Submitter : **Richard Frelke** **Date: 08/16/2007**

Organization : **Mobility Solutions, Inc**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

We provide custom mobility devices for the disabled community here in San Diego, California. We have been working in this community for over 25 years. We support fully the attempt to curb fraud and abuse in the Home Medical Equipment (HME) field. We are troubled by two facets of the proposed Surety Bond issue:
#1) All providers of service should be required to purchase a Surety Bond if that is going to be the standard. Do not exclude the larger national companies. If there is to be further financial obligations required for the small providers then it is only fair for larger companies to bear the same costs. Do not financially penalize small providers just because they are small providers!
#2) We beleive that companies that have been providing products and services for a number of years, let's say 5 years, without any issues with fraud or abuse should be exempted from the Surety Bond requirement. With the reduction in reimbursement and the rising costs of labor and fuel, any additional fees required will be a financial burden on our business. We have seen a number of local providers in the custom mobility market go out of business due to these factors and hope that further costs of business do not force us to close our doors!

CMS-6006-P-19 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : Mrs. Brenda Chapman **Date & Time:** 08/27/2007

Organization : Next To Me LLC

Category : Individual

Issue Areas/Comments

Impact

Impact

How can Surety Bond Requirement or DME suppliers stop fraud?
The only way to stop fraud is not to give these people a Medicare
Provider number and put them in jail for a long time. You keep letting them out and they just start a new company in a new place
and you give them a new medicare provider number.

Provisions

Provisions

Small DME companies are struggling to keep up with all the new
regulations CMS has emplimented lately that cost us more of our
operating money to prevent others from defrauding the system. Those
of us who give good and honest service to those in need are the ones
who suffer. It is your responsibility to keep the thieves from taking public funds - not those of us who are dedicated to good service. Please don't continue harming the small DME companies in
the small rural areas - we are doing all we can as is - do not put any more on us than we can stand. You have some responsibility to
keep fraud from happening on a continous basis. How about trying to
help those of us who are meeting the needs of the public while adhering to your rules and regs. We need your help now.

CMS-6006-P-20 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : Mr. David W. Ferry **Date & Time:** 08/28/2007

Organization : Blue Ribbon Health Services, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Above

Impact

Impact

65,000 surety bond

Provisions

Provisions

We already have to have a 50,000 surety bond in Florida for Medicaid. We feel this would put an extra unnecessary burden on states that already require a surety bond to participate in the state Medicaid plan.

CMS-6006-P-21 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Date & Time:** **08/29/2007**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

AS A DME PROVIDER I AM IN FAVOR OF POSTING A SURETY BOND , BUT WHAT I AM NOT IN FAVOR OF IS THAT A NATIONAL PROVIDER IS EXEMPT FROM POSTING A BOND FOR EACH BRANCH THEY OWN,WHAT IS THE DIFFERENCE. THEY SHOULD FOLLOW THE SAME GUIDELINES AS ANY OTHER PROVIDER. IF I HAVE 2 LOCATIONS I MUST PROVIDE A BOND FOR EACH LOCATION, IF I HAD 20 LOCATIONS, I WOULD HAVE TO DO THE SAME, BUT UNDER YOU PROPOSED RULE NATIONAL PROVIDER WOULD NOT.

Impact

Impact

SURETY BOND FOR DME PROVIDERS

CMS-6006-P-22 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : Mr. Steven Nelson **Date & Time:** 08/31/2007

Organization : Okeechobee Discount Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Several existing providers, major players have had millions of dollars in fines levied against them. In a few cases these fines have not been their first . Why then are they allowed to continue to part take in the Medicare program? They are the biggest offenders!

Impact

Impact

THe would be terrible burden placed on Pharmacy's if a Surety Bond was required for Pharmacy's witha DME department. Pharmacy's under existing laws(rules and regulations)are highly regulated and have been squeezed for the last penny that we have. Stop driving good business,"OUT OF BUSINESS"

Submitter : Mrs. Candi George **Date:** 08/31/2007

Organization : Words Plus Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-23-Attach-1.TXT

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 Bind Proposal.

Sincerely,

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

CMS-6006-P-24 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Kathy Miller** **Date & Time:** **09/05/2007**

Organization : **Care Partners**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-24-Attach-1.TXT

#24

xMy name is Kathy Miller and I am the Executive Director for Care Partners, a Home Health/ Home Infusion company located in Morgantown, WV. I have several concerns regarding the proposed Surety Bond requirement for all DMEPOS providers.

1. How are you establishing the amount of the bond? It states "up to the penal sum"; however, how is that to be established?
    a. A flat amount does not make sense. Small providers would be only a small risk for Medicare. Large providers would be a large potential risk.
    b. A percentage of gross revenue does not make sense. Some companies do a minimal amount of DMEPOS business (e.g. Infusion companies). Whereas, Medicare DMEPOS business is a large percentage of a true DME provider (provides wheelchairs and beds to seniors).

2. Before DMEPOS companies can explore the cost of the surety bond to them, we would have to know the form of the bond. Is CMS going to provide the form for the bond?

3. I understand the purpose behind the idea of insurance that CMS is dealing with a reputable company; however, there are better ways to do that and not increase the cost to the reputable providers. I have been informed that a true surety bond can cost upwards of 20% of the amount of the bond. Other ways to try to ensure that the company is reputable could be:
    a. A bank letter of credit
    b. A letter from an insurance broker verifying a company's worth

CMS has formally stated the problem is not with home infusion providers. However, since home infusion providers are lumped in as DMEPOS providers, we will be penalized unfairly. Also, I am concerned that the expense of the surety bond will outweigh the benefit of providing services to Medicare recipients. Medicare is already such a small piece of the infusion provider's business, what is the impetus for infusion providers to keep servicing Medicare recipients? Especially in rural areas, where the infusion providers are generally small providers, will this not create an access problem driving even more of our seniors into skilled nursing facilities and hospitals?

CMS-6006-P-25 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : Ms. Paulette Beninate **09/11/2007**

Organization : IV Services

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

.....CMS6006P.....
AGAINST this provision. As a home health pharmacy,Accreditation Organizations& Pharmacy Boards require we are a legitimate business working withing the law. We have regular inspections.....
We are deluged with regulations and increased expenses on a yearly basis.....

I am sick and tired of paying for crooks. Crooks will always try to find a way to be dishonest.....
To have this added expense with no renumeration for increased cost of doing business as every other business sector is allowed to do really is discouraging and frustrating.....

Do you wonder why there are no doctors who want to go into family practice?..... Do you realize the impact you have had on independent pharmacies with your shortsighted implementation of PartD?.....
(It wasn't shorsighted as far as the insurance companies go.
I am positive of that!!!!!!).....

Do you realize the problems you caused when you refused to ackknowledge home infusion as a highly specialized service and lumped it with part D? .....
.....
The inability to make business decisions to pass added expense on to the consumer makes me see red. The good ol boy network of big business and insurance lobby takes care of that.

Please don't insult me with this surety bond. It is not needed for honest providers.....

.....

Paulette Beninate, RPH,...
IV Services,.....
Gretna, La.

CMS-6006-P-26 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : Mr. John Rice **09/11/2007**

Organization : Mobility Scooters

Category : **Health Care Provider/Association**

Issue Areas/Comments

Impact

Impact

SURETY BOND REQUIREMENT FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT.

Provisions

Provisions

THIS IS ANOTHER ONE CMS'S RULES THAT IS DESIGNED TO PUT THE SMALL DME PROVIDER OUT OF BUSINESS. HOW IS A SMALL PROVIDER THAT MAKES LESS THAN $100,000 A YEAR SUPPOSED TO PUT A LARGE SURETY BOND. WE ARE AN HONEST DME PROVIDER AND TRY TO SERVICE A RURAL AREA IN SE TEXAS. $65,000 SURETY BOND WOULD PUT US OUT OF BUSINESS, THEN THERE WOULD BE NO DME PROVIDER IS THIS AREA TO SERVICE THE ELDERLY AND DISABLED.

CMS-6006-P-27 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mr. Rod Colver** **Date & Time: 09/17/2007**

Organization : **Host Management Co**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

Surety Bond. We believe that a surety bond should only be required of a brand new supplier or one who has had fraud charges or complaints filed against it. Requiring every supplier to have a bond goes after all of us when the problem is only a few.

CMS-6006-P-28 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Date & Time: 09/17/2007**

Organization : The Office of Advocacy - Small Business Admin

Category : Federal Government

Issue Areas/Comments

GENERAL

See attachment

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.

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[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 1, 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

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[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.

CMS-6006-P-29 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Dawn Jorgensen** **Date & Time: 09/17/2007**

Organization : **Mid-Columbia Healthcare Equipment**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

CMS lifted the requirement for this same surety bond for home health agencies. The same should go for DME suppliers. There is no sufficient evidence that requiring a surety bond will weed out those bad apples in our industry, it just continues to put burden after burden on suppliers of HME. There are in place the new quality standards and the new requirement forthecoming for accreditation, that is what this industry has needed. Not the surety bond requirement. This is clearly a bad idea.

CMS-6006-P-30 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mr. Ken Wells** **Date & Time: 09/17/2007**

Organization : **Tucker-Wells Medical, Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

I own a small, rural HME company and I don't think requiring companies to purchase a Surety Bond will have ANY impact on fraudulent suppliers. If someone is willing to commit fraud to obtain Medicare/Medicaid reimbursement why would a Surety Bond stop them from continuing this practice? If they are committing fraud then they would be willing to do whatever it took to continue this practice.
The only group that this rule would have a negative impact on is the honest, above board companies both large and small.

Surely there are more and better ways of detecting fraud within the system than requiring the honest suppliers, which I think would be over 95% of suppliers,to pay a penalty because of a few criminals. I urge you to find ways to detect fraud without imposing a penalty on the entire industry. I know you can do it.

Thank You.

CMS-6006-P-31 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Teresa Schreiber** **Date & Time: 09/21/2007**

Organization : **Schreiber Upper Extremity Rehab**

Category : **Occupational Therapist**

Issue Areas/Comments

Impact

Re: CMS-6006-P-1. 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. I would estimate 50% of my Medicare patients require some type of customized orthosis. Medicare currently comprises approximately 30% or my out-patient business. As a Certified Hand Therapist, local physicians refer to my facility for fabrication of a customized splint to individually fit the patient's needs for their diagnosis, whether it be arthritic changes, contracture management or special injuries, such as tendon, nerve or bone issues.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.

Provisions

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 also am concerned about the personalization or customization factor for these patients. In my experience, patients usually don't get the needed one on one care and follow-up from a general DME provider as compared to what I can provide in a clinic setting. This can have a great impact on recovery time in treatment.
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.

CMS-6006-P-32 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Robin Miller** **Date & Time: 09/21/2007**

Organization : **Fort Lauderdale Hand Clinic**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

See Attachment.

32(#1)

September 10, 2007 Re: CMS-6006-P-1

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

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 and Certified Hand Therapist in private practice, specializing in the treatment of the upper extremity patient, I have significant concerns regarding 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 # (there are 4 therapists in my practice) 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 on this proposed rule.

Sincerely,

Robin E. Miller, OTR/L, CHT
Owner/Clinical Director

CMS-6006-P-33 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Karen Miley** **Date & Time: 09/21/2007**

Organization : **Mrs. Karen Miley**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

"See Attachment"

September 21, 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: Karen Miley, OTR/L
3316 W. Palmer St. #3F
Chicago, IL 60647

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. 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.

CMS-6006-P-34 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mr. Brian Laney** **Date & Time: 09/21/2007**

Organization : **ASHT**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

Refer to ASHT letter/comments.

Impact

ASHT has sbumitted a letter with information concerning a Surety Bond Requirement for Suppliers of DMEPOS. I submit my mutual response to this requirement.

Provisions

I am in full agreement with ASHT on this matter.

CMS-6006-P-35 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Ann Maggard** **Date & Time: 09/21/2007**

Organization : **Rehabilitation Centers of Charleston**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

Thank you for the opportunity to comment on this proposed rule and I hope that you will consider the issues brought forward to you.

Impact

The supply of DMEPOS is an important componen in the treatmnent 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 my setting of Upper Extremity Rehab and close association with a Hand Surgeon, a vast majority of my patients are post surgery and require custom made orthoses to assure success of the surgery and functional use of the hand/arm. We use these orthoses to protect, support, increase motion and improve independent ADL function. The nature of our patients' acute and changing conditions requires the frequent adjustment of these orthoses to maintain and improve gains made in therapy. The importance of our continued ability to fabricate and make adjustments to these orthoses in a timely manner cannot be underestimated.

Provisions

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 acute and frequently changing nature, would preclude these patients from finding an effective alternative supplier. The loss of pracitioner/supplier enrollees and subsequently their ability to supply DMEPOS will aedverely affect both the cost of treatment and final outcome of these enrollee's patients. I suuport 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 to no additional protection to CMS since accreditation is already providing a greater level of security.

CMS-6006-P-36 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Mary Oswald** **Date & Time: 09/21/2007**

Organization : **San juan Hand Therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

see above

Impact

Please make an exception for thapists like myself whos job it is to make splints for people with a variety of different hand injuries. It is imperative that these patients receive splints for protection following an injury, to help facilitate healing, etc., however there is no way I can afford a $65000 surety bond, which, as I understand it, would come to aprox $2000/year. If this passes I simply would not be able to fabricate custom splints for my Medicare patients any longer and this is a major part of my job! Please help resolve this inexplicably costly and unnecessary provision. Sincerely, Mary Oswald MS,OTR, CHT Durango, CO

CMS-6006-P-37 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Kimberlee Morrison** **Date & Time: 09/21/2007**

Organization : **Bartlesville Physical Rehab**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

I feel that this is totally ludacris unless our facility can be guaranteed reimbursement for ALL DME. What is the point in being accredited, which is also ludacris for the amount that we get reimbursed, if we have to go through this also? It really deters us as professionals from the desire to offer the valuable experiences and knowledge that we have. Our patients rely on this and need this from us and you make if very challenging to offer all of the services that are available to them.

CMS-6006-P-38 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Kate Davey** **Date & Time: 09/21/2007**

Organization : **Mercy Clinics, Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

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.

Impact

September 21, 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: Kate Davey

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As a Physical Therapist and Certified Hand 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. 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.

Provisions

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. Why not encourage patients to be as compliant as possible with their treatment?????

CMS-6006-P-39 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Lydia Hohman, OTR/L CHT** **Date & Time: 09/21/2007**

Organization : **North Wales Hand Rehabilitation**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

I am writing to oppose the Surety Bond Requirement in CMS-6006-P. As an licensed occupational therapist and certified hand therapist, my small independent practice provides hand rehabilitation services to medicare patients. Proper care for my patients requires the fabrication of custom orthotics (splints) often used for protection after delicate surgeries and to assist in gaining range of motion in an injured hand or wrist. I believe that my licensure and certification requirements, along with my medicare accreditation, are sufficient evidence of both competance and ethical behavior. In addition, the $2,000.00 annual charge to purchase this surety bond would be a significant hardship on our small business, which already struggles to cope with insufficient reimbursement from local PPO and HMO insurers. Thank you for taking the time to consider my comment. Lydia Hohman, OTR/L CHT

CMS-6006-P-40 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Phyllis Peterson** **Date & Time: 09/21/2007**

Organization : **Phyllis Peterson**

Category : **Physical Therapist**

Issue Areas/Comments

Provisions

I own a small private practice in East Tennessee. I am a Physical Therapist and Certified Hand Therapist. No one else does what I do in my county. Having to jump though the hoops to become a DME provider (and pay someone ~ $1500 to do so) coupled with the new proposed requirement for the Surity Bond, makes it financially not feasible. All I want to do is fabricate custom thermoplastic splints for hand patients. Both requirements seem ridiculously unnecessary for my setting and patients. As a matter of fact, I will not be able to provide splinting if those are the requirments.

CMS-6006-P-41 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mr. Ryan Glover** **Date & Time: 09/21/2007**

Organization : **Armworks Hand Therapy, LLC**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

I would like to comment on the proposed initiative for a $2000/NPI# for the supply of DMEPOS. I own and operate a small hand therapy practice which would be greatly and negatively effected by such a ruling. The use of custom fabricated splints is a vital component of my treatment plan to ensure excellent therapy outcomes. My practice, and the overall care of the patient, would be greatly impacted by my ability to fabricate these splints. This proposed fee, on top of the accredidation process, would put undo hardship on my business. 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.

CMS-6006-P-42 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. susan locker** **Date & Time: 09/21/2007**

Organization : **Mrs. susan locker**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

see attachment

42

September 20, 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: Susan Locker
7016 Wildrose Terrace
Carlsbad, Ca 92011

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. 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.

CMS-6006-P-43 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Mary Gillam** **Date & Time: 09/21/2007**

Organization : **Mt.Clemens Regional Medical Center Rehab Svcs**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

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.

Impact

Impact: I feel that this rule may affect my ability to fabricate and supply orthoses. 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 business. 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. In addition, many of the orthoses we make are so individualized that most Orthotists do not deal with these types of splints. As well as, many need to be done within a certain time frame after surgery or injury and cannot be afforded to wait to have a future appointment set up with another orthotist. 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.

Provisions

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As an Occupational Therapist, 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. 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.

CMS-6006-P-44 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. priya joshi** **Date & Time: 09/21/2007**

Organization : **tri city medical center**

Category : **Occupational Therapist**

Issue Areas/Comments

Impact

September 10, 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: Name and Address

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. [If you have time, giving a percentage of DMEPOS billings to your overall charges to Medicare and/or how it affects your patients may support this contention] 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. [Feel free to add any personal effect this ruling will have on your practice.]

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.

CMS-6006-P-45 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Merry Johnson** **Date & Time: 09/21/2007**

Organization : **Ms. Merry Johnson**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

I agree with the statement made by ASHT as follows; ASHT strongly feels 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 provider/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.

CMS-6006-P-46 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Peggy Medina** **Date & Time: 09/21/2007**

Organization : **Second To Nature**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

Talk about taking away the competitive edge. I am one of only two suppliers who carry this specialty item in our town. I am already getting business from 2 therapists who are dissatisfied with the service they receive from the large corporate DME located here. Take away my business and this large company can pretty much do what they want. The nearest town with services is aproximately 40 minutes from here.

Provisions

This would definitely have a negative impact on my business. I run a small DME business, working mostly with ladies who have had breast cancer. I would not be able to post such a bond.

CMS-6006-P-47 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Emily Garza** **Date & Time: 09/21/2007**

Organization : **Good Samaritan Hospital**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

Please see my impact statement. The increase in these rulings are only going to limit the amount of providers, not have the services provided or increase the cost in the end. If there are not providers the patients can't get the services and then what... increase cost of healthcare related to the secondary health issues from not having the equipment: wounds, urinary infections, contractures, limited independence.

Impact

It will limit the amount of providers, thus limiting access to patients and the freedom to choose. Many states with fewer therapists may not even be able to afford the fee- causing patients to have to drive a long distance or go without. The most likely scenerio would be the person would go with out.

Provisions

It will limit the amount of providers, thus limiting access to patients and the freedom to choose. Many states with fewer therapists may not even be able to afford the fee- causing patients to have to drive a long distance or go without. The most likely scenerio would be the person would go with out.

CMS-6006-P-48 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mr. Eric Spreeman** **Date & Time: 09/21/2007**

Organization : **Hand Surgery Center, LLC**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

See Attachment

September 10, 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: Eric Spreeman, MHSA, OTR, CHT

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. Currently, DMEPOS comprises less than 3 percent of my annual billing. 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 my patients. Many of the DMEPOS suppliers in this area do not even stock the items that we need creating increased wait times which will further diminish/adversely affect the outcomes of my 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.

CMS-6006-P-49 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Jennifer Thomas** **Date & Time: 09/21/2007**

Organization : **Hand and Orthopedic Rehabilitation Center, LLC**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

See Attachment

September 24, 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: Jennifer Thomas, OTR/L, CHT
Owner, Hand and Orthopedic Rehabilitation Center, LLC

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As the owner of a small hand therapy clinic and an Occupational Therapist, specializing in the treatment of the upper extremity patient, I have significant concerns about how this rule would impact 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. A large percentage of my patients require custom orthoses, as many attend therapy immediately following surgery. 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 have worked hard to develop relationships with my local hand surgeons and orthopedic surgeons, and to have to inform them that they will have to send their patients to another facility (that may not have a CHT) or to another town, would be a very discouraging decision to make. I opened a small hand therapy clinic 2 years ago to meet the needs of my community, and have seen the costs go up in all areas, while reimbursement

continues to decline and become harder to collect. I am concerned there could be another rule that would affect my practice and my ability to provide quality care to all my 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.

Sincerely,

Jennifer Thomas, OTR/L,CHT

CMS-6006-P-50 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Jennifer Thomas** **Date & Time: 09/21/2007**

Organization : **Ms. Jennifer Thomas**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

See attachment

50

September 24, 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: Jennifer Thomas, OTR/L, CHT
Owner, Hand and Orthopedic Rehabilitation Center, LLC

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As the owner of a small hand therapy clinic and an Occupational Therapist, specializing in the treatment of the upper extremity patient, I have significant concerns about how this rule would impact 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. A large percentage of my patients require custom orthoses, as many attend therapy immediately following surgery. 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 have worked hard to develop relationships with my local hand surgeons and orthopedic surgeons, and to have to inform them that they will have to send their patients to another facility (that may not have a CHT) or to another town, would be a very discouraging decision to make. I opened a small hand therapy clinic 2 years ago to meet the needs of my community, and have seen the costs go up in all areas, while reimbursement

continues to decline and become harder to collect. I am concerned there could be another rule that would affect my practice and my ability to provide quality care to all my 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.

Sincerely,

Jennifer Thomas, OTR/L,CHT

CMS-6006-P-51 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Laurie Roundtree** **Date & Time: 09/21/2007**

Organization : **Hand Rehabilitation Specialists**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

See attachment

September 10, 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: Laurie Roundtree, OTR/L, CHT
1550 Bridgegate St.
Westlake Village, CA 91361

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. ***Our practice's DME bills are 10% of our overall bills to Medicare, and it would be impossible for us to pay $2000 per year even for ONE NPI number, though we have 5 therapists. It does not make sense that we would have to have even ONE $65,000 surity bond for a total of $11,000/year of orthotics costs to Medicare.*** 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. ***Please understand that a hand therapist cannot do hand therapy without the use of orthotics, and that we could not financially survive if we had to incur these excessive costs for DME.***

Impact: ***There is no doubt that this rule will affect my ability to fabricate and supply orthoses. Hand therapy practices are generally small and cannot tolerate this burden.*** 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. It is clear to me that this ruling would severely impact Medicare beneficiaries in a negative way, eliminating beneficial services and treatments, with little-to-no beneficial effect from presence of the bond.*** 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.

CMS-6006-P-52 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Mariann Moran** **Date & Time: 09/21/2007**

Organization : **Accelerated Hnad Therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

I do not feel that this sg=hould be required for Ots especially in light of the new regulations for certification. This may be needed for some suppliers but not applicable to doctors and therapists.

CMS-6006-P-53 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Debbie Phibbs** **Date & Time: 09/21/2007**

Organization : **Western Washington Orthopedic and Hand Center**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

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 and most practitioners have additional licensure and credentialing requirements that would cover these issues as well.

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

Sincerely,

Debbie Phibbs, OTR/L, CHT
425-317-9119
Everett Washington

Impact

This letter is written regarding concerns I have on the proposed rule CMS-6006-P-1. I am an Occupational Therapist and Certified Hand Therapist that works in a private practice setting. I am very concerned about the implications of implementation of this rule would have on my practice and patients.

The supply of DMEPOS is an important component in the treatment of my patients as I practice in an acute outpatient orthopedic setting. The overall impact of orthoses and the ability to provide these orthoses immediately and concurrently with therapy is critical to obtaining the appropriate and optimal outcome for patients, and more specifically for the post operative caseload that comprises 80-90% of my patient caseload.

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.

Provisions

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. Our office employs 3 part time female therapists, and allows flexible schedules to accommodate family needs. The $2000 per NPI number may make it unrealistic or undesirable to employ part time workers.

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. Additionally, I practice in a more rural area of Washington State, where additional providers are not readily available.

CMS-6006-P-54 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mark Hyland** **Date & Time: 09/21/2007**

Organization : **STI PT and Rehab**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

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.

