comply with these requirements. Therefore, the estimated total annual burden is 116,500 hours.

Section 424.57(c)(26)(v) 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 30 minutes. In addition, we anticipate that 1,000 suppliers will draft and submit the necessary documentation. We estimate the total annual burden to be 500 hours.

Section 424.57(c)(26)(ix) requires a DMEPOS supplier that no longer qualifies as a government-operated DMEPOS supplier to submit a surety bond to the NSC within 60 days of receiving notice that it no longer qualifies for a 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 a exception. We estimate the burden associated with this requirement to be 30 minutes. In addition, we anticipate that 10 suppliers will draft and submit the necessary documentation. We estimate the total annual burden to be 5 hours.

Section 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 30 minutes. In addition, we anticipate that 1,000 suppliers will comply with this requirement. We estimate the total annual burden to be 500 hours.

Section 424.57(c)(26)(xiii) imposes recordkeeping and reporting requirements. Section 424.57(c)(26)(xvi)(A) 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.

The burden associated with producing the documents upon request from CMS is estimated to be 30 minutes per DMEPOS supplier. We estimate that 1,000 DMEPOS suppliers will be asked to submit the requested documentation. The total annual burden associated with this requirement is estimated to be 500 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

| Regulation section | OMB control number | Number of respondents | Number of responses | Total annual burden hours |
|---|---|---|---|---|
| 424.57(c)(26)(i through iv) | 0938–New | 116,500 | 116,500 | 116,500 |
| | 0938–0685 | 400,000 | 400,000 | 1,000,000 |
| § 424.57(c)(26)(v) | 0938–New | 1,000 | 1,000 | 500 |
| § 424.57(c)(26)(ix) | 0938–New | 10 | 10 | 5 |
| § 424.57(c)(26)(xi) | 0938–New | 1,000 | 1,000 | 500 |
| § 424.57(c)(26)(xii) | 0938–New | 1,000 | 1,000 | 500 |
| Total | | | | 1,118,005 |

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

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group Attn.: William N. Parham, III, CMS–6006–P Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Attn.: Carolyn Lovett, CMS Desk Officer, CMS–6006–P, *carolyn_lovett@omb.eop.gov*. Fax (202) 395–6974.

## V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## VI. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption ''IMPACT'' at the beginning of your comments.]

### *A. Introduction*

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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).

We estimate that the surety bond requirement as specified in § 424.57(c)(26)(i) would cost approximately $198 million annually. This cost is based on the number of suppliers furnishing DMEPOS (approximately 99,000) multiplied by the average annual cost of a bond ($2,000). Based on information received from the industry, we estimated that the average bond cost is approximately $2,000 or 3 percent of the bond's value. We are seeking comments on the accuracy of this estimate.

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 soundness probably would 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.

While it is not possible to estimate with accuracy the savings that would result from the implementation of this proposed rule, we believe that surety bonds combined with other program integrity efforts should reduce the number of DMEPOS suppliers that currently bill Medicare fraudulently because DMEPOS suppliers would be subject to the scrutiny of surety companies. In addition, surety bonds would serve as a deterrent to others tempted to engage in fraudulent behavior because of the cost of the bond and the possibility of the need to post collateral.

The RFA requires agencies to analyze options for 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.

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 603 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 proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Table 2 examines the allowed charges to the unique billing numbers (a DMEPOS supplier may have multiple locations, for example, a chain organization, but use only one unique billing number), the vast majority of DMEPOS suppliers are small entities (based on Medicare reimbursement alone).

TABLE 2.—TOTAL NUMBER OF SUPPLIERS ARRANGED BY ALLOWED CHARGES FOR DATES OF SERVICE (JANUARY THROUGH DECEMBER 2005 BASED ON UNIQUE BILLING NUMBERS)

| Allowed charge | Number of suppliers reimbursed for DME | Number of DMEPOS suppliers reimbursed for non-DME only |
|---|---|---|
| $0 | 2,016 | 4,655 |
| $0.01–$999 | 2,544 | 6,624 |
| $1,000–$2,499 | 2,099 | 4,993 |
| $2,500–$4,999 | 2,285 | 4,459 |
| $5,000–$9,999 | 2,964 | 4,153 |
| $10,000–$24,999 | 4,568 | 4,328 |
| $25,000–$49,999 | 3,378 | 2,100 |
| $50,000–$99,999 | 2,780 | 1,245 |

