555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: +202.637.2200 Fax: +202.637.2201
www.lw.com

2

LATHAM & WATKINS LLP

FIRM / AFFILIATE OFFICES

Barcelona	New Jersey
Brussels	New York
Chicago	Northern Virginia
Frankfurt	Orange County
Hamburg	Paris
Hong Kong	San Diego
London	San Francisco
Los Angeles	Shanghai
Madrid	Silicon Valley
Milan	Singapore
Moscow	Tokyo
Munich	Washington, D.C.

File No. 034731-0021

September 28, 2007

BY FEDERAL EXPRESS

Mr. Kerry N. Weems
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS—6006—P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments Regarding CMS—6006—P: "Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)"; PROVISIONS[1]

Dear Administrator Weems:

On behalf of our client, Rotech Healthcare Inc. ("Rotech" or the "Company"), we submit these comments on the proposed Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) under Medicare Part B.[2] The Company recognizes that the Centers for Medicare and Medicaid Services ("CMS" or the "Agency") is required to implement the requirements for posting a bond, which correspond to changes made to section 1834 of the Social Security Act by section 4312(a) of the Balanced Budget Act of 1997 (BBA).[3] CMS retains discretion, however, to tailor the rule to the industry it affects. Rotech urges CMS to carve out an exception for companies that are both large chains and publicly traded. Such publicly traded companies are not the "fly-by-night operators" properly targeted by this proposed rule. In addition, CMS should not adopt the provisions of the proposed rule that limit the continuity of Medicare payments and should allow a sufficient transition period to ensure that surety bonds are made available to DMEPOS suppliers.

Rotech is a large, publicly traded chain supplier of home medical equipment, including oxygen and respiratory products and a variety of other DMEPOS items. The Company provides equipment and services in 48 states through approximately 490 operating centers. It provides a

---

1 This is the caption commenters are to use to flag issues. Please also note that throughout this comment letter, we have suggested revisions to proposed regulatory provisions. Changes to the proposed language are *underlined and italicized*.

2 *See* 72 Fed. Reg. 42,001 (August 1, 2007).

3 *See* Pub. L. 105-33.

wide range of respiratory therapy equipment, including oxygen concentrators, liquid oxygen systems, portable oxygen systems, ventilator therapy systems, nebulizer equipment, and sleep disorder breathing therapy systems, for rent or sale. Rotech also provides a comprehensive line of durable medical equipment, such as hospital beds, wheelchairs, walkers, patient aids and other ancillary supplies, for rent or sale, to serve the specific needs of its patients. The Company's principal customers are older patients with breathing disorders, such as chronic obstructive pulmonary diseases, chronic bronchitis, emphysema, obstructive sleep apnea and other cardiopulmonary disorders.

The proposed rule reintroduces a surety bond requirement previously proposed in 1998.[4] According to CMS, the proposed rule is designed in part to reduce the risk to the Medicare program posed by fraudulent DMEPOS suppliers.[5] This goal, while laudable, is not advanced by the proposed rule as drafted. Moreover, the proposed rule imposes undue burdens on large financially responsible DMEPOS suppliers who have long been in partnership with the Medicare program. Based on the Company's broad experience with DMEPOS, obligations as a public company, and establishment as a national chain, the Company believes that an exception should apply to Rotech and other similarly situated DMEPOS suppliers. The Company respectfully submits the following recommendations for CMS's consideration:

(1) **CMS Should Develop an Exception for Public Companies That Are Chain Organizations.** CMS should implement an exception for large, publicly traded chain suppliers of DMEPOS. Public companies undergo rigorous review both by the Securities and Exchange Commission ("SEC") and by the investing public. The transparency that results should assure CMS that publicly traded companies are not the kinds of companies Congress intended to target with the surety bond requirement. Not only are there additional assurances for public companies, but there have also been developments in the quality standards and accreditation process for DMEPOS suppliers that help to secure financial integrity. For example, new quality standards give CMS ample assurances of reliability not available when this surety bond requirement was introduced by Congress in 1998. Such new developments in oversight and increased awareness on the part of the DMEPOS community result in less risk to CMS of overpayments or fraudulent suppliers.

(2) **CMS Should Not Adopt the Proposal Limiting Continuity of Medicare Payments.** According to the rule's preamble, CMS's proposed 42 C.F.R. § 424.57(c)(26)(v) prohibits Medicare payments for any lapses in bond coverage. Although the provision relates to enrollment, it would penalize suppliers by considering reimbursed services during a lapse in bond coverage as overpayments. This results in a windfall for the Government and burdens beneficiaries who would be required to return products they need. Further, a gap

---

4 *See* 63 Fed. Reg. 2,926 (January 20, 1998).

5 *See* 72 Fed. Reg. 42,001 (August 1, 2007).

in coverage will not in many—and perhaps most—instances hinder the Medicare program's ability to recoup overpayments for services rendered during that time period. This is because CMS already has the ability to offset future payments identified and, moreover, a lapse may be only a *de minimus* time period that is later "cured" through subsequent bond coverage.

(3) **CMS Should Allow for a Sufficient Transition Period.** CMS should consider a transition period that allows for a sufficiently robust private market for surety bonds of the type it proposes to exist. The mechanics of procuring a surety bond on CMS's terms will be unfamiliar to all parties to the bond. At minimum, a grace period will be necessary to ensure a smooth transition to comply with the proposed rule.

Below are detailed explanations of each of the Company's comments.

I. CMS SHOULD IMPLEMENT AN EXCEPTION FOR PUBLICLY TRADED CHAIN SUPPLIERS

A. Rationale for an Exception for Large, Publicly Traded Chain Suppliers.

The preamble to the proposed rule solicits "comment[s] on whether [CMS] should establish an exception to the surety bond requirement for large, publicly traded chain supplier[s] of DMEPOS" as well as additional criteria to be considered in waiving this requirement as to these types of suppliers. Rotech believes that the goals of the surety bond requirement are met by waiving the requirement for national chain suppliers that are publicly traded because these suppliers are held financially accountable through SEC requirements and demands of shareholders. Large chains also have more extensive resources through a "home office" and this centralized oversight offers an additional layer of assurances that chain suppliers will meet their financial and other obligations. Further, the application of the rule to large, publicly traded companies may threaten and unnecessarily divert resources that can be better spent on patient services.

The Agency requires a chain supplier to hold a supplier number for each location[6] and now proposes to require a surety bond for each supplier number. Rotech supports the Agency's efforts to monitor the participation of DMEPOS suppliers without an established track record with the Medicare program. Under the proposed rule, however, surety bond requirements would be applied to all suppliers of DMEPOS to the same extent. Rotech firmly believes that this application is not only over-inclusive but also unnecessary and unduly burdensome on publicly traded chain suppliers of DMEPOS.

Due to the reporting requirements of public companies, there is more transparency in a public company's financial statement. Public companies are required by the U.S. Securities and

---

6 *See* 72 Fed. Reg. 42,009 (August 1, 2007).

Exchange Commission to report their financial condition on a short and long term basis.[7] In addition, large chain DMEPOS suppliers have multiple sites that spread out the risks of nonpayment. These companies also tend to have established relationships with the Medicare program and, in the aggregate, ample assets to support a large, publicly traded business. For these reasons, a public company poses a greatly reduced risk of nonpayment to the Agency and its collection efforts. Large, publicly traded companies are simply in a better position than other DMEPOS suppliers to provide assurances of ability to pay for any Medicare claims or assessments.

Moreover, the financial reliability the proposed rule seeks to encourage in the DMEPOS community will be undermined when large reliable national chains are burdened by surety bond requirements assessed on a per supplier number basis. While a single surety bond of $65,000 may not be overly burdensome, this requirement multiplied by 490 supplier numbers renders Rotech responsible for a $31.9 million surety bond. The proposed requirement imposes an additional operating expense that does not benefit patient care.

Congress did not intend for the surety bond requirement to materially affect national chains with established track records in the marketplace and with the Medicare program. The House Report authorizing this rule notes that the reason for the change is "to protect the Medicare program from 'fly-by-night operators' who can quickly and inexpensively set up sham businesses in order to fraudulently collect Medicare reimbursement."[8] This is not a concern for large, publicly traded suppliers.

B. Exception for Public Companies Is Supported for Change in DMEPOS Standards and Regulatory Environment.

Rotech supports CMS's proposed rule to require a financial guarantee bond for the return of overpayments. The Company believes, however, that the regulatory climate as well as the entire DMEPOS industry has undergone a dramatic transformation since the measure was first proposed in 1998. As previously mentioned, the proposed rule is intended to protect the Medicare program from "fly-by-night operators" who can quickly and inexpensively set up sham businesses in order to fraudulently collect Medicare reimbursement.[9] The DMEPOS industry has changed significantly since the BBA was passed in 1997. Through significant changes in the DMEPOS supplier standards, today suppliers must meet a host of new requirements, including

---

7 *See* 17 C.F.R. § 229.303 (requiring detailed quarterly and annual disclosure of the registrant's "financial condition, changes in financial condition and results of operations," including "any known trends or any known demands, commitments, events or uncertainties that will result in or that are reasonably likely to result in the registrant's liquidity increasing or decreasing in any material way"); *see also* 17 C.F.R. § 240.13a-1 (requiring annual reports), 17 C.F.R. § 240.13a-13 (requiring quarterly reports), and Form 8-K items 2.03 and 2.06 (requiring reporting of any material direct financial obligation or material impairment).

8 H. Rep. No. 105-149 at 1312.

9 *Id.*

new quality and financial standards and new accreditation requirements.[10] The Medicare program therefore is not in the same position it was in 1997, and does not need to secure additional protection from well regarded national chains which have long-standing relationships with the Agency. This is particularly the case for well-established DMEPOS suppliers that have a track record for not only services to Medicare beneficiaries over many years, but also to paying any debts owed during the course of its relationship with the Agency. As such, an exception is wholly appropriate for these types of large suppliers.

C. Recommendation: For Certain Categories of DMEPOS Suppliers, CMS Should Provide an Exception to the General Surety Bond Requirement.

In the proposed regulatory provision— 42 CFR § 424.57(c)(26)(ii): *Exception for Government-operated suppliers*—CMS should include an exception for publicly traded chain suppliers. Suggested revisions are as follows.

- Proposed Subsection (c)(26)(ii) should be modified as follows:[11]

  "(ii)*(A) 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.

  (B) Exception for Publicly Traded Companies. Publicly Traded DMEPOS suppliers that are part of a chain organization are provided an exception to the surety bond requirement. A publicly traded DMEPOS supplier is one that is subject to SEC reporting requirements."

- Proposed Subsection (c)(26)(ix) ("*Loss of a DMEPOS supplier exception*") would also be modified accordingly, to take into account those situations where suppliers are no longer a part of a publicly traded chain.

II. CMS SHOULD NOT IMPOSE A LAPSE IN PAYMENTS

The proposed rule deals harshly with any gap in surety bond coverage. Specifically, the rule's preamble proposes that CMS would not pay for any items or services provided by the supplier if there is any lapse in bond coverage, regardless of the length of that gap: "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 supplier would be held liable for the items and services (that is, the DMEPOS supplier would not be permitted to charge the beneficiary for

---

10 *See* 42 C.F.R. §§ 424.57(c)(22) – (25), 424.58. Each of Rotech's locations is accredited by the Joint Commission.

11 Lettering of previous and subsequent exception subsections would be revised to accommodate new subsection (ii)(b).

the items or services)."[12] This interpretation is unnecessarily blunt. Not only would the Medicare program receive a windfall, this type of nonpayment provision is not included in other Agency surety bond requirements. Further, beneficiary services may be needlessly interrupted if, for example, suppliers must pick up equipment if payments are to be refunded. Surely, a disruption in patient care, would not be in the interest of either the program or its beneficiaries.

Finally, given how the bond market operates, it is hard to see how CMS would be truly prejudiced by a lapse in coverage that was "cured" at a later date. So long as the lapse in bond coverage is sufficiently cabined, there should not be a disruption in services. CMS has ample collection opportunities so long as the DMEPOS supplier is an ongoing concern, including offsets and other routine actions. A *de minimus* lapse in coverage, therefore, would leave little risk to the Medicare program's ability to recoup overpayments for services rendered during that time period. Payments for medically necessary services should not be jeopardized by a short lapse in coverage.

III. CMS SHOULD PROVIDE FOR A TRANSITION PERIOD

In light of the uncertainty regarding the availability of acceptable surety bonds, CMS should take care to ensure that DMEPOS suppliers have an opportunity to assess the availability of surety bonds before requiring compliance with any surety bond requirement. The mechanics for obtaining a surety bond will be unfamiliar to many DMEPOS suppliers. All suppliers should have an opportunity to assess the cost associated with this new requirement. Moreover, the Agency should allow time for a sufficiently robust market for DMEPOS supplier surety bonds to develop.

The Medicare program is adequately protected from nonpayment with respect to large, publicly traded DMEPOS suppliers. The surety bond requirement intended to limit risks from doing business with "fly-by-night" DMEPOS suppliers do not apply to large, publicly traded companies. Therefore, the Company recommends that an exception be recognized for chain organizations that are publicly traded.

Thank you for considering Rotech's comments regarding the proposed regulations. Should you have any questions or comments, we can be reached at (202) 637-2200.

Sincerely,

Stuart S. Kurlander /mws

Stuart S. Kurlander
Esther R. Scherb
Of LATHAM & WATKINS LLP

---

12 72 Fed. Reg. at 42,004.

cc: Rotech Healthcare Inc.
Margaret Sarratt, Latham & Watkins LLP

Michael R. Hess
Chief Counsel, GVP Legal
Accredo Health Group, Inc.
1640 Century Center Parkway
Memphis, TN 38134
(901)385.3680 (v)
(901)261.6840 (f)
Michael. Hess@ accredohealth.com

September 27, 2007

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

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

Gentlepersons:

Accredo Health Group, Inc., a subsidiary of Medco Health Solutions, Inc., appreciates the opportunity to comment on the proposed rule requiring surety bonds for suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Accredo Health Group is a large, multi-state specialty pharmacy that provides clinically focused therapy management for patients with complex, chronic conditions, many of which are life-threatening. Each therapy that we manage is unique and requires appropriate interventions to encourage medication compliance and persistence. These interventions may include overnight emergency delivery, extensive patient and provider education, side-effect management and medication counseling, psychosocial support, and nursing support. We take great pride in our robust clinical capacity and the advanced care we provide to patients with the most complex conditions, such as hemophilia and pulmonary arterial hypertension.

PROVISIONS OF THE PROPOSED RULE

We appreciate CMS' interest in requiring surety bonds to limit risk to the Medicare program from fraudulent DMEPOS suppliers and to assure the recapture of overpayments. However, we have concerns about how the proposed surety bond rule

would apply to our business as a specialty pharmacy and DMEPOS supplier to the Medicare program.

Surety Bond Exceptions

Our letter addresses your solicitation of comments on whether you should establish exceptions to the surety bond requirement for licensed pharmacists who furnish DMEPOS items for the convenience of their patients and/or for large, publicly traded chain suppliers of DMEPOS. We believe you should provide for both types of exception.

Many pharmacists supply DMEPOS as a convenience for their patients because the DME is required for the administration of a prescription drug. As a specialty pharmacy, we have patients whose drug regimen includes products that are administered through a medical device. We became qualified as a Medicare DMEPOS supplier so that we could provide our patients with the prescription medications and related medical devices they need. We only provide DME when it is necessary for the administration of a drug. Typically, the drugs dispensed by our pharmacy are for rare disorders and are expensive; the associated DME required for administration of these drugs is usually a low cost item.

In addition to providing DME as a convenience to our patients, we also assure that the proper DME is matched to the drug. Many of the drugs we dispense have characteristics, such as a high pH, that require the use of a particular DME item with properties that will withstand the challenges posed by the drug.

Requiring pharmacies that furnish DMEPOS items as a convenience for their patients to obtain a surety bond may discourage them from providing this valuable service. We believe Medicare beneficiaries are better off when they can obtain all their medications, including those that must be administered via a medical device, from a single pharmacy. The Medicare program should encourage, not discourage, pharmacy participation as DMEPOS suppliers.

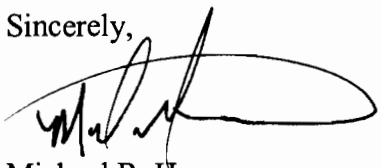
In the case of publicly traded chain suppliers, the Medicare program is dealing with sizable business entities that are subject to financial disclosure requirements and considerable scrutiny by various government agencies as well as their own shareholders. Publicly traded companies also have assets that make them much less likely to default on repayment requirements if billing errors are made. We believe an exception for "large, publicly traded chain suppliers of DMEPOS" should be expanded to include suppliers that are part of a chain pharmacy and are a corporate subsidiary of a large, publicly traded health care company, such as a pharmacy benefit manager (PBM), health plan, or health insurer. A pharmacy subsidiary of a publicly traded company is subject to the same level of disclosure and public scrutiny as the parent company. You may wish to adopt criteria for what would constitute a "large, publicly traded company", such as a dollar threshold for capitalization and/or annual gross sales volume.

Reduce Burden on Corporations with Multiple NPIs

If you do not adopt either of the proposed exceptions from the surety bond requirement discussed above, we believe that the Section 424.57 (c)(26) requirement for a DMEPOS supplier to obtain a surety bond for each location with a unique NPI is unduly burdensome for a large DME supplier like Accredo which has multiple locations and 43 NPIs. If a blanket exception is not established for specialty pharmacies like Accredo, then it should be sufficient for a single corporation with multiple locations that provide DMEPOS supplier services to obtain one surety bond, rather than requiring each facility owned by the corporation to obtain a separate surety bond for each NPI held by the corporation. If the primary goal of the surety bond requirement is to "use a private sector mechanism to screen DMEPOS suppliers that provide items and services to Medicare's beneficiaries and help insure that they are financially responsible" (Federal Register, Vol. 72, No. 147, at pages 42008-42009), one surety bond surely would accomplish that purpose. Requiring a single company to obtain and maintain multiple bonds is redundant and greatly increases the cost of doing business with the Medicare program for such a company.

On behalf of Accredo Health Group, Inc., I appreciate the opportunity to comment on proposed rule CMS-6006-P. We look forward to working with CMS to ensure that the rule provides appropriate protection for the Medicare program without imposing an undue regulatory burden on DMEPOS suppliers with multiple locations and multiple NPIs.

Sincerely,



Michael R. Hess
Chief Legal Counsel
Group Vice President, Legal

S:\BNShare\LTRS\Accredo Health Group\CMSltr092707.doc

US Oncology

October 1, 2007

HAND DELIVERED

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6006-PHubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-6006-P

Dear Mr. Weems:

US Oncology[1] would like to thank you for the opportunity to comment on Proposed Rule CMS-6006-P, "Proposed Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)" (the "Proposed Rule") published in the *Federal Register* on August 1, 2007.[2] As requested, we have keyed our comments to the relevant issue identifiers in the Proposed Rule.