Impact

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. [If you have time, giving a percentage of DMEPOS billings to your overall charges to Medicare and/or how it affects your patients may support this contention] 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.

Provisions

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.

CMS-6006-P-55 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Farrell Sheffield** **Date & Time: 09/21/2007**

Organization : **Tri-City Medical Center**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

Please consider a waiver for occupational therapists, as we have adequate public safeguards with state licensing, departmental competency annual review and JCAHO oversight.

Provisions

As an occupational therapist since 1977, I have provided orthoses in various settings, for adults and children, including Home Health, Acute Care, Acute Rehab and Outpatient. The upper extremity splints prevent deformity, reduce pain, promote function after injury, disease and surgery from newborn to older adult. Ths ability to provide this in an timely manner, is essential and can avoid costly loss of function and future expense with deformity, skin breakdown,etc. My current work setting is as a supervisor of occupational therapy in an acute/rehab district hospital.The ability, with specialized training, to respond to doctor's orders and apply pre fabricated or custom splints is essential to proper patient care. With JCAHO survey and California OT licensing, skills are addressed with continuing education and record review. The proposal to add such a costly surety bond is not indicated for qualified occupational therapists, and would certainly degrade and seriously endanger patient care.

CMS-6006-P-56 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Mary Ann Appleby** **Date & Time: 09/21/2007**

Organization : **Dallas Hand Rehabiitation**

Category : **Occupational Therapist**

Issue Areas/Comments

Provisions

To begin with, there is little profit in fabricating custom made splints. Adding $2000 for the cost of a surety to the already low profit makes absolutely no sense from a provider's point of view. Medicare rates have been dropping over the past few years. Possibly hospitals can afford this, but the individual providers like ours can't. The cost of supplies has steadily risen and staff support costs due to increased requirements to get reimbursement has diminished profits. Please don't further burden our profession.

CMS-6006-P-57 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Catherine Taylor** **Date & Time: 09/21/2007**

Organization : **ASHT - Hand Therapy Pros**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

From: Catherine Taylor, MS OTR CHT
Hand Therapy Pros
2135 E Main Street
Snellville, GA 30078

Re: CMS-6006-P-1

Dear Sir/Madam,

I am an occupational therapist with certification in Hand Therapy practicing in the Metro Atlanta Area. I was made aware of the proposed CMS-6006-P-1 requiring a bond to be obtained for pracitiioners supplying DMEPOS to Medicare clients.

I am a sole provider of Hand and upper extremity therapy with approximately 20 percent of my clients on Medicare. Of these clients, less than 5% of their treatment/charges is related to DMEPOS. Although the DMEPOS is only a small aspect of their total treatment it is an integral portion of their treatment plan, allowing clients to recover functional use of their UE by protecting injuries, facilitating ROM and assisting with functional activities. These DMEPOS usually are provided in a single visit but may occassionally require adjustment as the patient progresses to maximize effectiveness and address evolving goals.

My business would not be able to afford the bond and it would be impossible to provide ehical and effective therapeutic intervention without the provision of DMEPOS to my clients. I feel that although the application of DMEPOS to my clients is critical the impact financially for CMS will be financially negligible, thereby not warranting the use of the bond.

Thank you for the opportunity to express my concerns.

Cathie Taylor, MS OTR CHT

CMS-6006-P-58 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Dr. Gail Shafer-Crane** **Date & Time: 09/22/2007**

Organization : **ARM Assessment Rehabilitation Management, Inc**

Category : **Occupational Therapist**

Issue Areas/Comments

Impact

The requirement for obtaining a surety bond will be a prohibitive additional expense for small busninsses who provide essential services to Medicare patients.

Provisions

My rehabilitation center is a small business. We provide certified hand therapy to a number of Medicare patients. As an essential component of this therapy, the provision of custom splinting, already requires a significant level of oversite by the physician, insurance case managers, licensed and certified therapists (peer review), and public health. An additional bonding will not improve the quality of care to Medicare patients, but instead will reduce the number of qualified professionals able to provide this service in a cost effective, timely, and appropriate manner. My patients are referred immediately after surgery for initiation of treatment protocols that are time sensitive. The application of appropriate splints, the often daily adjustment of these splints, is an essitial companion to the "hands on" intervention by a skilled therapist. Custom thermoplastic splints are fabricated during the therapy session, revised during subsequent therapy sessions, and may even require revision between the beginning and the end of a session based on changes in the limb during the session.

Small rehabiliation centers, like mine, are already taxed by the DMEPOS appication and recurring certification requirement and accompanying expense. Immposition of additional expenses, such as this bond, should only be considered if it will infact improve the delivery of services to Medicare patients. I do not see how the imposition of this requirement will do anything to assure quality, timely, safe, and appropriate care.

CMS-6006-P-59 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Christa Baggott** **Date & Time: 09/22/2007**

Organization : **Hands Rehab**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

This proposed rule will affect my ability to fabricate and supply orthoses.

Impact

Comment for proposed rule CMS-6006-P-1.

Provisions

As a small business owner, this new $2,000 surety bond per NPI#, will be an undo hardship on my office. We utilize orthotics to protect after surgical repairs are made, as well as, to increase functional ROM in the upper extremtiy. The importance of our abiility to be able to make custom fabricated orthotics cannot be stressed enough.

CMS-6006-P-60 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Deborah Austin** **Date & Time: 09/22/2007**

Organization : **ASHT, AOTA, FOTA**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

Please stop...I'm in a small practice...this will affect my abiltiy to make splints for patients who need them...

CMS-6006-P-61 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **D Schanzer** **Date & Time: 09/22/2007**

Organization : **AHT**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

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.

Provisions

Re: CMS-6006-P-1

To: Centers for Medicare & Medicaid Services

Department of Health & Human Services
PO Box 8017
Baltimore, Maryland 21244-8017

From: D. Schanzer
17 Woodside Ave.
West Caldwell, NJ 07006

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. [If you have time, giving a percentage of DMEPOS billings to your overall charges to Medicare and/or how it affects your patients may support this contention] 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.

CMS-6006-P-62 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mr. Frank Giattino** **Date & Time: 09/22/2007**

Organization : **Mr. Frank Giattino**

Category : **Individual**

Issue Areas/Comments

Impact

I believe it to be unfair that we the individuals must pay for our medical supplies when bad enough you make us pay a co-pay on our medication.As an individual it is hard enough for me to make ends meet with limited income I have.I have to pay out of pocket expenses thgat come to approximately 50 dollars including my supplies I hope that you will find away to eliminate a co-pay for medical supplies.

Provisions

The way this impacts my life is I live on a budget and find it hard to buy food,pay for my prescriptions,pay my rent and utilities.I am a diabetic and I need several kinds of supplies to help manage my medical condition.It is unfair that I should have to pay for my supplies when less then a year ago medicare was paying and it helped me to live a little easier.

CMS-6006-P-63 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Peggy Boineau** **Date & Time: 09/22/2007**

Organization : **Sweeny Community Hospital**

Category : **Occupational Therapist**

Issue Areas/Comments

Provisions

September 22, 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: Peggy Boineau, OTR, CHT
305 Freeman Blvd.
West Columbia, TX 77486

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 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. 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. 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.

CMS-6006-P-64 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Kimberly Thruston** **Date & Time: 09/23/2007**

Organization : **American Society of Hand Therapists**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

September 10, 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: Kimberly Thruston,MOT,OTR/L,CHT
3440 Preddy Creek Road
Charlottesville, VA 22911

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. The ability to provide this to a patient is crucial for their overall benefit of treatment/outcomes which directly affects my ability to bill accordingly for this service due to my expertise as Certified Hand Therapist. 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 am only 1 of a few Occupational Therpaists, Certified Hand Therapists in my area who have the expertise to provide a service to patients who are in

need of overall functional use of their extremities. I am extremely qualified to treat patients when other forms of care have failed or others uncertain as to what to offer these patients. Utilizing the splinting process to promote function and recovery is essential to all individuals for returning to selfcare, work, and leisure activities which affect both physical and psychological outcomes in the individual in pain or who is injured.

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.

CMS-6006-P-65 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Cynthia Syiek** **Date & Time: 09/23/2007**

Organization : **Palm Drive Outpatient Rehabilitation**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

I support the exemption of physician and non-physician practitioners from this rule.

Provisions

As a certified hand therapist in a small practice, this rule would be a hardship to our clinic. Medicare patients make up approximately 25% of my practice and of those, 10% require splinting. I am fabricating 4 or 5 splints per month total. Custom splinting is imperative to successful outcomes of many of my patients. Frequently splinting, especially post-surgical splinting, requires frequent adjustments, i.e., due to the changes in swelling as the patient heals, or to modify and change tension/direction as the patient regains range of motion. If our clinic decides it is not cost effective to the clinic as a whole to supply and fabricate orthoses, many of my patients would be adversely affected.

CMS-6006-P-66 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Ms. Gail Blom** **Date & Time: 09/23/2007**

Organization : **Covenant Hand Therapy, PC**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

Keep Medicare reimbursement and expenses reasonable so that we can continue to service this important population.

Impact

Requirement of surety bond for DME providers

Provisions

Requiring this large expense to a small business like mine (4 therapists in an out-patient setting) would be unmanageable. I already struggle to make enough for operations and start- up loan payments. A majority of my patients are Medicare. I do not limit the number of Medicare patients I accept; many clinics in the area do. We provide top-notch service and products to our patients -- our clinical staff consists of licensed therapists....not minimally trained 'techs' which most clinics utilize. I do not consider this bad business, I consider it providing the best service possible.

As Certified Hand Therapists and a Certified Pedorthist, our staff is specialty trained beyond Bachelor degree or Master's level university work, we have made the extra effort to become certified in specialty areas; this requires many more Continuing Education hours than the average therapist.

Please consider an exception for out-patient therapy clinics providing DME to Medicare patients. It is imperative that small therapist-owned clinics such as mine continue to thrive so that Medicare patients have community access to high quality DME.

Thank you for your attention.

CMS-6006-P-67 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Mrs. Ellen Weinman** **Date & Time: 09/23/2007**

Organization : **Mrs. Ellen Weinman**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

September 23, 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: Ellen Weinman, OTR, CHT

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 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. We utilize orthoses to protect, support, affect motion, and improve independent ADL function. We see patients within a few days of surgery and they often need to have a custom splint fabricated immediately. 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.

CMS-6006-P-68 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Diana Williams** **Date & Time: 09/23/2007**

Organization : **Macon Orthopaedic & Hand Center**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

See Attachment

68(#1)

September 22, 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: Diana A. Williams, MBA, OTR, CHT

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 a Physician Owned Practice, specializing in the treatment of the upper extremity patient, I have significant concerns regarding the effect of this rule on patients and my practice.

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. Our practice offers a measurable portion of DMEPOS billings to our overall charges to Medicare. It is an important component to the overall treatment outcomes for these individuals and is not something that is a one time, one size fits all procedure. Our patients select our practice group because of the highly qualified and specialized physicians and non-physician practitioners. 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 therapist, the estimated $2000 cost of the surety bond per NPI # in addition to the new costs of accreditation would be an undo hardship on our practice. 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.

CMS-6006-P-69 **Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Submitter : **Diana Williams** **Date & Time: 09/23/2007**

Organization : **Macon Orthopaedic & Hand Center**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

See Attachment

September 22, 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: Diana A. Williams, MBA, OTR, CHT

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 a Physician Owned Practice, specializing in the treatment of the upper extremity patient, I have significant concerns regarding the effect of this rule on patients and my practice.

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. Our practice offers a measurable portion of DMEPOS billings to our overall charges to Medicare. It is an important component to the overall treatment outcomes for these individuals and is not something that is a one time, one size fits all procedure. Our patients select our practice group because of the highly qualified and specialized physicians and non-physician practitioners. 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 therapist, the estimated $2000 cost of the surety bond per NPI # in addition to the new costs of accreditation would be an undo hardship on our practice. 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.

Submitter : **Mr. Jerry Coverdale** **Date: 09/24/2007**

Organization : **Mr. Jerry Coverdale**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-6006-P-70-Attach-1.DOC

#70

September 10, 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: Jerry J. Coverdale, OTR,CHT

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 , 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. 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.

Jerry J. Coverdale, OTR,CHT
712 Palmetto St.
WPB, FL 33405
(561)827-4339
Jcover6248@aol.com

Submitter : **Dr. David Gilbert** **Date: 09/24/2007**

Organization : **Dr. David Gilbert**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. Micheal Reilly** **Date:** **09/24/2007**

Organization : **Dr. Micheal Reilly**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

#72

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Date: 09/24/2007**

Organization : **American College of Foot and Ankle Surgeons**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-73-Attach-1.DOC

#73

American College of
Foot and Ankle Surgeons

8725 West Higgins Road, Suite 555
Chicago, IL 60631-2724 USA
Tel: 773.693.9300
Fax: 773.693.9304

info@acfas.org
www.acfas.org
www.FootPhysicians.com

September 21, 2007

VIA ELECTRONIC SUBMISSION

Herb B. Kuhn
Deputy (Acting) Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6006-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-6006-P, Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), Proposed Rule (72 Fed. Reg. 42001, August 1, 2007).

Dear Mr. Kuhn:

The American College of Foot and Ankle Surgeons appreciates the opportunity to comment on the "Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)" proposed rule published in the *Federal Register* on August 1, 2007. The American College of Foot and Ankle Surgeons (ACFAS) is the professional society for more than 6,000 board-certified foot and ankle surgeons. The ACFAS mission is to advance the competency of our members and the care of our patients. ACFAS is writing to urge CMS to exclude all physicians, including podiatric physicians, from the proposed $65,000.00 surety bond requirement so that physicians can continue to supply DMEPOS items as part of the normal course of providing high quality care to their patients.

ACFAS applauds CMS' efforts to limit Medicare fraud in the DME program and ensure that Medicare beneficiaries receive only reasonable and medially necessary products and services. However, ACFAS has serious concerns about the potential effects a surety bond requirement would have on physicians, especially those in small group practices or solo practitioners. ACFAS' concern is that the surety bond requirement would impose an onerous and costly burden on physicians' practices forcing many physician suppliers out of the program. This would impede patients' ability to access immediate, safe, effective, quality care.

Consider a patient who presents complaining of foot pain following an injury. The patient is diagnosed with a foot fracture and it is determined that a walking boot is necessary to treat the

fracture. If a physician can no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall could result, which could result in other additional injuries.

Another example is a patient who sustains an acute ankle injury. The treating physician determines that an ankle brace and crutches are appropriate in treating the patient. If that physician can no longer supply DMEPOS, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe resulting in greater recovery time, increased risks for complications, and additional costs to the Medicare program.

There are many other scenarios that could be presented to demonstrate the detrimental effect a surety bond requirement for physicians will have on patients' access to safe, quality care. Again, ACFAS urges CMS to exclude all physicians, including podiatric physicians, from the surety bond requirement so that they may to continue to supply DMEPOS and provide patient care in the setting most medically appropriate to the patient's medical needs.

Thank you for your consideration of this serious issue. Please address any questions about our comments to Laura J. Walsh, JD, Director of Health Policy and Practice Advocacy, at (773) 693-9300.

Sincerely,

Daniel J. Hatch, DPM, FACFAS
President

Submitter : **Barbara Stanley** **Date: 09/24/2007**

Organization : **Capital District Hand Therapy Center**

Category : **Physical Therapist**

Issue Areas/Comments

Impact

Impact

October 20, 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: Capital District Hand Therapy Center
1201 Nott Street, Suite 105-A
Schenectady, New York 12308

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. I am a Physical Therapist employed in a 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.

Our clinic is very small (1 fulltime and 4 part-time therapists working an equivalent of 2 fulltime therapists jobs.) We are highly qualified with 4 of the 5 therapists holding CHT (specialize hand therapy) certification. Splinting is an essential part of our treatment program. Many of the splints we make, especially for our Medicare patients go hand in hand with the surgery that was performed. Without the ability to utilize splints for our Medicare patients, care would suffer. In addition, with reimbursement the way it is in the state of New York, and the number of uninsured patients in our practice, we are struggling to make ends meet.

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.

I encourage you to visit a practice that specializes in Hand rehabilitation and see for yourself the level of expertise that goes into the construction of these splints and the treatment of the patients. As result, I support the exemption of physician and non-physician practitioners from this rule unless there is a previous adverse history of Medicare fraud.

Thank-you for your time,
Barb Stanley PT

Submitter : Mrs. Kim Herron **Date:** 09/24/2007

Organization : Cherokee Medical Supply

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

With the implementation of competitive bidding already forcing hardships on DMEPOS suppliers, why is it necessary to compound the situation by adding a surety bond to an already stressed industry. It is very apparent that competetitive bidding is going to "weed out" the weak DMEPOS suppliers as well as some very reputable DMEPOS suppliers that simply can not compete with the larger suppliers. The implementation of a surety bond will simply be another compounding factor that will cause a hardship on the small DMEPOS suppliers that are truly trying to provide quality services and supplies to Medicare Beneficiaries. We would respectfully ask that this be reconsidered.

Impact

Impact

The proposed revision to the Social Security Act that would require all DMEPOS suppliers to furnish CMS with a surety bond with implementation of section 1834(a)(16)(B). This will cause an unnecessary hardship to small legitimate DME suppliers that are simply trying to provide quality supplies and services to Medicare beneficiaries.

Provisions

Provisions

Requirement of Surety Bonds for DMEPOS suppliers
Section 1834(a(16)(B)

Submitter : Mrs. Jan Zeldes **Date:** 09/24/2007

Organization : Northeast Orthopaedic Specialists

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Please do not do this! Please do not listen to the "bean counters" who say it will save medicare dollars. Our society cannot tolerate any more changes to the healthcare system for the worse. The United States cannot afford to fall further behind, cannot afford to punish its people any further. Especially those who have given so much to get to where they are, they deserve more. We all deserve more! Not less! Medicare dollars will not be saved just redistributed as the elderly get sicker from the inability to function independantly! Remember this, "Man through the use of his hands can influence the state of his mind" and health!! We will have a healthier America, if you do not enforce this docket!!
thank you,

Sincerely,
Jan Zeldes OTR/L

Impact

Impact

My statement is based upon the bond issue.

Provisions

Provisions

I would like to make several comments as to the impact on myself, the profession, and to the patients.

1. the patients: Orthotics are not a luxury, they are a necessity of treatment in many hand injuries that without their use the patients would lose most if not all the function of their hand. For example tendon injuries, they require a series of splints that are necessary to increase their length, protect against further damage (sutures tearing), and allow independent function. Hand injuries are not "fixed" with only surgery, or medication or even time. Without the use of splinting we would see a population of Americans with stiff and funtionless hands, possibly setting them up for the loss of the ability to perform any occupation, the need for welfare, housing, food stamps, loss of child support, even increased crime.

2. Myself. As an occupational therapist practicing hand therapy for over 20 years I have seen several changes in the industry with reimbursement costs. It has always been a struggle to stay ahead of the insurance companies changes in policies, and data requirements needed for reimbursement. Already, several insurance companies barely pay for treatment of the patients sometimes only $7.00 for over an hour of my time. That is hardly the pay that 5 years of college and countless hours of continuing education warrent. My salary has not increased on over 2 years and is 7% less than it was 14 years ago. The cost of living has not decreased in 14 years so my salary has barely been able to keep up with the changes in my electric, gas, food, clothing bills.
Now medicare is going to ask for me to pay for the right to make splints! How absurd! I can barely afford to put the gas in my car to get to work, I certainly cannot afford the fee that will be required for me to practice my field. How many more ways is the government going to try to stop me from being able to earn a living? How many other professionals are being asked the same of themselves? I have been making splints for 20 years, I am good at it. I do not know any other way to earn a living, why would you take away the ability to earn a living to support my family that I have struggled so hard to maintain? This fee would most certainly discourage me from performing hand therapy at all. Splinting is an integral part of this therapy, as crutial as gas to run a car and electricity to power a light bulb. This fee is a demonstration of the userous power of the government to make up their own rules to save money. People will suffer, patients will not get better, and therapist will not be able to practice their profession. Which brings me to the next point.
3. The profession: Therapists, doctors, even suppliers of the material for splints will all be affected. The therapists barely getting by, as well as the need for continued competency in the field, will be unable to meet the demands for this fee and those who can, although I have no idea who would, will be overworked. Therapists will no longer look to this avenue to practice, and the patients, the people you insure will be unable to get the proper services they require to heal. Health care will continue to suffer! The patients will become more dependent on society, family, and they will suffer. What about the 75 year old woman with no family who break her arm in a fall, or cuts her flexor tendons, who can she turn to if she cannot regain the use of her hand because of your new requirements. She will turn to you, the government, you will have to take care of her, home health care will have to go to her house and bathe her, dress her, feed her because she will be unable to do this for herself. This will cost thousands of dollars. But a simple splint, one that will allow her hand to knit and heal will only cost a couple hundred or even less.
This make no sense!!!

Submitter : **Date: 09/24/2007**

Organization :

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

September 24, 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: Ginger Rogers, LOTR, CHT
Brown Rogers Therapy
Baton Rouge, Louisiana
225-926-2400

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 regarding 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. For example, a client is evaluated and it is determined that a custom splint is required (for example, a tendon injury). The splint is fabricated on the client s first visit and he/she is educated on proper wear and care. This splint will be modified as the client makes gains in movement or his/her needs change over the course of treatment. Not only is this type of custom splint not available in a prefabricated form, but even in the case of prefabricated splints, to send the client to another location to receive a prefabricated off the shelf splint is time consuming and a waste of resources. If the client is required to go to another location to a large DME provider, many times the provider of this service is not a therapist, but simply an individual pulling boxes off of a shelf and trying the item on the patient. It makes no sense to involve another billing party in a treatment plan that I am responsible for. I am not even able to monitor the fit or the appropriateness of the splint chosen.

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.

Ginger Rogers, Occupational Therapist, Certified Hand Therapist
Brown Rogers Therapy
7417 Jefferson Highway
Baton Rouge, LA 70806

Submitter : **Ms. Sarah Stillings** **Date: 09/24/2007**

Organization : **Covenant Hand Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Hand therapy centers, especially those employing Certified Hand Therapists, provide an essential service to Medicare patients by being able to fit, adjust, and customize upper extremity splints for all types of diagnoses, working with the patient throughout the span of care. Fees that force these services to be provided only at a general orthotic fabrication center could very negatively impact these patients. This could lead to poorer functional outcomes and a greater drain on Medicare resources due to these patients' decreased independence.

Impact

Impact

Surety bond requirements will have a negative impact on hand therapy centers. Fabrication of custom splints and orthoses is a small but vital part of our business. The fees required would be excessive for the amount of income they generate.

Provisions

Provisions

Proposed surety bond requirements for DMEPOS providers.

Submitter : Mr. J. Christopher Kuhlmann, OTR/L, CHT **Date:** 09/24/2007

Organization : Maryland SportsCare & Rehab

Category : Occupational Therapist

Issue Areas/Comments

Provisions

Provisions

This proposed Bond requirement would have a significant negative impact on our private practice and would force us to stop the supply of DME in the form of customized thermoplastic splints for post surgical patients.

Submitter : **Ms. Elizabeth Gilliland** **Date: 09/25/2007**

Organization : **Delaware Curative Workshop, Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

September 25, 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: Elizabeth Gilliland
Delaware Curative Workshop, Inc
1600 Washington Street
Wilmington, DE 19802

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 and Executive Director of a not-for-profit outpatient rehab organization providing physical and occupational therapy services in seven locations througout the state of Delaware, I have significant concerns re: the effect of this rule on our ability to continue to meet the needs of our community and our patients. I am also extremely concerned with the patient outcomes and ability to access ongoing orthoses needs. As reimbursement from a number of payor sources are flat or continue to decrease it is a tremendous challenge to continue our 62 yr. history of providing services to our communities.

The supply of DMEPOS is an important component in the treatment of our 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: We feel that this rule may affect our ability to fabricate and supply orthoses. As a not for profit 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 our office and at this point could seriously determine our future viability. 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 do not believe that a surety bond would offer any 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,
Elizabeth Gilliland
Executive Director
Delaware Curative Workshop, Inc.
"Serving Delawareans Since 1945"

Submitter : **Ms. Catherine Cambridge** **Date: 09/25/2007**

Organization : **Delaware Curative**

Category : **Physical Therapist**

Issue Areas/Comments

Impact

Impact

The surety bond for fabricating/fitting splints

Provisions

Provisions

I am director for a non-profit out patient hand rehab. department with mutiple staff. We are trying to provide affordable healthcare to all including the uninsured. Any additional expense such as the proposed bond would increase our costs leaving less money to provide Hand therapy to the uninsured. Splints are an intrigal part of Hand Rehabilitation and sending hand patients to a duly bonded splint maker elsewhere would adversely effect the outcomes while driving the cost of care even higher.