TABLE 2.—TOTAL NUMBER OF SUPPLIERS ARRANGED BY ALLOWED CHARGES FOR DATES OF SERVICE (JANUARY THROUGH DECEMBER 2005 BASED ON UNIQUE BILLING NUMBERS)—Continued

| Allowed charge | Number of suppliers reimbursed for DME | Number of DMEPOS suppliers reimbursed for non-DME only |
|---|---|---|
| $100,000–$499,999 | 5,955 | 1,191 |
| $500,000–$999,999 | 1,762 | 220 |
| $1,000,000–4,999,999 | 1,345 | 105 |
| $5,000,000 or more | 208 | 7 |
| Total | 31,904 | 34,080 |

In reviewing Table 2, the term, durable medical equipment (DME) is defined at section 1861(n) of the Act. This definition, in part, excludes from coverage as DME, 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—

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to an individual in the absence of an illness or injury; and
- 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.

Conversely, suppliers of non-DME only refers to items or services furnished by prosthetics, orthotist, and supplies found in section 1861(s)(5) of the Act.

As of April 2007, there were 116,471 individual DMEPOS suppliers. However, due to the affiliation of some DMEPOS suppliers with chains, there were only approximately 65,984 unique billing numbers (31,904 + 34,080). According to Table 2, for fiscal year 2005, approximately 15,800 billing suppliers with allowed charges of less than $1,000 (2,016 + 4,655 + 2,544 + 6,624) would have been required to submit a surety bond if this proposed rule is implemented. Based on our analysis, we anticipate that almost all of these DMEPOS suppliers, excluding physician and other practitioners as defined in section 1842(b)(18)(C) of the Act, would elect to cease their enrollment in Medicare because their bond cost would exceed their profit from dealing in Medicare-covered items. Furthermore, the majority of the 13,836 DMEPOS suppliers with allowed charges $1,000 to $4,999 (2,099 + 4,993 + 2,285 + 4,459) would not recoup their bond costs from Medicare business. Also, a portion of DMEPOS suppliers in higher charge categories may decide to forego their Medicare enrollment as a DMEPOS supplier because of the added cost of the bond. 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. We believe that approximately 22 percent of the 15,000 DMEPOS suppliers are located in rural areas. We further believe that most, if not all, of the Medicare business conducted by these DMEPOS suppliers would be assumed by other DMEPOS suppliers remaining in the program (for example, by mail order or via the World Wide Web). To assist Medicare beneficiaries locate a replacement DMEPOS supplier who qualifies to continue to participate in the Medicare program, we would conduct education and outreach efforts to ease the transition from a departing DMEPOS supplier to a DMEPOS supplier that will remain in the program.

Section 202 of the Unfunded Mandates Reform Act 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 approximately $120 million. This proposed rule would have no consequential effect on State, local, or tribal governments. We believe that the private sector costs of this rule are greater than these thresholds.

Executive Order 13132 established certain requirements that an agency must meet when it issues a proposed rule (and subsequent 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.

*B. Alternatives Considered*

As specified in section 4312(a) of the BBA, a surety bond is required as long as an entity remains a DMEPOS supplier. In the proposed rule published in the January 20, 1998 **Federal Register** (63 FR 2926), we proposed that a DMEPOS supplier would be required to obtain a surety bond equal to $65,000 per TIN, the basic identification element for a DMEPOS supplier. However, with the more recent assignment of the National Provider Identifier (NPI), the TIN is no longer the basic identification element for a DMEPOS supplier. Accordingly, requiring a surety bond for each TIN is not consistent with the Agency's NPI implementation or with current Medicare regulations. In the Agency's Medicare Subpart Expectation Paper, the Agency states that each enrolled supplier of DMEPOS that is a covered entity under HIPAA must designate each practice location (if it has more than one) as a subpart and ensure that each subpart obtains its own unique NPI. Further, § 424.57(b)(1) requires that each practice location of a supplier of DMEPOS (if it has more than one) must, by law, be separately enrolled in Medicare and have its own unique Medicare billing number or NPI.

Accordingly, we are proposing a $65,000 bond per DMEPOS supplier NPI; the basic identification element for a DMEPOS supplier.

*C. Conclusion*

Any burden imposed by this proposed rule is legislatively mandated, and we have taken steps to ensure that the burden on DMEPOS suppliers is minimal. Surety bonds use a private sector mechanism to screen DMEPOS

suppliers that provide items and services to Medicare's beneficiaries and help ensure that they are financially responsible. Also, surety bonds help to ensure that the government can recoup taxpayer money from DME suppliers who default on their obligations to the Medicare program.