PROVISIONS

The Proposed Rule would require each Medicare-enrolled DMEPOS supplier to obtain a surety bond from an authorized surety in the amount of $65,000 for each National Provider Identifier the supplier holds within 60 days after publication of a final rule. The new surety bond requirement would be codified as a Part B supplier standard under 42 C.F.R. § 424.57. Thus, a supplier's obligation to have an acceptable surety bond in place would be continuous since holders of a Part B supplier number must meet the supplier standards "to be eligible to receive payment for a Medicare-covered item."[3]

As we understand it, the surety bond requirement is another step by CMS designed to combat Medicare fraud in the DMEPOS industry. It is expected to reduce the number of DMEPOS suppliers that currently bill Medicare fraudulently by subjecting prospective suppliers to the

[1] US Oncology, headquartered in Houston, Texas, is one of the nation's largest caner treatment and research networks. US Oncology provides extensive services and support to its affiliated cancer care sites nationwide to help them expand their offering of the most advanced treatments and technologies, build integrated community-based cancer care centers, improve their therapeutic drug management programs and participate in many of the new cancer-related clinical research studies. US Oncology is affiliated with 1,122 physicians operating in 442 locations, including 90 radiation oncology facilities, in 38 states.
[2] 72 *Fed. Reg.* 42,001 (Aug. 1, 2007).
[3] 42 C.F.R. § 424.57(b).

underwriting scrutiny of surety companies and by imposing costs and collateral requirements that could serve as a barrier to entry into the DMEPOS supplier market.[4] It should protect the Medicare program from fiscal losses attributable to unpaid overpayments or penalties as well. Furthermore, presumably, the need to continuously maintain a bond would encourage ongoing compliance with Medicare rules and regulations because a claim for incurred debt made against a supplier's surety likely would cause the supplier to lose its bond and, thus, be unable to maintain its Part B supplier number and its ability to conduct DMEPOS business with Medicare.

The Proposed Rule provides for an exception to the surety bond requirement for government-operated suppliers that have a good history of paying their Medicare debts.[5] The stated basis for this exception is that "government-operated suppliers have the power to tax; therefore, it is unlikely the DMEPOS suppliers will be unable to pay their Medicare debts."[6]

The Proposed Rule solicits comments on whether CMS should establish certain other exceptions to the surety bond requirement including an exception "for certain physicians and non-physician practitioners, such as those that occasionally furnish DMEPOS items for the convenience of their patients."[7] The Proposed Rule also asks about the appropriate scope for any such exception.

CMS Should Establish an Exception for Physicians from the DMEPOS Surety Bond Rule

US Oncology and its affiliated physician practices have a vested interest in the Proposed Rule because many network practices hold Part B supplier numbers so that they may bill Medicare for the infusion pumps they furnish to chemotherapy patients on therapy regimens that require long-duration infusions.

For a number of reasons, discussed in more detail below, we strongly support the establishment of a physician exception to the DMEPOS surety bond requirement. Congress never intended for physicians to be subject to a surety bond requirement for items and services they provide to their patients. The imposition of a DMEPOS surety bond requirement on physician practices also is inconsistent with basic Medicare principles. Furthermore, such a requirement is not needed to protect the Medicare program from fraud and abuse, which is the stated purpose of the Proposed Rule.

With respect to the scope of a physician exception, given the fraud and abuse function of the surety bond requirement, we are of the view that a physician exception should mirror the exception for government-operated suppliers in Proposed Rule 42 C.F.R. § 424.57(c)(26)(ii). In other words, the availability of the physician exception should be limited to practices with a good history of paying their Medicare debts, be they debts related to professional services billed under the physician fee schedule or debts related to the practice's supply claims processed through the DMERCs.

---

[4] 72 *Fed. Reg.* at 42007.
[5] 72 *Fed. Reg.* at 42003. Also see proposed 42 C.F.R. 424.57(c)(26)(ii).
[6] *Id.*
[7] 72 *Fed. Reg.* at 42004.

US Oncology · 700 13th Street NW, Suite 525 · Washington, DC 20005 · 202-638-3833 · Fax: 202-638-7677

Although the Proposed Rule is silent on the matter, given the taxing rationale sited for the government-operated supplier exception in the preamble,[8] we presume any § 424.57(c)(26(ii) exception also would be available to newly established government-operated suppliers without a payment track record. We would argue that a physician exception also should be available to newly established physician practices that have no billing history with Medicare. We are of this view because physicians initially enrolling in Medicare who simultaneously decide to seek a Part B supplier number undergo substantial government scrutiny from state licensing bodies and their local Medicare carriers (through the 855 Medicare enrollment process) as well as the National Supplier Clearinghouse ("NSC"). Moreover, physicians already face substantial limitations on their ability to furnish and bill for DMEPOS lawfully under the Stark Law. We believe physician practices normally receive the majority of their income from professional services and do not rely upon billings for DMEPOS for a substantial portion of their income. We note that for practices in the US Oncology network holding Part B supplier numbers, no practice receives more than 0.0004% of its annual revenues from DMEPOS claims.

1. *Establishing a Physician Exception to the DMEPOS Surety Bond Requirement Would Be Reflective of Congressional Intent*

In respond to reports of widespread fraud and abuse in the durable medical equipment ("DME") industry,[9] Congress included a provision in the Balanced Budget Act of 1997 (the "BBA")[10] requiring DME suppliers to hold a surety bond. That provision, which was codified at Social Security Act § 1834(a)(16), also gave CMS broad discretionary authority to expand the surety bond requirement beyond DME suppliers to some or all providers and suppliers of items and services to Medicare beneficiaries. Congress did not, however, intend for CMS to impose a surety bond requirement on physicians. The Conference Report on the BBA's surety bond requirement couldn't be clearer. It states:

> The Conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals.[11]

CMS should honor this intent by establishing an exception from the surety bond requirement for physician practices that elect to apply for Part B supplier numbers ("Physician Suppliers") that parallels the exception included in the Proposed Rule for government-operated suppliers.

2. *Establishing a Physician Exception to the DMEPOS Surety Bond Requirement Would Be Supportive of Basic Medicare Principles*

Two fundamental mandates, codified in the first two sections of Title XVIII of the Social Security Act, have guided the crafting of statutes and regulations governing the Medicare

---

[8] 72 *Fed. Reg.* at 42003.

[9] *See, e.g., Two Florida Defendants Convicted in $17 Million Medicare DME Scheme,* BNA's Health Care Fraud, vol. 09, no. 06 (March 16, 2005); *DME Provider Agrees to Pay $9 Million To Resolve Allegations of Medicare Fraud,* BNA's Health Care Fraud, vol. 10, no. 06 (March 15, 2006); *Some DME Fraud Successfully Tackled by HCFA, HHS IG Says*, BNA's Health Care Fraud, vol. 1, no. 7 (April 9, 1997).

[10] P.L. 105-33 (1997).

[11] Conference Report to Accompany H.R. 2015, Report 105-217, 105th Congress, 1st Session, p 722.

US Oncology · 700 13th Street NW, Suite 525 · Washington, DC 20005 · 202-638-3833 · Fax: 202-638-7677

program since the beginning of the program. The first requires the program to defer to a physician's judgment regarding the practice of medicine and the treatment of his or her patients.[12] The second requires the program to preserve Medicare beneficiaries' freedom to access care from the provider of their choice.[13]

In our view, these fundamental principles argue against imposing an entry barrier, in the form of a DMEPOS surety bond requirement, on physicians who wish to furnish DMEPOS items for the convenience of their patients. This is particularly true since, as a practical matter, such convenience items are the only types of DMEPOS that physicians may lawfully furnish and bill for under the Stark Law because infusion pumps and, in certain circumstances, canes, crutches, walkers, folding manual wheelchairs, and blood glucose monitors are the only types of DMEPOS covered under the in-office ancillary service exception.[14]

3. *Imposition of a Physician Surety Bond Requirement Is Not Necessary to Control Fraud and Abuse*

We are well-aware of the significant number of government investigations and civil, as well as criminal, prosecutions in the DEMPOS industry over the last decade. In light of the historic and ongoing abuse of the DMEPOS benefit, we understand CMS's interest in providing for more stringent controls on supplier enrollment and greater assurances that Medicare will be able to recover erroneous payments. However, the fraudulent DME supplier conduct that the HHS Office of Inspector General ("OIG") has repeatedly documented in a series of reports over the years were perpetrated by a series of unscrupulous individuals and business corporations, not Physician Suppliers who primarily furnish DMEPOS only as an ancillary service to their own patients.

Similarly, Physician Suppliers who furnish DMEPOS for the convenience of their patients do not pose the same type of threat to program integrity as do the "sham" businesses the OIG has recently identified in numerous site visits to suppliers in Florida and other states. The OIG apparently recognizes this reality because it elected to exclude self-identified physician suppliers was well as other suppliers, such as dentists and hospitals, from its 2007 compliance audit of the DMEPOS enrollment requirements, presumably based on its determination that these provider types posed less risk of the particular types of fraud under investigation in the study.[15] Furthermore, in the OIG's Report on *Protecting Public Health and Human Services Programs: A 30-Year Retrospective,* not one of the cited examples of fraud in the DMEPOS industry included a Physician Supplier.[16]

Physicians who bill Medicare are subject to a significantly greater level of government scrutiny than are companies only in the business of supplying DMEPOS to their customers. Although

---

[12] Social Security Act § 1801.
[13] Social Security Act § 1802.
[14] 42 C.F.R. § 411.355(b).
[15] *OIG Report*, No. OEI-04-05-00380, March 1, 2007, *available at* http://www.oig.hhs.gov/oei/reports/oei-04-05-00380.pdf.
[16] *OIG Report*, "Protecting Public Health and Human Services Programs: A 30-Year Retrospective," April 26, 2007, *available at* http://oig.hhs.gov/publications/docs/retrospective/AnniversaryPub.pdf.

US Oncology · 700 13th Street NW, Suite 525 · Washington, DC 20005 · 202-638-3833 · Fax: 202-638-7677

only a hand-full of states require DMEPOS companies to be licensed, all states subject physicians who wish to practice within their boundaries to stringent licensing requirements that involve assessments of personal background and integrity as well as professional qualifications and competences. Furthermore, all physicians providing professional services to Medicare patients must enroll in the Medicare program by submitting an 855 enrollment from for review by the local carrier that serves the area when the physician intends to locate his or her practice. Finally, if physicians wish to bill for DMEPOS supplies that are not covered under the physician fee schedule, they also must submit an 855-S enrollment form to the NSC and undergo the same review process as any other entity seeking to obtain a Part B supplier number. Given the existing levels of governmental review, requiring the scrutiny of a surety underwriter seems redundant. It also would add unnecessary costs to the practice of medicine at a time when physicians are already facing significant across-the-board Medicare reimbursement cuts under the 2008 Proposed Physician Fee Schedule.[17]

As an added program safety measure, in addition to the triple governmental review Physician Suppliers undergo, all physicians, including those holding Part B supplier numbers, are subject to the Stark Law, which prohibits them from referring patients for designated health services, to entities, including their own practices, with which they (or an immediate family member) have a financial relationship unless the relationship is permitted by one of the enumerated exceptions to the statute. Congress enacted the Stark Law as a prophylactic approach to the control of fraud and abuse, principally in the form of program overutilization. DME, prosthetics and orthotics are all designated health services under the Stark Law and, under the law's exceptions, physicians only may furnish and bill for a limited number of DMEPOS items which qualify as patient convenience items.

Congress and CMS historically have narrowly tailored the restrictions they have imposed on the scope of permissible physician ancillary services under the Stark Law with an eye toward preventing sham arrangements while "allow[ing] physicians to furnish [designated health services] DHS (including certain DME which would be subject to the surety bond requirement under the Proposed Rule) that are ancillary to the physicians' core medical practice in the location where the core medical services are routinely delivered."[18] In fact, it appears that Congress itself recognized the importance of allowing physicians to furnish infusion pumps for their patients in need of intravenous therapies since it expressly added such pumps to the law's in-office ancillary service exception so that doctors prescribing chemotherapy and other infused therapies for their patients could control the full gamut of drug administration.[19] Adding a surety bond requirement on top of existing Stark Law limitations would disturb the careful balance Congress and CMS have heretofore managed under the Stark Law between the fundamental Medicare principles in Social Security §§ 1801 and 1802 and the need to control fraud and abuse.

IMPACT

[17] 72 *Fed. Reg.* 38121 (July 12, 2007).
[18] 66 *Fed. Reg.* 856, 888 (Jan. 4, 2001).
[19] Social Security Act § 1877(b)(2).

US Oncology · 700 13th Street NW, Suite 525 · Washington, DC 20005 · 202-638-3833 · Fax: 202-638-7677

The Proposed Rule estimates that the majority of DMEPOS suppliers with Medicare allowable charges of less that $5,000 a year would not recoup the estimated average cost of a $65,000 surety bond through their Medicare DMEPOS business.[20] Given that physicians are in the business primarily of providing professional services and are only allowed to provide the types of DMEPOS supplies that are relatively inexpensive and only suited to meeting the convenience needs of their patients under the Stark Law, if Physician Suppliers are not excepted from the DMEPOS surety bond rule, most physician practices likely would be forced to inconvenience their patients by referring them elsewhere for infusion pumps and ambulatory assistance items. That certainly would be the case for practices affiliated with the US Oncology network. No US Oncology practice had DMERC allowable charges in 2006 and 2007 in excess of $1,500 even though, based on CMS' assessment, a bond would be unaffordable for practices with less that $5,000 in Medicare allowable DMERC charges.

If oncologists who furnish infusion pumps to their patients in need of long-term chemotherapy can no longer afford to continue as DMEPOS suppliers because of the cost burden of a surety bond, they likely would be forced to refer those patients to home infusion providers or, if the patient qualifies as home bound, to home health providers. It is ironic, given the apparent low potential for fraud among Physician Suppliers, that CMS has just initiated a demonstration project targeting billing fraud among home infusion therapy providers in South Florida. This demonstration is the third project announced by CMS since July 2007 in which the government is attempting to curb fraud among DME and home health providers in areas where fraud in those industries is especially high.[21]

****

In closing and on behalf of US Oncology and our nationwide network of cancer care specialists, thank you for this opportunity to provide our comments on Proposed Rule CMS-6006-P. As you know, we are grateful for the opportunity to engage in substantive discussions CMS officials, and we continue to stand ready should you have any questions about the foregoing issues, concerns, suggestions and analyses.

Sincerely,

Dan Cohen
Senior Vice President
Government Relations & Public Policy

---

[20] 72 *Fed. Reg.* at 42008.

[21] *Medicare Anti-Fraud Demonstration Requires Florida Infusion therapy Providers to Reapply.* BNA's Health Care Daily, vol. 12, no. 161 (Aug. 21, 2007).

US Oncology · 700 13th Street NW, Suite 525 · Washington, DC 20005 · 202-638-3833 · Fax: 202-638-7677

5

AMERICAN HOMEPATIENT

5200 Maryland Way
Suite 400
Brentwood, TN 37027
615-221-8884
615-373-1601 Fax

September 27, 2007

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Proposed Rule [CMS-6006-P] RIN 0938-A084[1]

Dear Acting Administrator Weems:

American Home Patient (AHP) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS') proposed surety bond regulation for DMEPOS suppliers. AHP is a leading provider of home health services in the United States. The company has 248 operating centers in 33 states and employs approximately 2,350 full-time employees nationwide. AHP has been accredited by the Joint Commission for over ten years. Every year we service approximately 200,000 Medicare patients with a complete line of home infusion and respiratory therapies and durable medical equipment and supplies.

The preamble to the proposed rule suggests that CMS intends both to deter fraudulent providers from entering the program and secure a source of funds to guarantee payment of a supplier's debts to Medicare. CMS has requested comments on all aspects of the proposed rule, including whether it would be appropriate to create an exception to the bond requirement for DMEPOS suppliers that are publicly traded companies. We believe that public companies, by virtue of being public, are already subject to a level of scrutiny and oversight that accomplishes what CMS intends to gain by implementing the proposed rule. Consequently, AHP supports an exception from the bond requirement for public companies. We explain our position in more detail below.

[1] 72 Fed. Reg. 42001 (August 1, 2007).

I. Comments

A. Public Companies are Already Subject to Extensive Scrutiny

Under the proposed rule, suppliers would be required to obtain a $65,000 bond for each national provider identifier (NPI) in order to bill Medicare. The original rationale for requiring suppliers to obtain a bond was to provide an independent assessment by a surety of the individuals and entities that wanted to do business with the program. Congress' intent was that the surety bond would serve as a tool to distinguish between legitimate suppliers and those that posed a risk of fraudulent billing to Medicare. CMS' goals in implementing the proposed rule are similar, but somewhat broader. The Agency intends to accomplish the following: (1) limit the Medicare program's risk from fraudulent DME suppliers; (2) enhance the Medicare enrollment process so that only legitimate DME suppliers are enrolled, or are allowed to remain enrolled; (3) ensure that Medicare recoups erroneous payments resulting from fraudulent or abusive billing practices; and (4) ensure that Medicare beneficiaries receive products and services from legitimate DME suppliers.

AHP agrees with the goals underlying the surety bond requirement. As a company we support measures to weed-out fraud and protect the Medicare program from abusive practices. While we agree that there may be value in the scrutiny that a surety may apply to certain entities, such as companies that are new to the Medicare program, the rationale to require that scrutiny does not apply to public companies that are subject to the Securities Exchange Commission's (SECs) extensive oversight and reporting regulations. Given that other controls that achieve the same result are already in place, the added cost and burden of obtaining a surety bond would not result in any additional deterrent effect when applied to a public company. Historically, Medicare has been the most vulnerable to fly-by-night operators that use artifice to enter the program, proceed to engage in fraudulent and abusive billing then close shop before (or soon after) they are detected. Consequently the Medicare program is left to chase a refund of the improper claims it paid. A publicly traded chain supplier is not capable of engaging in this fly-by-night fraud. AHP for example, has 248 locations. If one location were to close, CMS would still have the ability to pursue remedies against the other AHP locations and against the parent company.

Importantly, publicly traded companies are owned by the shareholders – the public --and must operate in a way that maintains public trust. These companies must comply with laws and regulations that subject them to disclosure requirements, internal review requirements and enforcement oversight. The goals behind these laws and regulations are to protect the public from deceit, misrepresentation and fraud by requiring the company to disclose its financial status and any significant events that may impact its operations. As part of its financial reporting obligation, a public company must engage an independent auditor to review its books on an annual basis. An independent audit by a certified public accounting firm subjects a public company to an in depth scrutiny that is far more extensive than what a surety might be expected to perform. Moreover, the audit

is publicly disclosed under SEC rules requiring public companies to publish an annual report. The annual report is available for public inspection by anyone who wants to review it, including CMS.

More recently, the Sarbanes-Oxley Act, passed by Congress in 2002, directly targets corporate fraud by requiring public companies to implement internal controls, enhancing financial disclosures, and imposing significant penalties for noncompliance. Sarbanes-Oxley requires the CEO and CFO of a public company to certify the company's financial statements under penalty of personal criminal liability for false statements. Certification with knowledge that the financial statements do not comply with the statute's requirements can result in a fine of up to $1 million and/or imprisonment of up to 10 years. In addition, Sarbanes-Oxley requires disclosures of financial information that fairly presents in all material aspects the financial condition of the company, any material change in the company's internal control over financial reporting, as well as disclosures to the company's auditors and the audit committee of the company's board of directors of all significant deficiencies and material weaknesses in the design or operation of its internal control over financial reporting, as well as any fraud, regardless of materiality that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Because public companies are already subject to extensive regulation and must report to their shareholders significant events that may impact their earnings, public companies invest a lot of resources in corporate compliance programs. DMEPOS suppliers that are publicly traded companies, invest significant financial and human capital on compliance programs in order to prevent inappropriate billing to the Medicare program. For example, AHP employs a Vice President of Compliance & Government Affairs who oversees the company wide compliance program. AHP staff receives periodic training on compliance matters, and we perform periodic self audits to assure ongoing compliance with Medicare program rules.