Submitter : **Mrs. Janet Blaylock** **Date: 09/25/2007**

Organization : **Hand Therapy of Delaware**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-6006-P-82-Attach-1.DOC

#82

Janet W. Blaylock, MOT, CHT
Hand Therapy of Delaware, a division of Delaware Curative
623 W. Newport Pike
Newport, Delaware 19804

September 10, 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: Janet W. Blaylock, MOT, CHT

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 regarding 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 or during their treatment to maintain and improve on gains made in therapy and to create gradual increasing demands. 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. I work in a small not for profit, 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 and might preclude the patient from recovering from their injury or disability. 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.

Submitter : Mr. Scott Ward, PT, PhD **Date:** 09/25/2007

Organization : American Physical Therapy Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-83-Attach-1.PDF

#83

APTA
American Physical Therapy Association

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

Combined Sections Meeting
February 6-10
Nashville, TN

PT 2008:
The Annual Conference
& Exposition of the
American Physical Therapy
Association
June 11-14
San Antonio, Texas

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 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

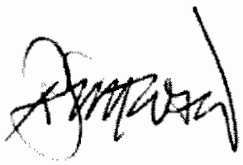
In conclusion, among its key recommendations, the APTA urges CMS to take the following actions:

- 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 or gaylelee@apta.org.

Sincerely,



R. Scott Ward, PT PhD
President

Submitter : **Mr. Raymond Alessandrini** **Date: 09/25/2007**

Organization : **Slocum-Dickson Medical Groupl, PLLC**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

September 25, 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: Raymond A. Alessandrini, OTR/L
1729 Burrstone Road
New Hartford, NY 13413

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 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. We utilize orthoses to protect, support, affect motion, and improve independent ADL function. . The nature of our patients acute, healing 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. There are many times that I see a patient post-operatively or following an acute injury for immediate splint fabrication. Not doing so can jeopardize their recovery or put them at risk for additional/further injury. 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.

Submitter : **Ms. Rhonda Coor** **Date: 09/25/2007**

Organization : **West End Orthopaedic Clinic**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern:

I wish to comment on the proposed regulation requiring surety bonds for all DMEPOS providers. Surely the additional cost burden of this bond will preclude many small providers from providing services to Medicare recipients. Those left providing services will be predominately the larger regional and national companies that have no direct affiliation with physician offices. The Medicare patient, unlike his or her commercial patient counterpart will not have the opportunity of immediate and timely care.

Rhonda S. Coor
Director of Operations
West End Orthopaedic Clinic, Inc.
804-915-4605

Impact

Impact

Proposed addition of surety bond requirements for DMEPOS providers

Provisions

Provisions

Inability for timely service for Medicare patients relative to others

Submitter : Mr. Michael Kleinpeter **Date:** 09/25/2007

Organization : Orthopedic Center, PC

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

It doesn't take an Economy Scholar to understand that physicians, other practitioners, and hospitals won't be around much longer with the decreased reimbursement, soaring expenses, and now this miscellaneous expense. I fully understand that fact that if a payer source doesn't have the money, nobody gets paid. But, there has to be a better way than charging $2,000 per year per NPI.

Impact

Impact

Surety Bond for those selling DMEPOS

Provisions

Provisions

I'll make it brief. For everyone in health care, expenses continue to go up and reimbursement continues to go down. The end road to all of this is going to be a decreased number (which may be the underlying purpose) of physicians/practitioners and a lack of participation in Medicare and other government insurance. We have 22 physicians with an NPI number so we are not prepared to pay $2,000 per year per MD.

Submitter : Ms. Jane Johnson **Date:** 09/25/2007

Organization : Community Orthopedic Surgery & Huron Valley Hand S

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-87-Attach-1.TXT

CMS-6006-P-87-Attach-2.TXT

CMS-6006-P-87-Attach-3.TXT

#87.

September 24, 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: Jane M. Johnson, MA, OTR, CHT
Community Orthopedic Surgery & Huron Valley Hand Surgery
420 W. Russell St., Ste. 109
Saline, MI 48176

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 employed Occupational Therapist, 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 many cases the orthoses through precise positioning, immobilization and coverage of the injured area is essential to the safety of the patient to prevent reinjury during their recovery from injury or post operatively. 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. Our corporation provides care for Medicare patients in three locations. The resultant estimated $6,000 cost of surety bonds would be very difficult for our corporation. 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 as is ours. 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. Precise individualized verbal and written fitting, wearing and care instructions are an essential part of the provision of this type of DMEPOS. 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.

Submitter : **Mrs. Linda Malear** **Date: 09/26/2007**

Organization : **Rehabilitation Centers of Charleston**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I support the exemption for physicians and non-physcian practioners.
The surety bond is an additional expense that will not provide additional protection.

Thank you for considering the impact on the treatent providers and the patients,

Linda Malear, OTR/L

Impact

Impact

Supplying DMEPOS is vital to the treatment of patients in my acute care hand clinic treating individuals suffering from traumatic injury due to falls, auto accidents etc, and other hand and upper extremity conditions.

Provisions

Provisions

This rule may affect the ability of the therapist to provide necessary orthotics for the patient. As reimbursement for treatments diminish, the cost of the surety bond in addition to the new accreditation costs will be an undue hardship. The costs of supplies continues to esculate further impacting the ability of therapists to provide cost effective treatment. If patients are limited in the ability to have acute care after injury, the costs will ultimately
rise. The loss of occupational therapy hand clinics may result in treatments being provided in more expensive orthotics and prosthetic clinics, at greater distances and hardships for the patient. This will impact the functional outcomes after injury.

Submitter : Mr. Troy Gibson **Date:** 09/26/2007

Organization : Kaleida Hand and Shoulder Rehabilitation

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-6006-P-89-Attach-1.DOC

#89

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: Troy D. Gibson, MS, OTR
Lead Therapist, Kaleida Hand and Shoulder Rehabilitation
3 Gates Circle 10th Floor
Buffalo, NY 14209

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, 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. 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. This ruling will place 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.

Troy D. Gibson MS, OTR

Submitter : Mr. William Walsh **Date:** 09/26/2007

Organization : Hand & Rehabilitation Specialists of NC

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

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.

Impact

Impact

As a Certified Hand Therapist and 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. With regard to our overall charges billed to Medicare, 25% are DMEPOS. 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 the gains made in therapy. the importance of our continued ability to fabricate orthoses and make timely adjustments cannot be underestimated.

Provisions

Provisions

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 estimated that up to 15% of individual practitioner/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 comprarable benefits from other local suppliers, I feel the acute and frequently changing nature of this type of DMEPOS is intimiately connected to the therapy they are receiving, would preclude these patients from finding an effective alternative supplier. The loss of practitioner/supplier enrolllees- and subsequently their ability to supply DMEPOS- will adversely affect the cost of treatment and the final outcome of these enrollees's patients.

Submitter : Ms. Margaret Antoine **Date:** 09/26/2007

Organization : West End Orthopaedics

Category : Occupational Therapist

Issue Areas/Comments

Impact

Impact

To Whom It May Concern:
I would like to comment on the proposed rule CMS-6006-P-1. I am an occupational therapist and certified in hand therapy. I work in a physician owned practice and specialize in the treatment of the upper extremity. I have concerns re: the effect of this rule on my patients and our practice.

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. Thirty five percent of the DMEPOS billing in our clinic is for Medicare patients. We use orthoses to protect, support, and improve the ability to perform ADLs. The importance of continued ability to fabricate orthoses and make timely adjustments cannot be underestimated.

Provisions

Provisions

I feel that this rule may affect my ability to fabricate and supply orthoses. As a small clinic, the estimated $2000 cost of the surety bond per NPI# in addition to the new costs of accreditation would be an undo hardship in my clinic. 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. The hardship on patients to have to travel to another supplier for a splint specified by our on-site hand surgeon has been encountered previously. What usually happens is that the orthosis or splint is inappropriate or inappropriatly fitted. Also, we remove post-op dressings on the initial visit then make the splint at the same visit per the specifications of the hand surgeon.

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 on this proposed rule.

Submitter : Margaret Fagan **Date:** 09/26/2007

Organization : Margaret Fagan

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attatchment

#92

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Plea.. note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : Ms. KIM NORTON **Date:** 09/27/2007

Organization : AMERICAN SOCIETY OF HAND THERAPISTS & AOTA

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

IT IS INTERESTING THAT USING PROFESSIONAL INTERVENTION IN APPLYING AND INSTRUCTING A PATIENT IN CORRECT USE AND FUNCTION OF DURABLE MEDICAL EQUIPMENT IS GRADUALLY BEING DOWNPLAYED - REMOVED FROM BEING A PRIMARY FACTOR. I KNOW OF MANY PATIENTS THAT HAVE HAD SURGERY - POSSIBLY NOT NEEDED OR COULD HAVE BEEN PREVENTED - BY PROPER USE OF EQUIPMENT, RESOLVING THE PROBLEM, OR BY AVOIDING RISK FACTORS SUCH AS FALLS BECAUSE OF POOR USE OF EQUIPMENT. EXERCISE AND PERSONAL INSTRUCTION IN DISEASE PROCESSES AND PREVENTION OF INJURIES FOR THE MAJORITY OF AMERICANS NEEDS TO COME FROM A PROFESSIONAL CLINICIAN - NOT FROM A CATALOGUE. I HAVE 28 YEARS OF EXPERIENCE AS AN OCCUPATIONAL THERAPIST AND 15 OF THOSE YEARS AS A CERTIFIED HAND THERAPIST. IN ADDITION TO APPLYING/ FABRICATING CUSTOM SPLINTS, I INSTRUCT PATIENTS IN THE MANNER TO WEAR SPLINTS I MAKE AND THOSE THAT ARE PURCHASED OVER THE COUNTER TO AVOID SURGERIES AND RISKS/ COMPLICATIONS THAT SURGERIES CAN BRING. I HAVE INSTRUCTED MANY PEOPLE IN THE SAFE USE OF BATHROOM EQUIPMENT/ AND SPECIFIC ONES FOR THE INDIVIDUAL. THE WHOLE DME REVAMPING SEEMS TO BE COSTING JUST AS MUCH BUT TAKING THE PROFESSIONALLY TRAINED THERAPIST OUT OF THE PICTURE. MAYBE THIS WILL GET TO THE RIGHT PERSON, AND SOMEONE CAN SEE THINGS FROM A DIFFERENT PERSPECTIVE! THE COST MAY END UP BEING THS SAME, BUT THE RISKS AND LACK OF EFFECTIVENESS GREATER. THANK-YOU FOR CONSIDERATION, KIM NORTON, MA, LOTR, CHT

Submitter : **Ms. Beth Brinton** **Date: 09/27/2007**

Organization : **Hand Rehabilitation Services**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

#94

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. William Davies **Date:** 09/27/2007

Organization : Orthopaedic Association of WI, SC

Category : Physician

Issue Areas/Comments

Impact

Impact

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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.

Provisions

Provisions

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As an Physician in a 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. 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.

Submitter : Dr. Rick Papandrea **Date:** 09/27/2007

Organization : Orthopaedic Association of WI, SC

Category : Physician

Issue Areas/Comments

Impact

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

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Submitter : Dr. Michael Tjarksen **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician

Issue Areas/Comments

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

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Submitter : Dr. John Bolger **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician

Issue Areas/Comments

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Submitter : Dr. Steven Merkow **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician

Issue Areas/Comments

Impact

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Submitter : Dr. Timothy Schultz **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician

Issue Areas/Comments

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Submitter : Dr. Hongsheng Zhu **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician

Issue Areas/Comments

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Submitter : **Dr. Daniel Holub** **Date: 09/27/2007**

Organization : **Orthopaedic Associates of WI, SC**

Category : **Physician**

Issue Areas/Comments

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

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Submitter : Dr. T. Scott Stanwyck **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician

Issue Areas/Comments

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

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Submitter : **Dr. Timothy Fowler** **Date: 09/27/2007**

Organization : **Orthopaedic Associates of WI, SC**

Category : **Physician**

Issue Areas/Comments

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

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I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As an Physician in a 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.

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Submitter : Dr. Matthew Bong **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician

Issue Areas/Comments

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

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Submitter : **Dr. Scott Schneider** **Date: 09/27/2007**

Organization : **Orthopaedic Associates of WI, SC**

Category : **Physician**

Issue Areas/Comments

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

Provisions

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I would like to take this opportunity to comment on the proposed rule CMS-6006-P-I. As an Physician in a 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. 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.

Submitter : Cynthia Filut **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Nurse Practitioner

Issue Areas/Comments

Impact

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

Provisions

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I would like to take this opportunity to comment on the proposed rule CMS-6006-P-I. As a Nurse Practitioner in a 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.

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Submitter : **Andrew Palmer** **Date: 09/27/2007**

Organization : **Orthopaedic Associates of WI, SC**

Category : **Physician Assistant**

Issue Areas/Comments

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I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As an Physician Assistant in a 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. 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.

Submitter : **Jeffrey Ambord** **Date: 09/27/2007**

Organization : **Orthopaedic Associates of WI, SC**

Category : **Physician Assistant**

Issue Areas/Comments

Impact

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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.

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Submitter : Jennifer Mirenda **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician Assistant

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Submitter : **Tracy Baroni Allmon** **Date: 09/27/2007**

Organization : **CVS Caremark**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-6006-P-111-Attach-1.DOC

#111

CVS CAREMARK

September 27, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attn: CMS-10137
7500 Security Boulevard
Mail Stop: C4-26-05
Baltimore, MD 21244-1850

Re: CMS-6006-P: Comments on Proposed Rule on Surety Bond Requirement for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Dear Mr. Weems:

I am pleased to submit the following comments on behalf of CVS Caremark. CVS Caremark is the No. 1 provider of prescriptions and related healthcare services in the nation. The Company fills or manages more than 1 billion prescriptions annually. Through its unmatched breadth of service offerings, CVS Caremark is transforming the delivery of healthcare services in the U.S. The Company is uniquely positioned to effectively manage costs and improve healthcare outcomes through its 6,200 CVS/pharmacy stores; its pharmacy benefit management services, mail order and specialty pharmacy division, Caremark Pharmacy Services; its retail-based health clinic subsidiary, MinuteClinic; and its online pharmacy, CVS.com.

CVS/pharmacies nationwide provide durable medical equipment (DME) to patients, in addition to providing prescriptions and over the counter medications. Our pharmacists and pharmacy personnel are trained not only in the provision of DME, but in the appropriate billing and counseling requirements. Similarly, our mail pharmacies also provide DME as a service to beneficiaries and clients. As such, we offer the following comments on the proposed rule.

Executive Summary

We understand and support the goals of the CMS in implementing the surety bond requirement of section 1834(a)(16)(B) of the Social Security Act (the Act), namely, to limit the risk to the Medicare program from fraudulent DME suppliers, to be able to recoup payments from fraudulent or abusive billing practices, and to ensure beneficiaries receive reasonable and necessary products or services. We believe that it is essential for the integrity of the program that CMS be able to evaluate the legitimacy and financial soundness of DME suppliers, and to exclude from participation those suppliers that have

a history of fraudulent billing practices and failure to pay their debts. This is necessary not only to protect the program from fraud and abuse and beneficiaries from unscrupulous suppliers, but also to ensure that legitimate DME suppliers are able to compete fairly on a level playing field, and are not driven out of the program by the unfair and abusive practices of others.

However, we are concerned that, as proposed, the surety bond requirement will have the unintended effect of penalizing legitimate DME suppliers and, ironically, will operate most punitively against the organizations least likely to pose a risk to the Medicare Trust Fund, namely, large organizations with many locations. This is because the minimum bond amount is based not on factors such as financial soundness or past payment history, but rather, on the basis of the number of NPIs held by an organization, so that it will inevitably impose a much higher cost, potentially in the order of millions of dollars, on large, national organizations.

In addition, since the market for surety bonds operates much like the general bond markets in that there is a finite supply of bonds, the proposed rule will have the effect of shrinking the available supply, making it much more difficult and expensive to obtain surety bonds. The result is that the larger, more creditworthy entities that shouldn't even need to obtain bonds will qualify for them, potentially exhausting the available supply. The entities that are smaller and/or less creditworthy, and so for which the bond requirement is truly needed, will potentially be shut out of the market and/or pay a much higher premium to place their bond offerings. This can be avoided by designing the surety requirement to be more targeted to those entities that pose a real risk of default to the Medicare Trust Fund, and exempting entities where there is sufficient other evidence of creditworthiness so that imposition of a surety bond requirement is unnecessary.

In light of this, and the fact that the surety bond requirement appears to operate largely as a "screening" mechanism, we concur with CMS' view that the value of the mechanism diminishes with continued participation in Medicare, and with CMS' proposal to create exceptions for certain categories of suppliers where other forms of screening are already in place and/or the risks of non-payment are low. Thus, we strongly support the proposed exceptions for large, publicly traded chains of DMEPOS suppliers, community pharmacies that furnish DMEPOS items for the convenience of their patients, and physician and non-physician practitioners that furnish DME items for the convenience of their patients. We also recommend that CMS create an exception for DMEPOS suppliers that meet the quality and financial standards to qualify for an award as a supplier under the recently established DMEPOS competitive bidding process.

In each of these situations we believe that there are more than sufficient alternate screening and accreditation mechanisms already in place, and in many cases multiple mechanisms, to provide CMS the assurance that the entity is legitimate, is financially sound, has a history of meeting its debts and making its payments on time, and adheres to quality and professional standards in the delivery of its products and services. Overlaying the surety bond requirement on these existing requirements would be unnecessary and costly, and impose an undue burden on these entities, as well as negatively impact the

surety bond market and those truly in need of surety bonds by significantly reducing the available supply. Requiring all DMEPOS providers to acquire surety bonds could have the unintended effect of discouraging the most reliable, highest quality and lowest-risk DMEPOS suppliers from continuing to participate in Medicare. Alternatively, the most reliable suppliers will acquire surety bonds and smaller entities will be unable to do so, thus significantly limiting beneficiaries' choices and the DME market.

Finally, we support the concept of higher or elevated surety bond amounts for entities that pose a higher risk to the program. We are concerned that linking the surety bond requirement to the number of NPIs held by an entity has the opposite effect, in that it multiplies the bond obligation by the number of DME supplier locations, even though the number of locations bears no relation to the risk factors listed by CMS. In fact, more locations and a larger enterprise arguably lower the risk of default or non-payment. Therefore, we recommend that CMS consider applying the surety bond requirement in a manner that is better calibrated to exact a higher cost from those that pose the greatest risk to the Medicare program and not penalize those that are of least risk. For example, instead of applying the bond requirement at the NPI level, the initial bond requirement could be applied at the enterprise or corporate group level, with the option to increase the number or amount of bonds based on an organization's risk profile and/or history with Medicare.

Recommendations: (i) Create exemptions for those entities that are already subject to a rigorous screening process and/ or federal and state regulatory standards. This would include large, publicly traded chains of DME suppliers, community pharmacies, health care practitioners and DMEPOS suppliers that qualify for the DMEPOS competitive bidding program. (ii) Apply the surety bond requirement in a manner designed to exact the higher surety amount from those entities that pose the greatest risk to the Medicare Trust Fund. This can be done by decoupling the requirement from the number of NPIs held by an enterprise, and instead applying the surety bond requirement at the enterprise level based on various risk factors, including financial stability, history with Medicare and other relevant information.

II. Specific Comments

A. Establish an exemption for large, publicly traded DMEPOS suppliers.

Recommendation: CMS should exempt large, publicly traded DMEPOS suppliers from the surety bond requirement. In order to qualify for the exemption, a chain should meet the following criteria: (i) have a minimum net worth for the chain as set by CMS (we recommend $5 million), and (ii) be publicly traded. Additional factors that CMS might consider include: (i) prior history of paying Medicare debts, (ii) revocation or suspension of a license to provide health care products or services, (iii) federal or state criminal convictions related to the delivery of health care products or services, and (iv) current involuntary exclusion from federal or state health care programs. These criteria should apply at the same level as the surety bond requirement itself.

Rationale: We strongly support an exemption from the surety bond requirement for large, publicly traded DMEPOS suppliers. We believe that large publicly traded entities pose a significantly lower risk to the Medicare Trust Funds and to the Medicare program as a consequence of their size, financial resources and public scrutiny. Similar to government-operated suppliers, which CMS views as unlikely not to pay their debts because of the power to tax, publicly traded suppliers have the financial resources and capital to repay their debts, and the ability to access the capital markets. In addition, these entities are already subject to onerous financial reporting and compliance requirements that serve the same screening purpose as does a surety, but in even greater depth and subject to considerably more scrutiny. For example, public companies are required to make regular filings, on at least a quarterly basis, to the Securities and Exchange Commission. These filings provide detailed information about their assets, liabilities, income and cash flow, business operations and legal proceedings in which they are involved. They are also required to comply with the Sarbanes- Oxley Act (SOX), which is the most far-reaching corporate reform law designed to combat corporate fraud in decades, and which imposes a host of financial disclosure requirements, internal controls, increased corporate responsibility, auditor and analyst standards, and harsh civil and criminal penalties for fraudulent conduct.

Large, publicly trade entities are rated for credit-worthiness by rating agencies such as Moody's and S&P, and are subject to intense financial and operational scrutiny by analysts and investors. As CMS states with respect to government-operated DMEPOS suppliers, publicly traded companies "by their nature, furnish a comparable or greater guarantee of payment than would be afforded [CMS] by a surety bond issued by a private surety." [1]Finally, because they are publicly traded, these entities are extremely sensitive to, and easily damaged by, allegations of impropriety, fraudulent conduct or failure to meet their debts or other obligations. As such, these companies already have a strong deterrent against fraudulent or other wrongful dealing with Medicare, since the negative ramifications would far exceed any possible gain and would exceed the deterrent effect of the surety bond costs.

In light of the above factors, we believe that imposing the surety bond requirement on these entities would be unnecessary and duplicative, and cause them to incur additional unwarranted costs. In addition, the combination of the organizational structure of such entities and Medicare's expectations concerning NPIs for each separate location of a DMEPOS supplier means that the surety bond costs for such entities would likely be extremely high, and unrelated (or inversely related) to the level of risk they pose. Rather than operate as a "deterrent" to prevent abusive or fraudulent behavior, the requirement would have a punitive effect against the very entities that are of least risk to the program.

Finally, CMS asked for suggestions as to criteria that should be used to grant this exemption. We believe that the primary criteria should be (i) a minimum net worth for the enterprise, such as at least $5 million, and (ii) that the entity is publicly traded. Other factors that CMS might consider, either to grant the exemption or otherwise cause an

[1] 72 Fed.Reg at 42003.

entity to no longer qualify for it are: (ii) prior history of paying Medicare debts, (iii) revocation or suspension of a license to provide health care products or services, and (iv) federal or state criminal convictions related to the delivery of health care products or services, and (v) exclusion from federal or state health care programs. As long as the surety bond requirement applies at the NPI level, these disqualifying factors should also apply only at the NPI level, so that if, for example, a chain with 100 locations has an issue at only one location, the exemption should be lost at only that location. Alternately, and as we have recommended, if the surety bond requirement applies at the enterprise level, then a disqualifying event at any location of the enterprise would affect the ability of the entire enterprise to qualify for the exemption, but elevated bond amounts should not be required unless there are multiple disqualifying events.

B. Establish an exemption for community retail and mail pharmacies and pharmacists that provide DMEPOS items for the convenience of their patients.

Recommendation: CMS should create an exemption from the surety bond requirement for licensed community retail and mail pharmacies and pharmacists, since they are already subject to extensive regulatory and professional standards and oversight, and thus pose a very low risk to the Medicare Trust Funds. These entities offer patients the convenience and benefit of obtaining their DMEPOS supplies together with their medications from a trusted and qualified health care professional, and provide DME as a patient service that allows continuity of care and enhances patient trust. The criteria for exemption should be licensure in good standing with the applicable state board of pharmacy. The exemption should be lost, and a surety bond required, if any of the following occurs: (i) revocation or suspension of pharmacy license, (ii) federal or state criminal convictions related to the delivery of health care products or services, or (iii) involuntary exclusion from federal or state health care programs. These criteria should apply at the same level as the surety bond requirement itself.