We use a financial guarantee bond for the return of overpayments regardless of their source. A guarantee bond would ensure more scrutiny and benefits to Medicare. In underwriting this type of bond, a surety would pay particular attention to financial statements, business practices, and overpayment history. This scrutiny would provide the Medicare program with some of the following benefits: (1) Proprietors who do not have relevant program experience would be deterred from entering the program; (2) existing Medicare DMEPOS suppliers would be examined as to their business soundness; and (3) DMEPOS suppliers with overpayments that do not repay their overpayments would be unlikely to obtain a subsequent surety bond and would be removed from the Medicare business. Generally, all DMEPOS suppliers would be deterred from incurring overpayments and would have an incentive to repay any overpayments that are discovered.

Screening by a surety appears to be most useful for new DMEPOS suppliers. The large number of DMEPOS suppliers entering the Medicare program with little scrutiny makes requiring surety bonds a useful mechanism for screening DMEPOS suppliers already in the program. However, the value of this scrutiny would probably diminish with a DMEPOS supplier's continued participation in Medicare.

We believe that the impact on benefit payments is indeterminable. In accordance with the provisions of Executive Order 12866, this rule 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 proposes to amend 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) to add the following definitions in alphabetical order: ''Assessment'', ''Authorized surety'', ''Civil money penalty'', ''Government-operated supplier'', ''National Supplier Clearinghouse (NSC)'', ''Penal sum'', ''Rider'', ''Sufficient evidence'', ''Surety bond'', ''Unauthorized surety'', and ''Unpaid claim''.

B. Adding paragraph (c)(26).

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—

(1) 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; and

(2) Has not been determined by CMS to be an unauthorized surety under this section.

*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.

* * * * *

*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 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.

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

*Sufficient evidence* 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.

*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.

*Unauthorized surety* mean a surety that—

(1) Fails, upon written request by the National Supplier Clearinghouse or CMS, to furnish confirmation of the issuance of a surety bond within 30 days.

(2) Fails to furnish evidence of the validity and accuracy of information appearing on a surety bond that a supplier has presented to the NSC or CMS showing the company as surety on the bond.

(3) Fails 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.

*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) *Surety bond requirements for DMEPOS suppliers.* Except as provided in paragraph (c)(26)(ii) of this section, each DMEPOS supplier that is a Medicare-enrolled DMEPOS supplier must obtain and furnish to the NSC, a surety bond of at least $65,000, from an authorized surety, as defined in paragraph (a) of this section of this section, for each NPI issued by Medicare.

(i) *Minimum requirements for a DMEPOS supplier.*

(A) A supplier enrolling in the Medicare program, making a change in their existing enrollment information, or responding to a revalidation or reenrollment request must submit a surety bond of $65,000 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.

(B) A supplier that seeks to become an enrolled DMEPOS supplier through purchase or transfer of assets or ownership interest 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 no sooner than the effective date of the surety bond as validated by the NSC.

(C) A DMEPOS supplier seeking to enroll a new location under a tax identification number for which it already has a DMEPOS surety bond in place may obtain a new surety bond or can submit an amendment or rider to the existing bond, showing that the new location is covered by an additional $65,000 surety bond.

(ii) *Exception for Government-operated suppliers.* Government-operated DMEPOS suppliers are provided an exception of 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.

(iii) *Terms of the surety bond.* 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 ($65,000) and surety and DMEPOS supplier responsibility as set forth in this section. CMS requires a supplier to submit a bond that on its face reflects the requirements of this section. CMS will revoke or deny a DMEPOS supplier's billing privileges based upon the submission of a bond that does not reflect the requirements of this section.

(iv) *Specific surety bond requirements.*

(A) The bond must guarantee that the surety must, 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:

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

(*2*) The amount of any unpaid claims, CMPs, or assessments imposed by CMS or OIG on the DMEPOS supplier, plus accrued interest.

(B) The bond must provide the following: The 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, provided CMS or OIG make a written demand for payment from the surety during the term of the bond except or after such term in accordance with paragraph (c)(26)(iv)(C) of this section.

(C) If the DMEPOS supplier fails to furnish a bond meeting the requirements of this subpart, 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—

(*1*) 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

(*2*) 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.

(v) *Cancellation of a bond.* The bond may be canceled by written notice from the DMEPOS supplier to the NSC and the surety. The DMEPOS supplier must provide written notice at least 30 days before the effective date of the action to the NSC and the surety. 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. The bond is automatically canceled and the surety is excused from any liability for future claims after the termination effective date. If CMS receives notification of a lapse in bond coverage from the surety, the DMEPOS supplier's billing privileges will be revoked. The surety must immediately notify the NSC if there is a lapse in bond coverage. The liability of the DMEPOS supplier and the surety to CMS is not extinguished by any of the following:

(A) Any action by the DMEPOS supplier or the surety to make amendment to a conforming bond that will terminate or limit the scope or term of the bond in a manner resulting in the bond no longer conforming to this regulation.