As a public company, AHP bears significant costs in complying with SEC and Sarbanes Oxley requirements and in maintaining the company's ongoing compliance with these laws and Medicare and Medicaid program rules. Our annual cost to comply with SEC and Sarbanes Oxley requirements is in excess of $1,000,000. We incur additional costs under our corporate compliance program. We estimate that obtaining a surety bond consistent with the proposed rule would add approximately $400,000 to $500,000 to our costs for the premium. This is not an insignificant amount for a business, even one that has good access to capital. Given that one purpose for requiring a bond is to screen suppliers by subjecting them to a surety's scrutiny, we see little added value to Medicare in requiring publicly traded suppliers to obtain a bond.

B. Public Companies are Unlikely to Default on Medicare Debts

The bond that would be required under the proposed rule is a financial guarantee bond. The preamble states that a surety would be liable to CMS for the face value of the bond when CMS notifies the surety that a supplier has "unpaid claims." Under this type of bond, the surety guarantees that a supplier's debts to the Medicare program will be paid (up to the limits of the bond). Public companies have the financial resources to satisfy their debts to the program and do not pose a risk of defaulting on their Medicare debts. As we noted above, CMS has the ability to verify these resources by examining the company's public filings. Consequently, to the extent that another rationale for requiring suppliers to obtain bonds is to guarantee the refund of overpayments to the Medicare program, we believe that it would be reasonable for CMS to create an exception for public companies.

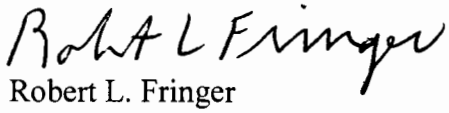
II. Conclusion

In closing, we reiterate our support for CMS' efforts to weed-out fraudulent suppliers from the Medicare program. We believe that the proposed rule should target individuals and entities, such as new suppliers, that pose a risk of fraud to Medicare. However, we see no added value to requiring publicly traded suppliers to obtain a surety bond. Public companies are not likely to perpetrate the kind of fly-by-night fraud a surety bond is intended to address given that they are publicly owned and must publicly disclose information that materially affects their operations. These suppliers already are subject to scrutiny that far exceeds the scrutiny a surety would give a supplier purchasing a $65,000 bond. Finally, public companies are unlikely to default on their Medicare debts.

For all the foregoing reasons we recommend that CMS create an exception from obtaining a bond for public companies. If CMS does not create an exception consistent with these comments, then it should limit the face value of the bond for public companies to a nominal amount tied to the supplier's tax identification number.

We sincerely appreciate the opportunity to submit these comments. Please feel free to contact me if you have any questions, or would like to discuss them further.

Sincerely,



Robert L. Fringer
Sr. Vice President, Controller & Principal Accounting Officer

6

Kevin L. Alexander, O.D., Ph.D.
President

American Optometric Association
243 N. Lindbergh Blvd., Floor 1 • St. Louis, MO 6314
(314) 991-4100 • (314) 991-4101 FA

September 19, 2007

Kerry Weems
Acting Administrator
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

Re: Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Dear Mr. Weems:

The American Optometric Association (AOA), which represents nearly 36,000 optometrists in the United States, appreciates the opportunity to comment on the proposed rule to implement a surety bond requirement for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) published in the August 1, 2007 issue of the *Federal Register*. Doctors of optometry (ODs) are independent primary care physicians who examine, diagnose, treat, and manage diseases and disorders of the visual system, the eye, and associated structures. They are also the most accessible eye care physicians in the United States, both for Medicare beneficiaries and the general population.

Provisions

The proposed rule would require DMEPOS suppliers to provide CMS with a surety bond of at least $65,000 as a condition of the issuance or renewal of a supplier billing number. This is intended to implement section 4312(a) of the Balanced Budget Act of 1997 (BBA), which mandated a surety bond amount of not less than $50,000 for suppliers of "durable medical equipment" (section 4312(c) of the BBA authorized the Secretary to apply this requirement to other categories of providers). As proposed, the surety bond requirement would apply to all DMEPOS suppliers, including physicians, except for suppliers owned or operated by a Federal, State, or Tribal entity (if they have provided CMS with a

comparable surety bond under State law and do not have any unpaid claims, civil money penalties (CMPs) or assessments). However, CMS invites comments on whether it should exempt: certain physicians and non-physician practitioners (such as those that occasionally furnish DMEPOS items for the convenience of their patients) from the proposed surety bond requirements.

AOA strongly believes that optometrists and other physicians should be exempt from any surety bond requirements. Requiring optometrists to post a surety bond is inappropriate for at least two reasons:

- First, optometrists are not a source of the problem the surety bond requirement was intended to address. This requirement was intended to provide Medicare with some recourse against unscrupulous suppliers who defraud Medicare and disappear before their fraud can be discovered. Optometrists, like other health professionals, work for years to qualify for State licensure and to develop successful practices in the areas they serve. Such ties make a "bill and run" strategy unlikely, and the revenues they receive from treating Medicare patients provide an alternative source of funds from which Medicare can recoup any overpayments.

- Second, AOA believes that the Congress fully intended to exempt physicians, including optometrists, from the surety bond requirements, even in their role as DMEPOS suppliers. For example, the conference report accompanying the BBA says the following: "The Conferees wish to clarify that these surety bond requirements [plural] do not apply to physicians and other health care professionals" [emphasis added]. Perhaps more importantly, section 4312(c) of the BBA, authorizing the application of surety bond requirements to providers other than suppliers of durable medical equipment -- the section of the statute which we presume CMS is relying upon to extend these requirements to suppliers of prosthetic devices (such as conventional eye wear furnished after cataract surgery) -- specifically says that this authority does not apply to "physicians and other practitioners."

With respect to this second point, we note that section 4312(a) of the BBA appears to refer to suppliers of durable medical equipment, not suppliers of orthotics, prosthetics or prosthetic devices. Further, although Congress did not indicate the reasons for creating an exemption for physicians and other health care professionals, it was probably based on the considerations discussed above—and on the view that requiring physicians to post a surety bond would be unduly burdensome in light of the relatively low volume of DMEPOS items they furnish in their offices. Of course, we are prepared to concede that the "physician exemption" to the surety bond requirement should be subject to reasonable limits. For example, a DMEPOS supplier should not be exempt from posting a surety bond simply because it is owned by a physician.

In addition to inviting comments about a possible exemption for physicians and non-physician practitioners, CMS also invites comments about possible exemptions for (1) licensed pharmacists; (2) large, publicly traded chain suppliers of DMEPOS; (3) rural DMEPOS suppliers; and/or (4) other categories of DMEPOS suppliers. However, unlike in the case of physicians and other health care professionals, we see nothing in the BBA or the accompanying conference report to indicate that CMS was given the authority to grant such exemptions or that the Congress intended such exemptions when the BBA was enacted in 1997. While we believe that persuasive arguments could certainly be made for exempting at least some of the preceding categories of suppliers, we believe that the lack of clear statutory authority or other indications of Congressional intent is a serious limitation.

In light of this, we would recommend that CMS not move forward with a final rule until it has discussed with the Congress the need for statutory changes in the requirements, in particular clear guidance about the types of exemptions that should be provided. A full 10 years have now passed since enactment of the surety bond requirement, suggesting that there is no real urgency to implementing this requirement at this time. Another matter that would perhaps benefit from a statutory change would be language authorizing a reduced surety bond amount (less than the statutory $50,000 minimum) for certain types of suppliers, such as smaller suppliers or those providing only a small quantity of Medicare-reimbursed DMEPOS, to the extent such suppliers did not end up being exempted altogether. Finally, should CMS believe that Congressional intent with respect to the exemption of physicians is not unambiguous, the course of action we recommend would provide an opportunity to obtain clarifying statutory language in this regard.

While AOA clearly believes that optometrists and other physicians should be exempt from any DMEPOS surety bond requirements, and even that it would be best for CMS not to proceed to a final rule at this time, we wish to take this opportunity to offer several, more technical comments about various elements of the proposed rule. First, CMS is proposing a surety bond requirement of at least $65,000, rather than the statutory amount of "not less than $50,000." In doing so, CMS notes that it has inflated the original statutory amount to reflect changes in the Consumer Price Index since 1997. On the other hand, at this time, CMS is <u>not</u> proposing to adjust the new $65,000 amount for inflation on an annual basis. If CMS elects to adopt a final rule at this time, we would encourage the agency to use the statutory minimum of $50,000, rather than any higher amount. While the higher amount proposed is intended to reflect the impact of inflation since 1997, the fact of the matter is that Medicare payment amounts for many DMEPOS products have actually been frozen or even reduced during one or more of the years since 1997; they certainly have not all benefited from regular, annual inflation adjustments. In addition, CMS itself projects that the surety bond requirements will significantly reduce the number of DMEPOS suppliers willing to serve Medicare beneficiaries. Taken together, we believe these two factors

argue against adopting a surety bond requirement in excess of the minimum amount currently specified in the statute (of course, as noted earlier in these comments, AOA urges CMS not to finalize the proposed rule at this time).

Second, each DMEPOS supplier not qualifying for an exemption would have to submit the initial surety bond no later than 60 days following publication of the final rule. Surely, a full 10 years following enactment of the BBA, CMS could provide affected DMEPOS suppliers far more than 60 days to comply with any new surety bond requirements. We would urge CMS to give at least 180 days, if not more, for affected DMEPOS suppliers to come into compliance.

Third, CMS is proposing that a surety bond would need to be submitted for each national provider identifier (NPI), that is, for each supplier location. However, in a proposed rule on the same surety bond issue published January 20, 1998, CMS had proposed to apply the surety bond requirement at the Tax Identification Number (TIN) level, meaning that a supplier with multiple locations would have required only a single surety bond. AOA believes that it would be totally unreasonable to expect a DMEPOS supplier with more than one location to secure more than one surety bond. Therefore, if CMS decides to adopt a final rule at this time, we would urge the agency to apply the requirement at the TIN level or some comparable level of "aggregation," rather than for each supplier location. This would help to minimize the negative impact of the requirement.

Fourth, CMS says it is also considering the option of establishing surety bond requirements above $65,000 under certain circumstances. For example, CMS says it could require a surety bond in the amount of $65,000 per high risk factor (such as Federal and State criminal convictions related to the delivery of health care items or services, and revocations of billing privileges any time during the last 10 years). Or CMS could establish elevated bond requirements for certain categories of DMEPOS suppliers. If CMS elects to adopt a final rule with respect to surety bonds for DMEPOS suppliers, AOA would recommend that the agency keep the initial requirement simple (one bond amount) rather than adopt multiple bond levels. We believe that CMS would need to gain some experience with a base surety bond requirement (if and when one is implemented) before it would be in a position to assess the need for a more complicated surety bond framework.

Notwithstanding the preceding, more technical comments about the proposed rule, we wish to close this section by emphasizing that AOA's primary concern is that <u>any</u> DMEPOS supplier surety bond requirements <u>not</u> be applied to optometrists or other physicians.

Impact

CMS assumes that the proposed surety bond requirements could cause as many as 15,000 DMEPOS suppliers currently serving Medicare beneficiaries

(especially those with annual Medicare allowed charges of less than $5,000) to cease their enrollment in Medicare. Unlike CMS, we are far less certain that such a mass exodus of suppliers would leave Medicare beneficiary access unaffected. Instead, we believe that this projected impact of the proposed surety bond requirements, which if anything is likely to be an underestimate, provides further grounds for delaying adoption of a final rule until the Congress has been given a further opportunity to assess the situation.

We hope that the above AOA input on the proposed rule is helpful. If you have any questions about our comments, please don't hesitate to contact Kelly Hipp, Director of Professional Relations, at 703-837-1346 or via e-mail at KHipp@aoa.org. We look forward to working with you in the future.

Sincerely,

Kevin L. Alexander OD, PhD

Kevin L. Alexander, OD, Ph.D.

6006-P
7

ahca
American Health Care Association

1201 L Street, NW, Washington, DC 20005-4046
Main Telephone: 202-842-4444
Main Fax: 202-842-3860 2nd Main Fax: 202-289-4253
Writer's Telephone: 202-898-2858
Writer's E-Mail: byarwood@ahca.org
www.ahca.org

October 1, 2007

Kerry Weems
Acting Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Room C5-15-12
Baltimore, MD 21244-1850

***Re: CMS-6006-P: Comments on Medicare Program; Surety Bond Requirements for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)* Proposed Rule, 72 Federal Register 42001, August 1, 2007**

Dear Mr. Weems:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the above referenced proposed rule. AHCA is the nation's leading long term care (LTC) organization. AHCA and its membership are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical long term care. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly, and disabled citizens who live in nursing facilities, assisted living residences, subacute centers, and homes for persons with mental retardation and developmental disabilities.

On August 1, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule that would implement section 4312 of the Balanced Budget Act of 1997 and would require certain suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) except those that are government operated, to obtain and retain a surety bond in the amount of $65,000. The $65,000 requirement is an inflation-adjusted figure from the $50,000 surety bond amount proposed in the 1997 Act.[1]

[1] CMS had previously issued a proposed rule implementing the statute in 1998 but had not as yet issued a final rule. The Medicare Prescription Drug Improvement, and Modernization Act of 2003 prohibits the Secretary from finalizing a proposed rule related to Title 18 that was published more than three years earlier except under exceptional circumstances.

The statute implementing this surety bond requirement applies these requirements to suppliers of DMEPOS. However it permits:

> "The Secretary, at the Secretary's discretion, may impose the requirements of *(the requirement)* with respect to some or all providers of items or services under Part A or some of all suppliers or persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C) who furnish items or services under this part." (Section 1834(a)(16)). (modifications added) [2]

AHCA is asking that CMS waive this requirement for nursing facilities[3] who are their own DMEPOS suppliers and who provide DMEPOS solely to their own residents. The impact of this requirement, when added to the demands of competitive bidding and the increasing cost of the many layered regulatory long term care environment, will be a wholly unnecessary burden to nursing facilities that obtain a supplier number and provide and bill for DMEPOS services directly.

Background

The proposed rule requires DMEPOS suppliers to provide CMS with a surety bond as a condition of the issuance or renewal of a supplier number. Each Medicare-enrolled DMEPOS supplier would be required to obtain a surety company bond for each National Provider Identifier (NPI) from an authorized surety in the amount of $65,000. CMS adjusted the amount of the surety bond requirement in 1997 ($50,000) by the Consumer Price Index (CPI) to calculate the new level. CMS is not proposing to annually adjust the surety bond amount annually by the CPI, but will consider further adjustments through future rulemaking.

The proposed rule notes that this requirement would apply to each location owned by the DMEPOS supplier, as each location is "required to be enumerated with a unique NPI." Therefore, as proposed, CMS would require each Medicare-enrolled DMEPOS supplier to obtain a $65,000 surety bond for each Medicare-issued NPI. The rule further proposes that a supplier that becomes a Medicare-enrolled DMEPOS supplier through the transfer or purchase of assets or ownership interest must provide a surety bond that is effective from the date of the purchase or transfer.

DMEPOS suppliers operated by a federal, state, local or tribal government agency would be exempt from the surety bond requirement if they provide CMS with a comparable surety bond required under state law and if the supplier does not have any unpaid claims, civil monetary penalties or assessments. Government suppliers that do not qualify for an exception must submit a surety bond. CMS reasons that government-operated suppliers

---

[2] The report language expressly identifies other providers that may be subject to this rule as "Home health agencies, comprehensive outpatient rehabilitation facilities, and rehabilitation agencies, as well as other health care providers including ambulance services must provide $50,000 or more as a surety bond. There is no express reference to nursing facilities or any legislative history discussing the nursing facility as the direct supplier of such services as being obligated to pay such a bond as a requirement of providing covered supplies to the residents.

[3] We are using the term nursing facilities to mean both facilities that provide Medicare skilled care and facilities that do not provide Medicare skilled care.

have the power to tax or receive the benefit of taxes, making it unlikely they would be unable to pay their Medicare debts. However, government-owned suppliers with a poor history of Medicare-debt payment would be subject to the surety bond requirements.

CMS estimates the average annual cost for a DMEPOS supplier for such a bond would be $2,000, or 3 percent of the bond's value. Due to the cost of the bond, CMS estimates that as many as 15,000 DMEPOS suppliers currently enrolled in Medicare would decide to stop providing supplies to Medicare beneficiaries if the rule is implemented. According to CMS, 22 percent of these suppliers are in rural areas but CMS believes that most of this business would be assumed by the remaining Medicare-enrolled DMEPOS suppliers.

CMS believes that establishing a surety bond requirement for DMEPOS suppliers would:

- Limit risk to Medicare from fraudulent DME suppliers;
- Enhance the Medicare enrollment process to ensure only legitimate DME suppliers are enrolled in the program;
- Ensure Medicare recoups erroneous payments that result from fraudulent or abusive billing practices by allowing CMS or its designated contractor to seek payments from a surety; and
- Ensure Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers.

Lastly, CMS is soliciting comments on whether exemptions should be provided for certain suppliers, specifically certain physicians and non-physician practitioners who occasionally furnish DMEPOS items as a convenience for their patients, licensed pharmacists who furnish DMEPOS items as a convenience for their patients, large, publicly traded suppliers of DMEPOS items; and rural DMEPOS suppliers. CMS also is seeking comments on appropriate criteria for such exemptions and the appropriate criteria that it may use for **establishing exceptions through a waiver of this requirement for other types of DMEPOS suppliers from the requirement to purchase a surety bond**.[4] We believe that nursing facilities should be exempt as there are other available requirements that ensure appropriate services are provided to residents of nursing facilities.

Discussion and Analysis

CMS should waive this requirement for nursing facilities that provide and bill for covered DMEPOS, in particular parenteral and enteral nutrition (PEN) therapy,[5] to their own

[4] 72 Federal Register at 42004.

[5] Parenteral and enteral nutrition (PEN), and related accessories and supplies, are covered under the Medicare program as a prosthetic device. If a provider provides PEN items under Part B, it must qualify for and receive a supplier number and bill as a supplier. *Medicare Claims Processing Manual, Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*.

residents for three critical reasons: first and foremost, nursing facilities have the authority to select the supplier of services for patients within the facility -- and have the ability to be their own supplier if that will optimize the potential for quality care. Secondly, the problems that the proposed rule seeks to address appear historically to be those, as explained by CMS itself the preamble to the original proposed rule of January 20, 1998, associated with certain small independent businesses that are essentially or exclusively suppliers of DME and not with nursing facilities that have acquired a supplier number – and now an National Provider Identifier (NPI) -- and provide DMEPOS to their own residents. Third, there are other legal and regulatory requirements imposed upon nursing facilities to ensure they are qualified to provide such supplies to their residents absent this requirement.

I. Adding The Requirement of A Surety Bond To That of Competitive Bidding Will Render It Impossible for Facilities to Supply DMEPOS To Their Residents

Section 483.30 of Part 42 Code of Federal Regulations (CFR) requires a facility to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident as determined by resident assessments and individual plans of care. Thus, the skilled nursing facility sector is responsible for meeting the vast array of resident medical requirements and has an obligation to be responsive to clinical needs in a very timely manner. This obligation cannot be ignored, nor should it be undermined.