Rationale: We believe it is appropriate to exempt licensed community retail and mail pharmacies and pharmacists from the surety bond requirement because these entities must comply with comprehensive state pharmacy laws and regulations in providing services to their patients, including professional and licensing requirements, as a condition of operation. These requirements impose rigorous professional education and training standards, quality and operating standards, as well as ethical and professional obligations. Community retail and mail pharmacies play a unique role in providing health care for Medicare beneficiaries. This includes providing non-service or cash and carry DMEPOS items such as diabetic supplies and other products, as well as dispensing prescription drugs to Medicare beneficiaries. State pharmacy laws establish the scope of pharmacy practice, and require pharmacists to follow the instructions of the patient's physician as well as providing the patient with products of FDA-approved manufacturers that follow the prescriber's prescription. This would include providing the patient with any needed information and pharmacist consultation on the use of the equipment and any needed supplies. As such, pharmacists are well-qualified and duty-bound to provide

Medicare beneficiaries with "products and services that are considered reasonable and necessary."

These professional and licensing requirements serve to screen out illegitimate or unscrupulous entities that, as stated by CMS, may be tempted to engage in fraudulent conduct. Not only do pharmacies and pharmacists undergo extensive and ongoing oversight as a result of these existing laws and regulations and licensing requirements, but they spend years investing in and building up their professional standing and reputation, and so have a strong incentive not to undertake any action or conduct which would tarnish this or put it at risk in any way.

Finally, since pharmacies and pharmacists provide DMEPOS supplies as only one service of many that they provide to their patients, their focus is first and foremost on serving the patients, and they have far more to lose than to gain by noncompliance with the Medicare requirements. Moreover, since their main business is the dispensing of medications, some could well be deterred from continuing to provide DMEPOS supplies as a result of the additional burden and cost associated with the surety bond requirements, especially when layered on top of all the other regulatory standards that apply to them. This is in contrast to DMEPOS suppliers that are not licensed health care professionals, and so have not undergone any such scrutiny and are not subject to any ongoing standards of practice or those DMEPOS suppliers that provide only more specialized (and frequently very expensive) DMEPOS products, where there has historically been some cause for concern about fraud.

We believe this exemption should apply not only to licensed pharmacists, but also to any pharmacy that dispenses DMEPOS supplies. As noted above, there are already sufficient other checks, such as onerous licensing requirements and regulatory scrutiny, that make pharmacists and pharmacies less likely to put the Medicare Trust Fund at risk, thus making it unnecessary to subject them to the additional scrutiny of surety companies or warrant imposing on them the additional costs to obtain a surety bond. Many pharmacists are also employed by pharmacies that are subparts of regional or national pharmacy chains that typically have multiple (even hundreds or thousands of) locations, and the surety bond requirements would operate in a particularly harsh and punitive way as a result of the interaction of the NPI Rule and the surety bond requirements. Specifically, by requiring a separate surety bond for each and every NPI, the proposed rule would potentially impose a cost of millions of dollars on large chain pharmacies, making it in prohibitively costly for them to continue to provide DMEPOS supplies to their patients, and thereby depriving the Medicare program of its most qualified and trusted DMEPOS suppliers.

C. Establish an exemption for physician and non-physician practitioners that provide DMEPOS items for the convenience of their patients.

<u>Recommendation:</u> CMS should create an exemption from the surety bond requirement for health practitioners and the clinics that employ them, since they are already subject to regulatory and professional licensing requirements and represent

a low risk of default or improper conduct. The criteria for exemption should be licensure in good standing with the applicable state regulatory agency. The exemption should be lost on the same basis as the other exemptions, namely: (i) revocation or suspension of license, (ii) federal or state criminal convictions related to the delivery of health care products or services, and (iii) involuntary exclusion from federal or state health care programs. These criteria should apply at the same level as the surety bond requirement itself.

Rationale: We believe it is appropriate to create an exemption for physician and non-physician health care practitioners, and for the health care facilities, such as outpatient clinics, that employ them. Similar to pharmacists, health care practitioners undergo extensive professional education and training, and are subject to rigorous licensure and regulatory oversight. Health care facilities, such as outpatient clinics, are also subject to state regulatory requirements, including licensure and accreditation standards. Given these regulatory standards, it is not necessary to require these entities to undergo additional screening and scrutiny from sureties. In addition, since health care practitioners have their licenses and professional standing at stake when providing DMEPOS supplies to their patients, they are highly unlikely to put this at risk by failing to pay their Medicare obligations or engaging in fraudulent or improper conduct. This is especially the case in light of the fact that the provision of DMEPOS supplies to their patients is ancillary to their primary role as health practitioners. Finally, physician and other health care practitioners have the training and professional responsibility to assist Medicare beneficiaries in obtaining the appropriate DMEPOS supplies as well as advising them on their use and related health issues associate with their conditions. As such, they provide a valuable service to beneficiaries and the Medicare programs, and their participation as DMEPOS suppliers should be encouraged, rather than discouraged by subjecting them to redundant and costly surety requirements.

D. Establish an exemption for entities that qualify for contract awards as suppliers under the DMEPOS competitive bidding program.

Recommendation: Establish an exemption for entities that qualify to bid under the DME competitive bidding program, since these entities have already undergone a most extensive and stringent review, and there is no reason to subject them to the cost and administrative burden associated with obtaining and maintaining a surety bond. This exemption should remain in place as long as the entity remains in good standing as an accredited supplier entitled to bid under the DMEPOS competitive bidding program.

Rationale: CMS states that the surety bond requirement is intended to: (i) limit the risk to the program of fraudulent suppliers, (ii) enhance the Medicare enrollment process to help ensure that only legitimate DME suppliers are enrolled, (iii) ensure that erroneous payments are recouped, and (iv) help ensure beneficiaries receive reasonable and necessary products from legitimate DME suppliers. CMS views the surety requirement as an effective "screening" mechanism for these purposes because the surety will scrutinize

the supplier, looking at its financial soundness and other factors. However, since CMS has the same concerns under the DME competitive bidding program, and has established an extensive and detailed review and accreditation process for this purpose, any entity that meets the standards set under the DME competitive bidding program should be exempt from the surety bond requirements, whether selected by CMS as a supplier for a particular region or not.

Under the DME competitive bidding program, all bidding suppliers must meet "financial standards, quality standards and accreditation standards."[2] With respect to the financial standards, CMS states that it is "committed to ensuring the financial soundness of contract suppliers in the competitive bidding program," [3] and that among the financial information it will seek is a bidding supplier's" debt-to-equity ratio and a financial credit worthiness score from a reputable financial services company," as well as information on general financial condition, net worth and solvency. Financial soundness, ability to pay off debts and credit history are precisely the issues CMS has focused on in the surety bond requirements to ensure that the DME supplier is able to and does meet its financial obligations under the program and does not put the Medicare Trust Funds at risk.

In addition to the financial standards, CMS imposes quality standards, and a CMS-approved accreditation organization must determine that a bidding supplier is complying with the quality standards. CMS states that "accreditation is a prerequisite to a supplier being eligible to participate in the Medicare DMEPOS Competitive Bidding Program. Therefore, our goal is to award contracts only to suppliers that conduct business in a manner that is beneficial to beneficiaries under the program."[4] Finally, bidding suppliers are subject to eligibility and enrollment criteria and disclosures, including disclosures regarding any revocations of a supplier number, sanctions, program-related convictions, exclusions, or debarments imposed against the supplier, its high level employees, chief corporate officers, members of the board of directors, affiliated companies, and subcontractors by any Federal, State, or local agency.

CVS/Caremark itself has just been through the accreditation process and has been accredited by the National Boards of Pharmacy (NABP) to participate in the DMEPOS competitive bidding process. The accreditation process is extremely thorough, and involves a detailed review of every aspect of an organization's operations. In light of these extensive and detailed requirements that focus on every aspect of a supplier's operations and background, and with particular emphasis on financial soundness, credit history, and compliance history, CMS can be quite sure that any entity that meets the qualifications for the DME competitive bidding program will be more than qualified to provide DME supplies. These entities will not only have demonstrated, beyond any doubt that they have the financial resources to meet their obligations, but also that they are high-quality, legitimate suppliers that are highly unlikely to attempt to or want to defraud the program or beneficiaries.

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[2] 72 Fed. Reg. 18036.

[3] 72 Fed. Reg. 18038.

[4] 72 Fed. Reg. 18019.

CVS Caremark appreciates the opportunity to comment on this important proposal. If you have questions regarding our comments or recommendations, feel free to contact me at (202) 772-3501.

Sincerely,

Russell C. Ring
S.V.P. Government Affairs

Submitter : Steven Baugrud **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physician Assistant

Issue Areas/Comments

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Submitter : Craig Richter **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physical Therapist

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Submitter : John Rydeski **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physical Therapist

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Submitter : Mary Beth Nawrocki **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physical Therapist

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I would like to take this opportunity to comment on the proposed rule CMS-6006-P-I. As a Physical Therapist in a 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. 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

Submitter : Nathan Matje **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physical Therapist

Issue Areas/Comments

Impact

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.

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Submitter : Erin Doxtator' **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Physical Therapist

Issue Areas/Comments

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Submitter : **Jennifer Sewall** **Date: 09/27/2007**

Organization : **Orthopaedic Associates of WI, SC**

Category : **Physical Therapist**

Issue Areas/Comments

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Submitter : Angela Wagner, PTA **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Other Health Care Professional

Issue Areas/Comments

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Thank you for the opportunity to comment of this proposed rule

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Submitter : Marissa Janatis, PTA **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Other Health Care Professional

Issue Areas/Comments

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Submitter : Karen Follansbee-Gragg **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Occupational Therapist

Issue Areas/Comments

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Submitter : Christine Kind **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Occupational Therapist

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Submitter : **Jody Lipski** **Date: 09/27/2007**

Organization : **Orthopaedic Associates of WI, SC**

Category : **Occupational Therapist**

Issue Areas/Comments

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Submitter : Angela Wetor **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Occupational Therapist

Issue Areas/Comments

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Submitter : Cynthia Borkenhagen **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Occupational Therapist

Issue Areas/Comments

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Submitter : Mr. Mark Smith, CEO **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Health Care Provider/Association

Issue Areas/Comments

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

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I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As The Chief Executive Officer of a 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.

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Submitter : Mr. Jeffrey Grancorbitz **Date:** 09/27/2007

Organization : Orthopaedic Associates of WI, SC

Category : Health Care Provider/Association

Issue Areas/Comments

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

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I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As the Director of Finances of a 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.

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Submitter : **Mr. Joseph Church** **Date: 09/27/2007**

Organization : **ASHT**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

September 10, 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: Joseph Church
1121 Jason Dr
Pass Christian, MS 39571

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. This is approximately 25% of my business & will do significant harm to my practice. 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.

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

Professionally,
Joseph Church, OTR/L-CHT

Submitter : **Mr. Jake VanLeeuwen** **Date: 09/27/2007**

Organization : **STI rehabilitation**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

September 27, 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: Jake VanLeeuwen, OTR/L, CHT

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.

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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 ----Jake VanLeeuwen, OTR/L, CHT

Submitter : **Ms. Sharmila Sandhu** **Date: 09/27/2007**

Organization : **American Occupational Therapy Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment- AOTA's comment letter

CMS-6006-P-130-Attach-1.DOC

#130.

AOTA The American Occupational Therapy Association, Inc.

Occupational Therapy: Skills for the Job of Living

Via online submission at www.cms.hhs.gov/eRulemaking

October 1, 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, Maryland 21244-8017

Re: **Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); CMS- 6006-P-1**

Dear Acting Administrator Weems:

On behalf of more than 37,000 occupational therapy professionals, the American Occupational Therapy Association (AOTA) submits the comments below in response to the proposed rule on the Surety Bond Requirement for Suppliers of DMEPOS published in the Federal Register on August 1, 2007 (See 72 Fed. Reg. 42001). AOTA appreciates the opportunity to comment on this regulation in connection with occupational therapists' role as suppliers of DMEPOS, namely orthotics, as an integral part of their ongoing patient care. Occupational therapy practitioners who supply orthotics typically operate as small businesses or independent providers and, therefore, AOTA is requesting an exception for occupational therapy practitioners from the surety bond requirement.

I. Background

Occupational therapy is a health, wellness, and rehabilitation profession working with people experiencing stroke, spinal cord injuries, brain injury, congenital conditions, developmental delay, joint replacements and surgeries, mental illness, and other conditions. Occupational therapists help people regain, develop, and build skills that are essential for independent functioning, health, and well-being in the home and community. Occupational therapy professionals have unique expertise in evaluating participation and enabling engagement in meaningful occupations (e.g., activities of daily living). Specifically, occupational therapy evaluation and treatment often is used pre- or post- orthopedic surgery or injury as well as to manage the negative effects of chronic conditions. It includes a multifaceted evaluation of a patient's range of motion, functional abilities, limitations (sensory, motor function, judgment, etc.), home and community needs, and other elements.

The American Occupational Therapy Association, Inc.
4720 Montgomery Lane
Bethesda, MD 20814-3425
301-652-2682
301-652-7711 Fax
800-377-8555 TDD
www.aota.org

AOTA wants to assure that CMS is clear regarding the manner in which occupational therapists are involved in the evaluation for, selection and fitting of, design and fabrication of, training for use of, and provision of DMEPOS items. The major examples of occupational therapists' roles include (1) the role of occupational therapists with patients requiring off-the-shelf (OTS) orthotics, (2) the role of occupational therapists with custom fabricated orthotics, and (3) the role of occupational therapists with patients requiring wheelchairs, scooters and related mobility devices.

Orthotics and Occupational Therapy

Often a patient's occupational therapy plan of care includes the use of orthotics to help perform activities of daily living, or as a preparatory tool to enable a patient to regain functional abilities and range of motion. Medicare-covered occupational therapy services include the design, fabrication, fitting, provision of, and training in the use of orthotics as part of a Medicare patient's occupational therapy plan of care. In addition, Medicare pays for the device itself as DMEPOS. Currently, occupational therapists who work in private practice settings and who supply orthotics to Medicare beneficiaries are permitted to supply orthotics by obtaining a supplier number from the National Supplier Clearinghouse in order to submit claims for orthotics that are billed using HCPCS Level II codes. Specifically, the DMEPOS item is billed using a HCPCS code and the separate occupational therapy services are billed using CPT codes. In this scenario, the occupational therapist is involved in: (1) evaluating the patient's need for the orthotic (2) selecting and providing the orthotic to the patient, which may involve fitting and training for the orthotic, and (3) providing continuing occupational therapy under a written plan of care as it concerns the orthotic and any additional appropriate occupational therapy services.

Wheeled Mobility and Occupational Therapy

In addition, occupational therapists work in a variety of settings to evaluate Medicare beneficiaries' seating and position needs for wheelchairs, mobility devices, and assistive technology. The mobility-related equipment may be provided to the beneficiary in one of two ways: (1) an outside mobility device supplier provides the device directly to the beneficiary and bills the Medicare program or (2) the occupational therapist is a device supplier by virtue of having obtained his or her own supplier number and bills Medicare directly. While an occupational therapist in theory could be a commercial supplier of wheelchairs, an occupational therapist in practice rarely obtains a billing number for the sole purpose of supplying and billing for mobility-related equipment and rarely supplies this equipment directly to the beneficiary. Rather, the occupational therapist typically performs seating and positioning evaluations and assesses the home environment for potential modifications related to the mobility-related equipment. In this practice scenario, the beneficiary obtains the mobility-related equipment from a commercial supplier, and the occupational therapist provides ongoing treatment, evaluating functional needs and enabling engagement in activities of daily living. The occupational therapy evaluation and treatment is directly concerned with the appropriateness of the device for the individual as well as with the individual's other occupational needs and goals.

We hope that this background information is helpful in reviewing and considering the following comments on the proposed rule.

II. Occupational Therapy Practitioners Should be Exempt From the Surety Bond Requirement for DMEPOS Suppliers

In the Proposed Rule, CMS specifically solicits comments on whether it should consider establishing an exception to the surety bond requirement for certain physicians and non-physician practitioners, such as those that "occasionally furnish DMEPOS items for the convenience of their patients." This is explicitly permitted under the governing statute; Section 1834(16) allows the Secretary to waive the requirement of a surety bond to physicians and other practitioners who furnish DMEPOS. ***AOTA strongly urges CMS to except occupational therapists from the surety bond requirement.***

A. Occupational Therapists, Like Physicians, Furnish DMEPOS Items for the Convenience of their Patients

CMS should waive the surety bond requirement for occupational therapists who furnish DMEPOS items that would ordinarily be furnished as an integral part of occupational therapy services. Previously, CMS agreed to except occupational therapists from the competitive bidding requirement for those items that would ordinarily be furnished as an integral part of occupational therapy services (See 72 Fed. Reg.17992 dated April 10, 2007). Specifically, CMS modified the relevant regulation in that case by adding a section to give occupational therapists the option to furnish competitively bid items without participating in the Medicare DMEPOS competitive bidding program. CMS stated, "we have determined that these are the items that would ordinarily be furnished as an integral part of occupational therapy and physical therapy services" (72 Fed. Reg. 17992, 18029). CMS should apply the same logic from its decision regarding DMEPOS competitive bidding to the surety bond requirement; namely that occupational therapists, like physicians, are not "commercial suppliers." Like physicians, occupational therapists furnish DMEPOS items only for the convenience of their patients, are regulated in every State, and furnish the full range of Medicare-covered services and items pursuant to the State scope of practice laws. ***The DMEPOS surety bond requirement program should be limited to "commercial suppliers" and should not be applied to physicians and non-physician practitioners, including occupational therapists, who furnish DMEPOS items as an integral component of a written plan of care specifically established to treat a particular beneficiary.***

B. Requiring the Posting of a Surety Bond Will Unduly Burden Occupational Therapists

Requiring the posting of a $65,000 surety bond will unduly burden occupational therapists. It is estimated that posting a surety bond in this amount would cost a small practice a minimum of $2,000 per year, per occupational therapist with a DMEPOS supplier number. Many occupational therapists in private practice are sole practitioners or work in small practices. Occupational therapists are not "commercial suppliers" with warehouse-like facilities that ship volumes of DMEPOS items. Occupational therapists are health care professionals treating patients using various clinical techniques, including the use of DMEPOS items. CMS must develop and implement steps that would proactively assist small suppliers, including occupational therapists, so that they may participate in the Medicare

program as orthotics suppliers. AOTA requests that CMS carefully consider the role of and impact on small suppliers like occupational therapists in creating exceptions to the surety bond requirement. ***AOTA urges CMS to use its authority in Section 1847(b)(6)(D) to protect small suppliers such as occupational therapists in private practice from the burdens of posting this bond.***

C. Requiring Occupational Therapists to the Post a Surety Bond Will Not Help CMS Achieve its Objectives

There are a number of reasons why the burden to occupational therapists in requiring them to post this bond is far greater than the benefit CMS would realize. CMS' has four goals in requiring the surety bond for DMEPOS suppliers:

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

Occupational therapists furnish DMEPOS items that would ordinarily be furnished as an integral part of occupational therapy services and are distinct from commercial suppliers. Since they either must enroll in the Medicare program as an occupational therapist in private practice, or must be employed by an enrolled provider (such as a hospital, rehab agency or the like); there are a number of regulatory requirements already in place to ensure that occupational therapists are legitimately educated, credentialed, and meeting state practice act requirements such as licensure. Furthermore, CMS will only pay for occupational therapy services that meet the medical necessity requirements under the Medicare regulations. ***For these reasons, occupational therapists already are of low fraud and abuse risk to CMS. There is no further compelling reason to require them to post this surety bond.***

III. Conclusion

AOTA appreciates the opportunity to submit these comments on CMS' proposed rule on the Medicare Surety Bond Requirement for Suppliers of DMEPOS. AOTA urges CMS to consider the impact of the proposed rule on occupational therapists as well as physicians, physical therapists, and other Medicare practitioners who supply DMEPOS items to their Medicare patients, but do not operate as commercial suppliers. AOTA strongly recommends that CMS specifically treat occupational therapists in the same manner CMS has agreed to treat occupational therapists, physical therapists, and physicians under the competitive acquisition program by granting occupational therapists an exception to the surety bond requirement.

AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the proposed rule. We look forward to a continuing dialogue with CMS on these issues.

Sincerely,

Sharmila Sandhu, Esq.
Regulatory Counsel

cc: Kristin Smith, CAE, Executive Director, American Society of Hand Therapists

Submitter : Ms. Shelby Diller **Date:** 09/27/2007

Organization : Healing Touch Physical Therapy

Category : Occupational Therapist

Issue Areas/Comments

Impact

Impact

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As a hand therapist from a physical therapist owned private business, specializing in the treatment of the upper extremity patient, I have significant concerns re: the effect of this rule on the 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.

Provisions

Provisions

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 our 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. These patients already have to pay for the supply or materials portion of the orthoses which we provide at cost, because this benefit is not allotted through Medicare coverage.

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.

Submitter : Mr. Michael Hess **Date:** 09/27/2007

Organization : Accredo Health Group, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

Impact

Impact

"See Attachment"

Provisions

Provisions

"See Attachment"

CMS-6006-P-132-Attach-1.PDF

#132

a Medco company

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.

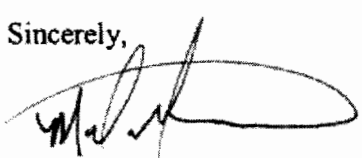
In the case of publicly traded chain suppliers, the Medicare program is dealing with sizable business entities that are subject to financial disclosure requirements and considerable scrutiny by various government agencies as well as their own shareholders. Publicly traded companies also have assets that 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

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Submitter : **Ms. jeanne Harper** **Date: 09/27/2007**

Organization : **private practice**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for allowing me to comment on proposed ruling CMS-6006-P-1

Impact

Impact

September 27, 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: Jeanne M. Harper

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, working in a rural setting, specializing in the treatment of the upper extremity patient, I have significant concerns regarding the effectiveness of this rule on my practice and patients.

The supply of DMEPOS is an important component in the treatment of all my patients. The overall impact of orthoses/braces and the efficient ability to provide these orthoses immediately and concurrently with therapy has a powerful effect on the final outcome of my clients. It is often important to apply timely intervention and monitoring to soft tissues to prevent loss of function. If this window of opportunity is lost, surgery would be required to correct an otherwise correctable soft tissue problem.

I utilize orthoses to protect, support, affect motion, and improve independent activities of daily living (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.

Provisions

Provisions

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. I work in a rural Health care setting and this proposal would mean that my clients would have to travel one to two hours one way into a large city, to procure, get fitted, and get adjustments to their splints/braces. 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 with regard to the provider in question. 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.

Submitter : **Mr. Kim Lockwood** **Date: 09/27/2007**

Organization : **Kansas Orthopaedic Center**

Category : **Occupational Therapist**

Issue Areas/Comments

Impact

Impact

I am an occupational therapist and certified hand therapist. I primarily provide custom fabricated orthotics (I.e. splints) in a physcian owned out-patient orthopedic clinic. My patients are seen for application of the DME many times post-opcratively. The orthotics are necessary for stabilizing fractures, reducing pain by limiting exacerbating forces through joints, or allowing damaged soft tissues to heal with minimal residual functional deficits. The proportion of my caseload that is medicare is well under 15%. We are located in a metropolitan area of Kansas, but serve the needs of a large rural population that is referred from western Kansas. I believe that unless I and other occupational therapist in similar settings are exempted from the surety bond requirement, the availability of services of highly qualified professionals to medicare patients will be adversly affected. The services and products I provide are delivered face to face since the items are primarily custom fabricated. They are not available via mail order or the world wide web.

In conclusion, I believe that the surety bond requirement will exclude more legitimate providers and limit medicare beneficiaries access to highly qualificd suppliers who voluntarily opt out of the program.