(B) The DMEPOS supplier's failure to continue to meet the requirements of paragraph (c)(26)(i) of this section or CMS determination that the surety is an unauthorized surety as defined in paragraph (a) of this section.

(C) Revocation of the DMEPOS supplier's billing privileges.

(D) Any action by CMS to suspend, offset, or otherwise recover payments to the DMEPOS supplier unless the action results in complete and final recovery of the debt.

(E) Any action by the DMEPOS supplier to—

(*1*) Cease operation.

(*2*) Sell or transfer any asset or ownership interest.

(*3*) File for bankruptcy.

(*4*) Fail to pay the surety.

(F) Any fraud, misrepresentation, or negligence by the DMEPOS supplier in obtaining the surety bond or by the surety (or the surety's agent) in issuing the surety bond.

(G) The DMEPOS supplier's failure to exercise available appeal rights under Medicare or to assign the rights to the surety.

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

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

(viii) *Submission date and term of the DMEPOS supplier bond.*

(A) Each enrolled DMEPOS supplier that does not meet the criteria for an exception under paragraph (c)(26)(i)(D) of this section must submit to the NSC an initial surety bond before (60 days following the publication date of the final rule).

(B) 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.

(ix) *Loss of a DMEPOS supplier exception.* A DMEPOS supplier that no longer qualifies for an exception as a government-operated DMEPOS supplier described in paragraph (c)(26)(ii) of this section must submit a surety bond to the NSC within 60 days after it knows or has reason to know that it no longer meets the criteria for an exception.

(x) *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 bond. There must be no gap in the coverage of the bond periods. If a gap in coverage exists, the NSC will revoke the supplier's billing privileges and 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 will be 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.

(xi) *Parties to the bond.* The surety bond must name the DMEPOS supplier as Principal, CMS as Obligee, and the surety (and its heirs, executors, administrators, successors and assignees, jointly and severally) as surety.

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

(A) CMS will revoke 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 (d) of this section, the revocation will be effective with 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.

(B) CMS will deny 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.

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

(xiv) *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 will reimburse 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.

(xv) *Effect of review reversing determination.* If a DMEPOS supplier has paid CMS on the basis of liability incurred under a bond and to the extent the DMEPOS supplier that obtained the bond (or the surety under paragraph (m) of this section) is subsequently successful in appealing the determination that was the basis of the unpaid claim or CMPs, or assessment that caused the DMEPOS supplier to pay CMS under the bond, CMS would refund 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.

(Catalog of Federal Domestic Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 10, 2007.

**Leslie V. Norwalk,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: June 22, 2007.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. 07–3746 Filed 7–27–07; 4:00 pm]

**BILLING CODE 4120–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 2 and 15

**[ET Docket No. 03–201; FCC 07–117]**

### Unlicensed Devices and Equipment Approval

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document seeks comment on recommendations for a spectrum etiquette in a Further Notice of Proposed Rule Making (Further NPRM) in this proceeding. Specifically, the Further NPRM seeks comment on a specific spectrum etiquette for unlicensed transmitters that operate in the 915 MHz band. The goal is to ensure that the different types of unlicensed devices that operate in a band have an opportunity for spectrum access.

**DATES:** Comments must be filed on or before October 15, 2007, and reply comments must be filed on or before November 14, 2007.

**FOR FURTHER INFORMATION CONTACT:** Hugh Van Tuyl, Office of Engineering and Technology, (202) 418–7506, e-mail: *Hugh.VanTuyl@fcc.gov,* TTY (202) 418–2989.

**ADDRESSES:** You may submit comments, identified by ET Docket No. 03–201, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *E-mail:* [Optional: Include the E-mail address only if you plan to accept comments from the general public]. Include the docket number(s) in the subject line of the message.
- *Mail:* [Optional: Include the mailing address for paper, disk or CD–ROM submissions needed/requested by your Bureau or Office. Do not include the Office of the Secretary's mailing address here.]
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Further Notice of Proposed Rule Making,* ET Docket No. 03–201, FCC 07–117, adopted June 19, 2007, and released June 22, 2007. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.*

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the *Federal eRulemaking Portal: http://www.regulations.gov.* Filers should follow the instructions provided on the Web site for submitting comments.
- For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to *ecfs@fcc.gov,* and include the