Many nursing facilities have established relationships with suppliers of covered products and supplies that are built on trust, service and responsiveness. Some nursing facilities obtain a supplier number and supply and bill for the services directly. Other nursing facilities obtain a supplier number and employ a third-party to bill for the services. The bottom line is that it is the responsibility of the facility to provide high quality DMEPOS services and items and all other services needed by the residents. That responsibility should include the flexibility to choose the best mode of providing them.

Recently, a huge challenge emerged to the ability of facilities to choose the best way to provide DMEPOS services. CMS has imposed competitive bidding on facilities who are their own suppliers. In its comments to the proposed competitive bidding rule,[6] AHCA urged CMS to exclude nursing facilities from the scope of the competitive bidding process. We argued that altering the acquisition of DMEPOS services could affect the ability of facilities to meet their regulatory obligations. We emphasized that the same types of concerns that led the agency to adopt special rules for pharmacy procurement to beneficiaries in nursing facilities should apply here. At a minimum, we hoped that CMS would be willing to study the affects that competitive acquisition will likely have on patients and institutions before extending the demonstration to include nursing facilities since earlier demonstrations did not support the proposed competitive bidding rule.

---

[6] *Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues,* 71 Federal. Register. 25654 (May 1, 2006). Proposed Rule. Comments submitted by AHCA on June 28, 2007.

CMS did not provide a comprehensive exemption for nursing facilities. Instead, in the final rule, the agency permitted both nursing facilities that provide skilled care and those who do not to furnish such items to competitively bid items **only** to their own residents. The facilities will still be required to submit a bid and have a bid in the winning range and they must indicate in their responses to the Request for a Bid (RFB) they intend to elect this option. If the facility is not selected as a contract supplier, it will have to use a contract supplier within the competitive bidding area to furnish competitively bid items to its residents.

As CMS is well aware, the initial registration and accreditation phase for the facilities in the designated areas was fraught with difficulty. Nevertheless, there are facilities that are bidding to continue providing covered supplies and have begun or completed the accreditation process. In addition, the entire process was very costly for each facility – one small chain reported staff time and other costs of over $4,000 per facility.

It is unclear how many facilities in the competitive bid areas will cease to provide DMEPOS to their own residents based on the bidding process alone. However, adding a surety bond requirement to the complications and cost of competitive bidding would further diminish the potential for facilities themselves to provide such services to their residents. Facilities will be forced to accept suppliers that they have not chosen and quality may be compromised.

The additional requirement of a surety bond is duplicative of the goals and purpose of the accreditation process. And the cost of the surety bond is in addition to others fees associated with a variety of requirements imposed on nursing facilities. These fees mount up.[7]

In short, CMS should not impose yet another costly requirement, a DMEPOS surety bond, which will deter nursing facilities from providing DMEPOS directly to the resident – unless the requirement is a necessity, a *bona fide* response to a *bona fide* problem. CMS has not demonstrated in the proposed rule that this is the case for facilities acting as their own suppliers. CMS appears rather to emphasize that the proposed rule is responsive to problems in the universe of small DMEPOS suppliers and is needed as a deterrent to illegal fraudulent behavior of some small independent entities.

---

[7] For example, nursing facilities, pursuant to 41 CFR 483.10(c)(7), already have to provide a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility. This surety bond is the commitment of the facility in an objective manner to meet the standard of conduct specified in §483.10(c)(2), that the facility will hold, safeguard, manage and account for the funds residents have entrusted to the facility. The facility assumes the responsibility to compensate the obligee for the amount of the loss up to the entire amount of the surety bond.

II. The Requirement of A Surety Bond for Furnishing DMEPOS Is Neither Appropriate Nor Necessary As a Fraud Deterrence for a Nursing Facility Who Is Its Own DMEPOS Supplier

A. Nursing Facilities Which Provide DMEPOS To Their Own Residents Are Not Commercial Model Suppliers Addressed by The Proposed Rule

As indicated above, the exemptions being considered by CMS for certain physicians and non-physician practitioners and licensed pharmacists is based on the fact that furnishing DMEPOS is not their primary activity – they furnish DMEPOS for the convenience of their patients. Their providing of DME in such a limited fashion does not reflect the DME supplier commercial model. Obviously, CMS believes that under such circumstances, where the primary activity is not supplying DME, a surety bond may not be warranted.

We agree and believe that nursing facilities also fall into this category. Nursing facilities are also furnishing DMEPOS, primarily enteral nutrients, equipment and supplies along with some orthotics, **solely** to their patients and for the safety and quality of the services provided to their patients. In terms of the provision of DMEPOS being an adjunct to another primary enterprise, nursing facilities are exactly like physicians and non-physician practitioners and licensed pharmacists and bear little to no resemblance to independent DMEPOS suppliers. In fact, CMS itself recognized this fact in the competitive bidding final rule. While CMS believed that the Medicare DMEPOS competitive bidding program should apply to institutional providers, it acknowledged that nursing facilities did not provide DMEPOS services to beneficiaries in the community and that this distinguished them from the norm and called for at least a limited exemption from competitive bidding. CMS stated:

> However, we believe that SNFs and NFs should be treated differently from other providers in terms of who they must furnish items to because **they generally do not use a commercial model of providing services throughout the community. Instead, they generally provide items only to patients that reside in their facility**.....we are finalizing our proposal under § 414.422(e)(2) to permit SNFs as defined in section 1819(a) of the Act, to furnish competitively bid items only to their own residents. We are extending this provision to NFs, as defined in section 1919(a) of the Act, because we believe the services they furnish, the customers they serve, and their business model are parallel to SNFs. 72 Federal Register 18027. Emphasis added.

CMS clearly believes that a surety bond is an appropriate deterrent to fraud in the DMEPOS commercial model supplier environment. CMS indicates that the DMEPOS industry is primarily made up of small entities (based on Medicare reimbursement) providing a broad array of items (e.g. blood glucose monitors, hospital beds, nebulizers, oxygen delivery systems, and wheelchairs) throughout the community. 72 Federal Register 42007. CMS in its original proposed rule was explicit regarding the types of problems that CMS was seeking to address regarding these independent suppliers; problems including misrepresentation to the government, misrepresentation to beneficiaries, false warranty information, lack of permanent telephones, false or non-

existent addresses, improper telemarketing, and mounting debt to the government -- in the nature of improper payments, interest, civil money penalties and assessments -- that could not be collected. A surety bond -- and the threat of its loss -- appeared to CMS, and obviously still does, to be an appropriate and reasonable tool for deterring potential illegal behavior in the **small independent commercial model** DMEPOS business environment. In this regard, it is to be noted that that CMS even questions whether or not it is an appropriate deterrence tool for large DME chains and asks for comments on whether or not to exempt them.

It is to be noted that the Small Business Administration (SBA) in its comments on the proposed rule[8] opposing the blanket application of the surety bond required to small DMEPOS businesses argues that CMS did not did not provide an adequate analysis of the problems in the DMEPOS industry to warrant blanket application to small DMEPOS suppliers; e.g., the percentage of the industry that is contributing to the fraud problem; are the problem providers mostly urban or rural; what is the percentage of recidivists etc.. The SBA concludes that such failure makes it impossible to reasonably justify the required amount of the bond, the costs and benefits of the regulation and whether significant alternatives exist that would minimize the rule's impact on small DMEPOS suppliers.

We reference the SBA's comments to make the point that while the impact analysis for small DMEPOS suppliers may be inadequate, there is absolutely no analysis nor any recognition at all in the proposed rule of the existence of nursing facilities that have their own supplier number and provide DMEPOS to their own residents. There is thus absolutely no rationale provided by CMS for applying a surety bond requirement to such facility suppliers.

Indeed, a rationale does not exist. To reiterate, Congress expressly has authorized the Secretary to waive this requirement for certain providers. Thus, CMS should maintain the consistency between the application of the competitive bidding requirement to facilities that provide DMEPOS to their own residents -- distinguishing them from commercial model suppliers -- and the application of this surety bond requirement.

B. The DMEPOS Surety Bond Is Not Needed In The Nursing Facility Environment

The independent small DMEPOS supplier is a stand alone entity. The supplier who is the nursing facility obviously is not and both the facility and the facility as supplier are part and parcel of a highly regulated industry with massive and unrelenting enforcement of regulations and voluminous guidance that govern every single aspect of the industry: the behavior of the care givers; the quality of care; the appropriateness of the level and the nature of the care; the timing of the care; the accuracy of records, the accuracy of claims etc. In short, many requirements that ensure appropriate services are provided to residents of nursing facilities.

---

[8] *Comment Letter* to Kerry Weems from the SBA, Office of Advocacy, on DMEPOS Surety Bond proposed rule, September 13, 2007, http://www.sbs.gov/advp/laws/comments/cms07_0913.html.

In addition, when a facility obtains a suppler number to provide its own residents with DMEPOS and bills Medicare, the facility and the supplier are one and the same with respect to Medicare – often or usually having the same federal tax ID number. In cases of denials and overpayment, the fiscal intermediary and /or Medicare Administrative Contractor has access to the Medicare reimbursement to both and can recoup from the facility funds owed to Medicare by the supplier.

It is clear that a requirement for imposing a surety bond would not be an effective tool in the nursing facility industry. Rather, it would be overkill. Violation of nursing facility e regulations and guidance calls forth the attention of surveyors, the fiscal intermediaries (FIs) and the carriers -- transitioning now to Medicare Administrative Contractors (MACs) addressing both Part A and Part B – the attention of the OIG, and that of any one of a broad array of Medicare integrity contractors and an equally broad array of penalties. Adding a surety bond requirement for the facility in its role as a supportive DMEPOS supplier to its residents cannot increase the effectiveness of the existing oversight. It can and will increase cost.

Conclusion

AHCA asks that the Secretary waive the provisions and provide for an exemption from the requirement of a surety bond for nursing facilities that provide DMEPOS to their own residents. Facilities should be encouraged to be a qualified supplier for their residents if that will optimize the potential for quality care and not further discouraged by the addition of a surety bond to the demands of competitive bidding. Secondly, there is no need for a surety bond as a deterrent to illegal behavior in the nursing facility environment that has manifold regulation, enforcement and numerous types of penalties addressing potential violations of governing law in every facet of their care efforts. Adding a surety bond requirement for the facility in its role as a supportive DMEPOS supplier to its own residents cannot increase the effectiveness of the existing oversight. It will increase cost.

Sincerely yours,

Bruce Yarwood
President and CEO

8

September 27, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8017
Baltimore, MD 21244-8017

To Whom It May Concern:

As a professional money manager with 50 years of investment experience, I feel the need to express my concerns regarding the proposed rule CMS-6006-P-1: Surety Bond Requirement for Suppliers of DMEPOS.

As many of my clients are professionals in the medical field, I feel qualified to offer a unique perspective on this situation. Many of my clients, who are products of highly renowned medical institutions around the country, own and operate small local practices. I feel that a uniform bond requirement of $65,000 for all suppliers produces a significant burden to these small businesses. In a time where our country's national savings rate is at a historic low, any measure that limits a professional's ability to save money through a retirement program seems counterintuitive.

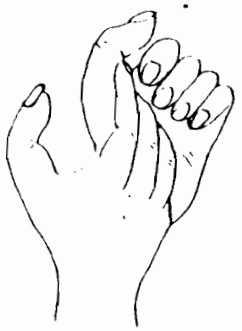
The estimated $2000 per year cost of the bond can be seen as an unneeded government intrusion, and will have a significant negative effect on small practices and their patients. In my experience, it is difficult enough for medical professionals to be paid through Medicare and insurance companies. This added burden appears to go too far, and I strongly support the exemption of physician and non-physician practicioners unless there is a history of Medicare fraud.

I appreciate the opportunity to comment on this proposal. I am confident that you will take the necessary steps to protect both those professionals and their clients who would be negatively affected.

Sincerely,

Richard Armstrong
Senior Vice President – Investments
The Armstrong & Walters Investment Group
Janney Montgomery Scott LLC

6060-P



CAPITAL DISTRICT HAND, PHYSICAL & OCCUPATIONAL THERAPY SERVICE, PLLC
1201 Nott Street, Suite 105-A
Schenectady, NY 12308

Specializing in Therapy and Rehabilitation for the Hand and Upper Extremity

Ruth Leadley, OTR, CHT
Hildy D. Reich, PT, CHT
Cecilia McClain, OT

9

Sept. 25, 2007

To: Centers for Medicare p/y
Dept. of Health & Human Srvcs.
PO Box 8017
Baltimore Maryland 21244-8017

From: Mrs. Dianne Levesque.
1020 Wendell Ave
Schenectady, NY, 12308

To whom it may concern.
my hand therapist has (Ruth Leadley, OTR CHT) treated me since May 2006. She has had to make me splints for my hands. Without her experience and service I would not be able to use my hands at all. To charge these new fees is going to close small providers like hers.

Thank You
Dianne Levesque

CENTRAL
Hand Therapy

10

September 26, 2007

Centers for Medicare and Medicaid Services
Department of Health & Human Services
PO Box 8017
Baltimore, Maryland
21244-8017

To Whom It May Concern:

Thank you in advance for taking the time to read my comments on the proposed rule CMS-6006-P-1. As an Occupational Therapist specializing in upper extremity rehabilitation this proposed rule gravely concerns me for the reasons stated below:

#1. It puts undue and unreasonable financial strain on therapists in small private practices. It is often this professional group who are the most qualified to fabricate and prescribe the most effective orthosis.

#2. It will delay treatment. If a patient cannot be provided with the necessary orthosis at the time of treatment, because they need to go elsewhere, this will delay the recovery process, and in some cases put the patient at risk for further injury if the right orthosis is not provided at that initial point of contact.

#3. It will allow unqualified individuals to fabricate custom splints because of their ability to pay, instead of having the most knowledgeable and qualified individuals doing the job. It is in the domain of both Occupational Therapy and Physical Therapy to fabricate custom orthoses to protect patients' surgical repairs of tendons, ruptures of ligaments, fractures etc. It is not in the scope of practice of any other professional group to do so.

#4. It will yet be another hoop for the already frustrated patient to jump through in their quest for good, timely health care in this country.

#5. This rule favors big business, and turns yet another aspect of patient care into a corporate decision making process, instead of a clinical decision making process.

Since there will be a pending accreditation process physician practices, Occupational Therapy and Physical Therapy practices should be exempt from rule CMS-6006-P-1.

Please do not underestimate the role Occupational Therapists and Physical Therapists play in this aspect of patient care.

Sincerely,

Julia Grover OTR/L, CHT
Central Hand Therapy, PC
PO Box 30550
Tucson, AZ 85751-0550

NATIONAL ASSOCIATION OF SURETY BOND PRODUCERS
1828 L Street, NW, Suite 720
Washington, DC 20036-5104
Tel: 202.686.3700
Fax: 202.686.3656
www.nasbp.org

Via Express Mail

September 25, 2007

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

Re: **File Code CMS-6006-P**: Medicaid Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (72 Fed. Reg. 42001, August 1, 2007)

Dear Centers for Medicare & Medicaid Services (CMS):

On behalf of the National Association of Surety Bond Producers (NASBP), an international trade association established in 1942 and located in Washington, DC serving a membership of firms with personnel of over 5,000 surety agents and brokers, who specialize in providing surety bonds to companies and individuals for construction and other commercial purposes, I am writing to express our support for the spirit and direction of the proposed rule published in the Federal Register on August 1, 2007, concerning a surety bond requirement for suppliers of durable medical equipment. To that end, NASBP offers general and specific comments to assist CMS to understand surety underwriting terminology, practices, and concerns so that the final rule will represent a workable and attractive standard for the surety community.

General Comments on Proposed Rule

The proposed rule correctly notes the substantial benefit of prequalification that will inure to the Medicare program by requiring that suppliers undergo the underwriting analysis of surety companies to obtain surety bonds to meet enrollment requirements. Each surety is an independent business and will adopt different underwriting approaches; however, as a general principle, sureties will examine the applicant's experience, financial resources, and character in considering whether to grant surety credit. Such careful scrutiny will indeed help to differentiate suppliers. The proposed bond amount of $65,000 is realistic and establishing a bond requirement for the majority of DMEPOS suppliers is consistent with standard suretyship.

To help CMS establish regulations and procedures that meet CMS objectives and that attract the maximum possible interest and participation by sureties, *NASBP will point out those aspects of the proposed rule that may serve as deterrents to achieving these goals.* From the surety perspective, key issues or concerns include the following:

- The proposed rule seems to obligate the surety to pay on claims simply by receiving notice and without receiving supporting documentation about the loss.
- The proposed rule does not appear to include a right by the surety to cancel the bond. The presence or absence of such a right is an important underwriting factor, particularly with respect to "continuous" bonds. It is important to note that the right to cancel by the surety does not mean the surety can be excused from liability for acts of its principal that occurred while the bond was in effect. It does mean, however, that by giving reasonable written notice to the obligee, a surety can be relieved from liability as to future acts. Such a clause is favored by sureties because, simply put, circumstances change. Without including such a cancellation right, sureties may be reticent to write these bonds.
- Bond coverage includes "civil money penalties" and other assessments which are variable and which shift the purpose of the bond from acting in the form of a guarantee for recouping substantiated losses to one serving, at least in part, as a form of penalty. Bonds should only cover amounts for proven losses and should not include amounts for civil penalties. Bonds incorporating amounts for civil money penalties within coverage usually are disfavored by sureties.

These concerns and others are discussed more fully below.

Specific Comments on Provisions of Proposed Rule

Below are selected provisions of the proposed rule on which NASBP wishes to provide specific comment.

1. Section 424.57 - Definition of "Unauthorized Surety."

The proposed rule provides that a surety shall be deemed unauthorized "if it had previously failed to comply with a reasonable request from us for payment against a bond." The example cited is "a request in writing, signed by an official of CMS or its representatives, or documentation about the amount payable by the supplier."

Comment:

In the event of notification of a default from a bond obligee, the surety has a duty to the obligee to respond promptly and investigate fully the claim being presented and to make payment to the obligee for loss it may incur for which the principal is legally obligated. To secure such payment, however, the obligee must provide the surety with sufficient proof of default of the principal. A

simple letter with nothing more (such as substantiating documentation) is not sufficient proof of the loss and should not constitute grounds for considering a surety as an "unauthorized surety."

2. Exceptions to the surety bond requirement for certain physicians and non-physician practitioners.

Comment:
NASBP believes that providing exceptions for the "occasional" or low volume supplier has merit. To that end, CMS could consider establishing a minimum threshold of payments as the delineation for an "opt out" exception for the furnishing of surety bonds by small volume suppliers. For example, a supplier with annual payments less than a stated dollar amount could opt out of the requirement to furnish a surety bond.

3. Exceptions to the surety bond requirement for certain licensed pharmacists.

Comment:
NASBP reiterates its position above that an exception should be considered for "occasional" providers, which could be accomplished through setting a threshold of payments at a stated dollar amount.

4. Exceptions to the surety bond requirement for large, publicly traded chain suppliers of DMEPOS.

Comment:
NASBP does not believe that CMS should exclude large, publicly traded chain suppliers, as this large volume group represents a significant risk exposure, particularly in the event of bankruptcy. However, CMS might consider establishing a maximum or cap on the aggregate dollar amount of the surety bonds required of such large volume suppliers so that they are not unduly burdened.