Submitter : **Mr. James Potasiewicz** **Date: 09/28/2007**

Organization : **GEMCO Medical**

Category : **Health Care Industry**

Issue Areas/Comments

Impact

Impact

Please accept our comments on CMS-6006-P Medicare Surety Bond Requirement. We support efforts to curtail fraud and abuse in the Medicare DMEPOS program, however, the rule as written does not appear to strengthen those efforts. Our suggestions for modification are as follows:

I CMS should exempt:
a. National, publicly traded suppliers since they are already highly regulated.
b. Rural suppliers who do not pose a higher risk.
c. All other DMEPOS suppliers who have been enrolled in the DMEPOS program for at least 10 years, who have never had their billing privileges revoked and who pose no increased risk.

All suppliers who do not fit any of the three (3) categories should be required to post bond.

I The Rule needs to clearly spell out the process and time frames by which CMS would request payment from the surety company.

I The Rule needs to contain provisions to protect a supplier in the event that it s bond is erroneously reported as lapsed or cancelled. Providers should have a reasonable,limited amount of time to prove that this is an error and that they have a valid bond.

I CMS should reduce the bond requirement back to the $50,000 level. The $65,000 amount is based on inflation, yet Medicare allowables have been reduced, frozen or increased by minimal amounts (1% to 4.8%) over that time frame. They have not increased by the 30% inflation factor.

It remains uncertain as to whether the Surety companies will issue such bonds. We have been in contact with three and two flatly stated that they would not issue such bonds. The third said they might consider it but only for suppliers with an established and totally unblemished record of participation in the DMEPOS program. They would not consider any supplier who had their billing privileges revoked.

CMS should consider delaying this entire process and give the new Supplier standards and accreditation requirements time to take effect.

Sincerely,

Jim Potasiewicz

Submitter : Mr. Fred McGee **Date:** 09/28/2007

Organization : Meriter Hospital Inc.

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-136-Attach-1.DOC

#136

September 10, 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: Fred McGee
Vice President, Planning & Business Development
Meriter Hospital
202 South Park Street
Madison, WI 53715

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1 on behalf of Meriter Hospital. Meriter Hospital is a community, not-for-profit hospital that has a number of occupational therapy programs that provide the services and products that would be impacted by this proposed rule including the Meriter Hand Clinic and Meriter Home Health; we have significant concerns re: the effect of this rule on the care of our patients.

The supply of DMEPOS is an important component in the treatment for hand therapy 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. It is often imperative that these patients be fitted immediately in our therapy department with the appropriate splint after post operative visits with the surgeon. To have patients leave without the appropriate custom fabricated or, to a lesser degree, the appropriate OTC splint can result in poor surgical outcomes, re-injury, ruptures, the need for surgery where none was previous needed or the need for repeated surgery. The therapists 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. For this reason, even when an appropriate OTC splint may exist, a custom fabricated low-temperature splint may still be the best option. The importance of our continued ability to fabricate orthoses and make timely adjustments cannot be underestimated.

Impact: Meriter Hospital believes that this rule may affect the ability of our occupational therapists to fabricate and supply orthoses. The estimated $2000 cost of the surety bond per NPI # in addition to the new costs of accreditation would be an undo hardship on the hospital. In our Occupational Therapy Department alone we nine outpatient Occupational therapists who would need to meet this requirement at a cost of $18,000! You estimate that up to 15% of individual suppliers will discontinue enrollment. It is Meriter's 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, 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.

Meriter Hospital supports the exemption of physician and non-physician practitioners from this rule unless there is a previous adverse history of Medicare fraud. In addition, 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.

Submitter : **Ms. Carol Harm** **Date: 09/28/2007**

Organization : **Meriter Hospital**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-6006-P-137-Attach-1.TXT

CMS-6006-P-137-Attach-2.DOC

#137

September 10, 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: Carol Harm, OTR, CHT
OT Program Coordinator
Meriter Hospital Occupational and Hand Therapy
Madison, WI 53715

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 a not-for-profit hospital, specializing in the treatment of the upper extremity patient, I have significant concerns re: the effect of this rule on the care of our patients.

The supply of DMEPOS is an important component in the treatment for hand therapy 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. It is often imperative that these patients be fitted immediately at our office with the appropriate splint after post operative visits with the surgeon. To have patients leave without the appropriate custom fabricated or, to a lesser degree, the appropriate OTC splint can result in poor surgical outcomes, ruptures, the need for surgery where none was previous needed or the need for repeated surgery. 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. For this reason, even when an appropriate OTC splint may exist, a custom fabricated low-temperature splint may still be the best option. 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. 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 department as there would be a minimum of 9 outpatient Occupational therapists who would need to meet this requirement at a cost of 18,000! 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.

Submitter : **Mr. Charles Sewell** **Date: 09/28/2007**

Organization : **National Community Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Impact

Impact

Many Medicare beneficiaries, particularly in rural and urban areas, depend on their local independent pharmacies to provide them with Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). The National Community Pharmacists Association (NCPA) provides the following comments to CMS-6006-P:

PROVISIONS

I. No Legislative Authority

CMS has no legislative authority to enact a surety bond requirement for DMEPOS suppliers. Section 1834(a)(16) of the Social Security Act (the Act) was amended by section 4312(a) of the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA) to require a DMEPOS supplier to provide CMS with, on a continuing basis, a surety bond of $50,000. CMS, however, chose to never publish a final rule regarding the proposed surety bond requirement. Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) prohibits the Secretary from finalizing a proposed rule related to Title 18 that was published more than three years earlier except under exceptional circumstances. As CMS never published a final rule, CMS is under no statutory obligation, and has no specific statutory authority, to implement that surety bond requirement. CMS now proposes to do so as a matter of policy -- and in opposition to Congress mandate that the Secretary not finalize old proposed rules. In addition, CMS cites no legislative authority to increase the expired -- and therefore null -- $50,000 surety bond proposed in 1997, to $65,000. Although we believe that this proposed regulation is not authorized we will still submit our comments on the proposal.

II. To Accomplish Its Goal of Limiting Fraud, CMS Should Grant an Exemption to Independent Pharmacists from the Surety Bond Requirement and Remove Fraudulent Suppliers from the DMEPOS Program

CMS principle policy goals for establishing a surety bond requirement for DMEPOS suppliers are to limit the Medicare program risk to fraudulent DME suppliers and to help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers. In order to meet these goals and ensure that Medicare beneficiaries have reasonable access to these vital supplies, CMS must grant an exemption to independent pharmacists from the requirement. Further, CMS should penalize fraudulent DME suppliers to a greater degree namely, remove suppliers that commit substantive fraud from the program.

A. CMS should promote access to health care by exempting independent pharmacists from the program

NCPA strongly supports CMS proposal to establish an exception to the surety bond requirement for licensed pharmacists who furnish DMEPOS for the convenience of their patients. (page 42004) The cost of obtaining a bond will be a disincentive for pharmacists due to the limited volume and rate of return for this business. A surety bond requirement would have the effect of discouraging or effectively preventing licensed pharmacists from providing DMEPOS to their patients. It would also serve as a barrier to new pharmacies who might otherwise seek entrance to the program. It is clear that the major abuse in this area is not found in the state regulated pharmacy industry.

In the Regulatory Impact Analysis (RIA) section of CMS-6006-P, CMS acknowledges that implementing the proposed surety bond requirement would result in a significant departure of half of DMEPOS suppliers from the program. In addition, CMS found that approximately 15,800 billing suppliers had allowed charges of less than $1,000, and thus almost all of these DMEPOS suppliers, excluding physician and other practitioners. . . . would obviously choose not put up $2,000 or more to acquire a $65,000 surety bond. Id. Furthermore, the majority of the 13,836 DMEPOS suppliers with allowed charges of $1,000 to $4,999 would not recoup their bond costs from Medicare business.
SEE ATTACHED

Provisions

Provisions

SEE COMPLETE COMMENTS ATTACHED TO WEBSITE FILING - THE IMPACT SECTION BEGINS AS FOLLOWS:

III. The Proposed Surety Bond Requirement, the Accreditation Process and the Dramatically Reduced Small Business Definition Will Negatively Impact the Ability of Independent Pharmacists to Participate in the DMEPOS program

A. DMEPOS is a small portion of the average independent pharmacy business

According to a 2004 Temple University NCPA survey, the average independent pharmacy sold $210,000 of home health care products (HHC) in 2002. For the

purposes of the study, HHC was defined as durable medical equipment, non-durable home medical equipment, devices and products. The 2003 NCPA-Pfizer Digest reported an average sales volume of $2,855,000 per independent pharmacy in 2002. HHC thus comprised $7.4% of the average independent pharmacy s sales in 2002. As the categories of DMEPOS partially overlap, this figure can be used as a ballpark ceiling figure for the percentage of independent pharmacy sales that can be counted as being DMEPOS. DMEPOS can be estimated as at most $266,400 of the current average independent pharmacy s sales (7.4% * $3.6 million). That study is consistent with the general industry belief that DMEPOS typically comprises only 6% - 8% of an independent pharmacy s sales, or $216,000 to $288,000 gross revenue. None of those figures is a large amount, and they do not call for heightened scrutiny.

B. The surety bond cost, combined with other DMEPOS costs, will drive independent pharmacists from the DMEPOS program

In the Regulatory Impact Analysis (RIA) section of CMS-6006-P, CMS acknowledges that implementing the proposed surety bond requirement alone would result in a significant departure of half of DMEPOS suppliers from the program. NCPA offers the following additional analysis based on estimates of annual costs for independent pharmacies to obtain Part B supplier numbers:

Quality Standards Compliance Manual $1,500 (one time purchase, but there will be additional update costs)
Accreditation Agency $2,500 - $5,000 (every 3 years)
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Staff Training/Education $2,000 ($2,000 for first time, but subsequently hired employees must be trained)
Total $8,000 - $10,500 (with at least a $3,000 annual cost in subsequent years)

The profit margin is so small that an extra initial $8,000 - $10,500 with future annual expenses of at least $3,000 will be cost prohibitive for many independent pharmacists. The RIA discusses the amount of DMEPOS that suppliers engage in relation to the costs of the bond. These cumulative costs are therefore significant for low volume DMEPOS independent pharmacists. This impact is significantly understated unless it is viewed in the context of the total cost for independent pharmacists to continue to participate in the DMEPOS program. These figures do not include the costs necessary to submit bids to sell certain non-diabetes DMEPOS that CMS has chosen for the first ten MSAs and will likely expand for future MSAs. Unless the costs of participating in the DMEPOS program are significantly lowered, through reducing accreditation expenses and pharmacists are exempted from the proposed surety bond requirement, many independent pharmacists will be forced out of the program, thus hurting patient access to vitally important medicines.

C. CMS small business definition is inconsistent and problematic

CMS made an arbitrary selection of $3.5 million in sales serving as the cutoff for classification as a small business that is subject to the 30% small provider provision in CMS-1270-F -- the April 2, 2007 final rule on implementation of the initial round of competitive bidding. This low ceiling greatly weakens the access protection aspect of the rule. A significant number of independent pharmacy owners have more than one store.

SEE COMPLETE COMMENTS ATTACHED TO WEBSITE FILING

CMS-6006-P-138-Attach-1.DOC

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

September 28, 2007

SUBMITTED VIA CMS WEBSITE: http://www.cms.hhs.gov/eRulemaking/

Re: CMS-6006-P

Dear Acting Administrator Weems:

Many Medicare beneficiaries, particularly in rural and urban areas, depend on their local independent pharmacies to provide them with Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). The National Community Pharmacists Association (NCPA)[1] provides the following comments to CMS-6006-P:

PROVISIONS

I. No Legislative Authority

CMS has no legislative authority to enact a surety bond requirement for DMEPOS suppliers. Section 1834(a)(16) of the Social Security Act (the "Act") was amended by section 4312(a) of the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA) to require a DMEPOS supplier to provide CMS with, on a continuing basis, a surety bond of $50,000.[2] CMS, however, chose to never publish a final rule regarding the proposed surety bond requirement. Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) prohibits the Secretary from finalizing a proposed rule related to Title 18 that was published more than three years earlier except under exceptional circumstances.[3] As CMS never published a final rule, CMS is under no statutory obligation, and has no specific statutory authority, to implement that surety bond requirement. CMS now proposes to do so as a matter of policy -- and in opposition to Congress' mandate that the Secretary not finalize old proposed rules. In addition, CMS cites no legislative authority to increase the expired -- and therefore null -- $50,000 surety bond proposed in 1997, to $65,000. Although we believe that this proposed regulation is not authorized we will still submit our comments on the proposal.

[1] The National Community Pharmacists Association (NCPA) represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies. These independents employ over 55,000 licensed pharmacists and over 300,000 additional employees across the United States.

[2] CMS-6006-P at pages 42002 - 42003 of the Federal Register, Vol. 72, No. 147, August 1, 2007.
[3] *Id.* at 42002.

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II. To Accomplish Its Goal of Limiting Fraud, CMS Should Grant an Exemption to Independent Pharmacists from the Surety Bond Requirement and Remove Fraudulent Suppliers from the DMEPOS Program

CMS' principle policy goals for establishing a surety bond requirement for DMEPOS suppliers are to "limit the Medicare program risk to fraudulent DME suppliers" and to "help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers."[4] In order to meet these goals and ensure that Medicare beneficiaries have reasonable access to these vital supplies, CMS must grant an exemption to independent pharmacists from the requirement. Further, CMS should penalize fraudulent DME suppliers to a greater degree – namely, remove suppliers that commit substantive fraud from the program.

A. CMS should promote access to health care by exempting independent pharmacists from the program

NCPA strongly supports CMS' proposal to "establish an exception to the surety bond requirement for licensed pharmacists who furnish DMEPOS for the convenience of their patients." (page 42004) The cost of obtaining a bond will be a disincentive for pharmacists due to the limited volume and rate of return for this business. A surety bond requirement would have the effect of discouraging or effectively preventing licensed pharmacists from providing DMEPOS to their patients. It would also serve as a barrier to new pharmacies who might otherwise seek entrance to the program. It is clear that the major "abuse" in this area is not found in the state regulated pharmacy industry.

In the Regulatory Impact Analysis (RIA) section of CMS-6006-P, CMS acknowledges that implementing the proposed surety bond requirement would result in a significant departure of half of DMEPOS suppliers from the program. In addition, CMS found that approximately 15,800 billing suppliers had allowed charges of less than $1,000, and thus "almost all of these DMEPOS suppliers, excluding physician and other practitioners. . . . " would obviously choose not put up $2,000 or more to acquire a $65,000 surety bond. *Id.* Furthermore, the majority of the 13,836 DMEPOS suppliers with allowed charges of $1,000 to $4,999 would not recoup their bond costs from Medicare business.

Many independent pharmacies provide diabetes and related supplies for their patients in addition to other DMEPOS and prescriptions. The negative impact of decreasing the number of independent pharmacies in the DMEPOS program will be most pronounced in rural areas, where independent pharmacies are concentrated. Medicare DMEPOS beneficiaries will either: 1) have to find and drive away from their communities to other pharmacies that are able to continue participation in the DMEPOS program; or 2) resort to mail order to obtain some supplies that need custom fitting and personalized patient care, such as therapeutic shoes and braces, and compression gradient stockings. Even so-called standard items such as canes, walkers and commodes should be adjusted by the pharmacist. Also many items are best not sent by mail, such as ostomy supplies, which are heat sensitive. Finally, the transportation and access problems of urban beneficiaries must also be considered.

[4] *Id.*

Much of DMEPOS fraud has been documented as occurring by suppliers at "phantom locations" – mail order and internet suppliers. The OIG for the Department of Health and Human Services' report: *South Florida Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits*, OEI-03-07-00150, March 2007 found that Medicare DMEPOS fraud is heavily committed by companies that do not maintain physical locations. It found that 836 of the 1581 South Florida businesses it surveyed fell into the category "Medical Supply Company – Other." Of those suppliers, 84 percent did not maintain physical facilities or were generally not accessible. In addition, NCPA seeks clarification on whether CMS is following the OIG's recommendations of requiring the NSC to enforce existing screening procedures.[5]

B. NCPA strongly advocates expelling fraudulent suppliers from the program

In order to protect patients and the Medicare program, NCPA believes that DMEPOS suppliers that commit substantive fraud should be permanently expelled from the DMEPOS program. There are two areas of concern: current DMEPOS suppliers with a prior "adverse history of criminal, civil or administrative sanctions for billing-related problems" (page 42005) and subsequent offenders who would be subject to the proposed elevated surety bond amount per high risk factor (page 42005).

NCPA believes that whatever problem exists with fraudulent suppliers, harsher treatment, including permanently removing them from the program after one or two fraudulent actions would be more effective. A finding of fraud includes, by definition, a finding of intent to violate the substance of the law. A first fraudulent action might merit an elevated surety bond and fine if it appears to be an

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[5] The NSC is charged with monitoring entry into the program. Pages 4 - 5 of the report reads:

. . .

Related Studies

A September 2005 Government Accountability Office (GAO) report (GAO-05-656) examined the procedures NSC uses to ensure that DMEPOS suppliers are legitimate businesses and are qualified to bill Medicare. GAO found that the screening procedures used by NSC, including on-site visits and checking State licensure, were insufficient to prevent illegitimate businesses from enrolling in the Medicare program. GAO estimated that NSC did not conduct 605 required on-site visits to suppliers in Florida, Illinois, Louisiana, and Texas. GAO made several recommendations, including establishing a minimum number of out-of-cycle, on-site inspections that NSC must perform each year as part of its contract. CMS generally concurred with the report's findings and stated that, beginning in fiscal year 2006, the requirement to perform out-of-cycle, on site visits would be added to NSC's contractual duties.

In 1997, OIG issued the report "Medical Equipment Suppliers: Assuring Legitimacy (CI-04-96-00240). In this study, OIG examined Medicare supplier enrollment practices in 12 large metropolitan areas in 5 states, including Florida. Based on unannounced site visits, the study concluded that the enrollment process was unreliable for detecting unethical and improper practices of suppliers, particularly because supplier enrollment at that time did not involve on-site verification of supplier application data. One of the options OIG recommended for ensuring the integrity of Medicare suppliers was for CMS to conduct on-site visits at applicants' physical locations. CMS concurred, but states that limited resources allowed on-site visits to be conducted only in high-risk areas.

In 2001, OIG issued a follow-up report (OEI-04-99-00670) that assessed how well DMEPOS suppliers were meeting the Medicare standards. OIG found that the expansion of the CMS site inspection program improved supplier compliance with the Medicare Standards. OIG made several recommendations to increase the compliance rates further, such as instituting random, unannounced site visits. CMS concurred with the recommendations.

. . .

isolated incident or it does not involve a significant amount of money. To effectively deal with a repeat offender, removal from the program is the best course of action.

IMPACT

III. The Proposed Surety Bond Requirement, the Accreditation Process and the Dramatically Reduced Small Business Definition Will Negatively Impact the Ability of Independent Pharmacists to Participate in the DMEPOS program

A. DMEPOS is a small portion of the average independent pharmacy business

According to a 2004 Temple University – NCPA survey, the average independent pharmacy sold $210,000 of home health care products (HHC) in 2002.[6] For the purposes of the study, HHC was defined as durable medical equipment, non-durable home medical equipment, devices and products. The 2003 NCPA-Pfizer Digest reported an average sales volume of $2,855,000 per independent pharmacy in 2002. HHC thus comprised $7.4% of the average independent pharmacy's sales in 2002. As the categories of DMEPOS partially overlap, this figure can be used as a ballpark ceiling figure for the percentage of independent pharmacy sales that can be counted as being DMEPOS. DMEPOS can be estimated as at most $266,400 of the current average independent pharmacy's sales (7.4% * $3.6 million). That study is consistent with the general industry belief that DMEPOS typically comprises only 6% - 8% of an independent pharmacy's sales, or $216,000 to $288,000 gross revenue. None of those figures is a large amount, and they do not call for heightened scrutiny.

B. The surety bond cost, combined with other DMEPOS costs, will drive independent pharmacists from the DMEPOS program

In the Regulatory Impact Analysis (RIA) section of CMS-6006-P, CMS acknowledges that implementing the proposed surety bond requirement alone would result in a significant departure of half of DMEPOS suppliers from the program. NCPA offers the following additional analysis based on estimates of annual costs for independent pharmacies to obtain Part B supplier numbers:

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Total	$8,000 - $10,500	(with at least a $3,000 annual cost in subsequent years)

The profit margin is so small that an extra initial $8,000 - $10,500 with future annual expenses of at least $3,000 will be cost prohibitive for many independent pharmacists. The RIA discusses the amount

[6] July 30, 2004

of DMEPOS that suppliers engage in relation to the costs of the bond. These cumulative costs are therefore significant for low volume DMEPOS independent pharmacists. This impact is significantly understated unless it is viewed in the context of the total cost for independent pharmacists to continue to participate in the DMEPOS program. These figures do not include the costs necessary to submit bids to sell certain non-diabetes DMEPOS that CMS has chosen for the first ten MSAs and will likely expand for future MSAs. Unless the costs of participating in the DMEPOS program are significantly lowered, through reducing accreditation expenses and pharmacists are exempted from the proposed surety bond requirement, many independent pharmacists will be forced out of the program, thus hurting patient access to vitally important medicines.

C. CMS' small business definition is inconsistent and problematic

CMS made an arbitrary selection of $3.5 million in sales serving as the cutoff for classification as a small business that is subject to the 30% small provider provision in CMS-1270-F -- the April 2, 2007 final rule on implementation of the initial round of competitive bidding. This low ceiling greatly weakens the access protection aspect of the rule. A significant number of independent pharmacy owners have more than one store. CMS requires those revenues be aggregated over all stores with common owner(s) for the purposes of this requirement, further limiting the effect of the 30% provision and hurting beneficiary access. (The 30% provision is supposed to ensure that at least 30% of the successful bids go to small businesses).

CMS does not discuss why it chose $3.5 million as the ceiling, as opposed to either the $6.5 million Small Business Administration definition that it used for the final rule implementing AMP (CMS-2238-FC, July 6, 2007), or the $6 million figure it used in CMS-1540-F, the August 18, 2006 final rule for DMEPOS that concentrated on competitive bidding. CMS should use the $6.5 million definition, as that is the more recent one.

The proposed surety bond requirement, in combination with accreditation and this arbitrary low ceiling for favorable small business designation, work to effectively bar many independent pharmacies from participating in the DMEPOS program, thus impacting beneficiary access to needed prescription medications and DMEPOS.

D. CMS underestimates the extent to which added DMEPOS costs will force independent pharmacists from the program, thus severely limiting patient access to DMEPOS and other medications

In its initial proposed rule on DMEPOS, CMS 1270-P, CMS claimed that 90 percent of current suppliers will continue to bid to supply DMEPOS, and that some 50 percent of suppliers will be chosen. NCPA conducted a survey of independent pharmacies after CMS issued CMS-1270-P. In that survey of the 10 MSAs that were that likely to be chosen to initiate CMS' accreditation/competitive bidding program, only 31 percent of the responding independent pharmacists indicated that they intended to submit bids to try to continue to sell DMEPOS.

E. While the proposed surety bond requirement and other DMEPOS requirements will have a variety of effects on independent pharmacists, depending on the nature and level of DMEPOS they provide, some will not even be able to sell diabetes test supplies

Currently retail pharmacy is exempt from competitive bidding requirements for diabetes supplies, and we urge CMS to maintain that exemption for the next 70 Metropolitan Statistical Areas (MSAs) that it will select in 2008. However, the requirements that CMS imposes upon the DMEPOS program pose serious threats to patient access to needed diabetes related medicines. For example, there will be cases where independent pharmacists will find that they can afford to continue providing their Medicare patients with diabetes supplies (i.e. test strips and lancets), but they will not be able to provide related services that require a winning bid, such as walkers, that the beneficiary needs. In addition, other patients will continue to need other competitively-bid DMEPOS to treat conditions that are unrelated to diabetes. Either way, the beneficiary is faced with having to travel to other locations to obtain all the supplies and consultation services and care, including Part D drugs that they previously obtained solely at the independent pharmacy. While CMS apparently believes that mail order is a viable option, in many instances the quality of care will severely diminish as fitting and care instructions are not adequate from a mail order, telephone-centered operation.

There will be many other cases where independent pharmacists will not be able to pay for the accreditation and surety bond costs necessary to sell only non-competitively bid DMEPOS – principally diabetes supplies. For these locations, the surety bond exemption is particularly important, as the margin on selling test strips and lancets is small.