5. Exceptions to the surety bond requirement for any other appropriate criteria.

Comment:
NASBP reiterates its position on "occasional" suppliers.

6. Sec. 424.57 (c) (26) (iv) (C) Liability for Claims.

Comments:
This provision appears to be in conflict with sub-section (B). Part (B) provides that "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...*"

Part (C) provides that "the surety remains liable for unpaid claims, CMPs, or assessments that ...*took place during the term of the bond or rider...*"

Standard practice in the surety industry would suggest that part (B) be revised to place liability on the surety whose bond was in effect at the time of each respective default as provided by (C).

7. Sec. 424.57 (c) (26) (v) Cancellation of a bond.
The proposed rule allows the DMEPOS supplier to terminate or cancel a bond upon proper notice (30 days) to the NSC.

Comment:
The surety also should be allowed the privilege of terminating or canceling the bond. Further, since the CMS is to be named the obligee, notice of cancellation, whether given by the surety or the principal, should be delivered to CMS. A copy also could be required to be sent to NSC.

8. Sec. 424.57 (c) (26) (v) Lapse in bond coverage.

Comment:
The proposed rule requires the surety to "immediately notify the NSC if there is a lapse in coverage." This requirement is unreasonable since the expiring surety would have no knowledge whether a replacement bond has been issued or if the billing privileges of the principal have been revoked. Providing the surety with the right to cancel the bond and requiring the surety notify CMS and NSC if the surety has received a notification of cancellation from the principal should be adequate.

9. Sec. 424.57 (c) (26) (v) (G) DMEPOS supplier's failure to appeal.
The proposed rule provides that "the liability of the DMEPOS supplier and the surety is not extinguished by...(G) The DMEPOS supplier's failure to exercise available appeal rights under Medicare *or to assign the rights to the surety."*

Comment:
Upon receipt of notification of a default from CMS or NSC, the surety should be provided the same rights to the appeal process as the principal. To provide otherwise would result in an unjust enrichment for the CMS.

10. Sec. 424.57 (c) (26) (viii) (A) Submission of initial surety bond to NSC.

Comments:
It is unclear whether the original application and documentation for approval is submitted to DHHS or NSC. The bond, all riders, and notices of cancellation, should be filed with DHHS to avoid any confusion or loss of data should the Department change contractors.

11. Sec. 424.57 (c) (26) (viii) (B) Continuous bond or annual bond.

Comments:
Requiring a bond that is continuous until canceled is the most efficient method and requires minimal maintenance of files.

12. Sec. 424.57 (c) (26) (x) Change of surety-liability.

Comments:
This provision appears to be in conflict with sub-section (B). Part (B) provides that "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...*"

Part (x) provides that "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.*"

Standard practice in the surety industry would suggest that part (B) be revised to place liability on the surety whose bond was in effect at the time of each respective default as provided by (C).

NASBP appreciates the opportunity to provide these comments to CMS. Although NASBP supports the overall direction and spirit of the proposed rule, NASBP respectfully requests consideration of its concerns and comments in the final rule. Further, NASBP would welcome a dialogue with CMS to assist CMS in developing specific proof of loss guidelines for bond claims and in clarifying bond requirements so they comport with prevailing practices and terminology.

Please do not hesitate to contact me at (202) 464-1173 or mmccallum@nasbp.org should you have questions or concerns about these comments.

Sincerely,

Mark H. McCallum
General Counsel & Director of Government Relations

cc: Richard A. Foss, NASBP
Lynne W. Cook, NASBP

ORTHOPEDIC CARE HAND CENTER
23-00 ROUTE 208 • FAIR LAWN, NEW JERSEY 07410
Tel: (201) 796-6140 Fax: (201) 796-6372

12

September 26, 2007 Re: CMS-6006-P-1

To: Centers for Medicare & Medicaid Services
Department of Health & Human Services
PO Box 8017
Baltimore, Maryland 21244-8017

From: Orthopedic Care Hand Center
23-00 Route 208
Fair Lawn, NJ 07410

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As an Occupational Therapist in private practice, specializing in the treatment of the upper extremity patient, I have significant concerns re: the effect of this rule on my practice and patients.

The supply of DMEPOS is an important component in the treatment of my patients. The overall impact of orthoses and the ability to provide these orthoses immediately and concurrently with therapy has an immeasurable effect on the final outcome. In just the past year of about 70 patients that were made custom fabricated splint, over 40 of them use Medicare as their primary insurance. A $2000 security bond would average almost 30% of what our office has billed DMEPOS in the past year, not including other equipment used. As a small provider, Orthopedic Care hand Center would not be able to afford this expense. For most of our Medicare patients, Medicare is the primary if not only insurance they use, being a participating member of Medicare offers most of our patients therapy that is affordable. Our inability to offer custom fabricated splints and other equipment through DMEPOS would place undo financial hardship on more than half of our patient population. We utilize orthoses to protect, support, affect motion, and improve independent ADL function. The nature of our patients' acute and changing conditions requires the frequent adjustment of these orthoses, often immediately following their treatment to maintain and improve on gains made in therapy. The importance of our continued ability to fabricate orthoses and make timely adjustments cannot be underestimated.

Impact: I feel that this rule may affect my ability to fabricate and supply orthoses. As a small business, the estimated $2000 cost of the surety bond per NPI # in addition to the new costs of accreditation would be an undo hardship on my office. You estimate that up to 15% of individual suppliers will discontinue enrollment. It is my opinion that many of

ORTHOPEDIC CARE HAND CENTER
23-00 ROUTE 208 • FAIR LAWN, NEW JERSEY 07410
Tel: (201) 796-6140 Fax: (201) 796-6372

these will be practitioner/suppliers whose DMEPOS billing is only a percentage of their business. While you are predicting that their patients will be able to find comparable benefits from other local suppliers, I feel the acute and frequently changing nature of this type of DMEPOS, intimately connected to the therapy they are receiving, would preclude these patients from finding an effective alternative supplier. The loss of practitioner/supplier enrollees- and subsequently their ability to supply DMEPOS- will adversely affect both the cost of treatment and the final outcome of these enrollee's patients. Orthopedic Care Hand Center is a small practice with only one full time therapist. My practice along with other small providers may be unable to continue billing for DMEPOS due to the fact that a $2000 security bond is a significant portion of our generated profit. Custom molded splints are an essential part of the therapeutic process and it is our obligation as providers to give our patients the most appropriate treatment to further future rehabilitation. Once again, a $2000 security bond will financially impede any care given to patients that require products that would be billed to DMEPOS.
I support the exemption of physician and non-physician practitioners from this rule unless there is a previous adverse history of Medicare fraud. I also feel that a surety bond would offer little or no additional protection to CMS since accreditation is already providing a greater level of security.

Thank you for the opportunity to comment of this proposed rule.

Sincerely,

Mary C. Bassman, O.T.R., C.H.T.

APTA
American Physical Therapy Association

1111 North Fairfax Street
Alexandria, VA 22314-1488
703 684 2782
703 684 7343 fax
www.apta.org

September 25, 2007

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention:CMS-6006-P
P.O. Box 8017
Baltimore, MD 21244-8017

RE: Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (72 FedReg. 42001, August 1, 2007)

Dear Mr. Weems:

On behalf of our 70,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) appreciates the opportunity to comment on the proposed rule regarding the surety bond requirement for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

Physical therapists provide orthotics, ambulatory aids, and mobility assistance devices to the patients they serve to help them improve their function. These items become an integral part of the treatment plan for the patients who need them. Thus, physical therapists have a significant interest in this rule.

As the Center for Medicare and Medicaid Services (CMS) proceeds with implementation of the surety bond requirement, APTA strongly urges you to ensure that this requirement does not diminish beneficiary access to medically necessary items or disrupt the delivery of care to Medicare beneficiaries.

Background Information Regarding Provision of DMEPOS by Physical Therapists

Physical therapists practice in a wide variety of settings including acute care hospitals, inpatient rehabilitation facilities, skilled nursing facilities (SNFs), rehabilitation agencies, home health, physical therapist private practice offices, and comprehensive outpatient rehabilitation facilities (CORFs). Physical therapists in private practice (PTPPs) enroll in the Medicare program, obtain individual provider numbers, and bill Medicare directly for the outpatient therapy services they furnish.

Currently, if a physical therapist in private practice bills for DMEPOS items, the therapist must obtain a National Supplier Clearinghouse (NSC) supplier number in addition to their individual National Provider Identifier (NPI). In contrast, physical therapists working in CORFs, rehab agencies, home health, and hospitals do not obtain their own NPIs. Rather, their therapy services are billed through the facility. If the facility bills for DMEPOS, the facility must obtain the NSC number or obtain the DMEPOS items from a NSC supplier that bills the Medicare program for the item.

DMEPOS items are provided by physical therapists as an integral part of their physical therapy plan of care. The clinical judgment and expertise of the physical therapist is critical in selecting a particular DMEPOS item for the patient and is based on the therapist's evaluation of the individual patient. The physical therapist ensures that the item is appropriate to achieve the patient's functional goals, is properly sized and fitted for the patient, and that the patient and/or caregiver is educated in the proper use of the item. In many cases, it is essential that the patient have timely access to these items because the DMEPOS item may be necessary to immobilize and support an injured body part or to facilitate safe mobility or post-surgical recovery.

Providers and Practitioners Furnishing DMEPOS Integral to Their Plan of Care Should be Exempt from the Surety Bond Requirement

Under the proposed rule, DMEPOS suppliers (rehabilitation agencies, hospitals, CORFs, SNFs, physical therapists in private practice, and other practitioners who choose to bill for DMEPOS items) would be forced to obtain a surety bond in the amount of $65,000 in order to continue to provide and bill Medicare for those items. Recent CMS data shows that there are currently 40,000 practitioners and providers enrolled as NSC suppliers, including approximately 1,078 physical therapists in private practice that also have NSC supplier numbers. CMS estimates in this proposed rule that, as of April 2007, there were 116,471 individual DMEPOS suppliers. When considering the affiliation of some DMEPOS suppliers with chains, CMS estimates that there were only 65,984 unique supplier numbers.

APTA strongly urges CMS to exempt from the surety bond requirement physical therapists in private practice, providers, and other practitioners enrolled in the Medicare program that provide DMEPOS integral to their plan of care. This exemption should not apply if they are solely in the business of furnishing items, not providing patient care.

The private practice setting for physical therapists provides a clear example of why an exemption or special consideration is necessary. Physical therapists in private practice typically are small businesses providing DMEPOS only to their own patients as an integral part of their service. It does not make sense to apply the same standards to PTPPs as those applied to large commercial suppliers who are exclusively in the business of providing items.

Physical therapists in private practice typically provide services only to their own patients. Yet, under the proposed surety bond requirement, these therapists would be required to get a costly surety bond before enrolling or re-enrolling as a DMEPOS supplier. Physical therapists in private practice often specialize in treating certain conditions and provide a limited range of DMEPOS items for those particular conditions, such as specializing in lower extremity care or upper

extremity care. Given the small size of physical therapy practices and the scope of services they furnish, the potential for fraud and abuse is limited. Additionally, the cost of a surety bond may force some physical therapists to not enroll or discontinue their enrollment as a DMEPOS supplier.

Medicare beneficiaries will be adversely impacted if physical therapists in private practice can no longer provide items to their patients in their offices. DMEPOS items such as prefabricated and custom orthotics and ambulatory assistance devices are commonly furnished by physical therapists in their office as part of an ongoing plan of care. Physical therapists must be integrally involved in providing DMEPOS items to their patients to ensure that the item is appropriate for the patient's condition or functional limitations, properly sized and fitted for the patient and the patient and or caregiver is instructed in the proper use of the item. In many instances, it is necessary for the physical therapist to provide the item before the patient leaves their practice. For example, physical therapists often provide patients with orthotics to immobilize a body part, such as fracture braces for humeral fractures, air casts for ankle sprains, or static wrist orthotics for carpal tunnel syndrome. When a physical therapist is treating a patient with a fracture or a sprain, it is necessary to immediately provide the patient with the orthotic to immobilize the injury. It would be unsafe and clinically inappropriate to delay the patient's access to items such as orthotics or ambulatory support devices.

Physical therapists also use orthotics to facilitate or augment a patient's movement. It is common for a patient who has had a stroke to develop weakness in his or her ankle dorsiflexors, resulting in a foot drop during the swing phase of gait. Physical therapists provide the patient with an ankle-foot orthosis to facilitate movement at the ankle so the patient will not risk tripping or stumbling during ambulation. Patient falls frequently result in further injury and a cascade of other adverse events. By fitting the patient with the appropriate orthosis in the office, the physical therapist can proceed with gait training to assess whether there are sensory or skin problems and determine whether the orthosis allows the patient to ambulate properly.

DMEPOS products are frequently needed as part of an ongoing plan of care for patients with musculoskeletal, neurological and pulmonary related conditions. Ambulation aids including canes, walkers and crutches are required for patients with progressively deteriorating ambulation status to facilitate balance, unload painful joints and minimize unnecessary energy expenditure associated with ambulation. It would be unsafe for a physical therapist to send a patient out of his or her office without a walker, crutches, or cane if the patient needs such an ambulation aid.

One of the goals of the surety bond requirement is to prevent fraud and abuse and ensure recoupment for overpayments. We do not believe that fraud and abuse has been a significant concern in the case of providers furnishing DMEPOS as an integral part of their ongoing plan of care. Because physical therapists often provide a limited number of DMEPOS supplies and are often in small practice settings, the administrative and financial burdens of obtaining a surety bond might eliminate an important source of DMEPOS supplies for Medicare beneficiaries. In the proposed rule, CMS offers estimates as to how many DMEPOS suppliers may decide not to enroll or discontinue their enrollment as a result of the surety bond requirement. As stated in the rule:

> "...For fiscal year 2005, approximately 15,800 billing suppliers with allowed charges of less than $1,000 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 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."

If CMS' estimates are accurate, the Medicare program would lose nearly 40% of DMEPOS suppliers. This could have a devastating impact on Medicare beneficiaries needing these items and services.

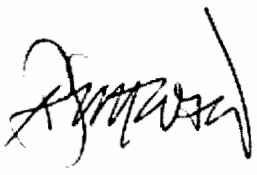
Conclusion
In conclusion, among its key recommendations, the APTA urges CMS to take the following actions:

- Exempt from the surety bond requirement physical therapists in private practice, providers, and other practitioners enrolled in the Medicare program who provide DMEPOS as integral to their plan of care.

- Ensure that beneficiary access is not jeopardized as a result of the potentially large number of DMEPOS suppliers who may not enroll or discontinue their enrollment as a result of the financial burdens the surety bond may impose.

Thank you for your consideration of these comments. We look forward to working with CMS as you proceed with implementation of this rule. If you have any questions regarding the issues raised, please contact Gayle Lee at 703-706-8549.

Sincerely,



R. Scott Ward, PT PhD
President

LITTLETON ORTHOPAEDICS PC
81 BETHLEHEM ROAD
LITTLETON, NEW HAMPSHIRE 03561
(603)444-0111
(603)444-0473 FAX

14

Lon W. Howard, MD, F.A.A.O.S.
Total Joint Replacements
Spine & Hand Surgery

Kariann Place, PA-C

September 28, 2007 Re: CMS-6006-P-1

To: Centers for Medicare & Medicaid Services
Department of Health & Human Services
PO Box 8017
Baltimore, Maryland 21244-8017

From: Lon W. Howard, MD
81 Bethlehem Road
Littleton, NH 03561

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As a physician in private practice, specializing in orthopaedic care, I have significant concerns re: the effect of this rule on my practice and patients.

The supply of DMEPOS is an important component in the treatment of my patients. The overall impact of orthoses and the ability to provide these orthoses immediately and concurrently with therapy has an immeasurable effect on the final outcome. We utilize orthoses to protect, support, affect motion, and improve independent ADL function. The nature of our patients' acute and changing conditions requires the frequent adjustment of these orthoses, often immediately following their treatment to maintain and improve on gains made in therapy. The importance of our continued ability to fabricate orthoses and make timely adjustments cannot be underestimated.

Impact: I feel that this rule may affect my ability to fabricate and supply orthoses. As a small business, the estimated $2000 cost of the surety bond per NPI # in addition to the new costs of accreditation would be an undo hardship on my office. You estimate that up to 15% of individual suppliers will discontinue enrollment. It is my opinion that many of these will be practitioner/suppliers whose DMEPOS billing is only a percentage of their business. While you are predicting that their patients will be able to find comparable benefits from other local suppliers, I feel the acute and frequently changing nature of this type of DMEPOS, intimately connected to the therapy they are receiving, would preclude these patients from finding an effective alternative supplier. The loss of practitioner/supplier enrollees- and subsequently their ability to supply DMEPOS- will adversely affect both the cost of treatment and the final outcome of these enrollee's patients.

I support the exemption of physician and non-physician practitioners from this rule unless there is a previous adverse history of Medicare fraud. I also feel that a surety bond would offer little or no additional protection to CMS since accreditation is already providing a greater level of security.

Thank you for the opportunity to comment of this proposed rule.

15

Physical Therapy Specialists Clinic, Inc.

P.O. Box 849 • 1480 West Eighth Street
West Plains, MO 65775
417-256-5669

MARY HASS SHEID, Licensed Physical Therapist

Date: September 26, 2007

RE: CMS-6006-P-1

To: Centers for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8017
Baltimore, Maryland 21244-8017

To Whom It May Concern:

As a practicing physical therapist who has her own practice, I would like to comment on the proposed rule CMS-6006-P-1; Surety Bond Requirement for Suppliers of DMEPOS. As a private practitioner I have a grave concern regarding the impact of this rule on the small practitioner/supplier and their patients.

While the supply of DMEPOS is only a portion of our overall Medicare billings, its importance to the efficient and effective treatment of our patients cannot be underestimated. Our ability to provide timely and appropriate orthotics that can be readily adjusted with the frequent changes common to our patients is critical for a final positive outcome. Anything that affects this ability to provide these vital supplies is of paramount importance to our association and its members. In particular, we would like to comment on several sections of this proposed rule.

1. We support an exemption for physicians and non-physicians practitioners. The supply of DMEPOS by these practitioners is only a component of their care of the upper extremity patient. While we request the exemption of all practitioner/suppliers, we would also support the exemption of those businesses falling under the SBA definition of a small business (less than 9 million in yearly DMEPOS receipts). We feel that a uniform bond requirement of $65,000 for all suppliers produces a disproportionate burden to small businesses when compared to large DMEPOS suppliers. Another alternative would be to require a bond from those practitioner/suppliers who have had an "adverse history" with CMS.

2. The proposed rule states that the surety bond requirement will increase scrutiny of suppliers through the requirements of the bond company. It is our position that the new accreditation rules provide a much greater scrutiny of the suppliers, including a mandatory on-site visit. A surety bond to screen suppliers is redundant, and if fact provides much less protection than the implementation of the accreditation rule.

Physical Therapy Specialists Clinic, Inc.
P.O. Box 849 • 1480 West Eighth Street
West Plains, MO 65775
417-256-5669

MARY HASS SHEID, Licensed Physical Therapist

3. Impact: The proposed rule nonchalantly predicts the loss of 15% of individual enrollees and 23% of DME suppliers due to expense. It states that this loss could be compensated by other suppliers in their area. We feel that his logic will produce a significant impact on our Medicare patients. With acute hand injury patients, it is critical that the supply and adjustment of the or the orthotics to the patient's changing needs, often immediately following therapy to help maintain the gains made from that treatment. These gains would be eradicated if time was loss while the patient leaves our clinic and attempts to find a supplier with the knowledge, skill, and immediate availability to make those adjustments. The loss of even 1 supplier/practitioner enrollee will severely affect the final outcome and cost of that practitioner's patients. We respectively feel that CMS has not considered this affect on their beneficiaries and the cost of their treatment.

In summary, I fell that this proposed rule will adversely affect Medicare beneficiaries through the loss of practitioner/supplier enrollees. We feel that the expense of this surety bond, following in close proximity to the increased accreditation costs and requirements, would cause many providers/suppliers to drop their enrollment. We support the exemption of physician and non-physician practitioners based on their status as small business owners and /or limited DMEPOS billing, and we feel that the impact of the loss of even one practitioner/supplier enrollee will adversely affect the final outcome for their patients.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Mary H. Sheid P.T.

Mary Sheid
PT, OCS

16

Response/Comments to Proposal of a DMEPOS Surety Bond Regulation:

File Code: CMS-6006-P August 31, 2007

The proposal for a Surety Bond appears to be an extreme measure for Medicare to impose on DME suppliers. The current rules and regulations in place are quite stringent.

The Quality Standards that were announced in August of 2006 requires performance measures that provide and ensure quality service is met by DME suppliers.

The reasons stated for the proposal of the Surety Bond are covered through the Quality Standards. Medicare's requirement for DME suppliers to become accredited will ensure and provide third party assurance that each supplier is compliant. The necessity of the Surety Bond would be a hurdle and a hindrance for suppliers that are striving to meet the current Quality Standards.

1. **Limit the Medicare program risk to fraudulent DME suppliers.**

   Medicare's Quality Standards already include stringent provisions to limit Medicare's fraud risk. According to the Quality Standards Section I, under part 5 of Administration, each supplier is required to:

   5. The Supplier shall implement business practices to prevent and control fraud, waste and abuse by:

   - *Using procedures that articulate standards of conduct to ensure the organization's compliance with applicable laws and regulations; and*
   - *Designating one or more individual in leadership positions to address compliance issues.*

2. **Enhance the Medicare enrollment process to help ensure that only legitimate DME suppliers are enrolled or are allowed to remain in the Medicare Program.**

   Medicare's Quality Standards already include stringent provisions to ensure that suppliers are legitimate. According to the Quality Standards Section I, under part 2 of Administration and part 4 of Administration each supplier is required to:

   2. *The supplier shall have a physical location and display all licenses, certificates, permits to operate. The licenses and certificates must be displayed in an area accessible to customers and patients. The supplier shall provide copies, upon request, to government officials or their authorized agents.*

4. The supplier shall:

- *Comply with Medicare Coverage, claim processing, and payment policies; and*

- *Comply with the Medicare disclosure of ownership and control information requirements at 42 CFR 420.201 through 420.206.*

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.

Medicare's Quality Standards already include stringent provisions to ensure that erroneous payments do not occur and are recouped if they do occur. According to Quality Standards, Section I under Financial Management each supplier is required to:

The supplier shall implement financial management practices that ensure accurate accounting and billing to beneficiaries and the Medicare Program. Financial records shall be accurate, complete, current, and reflect cash or accrual base accounting practices. The supplier shall maintain accounts that link equipment and items to the beneficiary and manage revenues and expenses on an ongoing basis, as they relate to beneficiary services including the following:

- *Reconciling charges to beneficiaries for equipment, supplies, and services with invoices, receipts, and deposits;*

- *Planning to meet the needs of beneficiaries and maintain business operations by having an operating budget, as appropriate o the business's size and scope of services; and*

- *Having a mechanism to track actual revenues and expenses.*

4. Help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate suppliers.

Medicare's Quality Standards already include stringent provisions to ensure the appropriateness of the products and services provided. According to the Quality Standards, under Section II, each supplier is required to:

II. General Product-Specific Service Standards

All DMEPOS must serve a medical purpose to be covered under the Medicare program and may require the physician to collaborate and coordinate clinical services with other healthcare professionals (e.g. orthotists, prosthetists; occupational,physical; and respiratory therapists; pedorthists;etc). In addition to the general product specific services, a supplier shall implement the supplemental product specific standards in Appendices A through C, as applicable to its business.

Please submit this response for consideration against the Surety Bond Proposal.

Sincerely,

Candi George

Candi George
Funding Supervisor
Words Plus Inc.
NSC# 0863800001
NPI# 1063417533

17

Norco
WELDING • SAFETY • MEDICAL
Supplies and Gases
1125
WEST AMITY ROAD
BOISE, ID
83705

BLUE CHIP ENTERPRISE
HQAA ACCREDITED
ISO 9001:2000 - TÜV
CERTIFIED QUALITY SYSTEM
THE BEST IN THE NORTHWEST
FAMILY BUSINESS AWARDS

(208) 336-1643 • TEL
(208) 433-6160 • FAX

September 20, 2007

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

Our organization desires to comment on the Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), which was posted in the Federal Register (72 FR 42001) on August 1, 2007. We are primarily concerned with the proposal to require a surety bond for each location that has a National Provider Identifier (NPI) number.

The original proposal, which was posted in the January 20, 1998 Federal Register (63 FR 2926), required that an organization provide a surety bond for each Taxpayer Identification Number (TIN). This requirement has since changed with the advent of the NPI number. Our concern, as a family-owned business with 25 NPI numbers, is the excessive annual costs of obtaining a surety bond for each of these locations. The government has estimated the cost of a $65,000 surety bond to be approximately $2,000, which when extrapolated would cost our company $50,000. This is an unreasonable burden to meet the government's surety bond requirement. Further, our bonding company has indicated that it will require "audited" financial statements from our organization plus financial statements from each owner. We have determined that these requirements may quadruple our costs for obtaining annual financial statements amounting to $80,000 per year - these costs are too onerous to bear and surely were not considered by the government when the surety bond issue was originally conceived.

The Department of Health and Human Services is soliciting comment on whether to establish an exception to the surety bond requirement for large, publicly traded chain suppliers of DMEPOS (p. 42004). We would ask that the department modify this solicitation to include all large chain suppliers of DMEPOS, including family-owned businesses, such as our firm. We request that large organizations be exempt from the surety-bonding requirement. In recent years, several initiatives, including mandatory accreditation for all DMEPOS suppliers, and provider scrutiny by the NSC have been employed to reduce fraud and abuse within our industry. We believe that these initiatives are sufficient to reduce fraud and protect beneficiary and governmental interests.

Sincerely,

Ned Pontious
President

18

September 3, 2007

Dear Sirs:

This is a comment on the proposed rule CMS-6006-P to require that all providers and suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to the Medicare program post "surety bonds." This NPRM was published August 1, 2007, at 72 FR 42001 (http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-3746.pdf). Since I am submitting comments electronically, well in advance of the closing of the comment period on October 1, 2007, I strongly encourage anyone who reads this comment to provide his own comments and to take into account my conclusions and recommendations, and add additional information and analysis.

I am particularly concerned that compliance with EO 12866 and the Regulatory Flexibility Act has become so perfunctory and *pro forma* that a proposed rule that patently violates both sets of legal requirements for justification of proposed regulations could be issued. The problem here is not just that this rule is substantively flawed, but that it seems that no one in a position of responsibility at HHS who reviewed this rule, or at other agencies, including at least OMB and SBA, was able or willing to say, "The emperor has no clothes."

This proposed rule directly violates Executive Order 12866. That EO requires that an agency "shall design its regulations in the most cost-effective manner to achieve the regulatory objective," "shall assess both the costs and the benefits of the intended regulation," shall "adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs," and shall tailor its regulations "to impose the least burden on society." The proposed rule not only does not meet these tests, it does not even make an attempt to meet them.

Of particular importance, because of the recently issued final rule for supplier accreditation (http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/E6-15980.pdf), and the previously existing rule requiring liability insurance, the proposed rule fails to take "into account ... the costs of cumulative regulations," as required by the EO. For DMEPOS suppliers there are actually three universal requirements for the purchase of external

review in place or proposed. (The third requirement is that suppliers purchase liability insurance, established in regulation a decade ago. One recent commenter described the same requirement in the Independent Diagnostic Imaging rule as representing "new heights of meddlesomeness" (http://healthblawg.typepad.com/healthblawg/diagnostic_imaging/index.html). Each of these imposes acknowledged dollar costs in the range of a thousand dollars a year or more (real costs, paid in cash dollars), on tens of thousands of suppliers whose total Medicare reimbursements range from zero to ten thousand dollars or less. How can the Federal government believe it sensible to impose costs on a supplier on the order of three or four thousand dollars a year to be allowed to provide services on which he makes only a few hundred dollars a year in profits? Such charges are to be imposed absent any evidence of wrongdoing or abuse of any kind or any showing that these costs save any appreciable amount of money for the government (when in fact they will cost the government money as explained below).

There is also a fourth alternative available to the government to reduce the risk of fraud and abuse, namely credit checks on suppliers through established credit-rating services, which can provide inexpensive and detailed credit reports on individuals and corporations. This alternative is particularly important because the real benefit of requiring suppliers to purchase surety bonds or to become accredited lies not in the bond itself protecting the government, but in the investigation performed by the businesses that sell the bonds. A "shady" supplier is unlikely to get the bond. Why pay a middleman when the government (or its contractor) can perform the credit check itself, or require applicant suppliers to provide the information through a verifiable submission? Furthermore, credit checks may provide a legally defensible way to comply with the spirit of the statute: HHS could require each supplier either to purchase a surety bond or to provide evidence satisfactory to HHS that the supplier has a credit rating that will enable it to pay 5 or 10 percent of its annual billings to Medicare if they are disallowed.

The proposed rule also violates the Regulatory Flexibility Act in that it fails to address obvious alternatives that would "minimize any significant economic 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 such small entities."

Likewise, it fails to conform to OMB's standards for analyzing regulations set forth in Circular A-4. The Circular says RIAs should analyze a "manageable number of alternatives" including "different enforcement methods," "different degrees of stringency," and "different requirements for different sized firms." None of this is done in the proposed rule. The so-called "Alternatives Considered" section neither presents nor analyzes any alternatives whatsoever. It simply explains that because about 99,000 NPI numbers will replace about 66,000 TIN numbers (the new NPI identification numbers apply to every business location and the existing TIN numbers to every business entity and cover all of its locations), the total cost to business will be increased by about 50 percent compared to a previous surety bond proposal published in 1998. In other words, the regulatory impact of this aspect of the proposal will increase total costs by roughly 50 percent because the government has chosen to use a numbering system that has this effect, rather than allowing multi-site businesses (e.g., chain drug stores) to pay for only one surety bond.

Incredibly, the preamble factually misdescribes the 1998 proposal, which did not propose a $65,000 surety bond level, but a sliding scale approach starting at $50,000, and rising to 15 percent of reimbursements (capped at $3 million). The result of the changes in level and scope together have the effect, unexplained in the preamble, of greatly increasing the cost to smaller suppliers and reducing the cost to larger suppliers compared to the earlier proposal. As a matter of record, the 1998 proposal was estimated to cost in total about $57 million for surety bonds, approximately one-fourth the currently estimated total. Some of this difference arises from the passage of time and its effects on the cost of bonds. Some arises from the increase in bond amount from $50,000 to $65,000, and the interaction of this change with the proposed change from business entity to business site as the locus for the requirement. However, the total number of affected entities is essentially unchanged.)

Implicit in all these legal requirements, and explicit in every authoritative source discussing the principles of cost-benefit analysis, is the principle that an agency cannot reasonably impose a rule comprised of two (or more) parts, one with net costs of a hundred million dollars, and one with net benefits of a hundred and one million dollars, and still claim that the rule is cost-beneficial because its net result is a gain of one million dollars. Every reasonable alternative must be considered and that alternative set of

requirements which maximizes social welfare or minimizes social costs is the only alternative that will "impose the least burden on society."

The proposed rule implies that any regulatory requirements imposed in the name of fraud and abuse are self-evidently so beneficial that they are exempted from the legal requirements for analysis that apply to all other rules, and can be promulgated despite their utter failure to achieve social benefits remotely commensurate with their social costs, and without even an admission of this failure or a showing that the Congress forced the unreasonable cost and a description of the changes in the underlying statute that would allow issuance of regulations that do not waste vast resources for negligible benefits.

This proposed rule is in obvious legal violation and dereliction of regulatory analysis requirements. This means that reviewers within HHS, at the Office of Management and Budget (OMB), and at the Office of the Chief Counsel for Advocacy at the Small Business Administration, have fallen prey to the same blind spot. OMB, of course, has a budgetary responsibility to reduce wasteful government spending, but this proposed rule would have the opposite effect. It is exquisitely ironic that rules promulgated to reduce government waste are given a "free pass" to be among the most wasteful of government rules. Institutions such as the General Accountability Office, the Office of the Inspector General at HHS, the AEI/Brookings Joint Center for Regulatory Studies, the Heritage Foundation, the CATO Institute, the Mercatus Center at George Mason University, and Regulatory Checkbook should sharpen their pencils and knives and address the regrettable propensity of Federal agencies and even the "regulatory cops" to allow so many unnecessarily wasteful rules to be issued and so many regulatory analysis requirements to be ignored.

In essence, I show below that by creating an exemption for what I will term the "smallest suppliers" and by making other changes (such as allowing an option for multi-site providers and reducing the bond amount to $50,000), HHS can change this rule from one that imposes vast net social costs to one that produces modest but positive net benefits.

According to the Regulatory Impact Analysis (RIA), this proposed rule would create costs to suppliers for purchase of surety bonds of about $198 million a year, but this does not even include what may the largest costs of the rule in this estimate: its effects on the access of the elderly to DMEPOS

supplies. Although the RIA fails entirely to estimate gross overpayment reduction benefits in any way, an optimistic but not totally unreasonable estimate might be $109 million a year (see below). Hence, this rule as proposed has net social costs of at least $89 million a year, and likely several times more.

Constraining HHS to some degree is an underlying (and ill-advised as drafted) statutory requirement in the Social Security Act, section 1834(a)(16)(B), that DMEPOS suppliers provide "a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000." HHS, taking this provision at face value, has proposed a rule that will cost Americans at least $89 million a year more than it saves.

In what follows I use the data in Table 2 of the Regulatory Impact Analysis (RIA) of the proposed rule, which shows the total number of suppliers at 66,000 (rather than 99,000 as estimated elsewhere in the RIA). However, I reach the HHS cost and affected supplier total by including the 33,000 additional sites in my estimate of the number of suppliers with annual billings and reimbursement at above $25,000 annually. The difference relates to multi-site suppliers, such as chain drug stores. Although HHS did not provide distributional information on the omitted entities, all or almost all would likely receive reimbursements in that amount or above.

The fraud and abuse warriors who seem to have proposed this rule have failed to demonstrate, or even allege, that this proposed rule has any consequential benefits whatsoever. However, in an attempt to remedy their omissions I have generated an optimistic estimate of potential savings. One would think that after a decade of requiring home health providers to post surety bonds there would be some credible estimate of potential savings from fraud reduction using this mechanism. It is quite possible that the reason no such estimate exists is that savings have proven to be almost nonexistent. (The GAO report quoted below states at page 3 that in the area of home health unrecovered overpayments were in the range of 1 percent or less of total reimbursements, which suggests that the potential for savings is exceedingly modest).

Using a model that greatly overstates potential fraud reduction benefits from low volume suppliers, and that ignores costs to the elderly, this rule might potentially reduce by 20 percent fraudulent overpayments and other charges that equal 5 percent of total reimbursements. Under these assumptions, total

budgetary savings (i.e. benefits) of the rule would be 1 percent of total annual DMEPOS reimbursements of about $10.9 billion. (This figure can be extrapolated from the proposed rule's Table 2. A recently published figure in 2007 CMS Statistics, Table 35, is that DMEPOS spending in 2005 was $10.2 billion.) This potential budgetary saving amounts to $109 million annually at current DMEPOS spending levels. According to HHS, total surety bond costs of the rules would be $2,000 per supplier times about 99,000 suppliers, or $198 million annually. (All assumptions and other details of the numbers resulting from my calculations can be obtained from my spreadsheet entitled "DMEPOS Surety Bond Benefit Cost Data" available at my email address below.)

In the interests of simplicity, I have not attempted to calculate the effects of the proposed rule in driving the smallest suppliers out of the program, although HHS acknowledges that these would be substantial. The 37,000 suppliers with annual Medicare billing of under $10,000 comprise over one third of total suppliers. Many small towns have only one or two suppliers and many of these will not find it economical to undergo the expense either of accreditation or of a surety bond, let alone both (or of a third expense, a liability policy as specified by HHS). The additional costs to patients who can no longer get a crutch as they leave the orthopedist's office (the orthopedist having declined to spend thousands of dollars to participate any longer as a supplier) are difficult to estimate or measure. They are not inconsequential, however, and will be of particular importance in rural and underserved areas where suppliers of any given type are few and far between.

The experience of the Medicare Prescription Drug Program, under which over a million veterans already enrolled to receive free medicines from the VA chose to enroll in PDP plans at their own expense demonstrates the importance to the elderly of convenient access. HHS knows where every supplier is located and could easily calculate the geographic locations of suppliers of different kinds of DMEPOS whose annual profits from the sale of DMEPOS could not pay the costs of surety bonds and accreditation, and who are therefore likely to leave the program, and it could calculate the resulting numbers of Medicare beneficiaries likely to be left without convenient access. In this regard, if the problem of fraud is located primarily in urban centers, such as Miami, and involves suppliers who do a large volume of business, a regulation that penalizes suppliers throughout the

West and Midwest, or in states such as Maine and New Hampshire, who do a small volume of business, is on its face mistargeted.

The HHS RIA numbers suggest, at least in relative terms, that the net benefits of the proposed rule can be analyzed as follows. Divide all suppliers into three cost tiers: reimbursements for DMEPOS of under $10,000 a year (37,000 very small suppliers), reimbursements between $10,000 and $25,000 a year (9,000 small suppliers), and reimbursements of over $25,000 a year (53,000 small, medium, and large suppliers). For suppliers with annual billings and reimbursement of $10,000 or less, savings to the government are $1 million a year and costs to suppliers are $74 million a year. That is, HHS will require these suppliers (mostly practitioners who provide DMEPOS as a convenience to their patients, such as podiatrists who examine feet and "on the spot" provide shoe inserts, or orthopedists who provide crutches to patients who shouldn't leave the office without them) to pay $74 million for surety bond polices and achieve a fraud reduction of under $1 million. For suppliers with annual billings of $10,000 to $24,999, savings to the government are $2 million a year and costs to suppliers are $18 million a year. For suppliers with annual billing of more than $25,000 a year savings to the government are $106 million a year and costs to suppliers are also $106 million a year. Total costs exceed total savings by $89 billion a year. The entire loss occurs in the lowest two tiers, $73 million in net costs for imposing surety bonds on the lowest tier alone.