IV. Conclusion

In sum, the proposed surety bond requirements, particularly when combined with the ceiling definition of small business and unnecessary accreditation costs, serve to substantially discourage independent pharmacists from continuing to participate in the DMEPOS program. In its Regulatory Flexibility Act ("RFA") discussion, CMS states that the role of the states is not impacted. Yet, this regulation will have the unintended effect of driving consumers away from their state regulated independent pharmacies to mail order and internet entities that are in most cases not subject to state regulation and the documented source of fraudulent activity. This proposal will have a negative impact on the states because it will prohibit them from using their consumer protection laws to assist their citizens. These new costs make it unfeasible for independent pharmacists to maintain Part B supply numbers, let alone submit supplier bids for certain DMEPOS. Implementation of the proposed rule will therefore lead to diminished access to health care for certain Medicare beneficiaries.

NCPA requests CMS to do the following:

- Exempt independent pharmacists from the surety bond requirement.
- Permanently expel from the DMEPOS program those suppliers that substantively defraud the system.

- Adopt a $6.5 million small business definition

We appreciate the opportunity to submit the enclosed comments on behalf of our membership. If you have any questions, please do not hesitate to contact NCPA via telephone at 703-683-8200 or via email at: Charlie.Sewell@ncpanet.org.

Sincerely,

Charles B. Sewell
Senior Vice President, Government Affairs

Submitter : Dr. Chris Robertozzi **Date:** 09/28/2007

Organization : American Podiatric Medical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-139-Attach-1.PDF

#139

APMA
American Podiatric Medical Association

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September 28, 2007

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

RE: CMS–6006–P
Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
(72 Fed. Reg. 42001, Aug. 1, 2007)

Comments submitted electronically at http://www.cms.hhs.gov/eRulemaking

Dear Mr. Weems:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's premier foot and ankle physicians and surgeons, is pleased to comment on the proposed rule that would require Medicare suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to obtain a surety bond.

PROVISIONS

The proposed rule would require all DMEPOS suppliers to obtain a surety bond. However, the Centers for Medicare & Medicaid Services (CMS) invited comments on the need for exemptions for various types of suppliers, including physicians and non-physician practitioners. The APMA believes very strongly that any surety bond requirement should not apply to physicians, including podiatric physicians, even in their role as DMEPOS suppliers. We have two compelling reasons physicians (defined in Section 1861(r) of the Social Security Act) should be exempt.

First, the APMA believes that the Congress did not intend surety bond requirements to apply to physicians, including podiatric physicians. We note, for example, that the conference report language accompanying the Balanced Budget Act of 1997 (BBA) includes the following expression of Congressional intent:

> "The conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals" [emphasis added].

Please note that the above excerpt from the conference report explicitly refers to surety bond requirements in the plural, which we believe is an indication that the Congress did not intend any of the surety bond requirements specified in section 4312 of the BBA to apply to physicians or non-physician practitioners. In addition to looking at the conference report, we believe that Congressional intent can be found in the statute itself. Section 4312(c) of the BBA, which provides authority for the Secretary to apply surety bond requirements to health care providers other than

suppliers of durable medical equipment, explicitly states that any such extension may not apply to "physicians or other practitioners, as defined in section 1842(b)(18)(C)..." We assume that it is this specific section of the BBA that is being relied upon by CMS in proposing surety bond requirements for suppliers of prosthetics, prosthetic devices, and orthotics. In making this assumption, we note that section 4312(a) of the BBA only refers to suppliers of durable medical equipment, not prosthetics, prosthetic devices or orthotics. In the past, the Congress has been explicit when it wished specific requirements to apply to all suppliers of DMEPOS, not just suppliers of durable medical equipment. For example, when Congress mandated new quality standards for DMEPOS suppliers (at section 1834(a)(20) of the Social Security Act), it explicitly enumerated the items and services to be covered by such standards to include not only durable medical equipment, but "prosthetic devices and orthotics and prosthetics." Moreover, we assume that specific reference to the phrase "excluding physician and other practitioners as defined in section 1842(b)(18)(C) of the Act" in the impact analysis accompanying the proposed rule (see page 42008 of the August 1, 2007 *Federal Register*, first column bottom) is an allusion to the language in section 4312(c) of the BBA, suggesting CMS recognition that the Congress had expressed a view with respect to the exemption of such practitioners from surety bond requirements.

Taken together, then, we believe that the conference report and statutory excerpts mentioned above provide considerable evidence that the Congress intended to exempt physicians, including podiatric physicians, from any surety bond requirements. We note, too, that there appears to be no similar expression of Congressional intent, vague or otherwise, with respect to large publicly traded suppliers, rural DMEPOS suppliers or the other categories of suppliers for which CMS has invited comments about possible exemptions.

Second, and more important than any legal consideration, the APMA believes that the application of surety bond requirements to physicians and other practitioners will seriously compromise Medicare beneficiary access to high quality care. In the case of physicians, including podiatric physicians, DMEPOS products are provided as an integral part of patient care. Further, in the case of physicians, DMEPOS products typically make up only a relatively small proportion of the total items and services routinely provided to Medicare beneficiaries. CMS itself projects that the proposed surety bond requirements will cause many if not all DMEPOS suppliers who now provide relatively small quantities of DMEPOS to Medicare beneficiaries to cease doing so, and the APMA believes that many such suppliers will be physicians. As noted by CMS in the proposed rule, physicians, including podiatric physicians, cannot incur the cost of a surety bond if there is little or no likelihood that this cost will be covered in the course of furnishing DMEPOS products to their Medicare patients. If the projected exodus of DMEPOS suppliers occurs, then what would happen to the Medicare beneficiary who presents to a physician's office with a problem or condition for which a specific item of DMEPOS would be of immediate benefit?

To consider this question further, we believe it would be useful to focus on some common clinical situations in podiatric medical practice. According to CMS, there are more than 7,300 podiatric physicians who are DMEPOS suppliers. Examples of how podiatric physicians utilize DMEPOS in patient care include the following:

- A patient presents complaining of foot pain and swelling after tripping on a sidewalk. The podiatric physician diagnoses multiple fractures of the metatarsals and determines that a Cam walker is necessary for immobilization of the injured foot. If that podiatrist no longer functions as a supplier, the patient will be forced to travel to another location to obtain the brace, treatment will be delayed or perhaps never implemented, and the patient will risk further injury to the foot.

- A podiatric physician may treat a patient with an acute ankle injury and determine that an ankle brace is necessary to stabilize the ankle and that crutches are necessary to limit weight-bearing on the injured extremity. If that podiatric physician is not a DMEPOS supplier because being so is no longer practical as a result of surety bond requirements, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

As should be obvious from the preceding examples, patients with conditions requiring acute care (e.g., fractures, foot or ankle injuries), must have immediate access to appropriate treatment, including DMEPOS items such as pneumatic walkers, non-pneumatic walkers, ankle braces, crutches, canes and walkers. These items need to be sized and fitted by the doctor. The patient needs to be instructed on proper use of the item, including weight-bearing activities. A delay in care could put the patient at risk for additional injury, which could result in increased costs to the Medicare program for the care of that patient. The physician might also need to supply an item at the point of service to meet the applicable standard of care. For instance, if the patient with the foot fracture falls because she is unable to bear full weight on the injured extremity and breaks her hip as well, additional expenses will be incurred by the Medicare program and the physician might face additional liability. Or, a delay in receipt of necessary DMEPOS items could result in the deterioration of the patient's medical condition. A stable fracture could become unstable, thereby increasing the severity of the existing injury. A fracture that could initially be treated with a closed reduction could require an open reduction, which would increase costs to the Medicare program. At the very least, a delay in treatment could lead to increased, prolonged disability or less than desired results that may have a permanent impact on the activities of daily living (ADLs) of the patient.

Even for non-acute cases, the clinical judgment and expertise of the physician remain essential. The selection of a particular item of DMEPOS, as well as its size and fit, should be based on the physician's evaluation of the patient. Instruction on the proper application or use of the item is important. The physician dispenses the item based on the pathology of the patient and can best explain why the item is necessary and how it must be used. The physician is able to check the fit of the item and can determine if the patient will be able to use it successfully. A different item may be needed than the one originally prescribed and the physician is the best person to make this determination. If difficulty in using an item is not immediately identified by the physician and the patient receives it from a separate supplier and the fit is incorrect, the patient may ultimately not use the item or may use it improperly, all of which could contribute to the deterioration of the patient's condition and lead to increased costs to the Medicare program. Or, some patients may return to the

physician's office with questions or for assistance, which would also increase costs due to the need for additional care or instruction.

In addition to clinical considerations, there are also obvious differences in the quantities of DMEPOS products provided by physicians compared to the amounts provided by suppliers who do nothing but furnish DMEPOS products. According to 2004 Medicare data on DMEPOS services, practitioners were responsible for 3.1 percent of DMEPOS allowed charges while entities categorized as "suppliers" were responsible for 96.4 percent of those charges. Most podiatric physicians, who operate as small businesses, supply limited quantities of DMEPOS items to Medicare beneficiaries as part of quality, appropriate, and necessary patient care. Requiring physicians to obtain surety bonds to continue to supply DMEPOS to patients at the point of service will disrupt Medicare beneficiaries' access to care that is in their best interest.

The APMA believes that access and quality of care considerations, and known differences in the quantities of DMEPOS products provided by physicians and DMEPOS-only suppliers, were among the factors that led the Congress to conclude (as discussed earlier in these comments) that surety bond requirements should not be applied to physicians.

In sum, the APMA urges CMS to exempt all physicians, including podiatric physicians, from the proposed DMEPOS supplier surety bond requirements when these individuals are furnishing DMEPOS as an integral part of the care provided to their own patients.

In addition to obtaining an exemption for physicians, which is the APMA's principal concern, we wish to take this opportunity to offer the following, three additional comments:

- First, if CMS concludes that there are good policy reasons for exempting certain categories of DMEPOS suppliers from any surety bond requirements (in addition to exempting physicians) the APMA recommends that CMS defer publication of a final rule until explicit Congressional guidance on this can be obtained. Similarly, if CMS remains uncertain about Congressional intent with respect to the exemption of physicians, despite the evidence reviewed above, we again recommend deferring publication of a final rule until this matter can be resolved by the Congress. Since 10 years have now passed since enactment of the BBA surety bond provision, there seems to be no particular urgency to publishing a final rule at this time.

- Second, if and when CMS imposes a surety bond requirement on any DMEPOS suppliers, the APMA recommends that the requirement be applied at the tax identification number (TIN) or similar level of aggregation, and not at the national provider identifier (NPI) level. A supplier with several locations or with more than one NPI (for whatever the reason) should not be expected to submit more than one surety bond.

- Finally, if and when CMS imposes a surety bond requirement on any DMEPOS suppliers, the APMA recommends that the agency give the affected suppliers at least 6 months, not 60

days, to comply. Providing an unduly short amount of time to comply seems especially unnecessary and ill-advised when the authorizing statute was enacted a full 10 years ago.

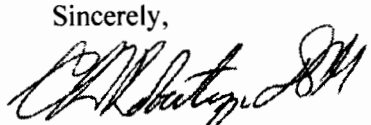
IMPACT

The proposed rule provides a confusing array of data with respect to the number of DMEPOS suppliers that would be affected. For example, in the impact analysis, in estimating the costs of obtaining surety bonds, CMS assumes that "approximately 99,000" suppliers will be involved (and that the average annual cost of a bond will be $2,000). However, in the section of the proposed rule summarizing collection of information requirements, CMS estimates that "approximately 116,500 DMEPOS suppliers" will comply with the proposed surety bond requirements. Any final rule should make sense of the conflicting array of data.

More importantly, CMS predicts that almost all of the nearly 16,000 billing suppliers with allowed charges of less than $1,000 in fiscal year 2005 will drop out of Medicare. CMS also predicts that the majority of the 14,000 with allowed charges between $1000 and $5,000 will also drop out. To be more precise, CMS projects 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." CMS also believes that "approximately 22 percent of the 15,000 DMEPOS suppliers are located in rural areas." The APMA believes that all of these projections should be cause for alarm, not support for implementing a final rule as proposed. A significant reduction in the number of DMEPOS suppliers will almost certainly have negative consequences for Medicare beneficiary access to DMEPOS, especially in rural areas. We cannot believe that this is what the Congress intended. In our view, CMS's estimated impact provides yet another rationale for deferring adoption of a final rule and for undertaking fresh consultations with the Congress now that a decade has passed since the BBA was enacted.

We hope the above comments are helpful. If you have any questions about them or need additional information from the APMA, please contact Rodney Peele, APMA's Assistant Director of Health Policy and Practice, at 301-571-9200 or via e-mail at RDPeele@apma.org.

Sincerely,



Christian A. Robertozzi, DPM
President

Submitter :

Date: 09/28/2007

Organization : **American Association for Homecare**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-140-Attach-1.PDF

#140

AMERICAN ASSOCIATION FOR HOMECARE

Via Electronic Transmission

September 28, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
http://www.cms.hhs.gov/eRulemaking

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:

The Centers for Medicare and Medicaid Services (CMS) is seeking comments on a proposed rule that would require a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to obtain a $65,000 surety bond for each of its National Provider Identification (NPI) numbers as a condition of Medicare enrollment. The surety bond requirement was included by Congress under §4312 of the Balanced Budget Act of 1997 (BBA), and CMS issued a proposed rule to implement it in 1998. Because that rule was published more than three years ago and was never finalized, CMS has initiated a new rulemaking proceeding.

The American Association for Homecare (AAHomecare) is the national association representing the interests of DMEPOS suppliers. AAHomecare members include a cross section of manufactures and suppliers that make or furnish DMEPOS items to Medicare beneficiaries in their homes. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost-effective, safe and reliable home care products and services in their homes. By virtue of our standing as representatives of DMEPOS suppliers, we are uniquely qualified to comment on the proposed rule.

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

I. INTRODUCTION

In implementing this rule, CMS intends to: (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. The $65,000 bond is an inflation-adjusted amount from the original $50,000 bond CMS proposed in 1998. Suppliers will be required to submit a bond when they enroll, report a change of information, reenroll, or otherwise revalidate their information. If a bond lapses and a gap in coverage results, Medicare will not pay for claims submitted during the gap. Importantly, the beneficiary will not be held liable for the items or services that a supplier furnished while it had a gap in coverage.

AAHomecare strongly supports all efforts to curtail fraud and abuse in the Medicare DMEPOS benefit; however we are concerned that the proposed rule will increase suppliers' cost and paperwork burden without accomplishing Congress' and CMS' goals. CMS' own analysis shows that the requirement to obtain a bond will cost suppliers approximately $198 million annually. CMS' analysis also suggests that the added costs inherent in the proposal could result in a reduction in the number of DMEPOS suppliers willing to serve Medicare beneficiaries, especially in rural areas. CMS data shows that in 2005 there were roughly 16,000 suppliers who billed the Medicare program less than $1000. There were also more than 13,000 suppliers who billed between $1000 and $4,999. Given that these suppliers are not likely to recover the cost of the bond from their Medicare business, CMS believes that many of them may decide to not obtain a bond and will lose Medicare billing privileges. In all, CMS predicts that as many as 30,000 suppliers currently enrolled in Medicare would stop serving Medicare beneficiaries. Twenty-two percent (22%) of these suppliers would come from rural areas.

Aside from the added costs and the potential reduction in access to DMEPOS suppliers for beneficiaries in rural areas, we are concerned that the proposed surety bond requirement does not substantively strengthen program integrity and may be duplicative of other initiatives which CMS has not fully implemented such as the requirement that suppliers meet quality standards and get accredited. Requiring suppliers to obtain a surety bond as a condition of Medicare enrollment may deter some of the more simplistic criminal fraud schemes, but it is unrealistic for CMS to expect that it will eliminate the most insidious type of fraudulent supplier – the one who initially appears to meet the minimum indicia of a legitimate business. This is the type of criminal element that has consistently evaded CMS' oversight and enforcement initiatives.

We believe that CMS is aware of the limitation inherent in its proposal given that the rule is broadly written to require forfeiture of the penal amount merely upon a determination that the supplier has "unpaid claims." In reality, the surety bond is only a repayment mechanism for the program and not a true deterrent to criminal or abusive billing practices. If the recent examples in Florida are any indication, anyone with a criminal intent, and the means to effectuate it, can bill and get paid for hundreds of thousands of dollars in claims before CMS or its contractors have identified the fraud. Other measures, such as more frequent auditing, "real time" auditing, and close monitoring of new suppliers would be more effective deterrents to the type of fraudulent, abusive, or criminal activity that CMS wants to foreclose.

Consequently, AAHomecare recommends that CMS reconsider its proposal to require all DMEPOS suppliers to obtain a surety bond for each NPI as a condition of enrollment. Instead, CMS should refine its proposal so that it more effectively targets the individuals and entities that are likely to pose risks to the program. Generally, AAHomecare recommends that CMS modify the proposed rule as follows:

- The surety bond requirement should apply to new suppliers only. Given that Congress intended the surety bond requirement to serve as a screening tool for Medicare, the value of requiring suppliers to post a bond decreases the longer a supplier has been in the program.

- CMS should not impose an inflation adjustment on the amount of the bond. The inflation adjusted bond will be 25% higher than the $50,000 bond originally contemplated by Congress. Since it appears that CMS' only rationale for increasing the bond amount is the passage of time, imposing this additional financial and administrative burden on suppliers is arbitrary.

- CMS should exempt rural suppliers and publicly-traded suppliers from the requirement to obtain a bond. Given its analysis of the impact of the proposed rule, CMS is understandably concerned about preserving access to DMEPOS for Medicare beneficiaries in rural areas. AAHomecare agrees that exempting rural suppliers that do not otherwise pose a risk to the program will assure appropriate access to DMEPOS items for rural beneficiaries. With respect to national, publicly-traded suppliers and suppliers owned by publicly-traded companies, these suppliers have adequate resources to refund any claims payments they receive in error. Importantly, publicly-traded suppliers are already heavily regulated because they are publicly-traded or owned by publicly-traded companies.

- Pharmacies, physicians, and other practitioners who bill the Medicare program for DMEPOS items should not be exempted from the requirement to obtain a surety bond unless they otherwise meet the criteria for another exemption.

- A final rule must include a mechanism to protect suppliers in the event the NSC or a surety mistakenly reports that a bond has been cancelled, or the surety goes out of business. At a minimum, suppliers should have notice that their billing number will be revoked and an opportunity to demonstrate that they have a bond *before* the revocation.

- Suppliers should not forfeit the bond except in the case of an assessment imposed after a finding that the supplier engaged in fraudulent or abusive billing practices.

- The bond amount should not be forfeited until there has been a *final* determination that a supplier is liable for an assessment or other penalty and the time to appeal the determination has expired. There is no valid rationale to impose forfeiture at an earlier date given that the surety is a third-party guarantor of the funds (up to the amount of the bond) necessary to pay the assessment or penalty.

Each of these issues will be discussed in greater detail in our comments below.

I. Comments

A. CMS Should Use the Tools to Fight Fraud Currently at Its Disposal

By way of background, a surety bond is a three-party agreement in which the surety agrees to compensate the bondholder if the conditions of the bond are met. The conditions, or the terms of the bond, determine when the purchaser defaults, triggering the surety's liability. The conditions of the bond and the amount of the bond influence both the cost of the bond and the underwriting criteria that the surety will apply. A bond could be written to guarantee payment of a debt, compensate the bondholder for the purchasers' fraudulent acts, or guarantee the purchaser's performance under an agreement. The risk of default posed by the purchaser of the bond will determine the level of scrutiny he receives from the surety, the cost of the bond, and whether the surety will require collateral. Given the diversity among DMEPOS suppliers and the multiple variables that will influence a surety's risk, it is likely that there will not be uniform underwriting criteria, at least initially. The type of bond required under the proposed rule is a financial guarantee bond to secure payment of suppliers' debts to Medicare.

When the surety bond provision was being considered by Congress, AAHomecare's predecessor organizations, NAMES and HIDA, supported the requirement. Then, as now, the supplier community was plagued by the actions of a few high-profile fly-by-night operators. In addition to their support for the $50,000 surety bond, industry representatives supported on-site inspections as a condition of enrollment and enhanced supplier standards in order to protect the Medicare program – and legitimate suppliers -- from the bad actors. The bond that the industry supported was a very narrowly tailored concept to target and prevent fraudulent and abusive conduct.

AAHomecare continues to support strong program integrity measures. However, we believe that circumstances today are different from those that justified support for surety bonds in 1997. While we agree that the Medicare program continues to be plagued by a hard core criminal element, unlike in 1997, CMS has other tools in its arsenal against fraud. In 1997, the National Supplier Clearinghouse (NSC) did not routinely perform on-site inspections before issuing billing numbers. Today the NSC is required to perform an on-site inspection of every applicant for a Medicare billing number. CMS and the NSC should work to further strengthen the enrollment process and require closer scrutiny and more extensive monitoring of suppliers that are new to the program. For example, new suppliers should be subjected to at least one "validation" visit before their first reenrollment.

New suppliers should also be subject to more scrutiny in the claims process. We suggest that CMS implement a coordinated program with the DMEPOS Medicare Program Safeguard Contractors (PSC), Medicare Administrative Carriers (MACs), and the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) to monitor a new supplier's billing during the initial term of its Medicare billing number (i.e., three years). This type of monitoring can promptly identify questionable billing and can be implemented relatively quickly since the mechanisms to do it are already in place. It is our understanding that in jurisdictions where there have been high rates of

fraudulent billing CMS and other oversight agencies are engaging in this kind of concerted claims monitoring effort. Close monitoring of new suppliers' billing patterns circumvents the "pay and chase" scenario that has characterized the activities of these fraudsters. Applying this heightened scrutiny to new suppliers is not unlike the process used by some professional credentialing bodies where individuals granted first-time privileges may be subject to an initial period of supervision. This type of monitoring, coupled with a second on-site inspection, would facilitate quick action if fraudulent activity is identified.

Further, in 1997 there were only eleven supplier standards. These standards were minimum business standards setting a very low threshold for entities applying for a DMEPOS billing number. The supplier standards in effect today more specifically address suppliers' business operations. Importantly, suppliers today must meet quality standards and must demonstrate their compliance with the standards through accreditation. CMS published quality standards for DMEPOS suppliers last year. The quality standards address a supplier's business operations and also include standards that are specific to the kind of DMEPOS the supplier furnishes to beneficiaries.[2] Moreover, the standards include requirements for the kinds of problem areas that a surety bond is intended to address.[3] AAHomecare agrees that all DMEPOS suppliers who want to bill Medicare must comply

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[2] The DMEPOS quality standards include general business and product standards that apply across the board to all DMEPOS suppliers. Additionally, the standards include products specific standards that address quality issues for specific products and services:

> **Business Services** - includes Administration, Financial Management, Human Resource Management, Consumer Services, Performance Management, Product Safety and Information Management.
>
> **General Product-Specific Service Standards** - includes Preparation, Delivery and Setup, Training/Instruction to Beneficiary and Caregiver and Follow-up.
>
> **Appendix A** - deals with respiratory equipment, supplies and services.
>
> **Appendix B** - deals with manual wheelchairs and power mobility devices including complex rehab and assistive technology.
>
> **Appendix C** - deals with custom-fabricated, custom-fitted, custom-made orthotics, prosthetic devices, somatic, ocular and facial prosthetics and therapeutic shoes and inserts.

[3] For example, the quality standards include a standard that specifically addresses the financial integrity of the DMEPOS supplier. The standards provides:

> Financial Management
> 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 to the business's size and scope of services; and
> - Having a mechanism to track actual revenues and expenses.

with quality standards and get accredited. Requiring suppliers to get accredited in order to begin billing the Medicare program removes the incentives that make the Medicare program attractive to fly-by-night operators because the supplier must operate as a legitimate business to pass accreditation. Currently, only suppliers in competitive bidding areas that want to submit bids are required to be accredited. We strongly encourage CMS to make this an across-the-board requirement for all suppliers.