These numbers demonstrate that it is an extraordinary waste of American citizens' money to require surety bonds of the smallest DMEPOS suppliers who bill $10,000 a year or less, substantial waste to impose this requirement on suppliers who bill between $10,000 and $25,000, and a possibly break even investment to require surety bonds of suppliers who bill more than $25,000. These estimates do not include increased access costs (or corresponding health costs) to elderly and other Medicare beneficiaries who lose convenient access. Any reasonable estimate of the possible range of savings from fraud reduction (say, one-tenth as much as above up to twice as much as above) will leave these conclusions unchanged for the lowest two tiers. The highest paid suppliers may or not be cost-effective candidates for surety bonds—absent serious empirical evidence, that cannot be reliably estimated. However, the correct policy decision for the lower two tiers is absolutely clear.

The matter involves additional issues. The GAO has reported on the use of surety bonds for home health agencies in "Medicare Home Health Agencies: Role of Surety Bonds in Increasing Scrutiny and Reducing Overpayments," January 1999. According to the GAO, the essential benefit of surety bonds lies not in the amount of the bond, but in the scrutiny that sureties provide as they review applicants. "Sureties scrutiny, which focuses primarily on an agency's business practice and financial status, is probably most valuable for screening new" DMEPOS suppliers (page 3). In that report, "According to HCFA officials, physicians who supply DME incidentally to their providing professional services will be exempt from surety bonds" (page 19). HHS has given no reason in the NPRM to ignore these points in drafting this proposed rule. That GAO report also recommended that agencies with a proven track record in returning overpayments should be exempted from a surety bond requirement (page 22). (The GAO assumed, in my view incorrectly, that this latter reform would require Congressional action. See the discussion below.)

Exempting professionals (including all professionals who are licensed by states, acting within the scope of their licenses, and providing DMEPOS from their office) is an important option that HHS should adopt, and one that would rectify much of the waste that would otherwise be generated by this rule. To the credit of HHS, this option is proposed specifically in the preamble of this NPRM, though ignored and unanalyzed in the RIA.

One additional category of cost could be analyzed and measured by HHS. As in all competitive markets, the cost of surety bonds will be passed on to payers. Payers are overwhelmingly insurance companies and the sponsors who pay their premiums, including those government insurance programs that rely on private insurance carriers. Those programs include Medicare Advantage, Medicare Part D, the Federal Employees Health Benefits Program, and the Medicaid and SCHIP programs that contract with HMOs and other private insurers. In total, these programs cover about one-fifth of total health care spending in America. Assuming that the costs of surety bonds are passed on to insurers, the Federal government's share of the benefit cost calculus can be reestimated as follows. For the first tier, suppliers with annual billings of under $10,000, the government will save $1 million in increased fraud recoveries, and lose approximately one-fifth of the $74 million in surety bond costs or $14 million, for a net cost to the Federal taxpayer of about $13 million. The effects of the proposed rule on net taxpayer costs from the other two tiers are only somewhat less egregious. There is an even larger Federal budgetary cost because most private health

insurance is tax preferred, leading to most of the remainder of the $74 million being exempted from the average 30 or 35 percent marginal tax rate of taxpayers. Hence, surety bond costs paid by suppliers reduce Federal tax revenues and increase direct Federal spending by half or more of the total amount paid.

The amount of the surety bond is its least important feature from the fraud and abuse recovery perspective. Yet, inexplicably, HHS proposes to require that the minimum amount of surety bonds be raised from the legislated minimum level of $50,000 to $65,000, on the irrelevant ground that inflation has occurred since the statute was enacted and adjustments should therefore be made to bond amounts. Nothing in the statute or its history indicates that the Congress ever contemplated inflation adjustments, or that it thought that the bond amount, as such, should be made higher than the minimum amount enacted. This increase will have an essentially zero effect on fraud and abuse recoveries, but will drive an increased number of providers out of business, and increase the cost of bonds for remaining providers by approximately one-third, e.g., from $1,500 to $2,000 on average. The estimated surety bond costs of the current proposal would otherwise have been about $150 million, but this seemingly small increment raises those costs to about $198 million, with no corresponding increase in benefits. The net social cost would have been more than halved, to $40 million instead of $89 million (disregarding effects on Federal budgetary deficits), had this increase been assessed with regard to its full implications and dropped as it should have been. This proposed increase instead creates an unjustified cost to both the private and pubic sectors, with zero economic benefits and increased costs to the Federal budget because these costs will be passed on to both Federal and private insurers, directly or through tax preferences.

This also illustrates the importance of a careful RIA. Had HHS analyzed the costs and benefits of major alternatives, including the substantial costs and negative benefits of raising the surety bond amount, the embarrassing implications of this mistake would have been exposed in the RIA and it never would have been proposed in the NPRM.

Requiring bonds only from new supplier entrants, the only category realistically likely to save the government money, would change the results of the previous calculations from a net loss of $89 million to society to a net gain of $38 million (or $43 million with surety bond amounts reduced to $50,000). In this calculation I assume that 15 percent of the lowest tier, 10

percent of the middle tier, and 5 percent of the highest tier are new entrants each year. I also assume a much higher level of overpayments (20%) and much greater savings from surety bonds (50%). Net effects would still be negative for the lowest tier, and roughly break-even for the middle tier, but highly positive for the highest tier. Of course, this arguably assumes an unrealistic level of reduced overpayments unrecovered, and if savings estimates are cut in half (still arguably too optimistic an assumption), net benefits fall to minus $8 million in the lowest tier, minus one half million dollars in the middle tier, and plus $23 million in the highest tier, for a net saving of about $14 million. This alternative would reduce the number of suppliers purchasing surety bonds to about 9,000, of whom 6,000 would be in the smallest tier (still enough as to pose potential problems of rural access).

If the only issue involved were how to construct the surety bond requirement, in a vacuum, the conclusion to this point is clear. Reduce the bond amount to $50,000 and require bonds only of new entrants. I hereby recommend that HHS explore this option and related alternatives with care in the final RIA, and compare net results with other alternatives including the rule as proposed, with tiering by supplier reimbursements.

Another major option that HHS should adopt, and whose net results should be compared and displayed in a proper RIA, would be to exempt completely suppliers who are licensed by states to provide medical services (e.g., physicians and podiatrists) and who are providing DMEPOS incidentally to their professional practice. These professionals, having received been reviewed for professional integrity and other characteristics by State authorities, and almost all falling in the smallest tier, pose insignificant risks of fraud and abuse. If almost all of the smallest tier of providers fall in the licensed professional category, an additional 6,000 suppliers could be exempted, and net savings would rise to $50 million, from this one change alone. To the credit of HHS, it specifically requested comments on this option. To its shame, it failed to estimate in dollar terms the immense improvement this option would create in net social costs.

A final bond requirement option would be to reconsider the effects of the rule on the largest suppliers. Two simple changes could greatly reduce wasteful costs for this group. First, multi-site suppliers could be given the choice of buying a $50,000 bond for each site, or of buying one bond equal to 5% of their total reimbursements at all sites. Second, suppliers at any

level of reimbursement, but undoubtedly most useful to those at the upper end, could be given the option of demonstrating that they are public corporations covered by Sarbanes-Oxley, and have cash reserves or lines of credit equal to 5% of total Medicare reimbursements at all sites. This should be allowed as the functional equivalent of and superior to a surety bond.

There is yet another major set of alternatives, however. The accreditation rule issued a year ago, which is just beginning to go into effect, has effects almost identical in size and distribution of costs to those of the surety bond rule. The accreditation and surety bond costs are additive, but their benefits are not. The kind of investigation needed to accredit a supplier is substantially equivalent in effect (e.g., in uncovering "fly by night" operators) to the kind of investigation needed to issue a surety bond to a supplier. Both require an examination of the business practices of the person or corporation reviewed. I recommend that without exception all suppliers whose annual reimbursements are below $10,000 (better yet $25,000) be exempted from accreditation. It could be argued that this cannot be accomplished in this particular rule due to a legal requirement called "logical outgrowth," but it is possible that this requirement would be overcome. Certainly the relationship of accreditation to surety bonds in both purpose and effect is substantially similar and their cumulative effect is vital to analyze in making proper and reasonable decisions about either. Accordingly, I recommend that HHS make this important change to the accreditation rule, while allowing the exempted providers to participate in every respect as if they were accredited. A provider who sells only a few thousand dollars of supplies a year as a convenience to his patients or his customers should not have to meet either requirement.

If changes to the accreditation requirement cannot be legally accomplished in this rulemaking, the accreditation exception should be proposed in the forthcoming rule currently listed in the Unified Agenda as "Additional Safeguards" on suppliers. That rule should be retitled "Reformed Safeguards" and accreditation eliminated for suppliers who bill less than $10,000 a year. Whichever regulatory vehicle is used, these suppliers should not have to pay an estimated $1,000 a year for accreditation (let alone an additional $2,000 a year for a surety bond) given the *de minimus* risk they pose to the financial integrity of the Medicare program. In total, they account for less than $100 million in annual spending, only about 1 percent of total DMEPOS spending, and the cumulative cost of these requirements is gravely disproportionate to the trivially small program integrity risk they

pose. The accreditation requirement is likely to create essentially zero benefits for patient health and safety because these professionals are subject to numerous other peer, regulatory, and legal pressures. Just as in the case of surety bonds, accreditation costs will be passed on to private insurers and have the net effect of raising net Federal spending for at least the two smallest tiers of suppliers. Hence, under one rule or the other the lowest billing tier should be exempted.

The statute as enacted may not appear, on its face, to allow some of the policy decisions I propose. It seems to say that all suppliers will have to be accredited and that all will have to have surety bonds. However, nothing prevents HHS from creating "reasonableness" exceptions to these requirements. The Congress certainly did not intend to impose requirements that could have no effect other than to drive reputable suppliers in the smallest tier out of the program, particularly as this would deprive rural and other beneficiaries of practical access to services. Nor did the Congress intend to impose requirements that would cost the Federal budget more than they would save. The relevant legal question is whether there is any arguable interpretation of these laws that would allow the Secretary to avoid unintended and harmful effects on the program that were not intended by the Congress. There is a much precedent in favor of exercising such Secretarial discretion. Three decades ago the Congress enacted a civil rights statute called Section 504 of the Rehabilitation Act. That statute did not explicitly provide for exceptions or exemptions. Like all civil rights statutes, it had to be strictly construed. Nonetheless, the Secretary was able to create an exception for small health and human services providers with fewer than 15 employees. That exception led to no serious criticism of the Department and no legal challenge. Following that precedent, the case for the policy exceptions and exemptions discussed above is robust. Some of these alternatives may be legally easier to support than others, but surely there is some legal rationale for at least some of these alternatives.

Of course, even were some legal impediment to prevent the promulgation of a final rule that adopts an alternative that minimizes net social costs, that in no way eliminates the obligation of HHS to analyze that alternative under the relevant statutes and Executive Orders. In fact, the HHS obligation would be to issue the most cost-effective rule possible under the law, explaining to the public and the Congress what legal provision prevents the adoption of a better alternative, and to estimate and present the various costs of failing to enact a repeal or reform of that provision. Hence, regardless of

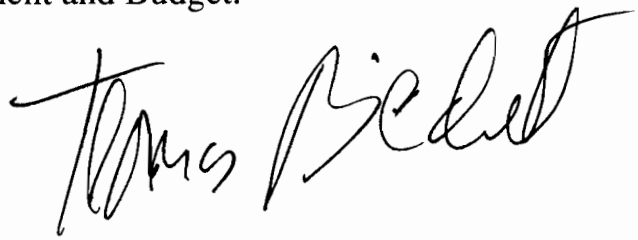
any legal boundaries, HHS remains obligated to publish an RIA that analyzes the major sensible alternatives and options and carefully delineates their costs and benefits. As argued in this comment, that certainly includes options that distinguish among DMEPOS suppliers based on the amount of reimbursement they obtain, based on their history within the program (e.g., new entrants versus established and reliable businesses), their professional or corporate status, or a combination of these.

I conclude this comment by pointing out that a recent report by the Office of the Inspector General of HHS, entitled "South Florida Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits" (http://oig.hhs.gov/oei/reports/oei-03-07-00150.pdf), found that approximately half of the suppliers in South Florida failed to comply with existing requirements imposed on suppliers, such as maintaining a physical facility that is accessible during business hours, and having a business telephone listed under the business name. This report said, "the screening procedures used by [HHS] were insufficient to prevent illegitimate businesses from enrolling in the Medicare program" (page 4). In other words, HHS has rules on the books that would, if effectively enforced, allow HHS to identify and eliminate what appears to be rampant fraud and abuse in at least some geographic areas. This proposed rule would, unless revised, create an unintended and costly diversion from the important task facing HHS in proceeding against these suppliers, and divert resources from on-site visits and other steps needed to reduce fraud and abuse by DMEPOS suppliers. HHS should not impose additional costs on the vast majority of suppliers who operate completely within the rules, but rather focus its resources on those which it can readily find violating its existing fraud and abuse rules.

I wish HHS success in reforming this rule and simultaneously finding ways to reduce actual fraud without imposing unnecessary costs on small businesses.

I am sending this comment both electronically and by mail, with a copy to the Office of Management and Budget.

Sincerely,
Thomas A. Becket
tabecket@aol.com



p.s. I have tried to submit this comment electronically. However, your web site provides no positive feedback as to whether a comment has been received. You need to improve the "user friendly" aspects of that web site in this and other important ways.

DMEPOS Surety Bond Benefit Cost Data

Table 1. Data Taken from Table in Proposed Rule Using TIN Figures

		Suppliers Reimb. for DME	
Allowed Charges/Reimbursement Interval	Assumed Average Charge	Number	Amount Reimbursed (K)
$0	$0	2,016	$0
$.01-$999	$500	2,544	$1,272
$1,000-$2,499	$1,750	2,099	$3,673
$2,500-$4,999	$3,750	2,285	$8,569
$5,000-$9,999	$7,500	2,964	$22,230
$10,000-$24,999	$17,500	4,568	$79,940
$25,000-$49,999	$37,500	3,378	$126,675
$50,000-$99,999	$75,000	2,780	$208,500
$100,000-$499,999	$300,000	5,955	$1,786,500
$500,000-$999,999	$750,000	1,762	$1,321,500
$1,000,000-4,999,999	$3,000,000	1,345	$4,035,000
$5,000,000 or more	$10,000,000	208	$2,080,000
Total		31,904	

Table 2. Benefits and Costs of Universal Requirement Assuming Overpa

Allowed Charges/Reimbursement Interval	Total Amount Reimbursed (K)	Ovepayments at 5% (K)	Surety Bond Savings at 20% (K)
$0	$0	$0	$0
$.01-$999	$4,584	$229	$46
$1,000-$2,499	$12,411	$621	$124
$2,500-$4,999	$25,290	$1,265	$253
$5,000-$9,999	$53,378	$2,669	$534
$10,000-$24,999	$155,680	$7,784	$1,557
$25,000-$49,999	$205,425	$10,271	$2,054
$50,000-$99,999	$301,875	$15,094	$3,019
$100,000-$499,999	$2,143,800	$107,190	$21,438
$500,000-$999,999	$1,486,500	$74,325	$14,865
$1,000,000-4,999,999	$4,350,000	$217,500	$43,500
$5,000,000 or more	$2,150,000	$107,500	$21,500
Additional NPI Entities	Included	Included	Included
Total	$10,888,943	$544,447	$108,889

Table 3. Tiered Benefits and Costs of Universal Requirement in Three Si

Allowed Charges/Reimbursement Interval	Total Amount Reimbursed (K)	Ovepayments at 5% (K)	Surety Bond Savings by Tier (K) at 20%
$0-$9,999	$95,663	$4,783	$957
$10,000-$24,999	$155,680	$7,784	$1,557
$25,000 or more	$10,637,600	$531,880	$106,376
Total	$10,888,943	$544,447	$108,889

Effects of reducing Bond amount to $50,000 and its cost to $1,500:

Table 4. Tiered Benefits and Costs of Covering only New Entrants at 15

Allowed Charges/Reimbursement Interval	Total Amount Reimbursed (K)	Ovepayments at 20% (K)	Surety Bond Savings by Tier (K) at 50%
$0-$9,999	$14,349	$2,870	$1,435
$10,000-$24,999	$15,568	$3,114	$1,557
$25,000 or more	$531,880	$106,376	$53,188
Total	$561,797	$112,359	$56,180

Table 5. Tiered Benefits and Costs for New Entrants with Bond Amount

Allowed Charges/Reimbursement Interval	Total Amount Reimbursed (K)	Ovepayments at 20% (K)	Surety Bond Savings by Tier (K) at 50%
$0-$9,999	$14,349	$2,870	$1,435
$10,000-$24,999	$15,568	$3,114	$1,557
$25,000 or more	$531,880	$106,376	$53,188
Total	$561,797	$112,359	$56,180

Table 6. Tiered Benefits and Costs with Bond Amount Reduced to $50,0

Allowed Charges/Reimbursement Interval	Total Amount Reimbursed (K)	Ovepaymen ts at 20% (K)	Surety Bond Savings by Tier (K) at 25%
$0-$9,999	$14,349	$2,870	$717
$10,000-$24,999	$15,568	$3,114	$778
$25,000 or more	$531,880	$106,376	$26,594
Total	$561,797	$112,359	$28,090

Note: These tables do not estimate the effects of several other reforr comments. Those additional reforms could essentially eliminate costs reduce them to the highest tier, thereby increasing net benefits subs

Suppliers Reimb. for non-DME Only				
Number	Amount Reimbursed (K)	Total Number Suppliers	Cumulative Number Suppliers	Total Amount Reimbursed (K)
4,655	$0	6,671	6,671	$0
6,624	$3,312	9,168	15,839	$4,584
4,993	$8,738	7,092	22,931	$12,411
4,459	$16,721	6,744	29,675	$25,290
4,153	$31,148	7,117	36,792	$53,378
4,328	$75,740	8,896	45,688	$155,680
2,100	$78,750	5,478	51,166	$205,425
1,245	$93,375	4,025	55,191	$301,875
1,191	$357,300	7,146	62,337	$2,143,800
220	$165,000	1,982	64,319	$1,486,500
105	$315,000	1,450	65,769	$4,350,000
7	$70,000	215	65,984	$2,150,000
34,080		65,984		$10,888,943

ıyments at 5% and Savings of 20% Percent

Surety Bond Costs at $2,000 (K)	Net Cost or Savings (K)	Suppliers Affected
$13,342	-$13,342	6,671
$18,336	-$18,290	9,168
$14,184	-$14,060	7,092
$13,488	-$13,235	6,744
$14,234	-$13,700	7,117
$17,792	-$16,235	8,896
$10,956	-$8,902	5,478
$8,050	-$5,031	4,025
$14,292	$7,146	7,146
$3,964	$10,901	1,982
$2,900	$40,600	1,450
$430	$21,070	215
$66,000	Included	33,000
$197,968	-$89,079	98,984

ize Intervals

Surety Bond Costs at $2,000 (K)	Net Cost or Savings (K)	Suppliers Affected
$73,584	-$72,627	36,792
$17,792	-$16,235	8,896
$106,592	-$216	53,296
$197,968	-$89,079	98,984
$148,476	-$39,587	

i%, 10%, and 5% Turnover in Three Size Intervals

Surety Bond Costs at $2,000 Times Turnover Percent (K)	Net Cost or Savings (K)	Suppliers Affected
$11,038	-$9,603	5,519
$1,779	-$222	890
$5,330	$47,858	2,665
$18,146	$38,033	9,073

Reduced to $50,000

Surety Bond Costs at $1,500 Times Turnover Percent (K)	Net Cost or Savings (K)	Suppliers Affected
$8,278	-$6,843	5,519
$1,334	$222	890
$3,997	$49,191	2,665
$13,610	$42,570	9,073

00 and Projected Savings Reduced to 10% of 5%.

Surety Bond Costs at $1,500 Times Turnover Percent (K)	Net Cost or Savings (K)	Suppliers Affected
$8,278	-$7,561	5,519
$1,334	-$556	890
$3,997	$22,597	2,665
$13,610	$14,480	9,073

n proposals I make in my written
to the lowest tier and greatly
tantially.

Cumulative Amount Reimbursed (K)	Cumulative Percent of Total Suppliers	Cumulative Percent of Total Reimbursed
$0	10%	0%
$4,584	24%	0%
$16,995	35%	0%
$42,285	45%	0%
$95,663	56%	1%
$251,343	69%	2%
$456,768	78%	4%
$758,643	84%	7%
$2,902,443	94%	27%
$4,388,943	97%	40%
$8,738,943	100%	80%
$10,888,943	100%	100%

$10,888,943

SBA
Office of Advocacy
www.sba.gov/advo

Advocacy: the voice of small business in government

September 13, 2007

Kerry N. Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Re: Medicaid Program; Surety Bond requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (72 Fed. Reg. 42001, August 1, 2007)

Dear Administrator Weems:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.[1]

On August 13, 2002, President George W. Bush signed Executive Order 13272, requiring Federal agencies to implement policies protecting small businesses when writing new rules and regulations.[2] Executive Order 13272 instructs Advocacy to provide comment on draft rules to the agency that has proposed a rule, as well as to the Office of

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. §612(a).
[2] Exec. Order No. 13,272 § 1, 67 Fed. Reg. 53,461 (Aug. 13, 2002).

Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.[3] Executive Order 13272 also requires agencies to give every appropriate consideration to any comments provided by Advocacy. Under the Executive Order, the agency must include, in any explanation or discussion accompanying publication in the *Federal Register* of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[4]

In the rule's preamble, The Centers for Medicare and Medicaid Services (CMS) states that the public policy underlying this regulation's requirement for surety bonds, among other reasons, is to limit the Medicare program's risk to fraudulent durable medical equipment (DME) suppliers.[5] CMS also notes that, "the vast majority of DME suppliers are small entities (based on Medicare reimbursement alone)."[6] CMS further acknowledges that of the approximately 116,500 individual DME suppliers, a large number will either not recoup their bond cost, or will decide to forgo their Medicare enrollment as a supplier.[7] CMS calculates that if the rule is implemented 15,000 DME suppliers (suppliers affiliated with chain business entities) and 17, 471 individual DME suppliers currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries.[8] CMS also admits that Medicare beneficiaries will be directly affected by small DME suppliers' decision to leave the program.[9] The effects of this rule will be especially felt in rural areas where CMS estimates that 15,000 DME suppliers provide supplies to Medicare beneficiaries.[10]

As Chief Counsel for Advocacy, I am submitting comments on this rule because I am concerned about the rule's compliance with the requirements of the RFA and EO 13272. Also, my office has received several oral and written contacts from small businesses, mostly small durable medical equipment suppliers, and their representatives, that are concerned with the CMS proposed rule requiring surety bonds for DME suppliers that participate in the Medicare program. Those stakeholders argue that CMS has failed to take into account the effect of cumulative regulations on the industry; that CMS failed to appreciate and analyze the economically burdensome nature of this regulation on the small suppliers; that there are reasonable alternatives to the rulemaking that would help mitigate the burdensome nature of the rule on small suppliers; that the rule gives large DME suppliers a competitive advantage over small suppliers; and that in light of other proposed and/or final regulations on the DME industry (e.g., the DME competitive bidding rule and accreditation rule) this rule will force many of the small suppliers out of business.

---

[3] E.O. 13272, at § 2(c), 67 Fed. Reg. at 53,461.
[4] Id. at § 3(c), 67 Fed. Reg. at 53,461.
[5] The rule was published in the *Federal Register* at 72 Fed. Reg. 42001 (August I, 2007).
[6] Id. at 42007.
[7] Id. at 42008.
[8] Id.
[9] Id.
[10] Id.

I. CMS's Regulatory Impact Analysis Needs Improvement

The RFA requires administrative agencies to consider the effect of their actions on small entities, including small businesses, small non-profit enterprises, and small local governments.[11] When an agency issues a rulemaking proposal, the RFA requires the agency to "prepare and make available for public comment an initial regulatory flexibility analysis [IRFA]" which will "describe the impact of the proposed rule on small entities."[12] The law states that an IRFA shall address the reasons that an agency is considering the action; the objectives and legal basis of the rule; the type and number of small entities to which the rule will apply; the projected reporting, record keeping, and other compliance requirements of the proposed rule; and all Federal rules that may duplicate, overlap or conflict with the proposed rule. The agency must also provide a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.[13]

Advocacy acknowledges that section 4312 of the Balanced Budget Act of 1997 requires CMS to obtain a surety bond before issuing or renewing a provider number for a supplier of DME. However, even when a regulation is statutorily mandated, agencies are obligated by law to adhere to certain requirements prior to issuing a proposed regulation. CMS's justification for the rule, to eliminate fraud and abuse in the Medicare system, does not outweigh the need for transparency and analysis of the impacts of the rule on the affected industry; especially when the economic burden on the affected industry is created from CMS's interpretation of the enabling legislation.

While the RFA does allow an agency to forgo certain analysis if it can certify that the regulation will not have a significant impact on a substantial number of small entities, that certification must be factually based. It is not clear from the RFA section of the rule if CMS intends for information contained in the RIA to serve as an IRFA for the purposes of the RFA.[14] This should be made clear in the final rule when CMS drafts its final regulatory flexibility analysis (FRFA) pursuant to section 604 of the RFA.

Advocacy appreciates that CMS performed a Regulatory Impact Analysis (RIA) of the proposed rule. However, many of the RFA's requirements were overlooked and the economic analysis is incomplete. While CMS does provide information on the number of small DME suppliers likely to be affected by the rule,[15] it does little analysis of how the rule will economically impact the small suppliers. It is obvious that it will be more difficult for small suppliers to absorb the cost of the bond than it will be for larger suppliers. CMS provides data on how many businesses are likely to forgo enrollment in Medicare or are likely to go out of business because of the surety requirement; but there

---

[11] 5 U.S.C. §§ 601, et. seq.; Northwest Mining Association v. Babbitt, 5 F. Supp. 2d 9, (D.D.C. 1998).
[12] 5 U.S.C. § 603(a).
[13] 5 U.S.C. § 603(c).
[14] CMS does certify that this rule will not have a significant economic impact on a substantial number of small rural hospitals. 72 Fed. Reg. 42007.
[15] Id.

is no information on business revenue and/or profit, number of employees, paperwork analysis for suppliers obtaining the surety bond,[16] or the cost of compliance based on the size of the supplier. It is reasonable that small suppliers will deem the bond uneconomical and therefore make a business decision not to participate in the Medicare DME program. According to industry sources many DME businesses are already required by federal or state entities to obtain surety bonds at an approximate cost of $2,000 annually in order to provide DME to consumers. However, those sources are concerned that the regulation's increase in the cost of the surety bond will raise the annual cost significantly when they are already operating on small revenue margins. Allowing a significant percentage of businesses to disappear from an industry that is largely populated by small entities is tantamount to sectioning the market into those who can afford the bond and those who cannot. This market manipulation is based less on the rule's public policy objective of preventing fraud and more on the affected small businesses' economic ability to pay for the bond. CMS should have sought public comment on the reasonableness of the increase of the bond amount to $65,000, which amounts to an increase of 25% over the original $50,000 bond requirement.

CMS does not provide an analysis of the percentage of the industry that is contributing to the fraud problem. Are the fraudulent suppliers more likely to found in urban or rural areas? What percentage of the suppliers are recidivists? Are the offending suppliers primarily large or small businesses? CMS simply assumes that suppliers that do not repay overpayments will not be likely to obtain the bond necessary for enrollment in the program. Failure to analyze these issues makes it impossible to reasonably justify the required amount of the bond, the costs and benefits of the regulation and whether significant alternatives exist that would minimize the rule's impact on small DME suppliers. All of these issues go directly to the Congressional intent behind the provisions of the RFA.

The analysis also fails to estimate the number of new suppliers estimated to enter the program and their anticipated size. It may prove difficult for new suppliers with few assets and little credit history to obtain the necessary bond for participation in the program.

Advocacy suggests that CMS do a better job of analyzing the requirements of this rule on small DME suppliers in the final rule pursuant to the provisions of the RFA.

II. CMS's discussion of alternatives does not comply with the RFA.

Section 603(c) of the RFA provides that each IRFA shall contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed

[16] On page 42006, CMS outlines the paperwork burden that it will take each DME supplier to comply with sections 424.57(c)(26)(i) through (iv) this rule, which comprises the primary responsibilities for all DME suppliers under the regulation. If one totals all of the possible requirements outlined therein it amounts to a total of three (3) hours, understanding that each supplier may not be required to comply with each section. This total does not provide an estimate for the time necessary to obtain the bond from a surety.

rule on small entities. CMS's discussion of alternatives does not comply with this section of the RFA as it neither presents, nor analyzes any alternatives. The section of the RIA on alternatives is simply a recitation of the rule's preamble, and a justification for increasing the amount of the bond from $50,000 to $65,000 based on the lapse of time since the proposed rule was previously published in 1997.

Based on discussion with industry sources and Advocacy analysis of the rule, some suggested alternatives for CMS's consideration include:

1. CMS should outline the reasoning behind, and better analyze, its justification for increasing the amount of the surety bond from $50,000 to $65,000 beyond just the lapse of time between the previously proposed rule in 1997 and now. Section 4312 of the Balanced Budget Act of 1997 does not provide for an increase in the surety bond based on inflation and there seems to be no Congressional intent for such an increase. The $15,000 difference between $50,000 and $65,000 may act a barrier to entry for new suppliers seeking to participate in the Medicare DME program and, it may force existing businesses to a make business decision whether to continue providing DME to Medicare beneficiaries. CMS should assess whether the increase in the surety bond amount raising the regulation's costs from approximately $150 million to $198 million will have any appreciable increase in the benefit from the rule.

   CMS seeks public comment on whether to exempt large, publicly traded chain suppliers from the surety bond requirements.[17] If flexibility exists for these suppliers, CMS cannot in good faith neglect to analyze alternatives that exempt smaller suppliers, or entertain reducing the required bond for those suppliers. Eliminating small suppliers from the industry benefits the larger companies and is anti-competitive. In more rural settings the options for Medicare beneficiaries will be greatly reduced. CMS suggests that beneficiaries will not face much difficulty obtaining medical equipment due to outreach and accessibility to mail order and the World Wide Web.[18] However, the reality of the situation is that a multitude of small DME suppliers operate in rural areas and their success has been based on their proximity to beneficiaries.

2. Casting such a wide regulatory net does not assure elimination of the bad actors in the Medicare program. If CMS better analyzed the demographics of those suppliers who are more likely to perpetrate fraud, it might be in a better position to determine which small DME suppliers are not likely to be part of the problem. Any suppliers not deemed to be bad actors should then be both grand-fathered into the program and not required to obtain the bond, subject to a lesser bond requirement, or allowed to post one bond for multiple business sites.[19] This

[17] 72 Fed. Reg. 42004.
[18] 72 Fed Reg. 42008.
[19] Section 424.57(c)(26)(i)(c) specifies that a DME 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 national provider identifier (NPI).

suggestion seems reasonable as CMS is seeking public comment on whether to require an increased surety bond from a supplier that is deemed to an increased risk to the Medicare Trust Fund.[20]

3. CMS alleges a benefit to replacing 66,000 TIN numbers, the basic identification element for a DME supplier, with 99,000 NPI (national provider identifier) numbers. However, CMS does not adequately provide the reasoning behind the transition from TIN to NPI and does not analyze the impact of the decision on the DME industry. For example, does the move to NPI actually increase the costs of the regulation because multi-site businesses must now acquire multiple surety bonds?

4. Small DME providers are concerned that the requirements of this regulation may result in increasing costs to small suppliers and reducing costs for large suppliers. According to industry sources, the 1998 proposed DME surety bond rule provided for a sliding-scale approach to the bond for DME suppliers. The surety bond started at $50,000 and rose to 15% of reimbursements (capped at $3 million). Advocacy believes that an alternative, a tiered system, will improve the percentage of small suppliers remaining in the market without compromising the public policy objective. CMS should analyze whether a $50,000 surety bond for small suppliers and $65,000 for other suppliers would meet its regulatory objective. As a result of this change a more equitable percentage of small suppliers will remain in the market.

5. Some industry representatives note that the proposed rule requires that annual "audited" financial statements be obtained by each organization. Many companies have an external auditing firm provide annual financial statements; and the industry representatives are concerned that the costs associated with obtaining "audited" statements is exorbitant and, they believe far in excess of the government's intention with the original legislation. They ask that CMS consider that annual financial statements not have the additional requirement of being "audited" statements. This alternative should be analyzed by CMS.

III. Pursuant to the RFA, CMS is required to discuss all Federal rules that may duplicate, overlap or conflict with the proposed rule.

Industry representatives have suggested to Advocacy that the cumulative affect of this rule with other regulations that already govern their participation in the Medicare DME program serve as a significant economic burden. Further, they indicate that pre-existing regulations (e.g. the accreditation and liability insurance rules) could be modified to prevent any fraud in the program rather than subjecting the industry to a new set of regulations. Still, industry representatives suggest that CMS should comply with section 603(b)(5) of the RFA and identify all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule.

[20] 72 Fed. Reg. 42005.

IV. Public policy requires CMS to analyze the rule's impact on Medicare beneficiaries.

CMS should analyze other affected entities/persons based upon this rule's direct and foreseeable effect on others besides DME suppliers. CMS acknowledges that the rule wall result in loss of 22,000 rural suppliers, but suggests that this loss to Medicare beneficiaries can be offset by public education of beneficiaries so they can better choose another supplier, perhaps through the use of mail order or the World Wide Web. CMS should better analyze how this regulation will affect Medicare beneficiaries in rural areas, many of whom may not have Internet access, and may encounter real difficulty obtaining DME if a significant number of DME suppliers cease to exist. Clearly, Congress did not intend that this regulation would have a negative impact on patient safety, a possible unintended result of the legislation, which should be analyzed by CMS.

IV. CMS's surety scheme may hinder DME suppliers' ability to obtain bonds.

Advocacy was intimately involved in the surety bond and capitalization requirement regulation for home health care agencies.[21] In that regulation, one that is somewhat similar to the DME supplier rule, the surety bond industry was concerned about how their industry would be affected by the regulation on home health care agencies.

Concern by the surety industry led to Congressional review. Specifically, a bi-partisan group of three senators from the Senate Finance Committee, on January 26, 1998, asked CMS, formally called the Health Care Financing Administration (HCFA), to delay and modify the requirement that all home health agencies secure a surety bond. The Senators believed that home health agencies would not be able to obtain bonds by the original February 27 deadline. As quoted in a BNA news article, the senators wrote that:

> "HCFA has imposed conditions that go beyond the standard in the surety bond industry. Some of the biggest problems include cumulative liability, a short period of time in which to pay claims, and bond values of 15 percent of the previous year's Medicare revenues with no maximum, the letter said. 'The cumulative effect is that many surety companies are opting not to offer bonds to Medicare [home health agencies] at all,' the letter said. 'Those companies which are offering the bonds are doing so at a cost which is prohibitive, or with demands for collateral or personal guarantees that HHAs cannot provide.'
>
> The letter said Congress enacted the surety bond requirement to keep risky agencies out of the Medicare program. However, HCFA's rule seems to use the bonds as security for overpayments to providers, the letter said.

[21] 63 Fed. Reg. 10,730 (March 4, 1998).

'We simply doubt that it is realistic to expect bonding companies to embrace a role as guarantors for overpayments from HCFA,' the senators wrote."[22]

CMS failed to discuss and analyze how this regulation would directly affect the surety industry and the ability of suppliers to obtain bonds. CMS should do so in the final rule.

Conclusion

In summary, Advocacy requests that CMS give consideration to the issues raised herein. Advocacy encourages CMS to better analyze the possible effects of this regulation on the DME industry, Medicare beneficiaries, and the surety industry in the final rule.

Advocacy appreciates being given a chance to provide CMS with these comments. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel, Linwood Rayford at (202) 401-6880, or www.linwood.rayford@sba.gov.

Sincerely yours,

Thomas M. Sullivan
Chief Counsel Advocacy

Linwood L. Rayford, III
Assistant Chief Counsel for Food, Drug
and Health Affairs

cc: The Honorable Susan Dudley, Administrator, Office of Information and Regulatory Affairs

[22] *Senators Ask HCFA to Delay Final Rule Requiring Surety Bonds of All Agencies*, BNA DAILY REPORT FOR EXECUTIVES, Jan. 27, 1998, at A-24.

20

MEDICAL SERVICES OF AMERICA, INC.

CORPORATE HEADQUARTERS

171 Monroe Lane • P.O. Box 1928 • Lexington, South Carolina 29071
(803) 957-0500 • FAX (888) 342-6190

September 10, 2007

SEP 12 2007

Centers for Medicare & Medicaid Services
Department of Healthcare and Human Service
Attention: CMS-6006.P
PO Box 8017
Baltimore, MD 21244-8017

RE: Federal Register Proposed Rule – CMS-6006.P (42 CFR Part 424) Surety Bond Requirements for Suppliers of DMEPOS

Dear CMS Representative:

Below please find our comments to the Federal Register Proposed Rule 42 CFR Part 424, [CMS-6006-P], RIN 0938-AO84.

1. CMS-6006-P – PROVISION: Financial Statements have been used recently by CMS to determine the financial stability of DMEPOS Provider's applying for competitive bidding. Financial Statements should be an acceptable alternative to a surety bond, and should be used periodically (for example, annually) thereafter for financial assessments.

2. CMS-6006-P – PROVISION: As indicated there are several providers that belong to a chain organization. There should be a cap applied to the amount of the surety bond required for providers that belong to a chain, without regard to the public ownership, as some state Medicaid programs allow. As an example the State of Florida's Medicaid program administered by ACS State Healthcare caps the number of bonds required at 5, for a maximum of $250,000 for providers in a chain.

3. CMS-6006-P – PROVISION: DMEPOS should re-credential annually, where they would be required to provide year end financials, current information, and insurance renewals.

4. CMS-6006-P – PROVISION: DMEPOS are also being required under competitive bidding to be accredited by a Medicare Approved agency. Accreditation is another way CMS is ensuring the quality of care provided to Medicare beneficiaries. DMEPOS that are accredited and are able to provide financials should be considered exempt from the Surety Bond requirement.

5. CMS-6006-P – PROVISION: 60 days after the publication date of the final rule does not give adequate time to either the Surety Company or the DMEPOS to find and secure a Surety Bond when 116,500 requests will be made. A minimum lead time of 6 months is recommended for implementation of any surety bond amount.

We thank you for this opportunity to respond to the proposed rule.

Sincerely,

John D. Keim
Vice President / CFO