Basic principles of administrative law require agencies to publish the factual basis for their proposed actions to encourage meaningful public comments. CMS has not provided any data requiring all suppliers to post a bond. Of particular relevance would be data to show the prevalence and demographics of suppliers who default on their Medicare debts inasmuch as the proposed rule would require suppliers to post a financial guarantee bond securing "unpaid claims."[4] We believe that the number of problem suppliers is very small and limited to those individuals with bad intent and to those who obtain Medicare billing numbers through misrepresentation. In fact, we are confident that CMS agrees that the overwhelming majority of suppliers do not commit fraudulent acts or default on their Medicare debts. Consequently, we recommend that the bond requirement apply only to new suppliers. Inasmuch as Congress' primary goal for requiring suppliers to post a bond was to have a surety scrutinize and assess the risk to Medicare posed by a supplier, the benefits of this scrutiny diminish the longer the supplier has been in the program. The General Accountability Office (GAO) agreed with this observation in a 1999 report critiquing the proposed surety bond regulation for home health agencies (HHAs).[5]

When the GAO reviewed CMS' surety bond regulation for HHAs, it concluded that conditioning the bond on the refund of overpayments is likely to increase the cost of the bond because instances of overpayments may occur more frequently than findings of fraudulent or criminal behavior. Sureties issuing financial guarantee bonds are more likely to review a supplier's books and might request audited financial statements. Because most small suppliers do not have audited financial statements, this requirement could pose a serious hurdle to their compliance. Sureties are also more likely to ask for collateral to secure the issuance of a financial guarantee bond. The cost of the collateral will vary depending on its liquidity. Sureties will likely favor highly liquid collateral such as letters of credit which will require suppliers to incur an additional expense. We believe that this type of review is sensible when it is applied to suppliers that are new to the Medicare program. We do not believe there is added value in imposing these additional costs and paperwork burdens on suppliers that have undergone two Medicare enrollment cycles and are thus established in the program.

Established suppliers, those that have undergone two enrollment cycles, should not have to post a bond because the deterrent value of the surety's scrutiny will be small compared to the financial and administrative burden imposed on the supplier. Similarly, established suppliers opening new locations and acquisitions of established suppliers should not require bonds. Again, the value to

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[4] If the goal of the bond is to secure "unpaid claims," CMS has authority to obtain repayment of overpayment amounts via recoupment.

[5] U.S. Government Accountability Office. (1999, Month). *Medicare Home Health Agencies, Role of Surety Bonds in Increasing Scrutiny and Reducing Overpayments* (Publication No. GAO-99-23) Retrieved September 27, 2007, from GAO Reports: Main Page via GPO Access: http://www.gpoaccess.gov/gaoreports/index.html

Medicare of the surety's screening criteria in these cases will be small compared to the burden imposed on suppliers. It would be inadequate for CMS to rely exclusively on surety bonds to accomplish the program integrity goals CMS has identified in the proposed rule. Instead, we recommend that CMS combine the surety bond requirement with enhanced monitoring and oversight of new suppliers as we described above.

B. CMS Has Not Stated an Adequate Rationale for Applying an Inflation Adjustment to the Value of the Bond

The proposed rule would require suppliers to obtain a surety bond for $65,000, an inflation-adjusted amount from the $50,000 bond called for under §4312 of the BBA. It appears that CMS' primary rationale for making an upwards adjustment of 25% in the value of the bond is the time that has lapsed since the enactment of the BBA. Although CMS frankly acknowledges that the additional costs imposed under its proposal will drive smaller suppliers away from the program, CMS makes no effort to explain how this added financial burden to suppliers achieves the program integrity goals of the proposed rule. As the Small Business Administration (SBA) Office of Advocacy states in its comments on the proposed rule, CMS has an affirmative obligation under the Regulatory Flexibility Act to consider the effects of their regulations on small entities.[6] In this case, using CMS' own estimates of the proposed rule's economic impact, increasing the bond amount to $65,000 increases the financial impact of the bond from roughly $150 million to $198 million. Adding to the economic impact of the bond for all suppliers, but especially for small suppliers, is that sureties may require suppliers to furnish audited financial statement or post collateral for the bond. As we noted above, these requirements will increase all suppliers' costs to post a bond, but will be especially onerous for smaller suppliers.

The original intent of the surety bond requirement was to assist HCFA[7] in "weeding-out" illegitimate suppliers. To the extent that the purpose of the bond is to verify the legitimacy of a provider's business, the original sponsors of the Medicare Anti-Fraud Amendments of 1997 believed that a $50,000 bond was adequate. In commenting on HCFAs surety bond regulation for HHAs,[8] Representative Stark stated: [M]y intention in copying the Florida law was a simple $50,000 that would quickly separate . . . the good guys from the fly-by-nights. All of the extra provisions in the regulation on 15% of payments[9] are unnecessary to achieve that basic purpose.[10] Representative Thurman from Florida, an original sponsor of the surety bond amendment, based the legislation on her experience with the success of the surety bond program in Florida. She expressed

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[6] See Letter dated September 13, 2007 from Thomas M. Sullivan, Chief Counsel Advocacy, SBA Office of Advocacy to Kerry Weems [Acting] Administrator, CMS available at www.sba.gov/advo/laws/comments/cms07_0913.html last accessed on September 17, 2007.

[7] Health Care Financing Administration, now CMS.

[8] 63 Fed. Reg. 292 (January 5, 1998)..

[9] The surety bond regulation for HHAs required them to post a bond for $50,000 or 15% of their billing to Medicare.

[10] Letter dated February 12, 1998, from Representative Stark to Nancy Ann DeParle, Administrator, Health Care Financing Administration.

[11] Letter dated January 28, 1998, from Representative Thurman to Nancy Ann DeParle, Administrator, Health Care Financing Administration.

similar concerns in a letter to HCFA about its HHA surety bond regulation, stating that the fifteen percent (15%) rule may be onerous and impose an "undue financial burden on reputable HHAs."[11]

As Representative Stark noted in his 1998 letter, increasing the face value of the bond does not increase any potential deterrent effect in obtaining a bond. Moreover, as the SBA Office of Advocacy noted in its comments, the additional $15,000 could make it difficult for smaller suppliers to obtain a bond, or to obtain a bond at an affordable rate, thus, driving them away. This additional cost is burdensome and arbitrary, especially in light of the fact that reimbursement for DMEPOS items has been consistently declining since 1998 and the new competitive bidding program for DMEPOS will result in a further loss in the number of DMEPOS suppliers in the Medicare program. If CMS determines to proceed with this regulation, we recommend that it not apply an inflation adjustment to the bond amount.

C. If CMS Finalizes the Proposed Rule, It Should Establish Exceptions for Suppliers that Do Not Pose Risks to the Medicare Program

CMS is also considering whether to exempt rural suppliers and large national chain suppliers from the requirement to obtain a bond. As we noted above, we believe that the policy rationale that existed in 1997 for requiring bonds have greatly diminished given the tools that CMS now has to fight fraud. Consequently, this new requirement should be narrowly targeted to suppliers likely to pose risks to Medicare. Where risk factors are not present, CMS should exempt suppliers from the requirement. Given its analysis of the impact of the proposed rule, CMS is understandably concerned about preserving access to DMEPOS for Medicare beneficiaries in rural areas. We support exceptions for rural suppliers in good standing with the Medicare program and that otherwise meet program requirements such as accreditation.

National, publicly-traded suppliers and suppliers that are wholly-owned subsidiaries of public companies, pose a very low risk of engaging the sort of fly-by-night fraud that CMS intends to deter. As such, there would be little program benefit to requiring public companies, or subsidiaries of public companies, to also obtain a bond. Moreover, these suppliers are well-capitalized and do not pose a risk of default on their Medicare debts which, as we discuss below, appears to be CMS' intent in crafting this rule. Importantly, suppliers in this category are already heavily regulated by laws and regulations governing public companies under the Securities Exchange Act.

For example, the U.S. Securities and Exchange Commission rules require public companies to disclose meaningful financial information and other information to the public, not only to inform the public but to prohibit deceit, misrepresentation and fraud. Therefore, protections already exist which would make the need for a surety bond unnecessary in this instance. Every public company must be registered, which requires disclosure of information on management and financial statements audited by an independent auditor. Then, once registered, every public company must submit periodic reporting, as required by the Securities Exchange Act and more recently by the Sarbanes-Oxley legislation. The disclosures of the Sarbanes-Oxley Act are designed to enhance corporate responsibility, enhance financial disclosures and combat corporate and accounting fraud.

An annual report is required to be publicly disclosed for every public company. The annual report must contain, among other information, financial reports audited by an independent auditing company, description of the business and risk factors, relevant legal proceedings, and other business concerning the operations and financial condition of the company. The annual report must also contain a report of management on the company's internal control over financial reporting which states management's responsibility for establishing and maintaining an adequate internal control structure and procedures for financial reporting, statement identifying the framework used by management to conduct their evaluation of the internal control and an assessment of the effectiveness of the company's internal control structure and procedures for financial reporting. The principal executive and principal financial officers, subject to federal criminal provisions, must certify the accuracy of this report. In addition, the independent auditing firm must also attest to and report on the internal control assessment made by management. To make this attestation, the independent auditor will generally conduct quarterly reviews which can include personal interviews with key employees regarding the management's internal control over financial management and reporting.

The company must also file a public quarterly report, which must contain some of the same information as in the annual report. This quarterly report must also contain, pursuant to the Sarbanes-Oxley Act, a certification of the reports by the principal executive and principal financial officers, subject to federal criminal provisions. In addition to the mandatory, public reporting, publicly-traded companies are also subject to audit and investigation by the SEC. Accordingly, in regards to publicly-traded companies, CMS' goals of combating fraud and ensuring financial viability are met by regulations already in place. Moreover, CMS has access to extensive publicly available information about these companies.

CMS is also interested in receiving comments on whether it should permit exceptions to the bond requirement for other types of suppliers such as pharmacists or physicians who furnish DMEPOS to their patients. Consistent with our comments above, to the extent a supplier poses a low risk to the program and meets an exception, suppliers that are physicians and pharmacies should be exempted. However, we see no basis on which to conclude that these individuals and entities should be exempted solely because they are physicians, practitioners, or pharmacies.

Finally, we see no need to impose a tiered approach to determining what bond amount to impose on a supplier based on past conduct. For established suppliers, as we described above, CMS and the Office of Inspector General (OIG) have significant administrative remedies to address misconduct which include: excluding the supplier from the program and imposing hefty administrative remedies. As we explained in our comments above, CMS should limit the bond requirement to new suppliers, consistent with Congress' original intent under the BBA.

D. The Final Rule Must Include Procedural Protections for Suppliers

The proposed rule requires a bond to guarantee refunds on overpayments assessed for reasons other than fraud. Specifically, the bond amount is forfeited as soon as CMS or the OIG makes a demand for payment on the basis of an overpayment or other assessment. The proposed rule goes so far as to require payment under the bond as soon as the overpayment is identified without regard to whether

the supplier has the right to seek a review. We believe that the conditions of the bond as currently crafted are overreaching and inconsistent with Congress' intent when it passed §4312. As we noted above, the intent behind requiring a bond was to, in the words of Representative Stark, "separate the good guys from the fly-by-nights." In other words, a default on the bond should be based on a finding of wrongdoing, not merely on the existence of debt which may be disputed and subject to appeals. The surety's liability should be triggered only when there has been a ***final*** determination of an assessment for fraud or other misconduct against a supplier and the time to file an appeal has expired. There is no rationale to impose liability under the bond before a final determination is entered because the bond, by its terms, guarantees payment of the assessment.

Importantly, the final rule must include procedural protections for suppliers incase the surety fails or the NSC has incorrect information about the supplier's bond. The consequences for not having a bond are severe and suppliers should not suffer penalties unless they have been notified of a problem and an opportunity to correct a deficiency. We understand that CMS is finalizing a rule on appeals of Medicare enrollment determinations. CMS should clarify in the final surety bond regulation that existing review procedures apply to adverse determinations concerning bonds.

II. Conclusion

For all of the foregoing reasons, we request that CMS modify the proposed rule as we have requested above. Specifically, the requirement to obtain a bond should be tailored to those individuals and entities which are most likely to pose a risk to the Medicare program. AAHomecare sincerely appreciates the opportunity to submit these comments and will be available to assist you on program integrity efforts involving DMEPOS.

We look forward to working with CMS to develop and implement effective anti-fraud and abuse measures and would appreciate the opportunity to meet with CMS staff to discuss these comments in detail. Please contact me should you have any questions about these comments, or if I can be of any assistance.

Sincerely,

Tyler Wilson
President
American Association for Homecare

Submitter : Mr. James Walsh **Date:** 09/28/2007

Organization : VGM Group, Inc.

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-141-Attach-1.DOC

#141

Van G. Miller & Associates

Real Programs. Real Service. Real Value.

September 28, 2007

Kerry N. Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert Humphrey Building
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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:

Our comments on the proposed rule are listed below in order of the "Issue Identifiers" used in the proposed rule itself. We note the proposed rule comes nearly 3 years after the law which put it back on track was passed and nearly 10 years after the underlying law was passed. Never the less the industry and those who will be affected by the rule are only given 60 days to absorb and comment on the 60+ page proposal. This is unfair and will undoubtedly result in many being unable to submit meaningful comments.

Preliminarily, the VGM Group is a private membership based entity that provides business services to over 3,500 DMEPOS type businesses. The large majority of these businesses would qualify as "small businesses" under current SBA rules. About two-thirds of them are HME's and the rest are orthotic and prosthetic practitioners.

The surety bond requirements first specified in BBA 97 were reflective of a much different era. There have been many changes in the environment in which HME's operate since that time and while CMS may not have the latitude now to deal with all those changes it does have wide latitude in rule making and that latitude should, to the extent possible, be exercised to make the new rule relevant to the time period we now are in. Specifically, HME's now are required to become accredited and most are about to be subject to additional scrutiny and cost controls via a competitive acquisition schema. Also, CMS and its contractors have stepped up enforcement and monitoring of HME expenditures to a much higher level than existed 9 or 10 years ago. In fact if

CMS had taken the actions it is now engaged in back in the mid-90's there is a very good chance that the bond requirement would never have become law.

The Medicare Modernization Act made clear that Congress had great concerns about the impact of remedial legislation on small HME suppliers. That law required that special attention be given by CMS in developing the competitive acquisition program to assure that small suppliers are not driven from the market by a system that give advantages to larger or national companies. Since BBA and its bond requirement preceded MMA it is safe to assume that it is still the intent of Congress that smaller providers be carefully protected from unintended consequences of the application of regulations to them. We believe that the proposed rule does not protect smaller suppliers and, if finalized in the form indicated, will place the smaller HME entities at a distinct disadvantage which is just the opposite of what congressional intent is in these regards.

Provisions Section

In defining terms we suggest that you carefully specify each of the definitions suggested. We recommend that you do not "bootstrap" the federal surety approval list as the only source for bonds under the program. The rule should allow other less traditional bonding methods in this area that has not had a wide-spread surety bond requirement before. New providers need to be developed and that will take time. You should specify a system for approval of new surety systems that are adaptable to the HME market and the risks of that market. Only by developing a number of bond providers and a competitive market will this program ever have a chance of keeping bond costs to providers reasonable.

The term "timely basis" is used in conjunction to requests for information from CMS to a surety. It is our experience that time is looked at differently by CMS when applying that concept to itself and others (with rule making and comment periods, for example) and we submit that any required response times be reciprocal and balanced. Likewise "due process" requires that no arbitrary and summary decisions be made by CMS with regards to its dealing with bond issuers. We must remember that the bond market will respond with pricing and terms commensurate with CMS's actions on bonds.

In proposing a $65,000 bond due to increases in prices since the surety bond was first proposed you are making a bad situation worse. If one supposes the rule is necessary at all then the originally proposed amount is more than sufficient to achieve its purpose. You should understand that HME's have not been getting price increases on their products/services for the last 10 years! In fact prices are falling on most reimbursement in part due to the lead of CMS. For you now to suggest that an increase in a COST item is appropriate is disingenuous and unfair. Also, if the bond is intended to help insure the integrity of the system the amount is less important than the process of vetting the applicants that will take place regardless of the bond face amount.

While we can understand that the one bond "per NPI number" requirement might roughly measure volume of exposure to CMS, we submit that CMS must also measure the burden on the DMEPOS entity in meeting program requirements. This was pointed out in comments from the SBA Advocacy group and we adopt their points on this issue as well. The burden placed on small businesses by this rule must be fair and must apply to larger businesses as equally as possible.

We submit that even a cursory review of newspaper headlines for the past few years will dispel the idea that "big businesses" don't fail. The do fail and they fail regularly and spectacularly. There is no legitimate basis to except larger businesses on a risk basis from this rule.

Further, it is not fair or protective of small business to exempt larger businesses from the financial burden that this rule places on a DMEPOS. Even if (and we deny it is a fact) a larger business is less likely to fail and cost the government money, that large business branch office competes daily against the smaller company down the street. If the small business has to pay $2,000 or more to get a bond and the large business doesn't then the larger business has that much more money available to compete, discount, pay better wages or whatever. Is this what congress intends when it asks that small business be protected from unfair competition aided by unthinking government regulations?

If it is necessary for this program to proceed than the bond amount has to be kept as low as possible, the largest possible number of bond providers has to be developed and ALL businesses have to pay the regulatory burden price of the program. (We can suggest that one possible way of equalizing the burden for "big businesses" that don't want a bond is to require a payment to CMS in lieu of a bond...perhaps set at the price that the average bond cost the year before...as a "bond waiver" fee. Such a program would equalize the burden easily, maximize the taxpayer benefit of the program and keep unnecessary funds from going to sureties rather than the taxpayers.)

Physicians should not be exempted from the bonding requirements. Every major fraud committed in this area has involved physician complicity in some respect. Physicians are no less likely to cost the federal program money than others and a bond should not be difficult for them to obtain. (It is also necessary to equalize the competition between providers that all have similar financial burdens.)

We don't believe that it is fair to deny payments to providers absent notice from CMS that there has been a bond lapse. Denial of payments is draconian and the time period between when a bond expires and CMS can get a notice out should not be large. A simple notice from CMS that the bond is not in effect and that payments will cease in 30 days is fair and sufficient. To retroactively apply a denial is too great of a penalty for what could well be a simple administrative lapse.

The proposal that the program start on 60 days notice is unreasonable. It will take time for the surety industry to adopt forms and procedures for this program. It will take time to educate DMEPOS purchasers of bonds on how to apply for them and how to buy them. It seems absurd to suggest that while it took years for a rule to be produced that the industry only has 60 days to come up with systems for a product that barely existed before. A more appropriate period would be at least 180 days.

Bonds should be annual and the procedures for policing them should be built in to the supplier standard enforcement process. Again, failure to obtain a bond should be treated in a similar fashion to other administrative lapses. Notice of deficiency should be given and a cure period stated clearly. Failure to obtain the bond by the cure date should then result in whatever sanction is appropriate.

There should not be a requirement to "file" the bond itself. Like liability insurance or licenses, the bond is simply "required" by the program. The HME supplier has to prove it is in place when inspected and repercussions follow if it is not. The filing idea is an administrative nightmare that will undoubtedly result in many, many errors and problems. If CMS wishes to always have contemporaneous information on who is the surety for any supplier then the automated NPI system should be adopted to get and retain such information.

Collecting on a bond should involve adequate due process protections for a surety. While that process can start with a letter from CMS the surety should have the ability to "look behind the curtain" to be sure that the recoupment has not already been accomplished before sending in the bond funds. The same process should apply in reverse...if CMS makes a recoupment AFTER asking the surety for funds then the burden should be on CMS to automatically refund the payment to the source of the funds...the surety.

It is not within scope of the rule to interfere with the private contract rights of the surety and DMEPOS. The terms of their contract are both negotiable and private. Due process in the private insurance contract situation is regulated at the state level and the parties to these contracts can take care of themselves.

Many, many DMEPOS have "billing-related problems" with CMS. To suggest that vague criteria for a punitive bond requirement is not useful. It will be difficult if not impossible for an HME to get a bond from any provider if such low level definitions are used. We suggest that only an "unpaid final action" that is still unsatisfied at the time of the bond application should be used to define a DMEPOS that is subject to any greater bond level.

You suggest that punitive bond level requirements be reduced after a time period has elapsed. Three years is more than enough for that. More importantly, we suggest that the requirement for ANY bond be eliminated after a business has had satisfactory relations with CMS for a 3 year time period. If that is deemed impossible under the statutory language then we suggest that the bond level be reduced by $10,000 for each successful year of relationship with CMS until it reaches a minimum threshold of $10,000 which will then be in effect until there is a problem of some kind.

Information Collection Section

The general tone of the proposed rule evinces a lack of understanding on the complexity of the bond market. Getting these bonds issued is going to be a major problem for most HME businesses. Yes, some larger HME's, some government owned institutions and some public companies will be able to obtain them easily. However all others will have to go through an application process that is grueling and often unsuccessful. There will be difficulty with accounting records, lack of audited statements, lack of liquidity and general lack of financial ability. Such is the state of the HME retailer after 10 years of relentless downward price adjustments and increasing regulatory and administrative burdens. Therefore, our suggestion is that any bond requirements be slowly phased in, as automated as possible and that bond forms be carefully vetted and discussed with the surety industry before publication by CMS.

The suggested "burden" in hours and dollars is too low in regards to getting the bond and keeping the bond in place. IF a provider had all the information available for filling out a bond application it might take him half an hour. Getting all the information and attachments will more

likely take him 2 – 4 hours and that is PER application. He may have to submit many applications to secure a bond. He may have to deal with bankers and accountants to get the bond. He may have to borrow money to pay for the bond.

Impact

We are curious as to why CMS is unable to estimate the financial soundness of the DMEPOS suppliers it regulates. It would seem to be fundamental that CMS develop an understanding of just that before proposing regulations of any kind. Certainly without that understanding the development of a rule on surety bonds would be very dangerous. If the financial condition of the industry had been drastically diminished by repeated cuts in reimbursement a rule imposing surety requirements could damage the ability of the DMEPOS to continue to satisfy the needs of beneficiaries. We believe that this is just what is going to happen here if the financial and regulatory burden of the rule is not tempered and implementation delayed.

Of course the financial soundness of the DMEPOS is going to be a factor in price of the bond. More importantly the financial soundness of the DMEPOS may result in bonds simply not being available. This is one of the reasons for keeping the face amount of the bond low and allowing sufficient time for a competitive market to be formed for bonds.

We tend to disagree with your belief that a surety bond will reduce outright fraud. In our estimation a company or individual willing to defraud the federal government will have no problem defrauding an insurer as well. Are you suggesting that commercial insurers are more capable than CMS and its contractors at finding the cheats and thieves? We don't believe that is going to be the case and the $65,000 bond is going to look silly next to millions in dollars of fraudulent claims. This is the wrong solution for fraud.

We agree with your analysis that the costs and complexity of the surety bond program will drive thousands of DMEPOS suppliers out of the Medicare system.

Your suggestion that the customers of the "out of the business" DMEPOS would go to another supplier is correct. What else could they do? The question is why would this help the program? Why would this help the beneficiary? The retail markets in the United States are vibrant and progressive. Choices are available here that boggle the mind and amaze people in most other parts of the world. These choices and the expanded access to them are the product of multiple vendors competing with each other for consumer business. Putting people out of business was not the intent of the Medicare system and should not be the intent of rule makers. These are honest hard working family owned businesses trying to live by all the rules and regulations that are promulgated. They bill and collect only what Medicare says is the right price for a product. They can't get paid at all if the product is not necessary. They are providing a valuable service to seniors and the disabled. It is shameful to adopt a rule that knowingly puts their businesses at serious risk.

There must be real time access to supplier information for the bond issuers to evaluate the risks assumed. If this information is not real time or is not available the bonds may not be available or the cost will be excessive to cover the risk of the unknown information.

Other Comments

We adopt the comments of the American Association for Homecare except for their comments regarding an exception for larger companies. For reasons stated above we believe that the excessive burden of this proposed rule must be spread equally to larger companies.

Thank you for your consideration;

James E. Walsh Jr.

President and General Counsel,

VGM Group, Inc.

Submitter : Mr. John Beard **Date:** 09/28/2007

Organization : Alacare Home Health Services, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

Impact

Impact

Generally, Alacare, as a long-standing Medicare participating DME provider, recommends that CMS modify the proposed rule as follows:
' The surety bond requirement should apply to new suppliers only. Given that Congress intended the surety bond requirement to serve as a screening tool for Medicare, the value of requiring suppliers to post a bond decreases the longer a supplier has been in the program.
' CMS should NOT exempt rural suppliers and publicly-traded suppliers from the requirement to obtain a bondunless they otherwise meet the criteria for another exemption.
' Pharmacies, physicians, and other practitioners who bill the Medicare program for DMEPOS items should not be exempted from the requirement to obtain a surety bond unless they otherwise meet the criteria for another exemption.
' A final rule must include a mechanism to protect suppliers in the event the NSC or a surety mistakenly reports that a bond has been cancelled, or the surety goes out of business.
' Suppliers should not forfeit the bond except in the case of an assessment imposed after a finding that the supplier engaged in fraudulent or abusive billing practices.
' The bond amount should not be forfeited until there has been a final determination that a supplier is liable for an assessment or other penalty and the time to appeal the determination has expired. There is no valid rationale to impose forfeiture at an earlier
date given that the surety is a third-party guarantor of the funds (up to the amount of the bond) necessary to pay the assessment or penalty.
' The bond amount should not be forfeited, in any circumstances, until after the supplier has been issued a notice and given an adequate opprotunity to respond and show cause why the bond should not be forfeited.

Submitter : **Douglas Noaeill** **Date: 09/28/2007**

Organization : **Great Land Infusion Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-6006-P-143-Attach-1.DOC

#143

To the Centers of Medicare and Medicaid Services:

I would like to make comments on the proposed Surety bond of $65,000.00 for all DMEPOS providers, to provide guidance to the rule as it applies to pharmacies and rural areas. I ask CMS to exempt home infusion pharmacies and small volume pharmacies from the required surety bond unless they have had prior adverse history.

Pharmacies are strictly regulated and monitored by state and federal agencies. Pharmacies must not only get state business licenses, but the employees must have professional licenses from the state, including technicians. Pharmacies are regulated and subject to inspection by the state boards of pharmacy to assure compliance with state and federal laws and regulations. Pharmacies are also subject to inspections by the DEA and held accountable to the Controlled Substance Act.

There will always be a means to fraudulently bill for services and someone out there willing to try to do so. I do not see this surety bond as a means to stop fraud in small volume pharmacies and home infusion pharmacies, but it is a means to decrease the availability of services to patients that need care. I find it difficult to believe that home infusion services (medications that are administered intravenously in the home) can not be verified very easily by creating a cross check system. For example I am reimbursed for an infusion of Fluorouracil (5FU) if given to treat Colon Cancer. I must receive a prescription for the 5FU infusion from an oncologist (Medicare should have a billing record from the physician). To get the diagnosis of Colon Cancer the patient will have had a thorough workup by an oncologist, with a colonoscopy and/or an MRI and/or a biopsy of the suspected tissue and various lab results. All of these procedures will have been billed to Medicare and therefore documented within the Medicare system. This could be used as a means of crosschecking the legitimacy of our claims for the services provided. I do not believe suppliers of other DME products have as many potential checks within the Medicare system to verify the treatment is legitimate to the diagnosis.

I would therefore ask CMS to exempt home infusion pharmacies from the required surety bond unless they have had prior adverse history. Especially since only a fraction of the home infusion services available are eligible for Medicare reimbursement.

Douglas Noaeill, RPh

Great Land Infusion Pharmacy
2421 E. Tudor Rd #107
Anchorage, AK 99507
(907)-561-2421

Submitter : Ms. Lynn Schubert **Date:** 09/28/2007

Organization : The Surety & Fidelity Association of America

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-144-Attach-1.DOC

CMS-6006-P-144-Attach-2.DOC

#144

The Surety & Fidelity Association of America

1101 CONNECTICUT AVENUE, NW, SUITE 800, WASHINGTON, DC 20036 TEL: (202) 463-0600 – FAX: (202) 463-0606
website: http://www.surety.org
E-mail: information@surety.org

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

Via electronic format: http://www.cms.hhs.gov/eRulemaking

Re: File Code CMS – 6006 – P; Proposed Rule on Medicare Program: Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); 42 CFR Part 424; 72 Federal Register 42001 (August 1, 2007)

Dear Sir or Madam:

The Surety & Fidelity Association of America ("SFAA") is a national trade association of companies licensed to write fidelity and surety insurance in the United States. SFAA's approximately 500 members are sureties on the vast majority of bonds written in the United States and include virtually all of the surety companies on the Treasury Department's Listing of Approved Sureties (Department Circular 570).

On behalf of SFAA's members, we are submitting this letter in response to the request for comments to the above described Proposed Rule. We support the Centers for Medicare & Medicaid Services (CMS) in its publishing of a rule to implement section 1834(a)(16)(B) of the Social Security Act, as amended by section 4312 (a) of the Balanced Budget Act of 1997 (BBA), and hope that our comments will assist you in implementing the surety bond requirement in a way to provide the greatest protection to CMS while ensuring that the bond is available in the marketplace. We appreciate that CMS is implementing this statutory requirement and recognizes in the proposed rule both the prequalification and claims payment values of surety bonds.

While we support the implementation of the surety bond requirement, we are concerned with some of the suggestions in the proposed rule. We will respond to certain definitions and other provisions being proposed as additions to 42 C.F.R. §424.57(a) and (c)(26).

PROVISIONS

The following comments address specific proposed rule language. CMS also has asked for comments on various suggestions, which we will address following this section.

Definition of "penal sum." [424.57(a)] The penal sum of a bond is the amount of the bond and the upper limit on the surety's payment obligation. It is not a "penalty" to be paid. The surety's obligation is to pay what the principal owes up to the penal sum. The proposed definition of penal sum suggests that the amount of the bond could be forfeited. This will cause problems for DME suppliers attempting to qualify for bonds. SFAA suggests that the definition be revised as follows:

> *Penal sum* is the amount of the bond and the maximum obligation of the surety if a loss occurs.

Definition of "sufficient evidence." [424.57(a)] A surety is a guarantor of the principal's obligations and is entitled to indemnity from the principal if it makes a payment. The surety, however, has to act in good faith to verify that it owes what it pays. If CMS makes a claim, it should include documents supporting its claim. The proposed definition says that CMS "may" provide documentation. The definition of "sufficient evidence" is especially important because the surety will be obligated to pay upon receipt of "sufficient evidence" or risk being barred as an "unauthorized surety." SFAA recommends that the definition be revised to state:

> *Sufficient evidence* means documents CMS supplied to the surety that established both the amount of Medicare funds a DMEPOS supplier received in excess of amounts due and payable under applicable statutes and regulations and that this amount was an obligation of the surety.

Definition of "unauthorized surety." [424.57(a)] Paragraph (3) of the definition of "unauthorized surety" would bar any surety that did not pay a request for payment within 30 days. There is no requirement that the request be supported by sufficient evidence. SFAA recommends that paragraph (3) be revised to state:

> (3) Fails to pay CMS any amount owed, up to the penal sum of the bond, within 30 days of receipt of a request for payment and sufficient evidence to support the request.

Surety bond requirements for DMEPOS suppliers. [424.57(c)(26)]. The new proposed bond amount is $65,000. We are concerned that small DMEPOS suppliers will have difficulty obtaining a bond of this size, and that it might not reflect the amount of risk. In addition, large suppliers with a high volume of payments from Medicare need a larger amount to cover their risk. We suggest that the bond be set at 15% of annual billings, with a minimum bond amount of $50,000 and a maximum bond amount of $3,000,000.

Terms of surety bond. [424.57(c)(26)(iii)] Rather than leave the actual terms of the bond up to each supplier or surety, and then have to review each submission to verify that it qualifies, CMS should mandate a standard bond form that each supplier and surety will have to use. This will make it easier for the suppliers to obtain the bond, remove any uncertainty as to whether a particular bond complies, and relieve CMS of a great deal of work reviewing the terms of every bond submitted. SFAA would be glad to work with CMS to develop such a standard form.

Specific surety bond requirements. [424.57(c)(26)(iv)] If the DMEPOS bond requirement is to be successful, the terms of the surety bond have to be reasonable. Sureties have to be able to provide the bonds to qualified suppliers, and decline to bond unqualified suppliers, based on the merits of the applicant. If the terms of the bond alone place an unreasonable risk on the surety, the bonds will not be available to any but the largest, best-capitalized suppliers. It is, therefore, extremely important that CMS carefully consider the bond terms and make sure that they conform to reasonable standards.

First, the penal sum of the bond has to be the limit of the surety's obligations. If the surety cannot be sure or its maximum exposure, it cannot underwrite the risk. Second, as is discussed in more detail below, the surety should be able to cancel the bond on 30 days advance notice. The surety would remain liable for any overpayments or other defaults that occur prior to the effective date of the cancellation, but would be able to prevent future losses. Third, there must be a reasonable time limit on the surety's exposure so that at the end of that period, if no claims have been made, the surety can close its books on the bond and return any security or collateral the principal provided.

To limit the surety's liability to the penal sum of the bond, SFAA recommends that the regulations, and any required bond form, include:

> Regardless of the number of years this bond is in force, the number of premiums paid, or the number of claims made, the Surety's aggregate liability shall not be more than the penal sum stated above.

Permitting the surety to cancel the bond as to future events will protect CMS as well as the surety. A bond is an essential requirement for participation. If the surety learns that a DMEPOS supplier is violating rules or obtaining overpayments, the surety should be able to cancel the bond. The surety would remain liable for overpayments and other debts already incurred, but it would avoid having to sit by and watch its obligations increase. Since the bond would no longer be in force, the supplier would be ineligible for reimbursement for supplies furnished after the effective date of cancellation. In effect, the surety's cancellation of the bond would protect CMS from having to continue doing business with violators. A right to cancel protects the system from fraud and abuse. Of course, if the surety is mistaken the supplier can simply obtain a replacement bond. SFAA recommends that the regulations and any bond form provide:

> The Surety may terminate its liability for future acts of the Principal at any time by giving thirty (30) days written notice of termination of the bond to the Obligee.

Proposed Paragraphs (B) and (C) of §424.57(c)(26)(iv) partially address the time limit of the surety's liability. Paragraph (B) provides that the bond in force when the claim is made is responsible. This at least implies that the earlier bond in force when the events giving rise to the claim occurred is not responsible. In effect, any bond is discharged from liability (except for claims already made) once the supplier furnishes a new bond that complies with the regulations.

If at any point the supplier fails to furnish an acceptable bond, then for up to two years CMS can make claims on the existing bond based on overpayments or other events that took place during the bond term. Subparagraph (C)(2), however, starts the two year period from the later of the date the supplier failed to submit a required bond or "the date the DMEPOS supplier's billing privileges were terminated." While in theory there should not be much difference between these two starting dates since the supplier's billing privileges should be terminated as soon as it fails to renew or submit a bond, sureties will be concerned that though oversight CMS may not promptly terminate the supplier's billing privileges. The surety then would face a liability period far longer than the anticipated two years solely because of the neglect of CMS or one of its contractors. This will cause sureties asked to write bonds for DMEPOS suppliers grave concerns, and SFAA suggests subparagraph (C)(2) be amended to state:

> (2) Were imposed or assessed by CMS or the OIG during the 2 years following the date the bond terminated, expired or was cancelled.

Cancellation of a bond. [424.57(c)(26)(v)] As is discussed above, it is very important that the surety be able to cancel the bond by providing advance written notice to the DMEPOS supplier, CMS and the NSC at least 30 days before the effective date of the cancellation. If the supplier provides a new bond, then the cancelling surety has no further exposure (other than for claims already made). If the supplier does not furnish a new bond, the supplier's billing privileges are revoked and CMS will have two years to discover and assert claims arising out of overpayments or other events occurring during the term of the bond.

It should also be clarified that the events listed in subparagraphs (A) through (G) of paragraph (v) do not extinguish any pre-existing liability, but cancellation of the bond does prevent new liability from accruing. SFAA suggests that the last sentence of paragraph (v) immediately preceding subparagraphs (A) through (G) be revised to state:

> The liability of the DMEPOS supplier and the surety to CMS arising out of overpayments or other events that occurred prior to cancellation is not extinguished by any of the following.

Change of surety. [424.57(c)(26)(x)] As written, the last two sentences of paragraph (x) seem to contemplate that a bond will remain in force but the identity of the surety will be changed. Although perhaps possible, this would be exceeding unlikely. If the DMEPOS supplier wants to change sureties, the normal method would be to execute a new bond with the new surety and substitute the new bond for the existing one. The respective liabilities of the sureties would then be controlled by subparagraphs (B) and (C) of the specific surety bond requirements [424.57(c)(26)(iv)]. If the DMEPOS supplier provides an acceptable bond from a different surety, the new bond should be liable for any claims made after its effective date "regardless of when the payment, overpayment or other event giving rise to the claim" occurred, and the replaced bond and its surety should have no further liability other than for claims already made. SFAA recommends striking the last two sentences of paragraph (x).

The CMS also has asked for comments on the following questions and suggestions.

Exemption from the bond requirement for certain DMEPOS.

Generally, surety bonds should be required for an entire category of licensees, rather than exempting certain lower risk licensees. Requiring a bond from only a small segment of a group, because that segment represents the higher risk and is the most likely to cause future losses, is a selection against the surety, commonly called adverse selection. A surety needs to underwrite the entire group in order to adequately price and spread the risk of exposure. Adverse selection discourages sureties from participating in a market and would make obtaining the bond more difficult for those subject to the requirement. This principle would apply to the following proposed exemptions:

- DMEPOS suppliers operated by federal, state, local or tribal government agencies unless the government-operated DMEPOS has a poor record for paying its Medicare debts.
- Publicly-traded chain suppliers of DMEPOS items.
- Rural providers.

Similarly, those who occasionally furnish DMEPOS items should be required to post a bond as well, but it could be a bond with a lesser penal sum due to the lesser amount of items provided annually. Those in this class of DMEPOS suppliers that have an incidental involvement in the Medicare program, as evidenced by certain minimum annual billings, to be established by CSM, could provide a reduced-minimum bond of $25,000. When annual billings exceed the incidental amount, then the $50,000 minimum bond would be required. This principle applies to the following proposed exemptions:

- Certain Physicians and non-physician practitioners who occasionally furnish DMEPOS items.
- Licensed pharmacists who furnish DMEPOS items for the convenience of their patients.

Elevated Bond Amounts for Higher Risks

Consideration is being given to increasing the minimum bond amount for higher risk DMEPOS suppliers based on the number of occurrences of final adverse actions, such as criminal convictions, revocation or suspension of licenses. The bond would be increased in increments of $65,000 for each occurrence.

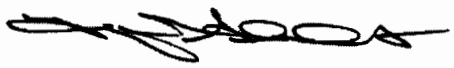
The second proposal is to determine the amount of the bond by classifying DMEPOS suppliers into categories:

- New DMEPOS suppliers;
- Current DMEPOS suppliers with no prior adverse occurrences; and
- Current DMEPOS suppliers with prior adverse occurrences.

Additional risk is addressed by sureties in the underwriting process. A surety evaluates whether or not to write a bond based on whether or not the surety believes the principal will perform its obligations. High risk criteria are taken into account in the decision whether or not to write the bond and whether or not collateral is required from the principal. The amount of the bond should address the potential amount of a claim, based on the annual billings, not the potential likelihood of a claim.

SFAA appreciates the opportunity to comment on this proposed rule and looks forward to working with CMS as you move forward. We would be happy to provide a standard bond form for you and meet with you at your convenience to discuss any questions you might have.

Sincerely,



Lynn M. Schubert
President

Submitter : **Ms. Cheryl Nelson** **Date: 09/28/2007**

Organization : **Ms. Cheryl Nelson**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for your consideration on this matter

Impact

Impact

I am an occupational therapist/certified Hand Therapist, specializing in the treatment of the upper extremity. I am very concerned regarding the effect of this rule on my patients.

Provisions

Provisions

I feel this rule may affect my ability to fabricate and supply custom splints. Patients would not be able to find comparable benefits from other suppliers.

Submitter : Virginia Clark **Date: 09/29/2007**

Organization : Hand Rehab Services

Category : Occupational Therapist

Issue Areas/Comments

Provisions

Provisions

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. I am an Occupational Therapist and Certified Hand Therapist specializing in the treatment of the upper extremity patient. I have grave concerns regarding the impact this rule will have on my patients and your beneficiaries. As a small business owner, the estimated cost of $2000 per NPI number on top of the recent addition of accreditation fees would be an undue hardship, and may cause me to reconsider the efficacy of participating in the supply of orthotics to Medicare patients. This would be a very significant loss to my patients in terms of the effectiveness of my treatment. The type of orthoses fabricated by therapists is very different from the prefabricated and/or one time orthoses found in other professions. The acute and changing nature of our patients requires the frequent adjustment of these devices as their condition modifies. Orthotics are intimately connected to treatment in the upper extremity patient, and the need for immediate adjustments to protect and improve function cannot be underestimated. The fabrication of these orthoses and the frequent adjustments they entail cannot be performed by a different non-treating professional. Unless they are treating the beneficiary, these suppliers will not completely understand the treatment goals and plan of the therapist, and delays in fabrication and/or adjustment will reduce the effectiveness of that orthotic device.

The loss of even one practitioner/supplier from the rolls of orthotic suppliers due to costs will significantly affect that practitioner's ability to provide timely and effective treatment and ultimately their patients' final outcome. Orthoses are a critical component of the treatment of the upper extremity patient, and I am very concerned that many therapists will decide that the recent additional cost in the provision of orthotics will be prohibitive.

Accreditation, along with its on-site inspection of DMEPOS providers is sufficient protection for CMS, and indeed offers greater protection than a surety bond. I therefore support the exemption of non-physician practitioners from this rule unless there is a previous history of Medicare fraud.

Thank you for the opportunity to comment on this ruling.

Submitter : **Dr. John Coster** **Date: 09/29/2007**

Organization : **Rite Aid Corporation**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-147-Attach-1.DOC

#147

With us, it's personal.

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October 1, 2007

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

Subject: CMS-6006-P: 42 CFR Part 424; Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Dear Sir or Madam:

The Rite Aid Corporation is writing to respond to the proposed requirements that suppliers of DMEPOS be required to obtain a $65,000 surety bond for each location that is enrolled as a Medicare supplier. Obtaining the surety bond would be a condition of receiving or renewing a Medicare provider number.

Rite Aid is one of the nation's largest drug chains, operating 5,100 pharmacies in 31 states and the District of Columbia. Rite Aid is a $27 billion, well-established, publicly-traded company. We have been in business for many years and intend to continue to operate retail pharmacies for a long time. We just recently completed the acquisition of the 1800-store Brooks Eckerd drug chain. We are a major provider of prescriptions and other health care products and services to Medicare beneficiaries. This includes items of durable medical equipment such as diabetes testing supplies, crutches, canes and related items.

Rite Aid believes that Medicare beneficiaries gain significant health and convenience benefits from being able to obtain their DME supplies – especially diabetes testing supplies – at their local pharmacy. Beneficiaries often use a single pharmacy to obtain their prescription medications, over the counter products, and DME products. This makes it easier for beneficiaries to manage their health, but also promotes integrated and coordinate care and results in better health outcomes.

We believe that government policies should promote access to established, reputable retail pharmacies such as Rite Aid, rather than reduce incentives for such pharmacies to participate in the DME program. We believe that this proposed regulation would reduce participation of the type of reputable and reliable retail pharmacies whose involvement has provided a critical element in the success of the Medicare DME program.

In theory, a surety bond requirement for DME providers would protect the Medicare program as well as Medicare beneficiaries from fraud and abuse. While we are aware of several high-profile cases of fraud and abuse against the Medicare program by some questionable DME providers, it would appear that the bulk of CMS' documentation supports the conclusion that the overwhelming majority of providers are credibly providing DME products and services to Medicare beneficiaries and billing appropriately. This very broad proposal would penalize the providers in the program that have been diligently serving Medicare beneficiaries and billing Medicare appropriately.

Moreover, CMS is also requiring (under a separate program and regulation) that Medicare DME providers receive accreditation from a CMS-accredited organization in order to continue to provide DME under the new competitive bidding program. This program will go into effect early next year in 10 MSAs, and is projected to rapidly expand after that time. CMS has also said that all DME providers will also have to be accredited at some point in the near future to provide Medicare DME items, whether in the competitive bidding program or not. It is duplicative and expensive for DME providers to spend a significant amount of money on accreditation and then also have to spend additional monies for a surety bond.

If there is an actual belief in the value of the accreditation program, successful completion of that requirement should obviate the need for a surety bond. CMS could surely require that accreditation be suspended for providers that were found to be inappropriately billing the Medicare program. The proposed regulation does not describe why this surety bond requirement is needed given these new accreditation requirements.

We would support a provision in the final regulation that would exempt established and well known retail pharmacies from the surety bond requirement. CMS suggests a "risk-based" system to determine which providers would need to obtain surety bonds. Applying surety bonds to providers who have engaged in questionable billing practices in the past makes the most sense, and is a justifiable requirement based on the record of past practices.

DMEPOS providers that have any prior history of criminal, civil or administrative sanctions against the Medicare program should not be exempt from these surety bond requirements. Moreover, these requirements should only be applied based on the number of locations that might have been involved in the fraud and abuse, unless there is evidence of corporate wide efforts to engage in these practices.

New providers that do not have any prior billing history with Medicare could be subject to the new surety bond requirements, unless these new providers are simply part of an existing corporation – such as Rite Aid – that is opening up new pharmacies or taking ownership of another pharmacy. Rite Aid should not have to obtain surety bonds for existing pharmacies or any new pharmacies that we open or acquire, given that we are already licensed by state and Federal authorities and are a publicly-traded company.

Rite Aid pharmacies – as well as the pharmacists that practice in them – already have to meet rigorous Federal and state licensure standards to operate as retail pharmacy. For example, retail pharmacies are required to be licensed by the Board of Pharmacy in the state in which the pharmacy is located. State boards of pharmacy may deny the licensure application for pharmacies they believe are incapable of providing services in a satisfactory manner. State boards of pharmacy establish rules for pharmacist conduct and pharmacy operations and criteria for revocation of such privileges. Pharmacies can be disciplined by the state boards of pharmacy for a range of activities, including violation of state and federal fraud and abuse laws.

Retail pharmacies also have to obtain Federal licenses, such as a permit to dispense controlled substances from the Federal Drug Enforcement Administration (DEA). These requirements substantiate the extent of governmental authority and leverage over retail pharmacies if there are any issues relating to fraud and abuse.

Our pharmacists are employees of the company and have no incentive to overcharge Medicare or commit fraud and abuse. Compensation is not tied to the volume of Medicare prescriptions filled or DMEPOS items furnished. Further, chain pharmacies, such as Rite Aid, have very effective safeguards in place to ensure that a rouge employee does not obtain any benefit from defrauding the Medicare program. For example, pharmacies separate service delivery functions from those related to billing. Beyond initial intake and determination of eligibility of coverage at the point of sale, pharmacists and pharmacy staff do not engage in claims processing.

In fact, because of the complexities to successfully bill Medicare Part B claims – which are not "real time", on-line like most other claims billed by retail pharmacies – we have to contract with (and incur additional costs) a separate Part B claims processing company that often experiences significant challenges in billing Part B DME claims. Our pharmacists are not involved with billing Medicare Part B. In addition, Medicare will only pay for DME claims that are on a prescriber's written prescription. Pharmacies cannot bill "fraudulent" oral prescriptions that, allegedly, were called in to the pharmacy by the prescriber..

Deleted:

More importantly, requiring surety bonds from state licensed pharmacists and pharmacies could jeopardize Medicare patients' access to important DMEPOS items and create severe economic hardships for community pharmacies. As noted, the Rite Aid Corporation operates 5,100 pharmacies in the United States, and each pharmacy provides some quantity of DME to Medicare beneficiaries.

Selling DME is a small part of Rite Aid's overall business, so any new financial participation requirements – including the millions of dollars in costs of accreditation and surety bond requirements – will trigger a review of our participation in the program. For example, assuming that each surety bond would cost about $2,000 per location, our costs to obtain surety bonds would total about $10,000,000 annually for all our pharmacies.

These new surety bond costs would be incurred in addition to any other costs we might incur from having to accredit and reaccredit our pharmacies under the new competitive bidding program for DME, and contracting with a separate claims processor just to bill Part B DME claims. Our initial estimates indicate that these accreditation costs may be several thousands of dollars per location.

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Moreover, CMS is seeking to shift beneficiaries who need diabetes testing supplies from retail suppliers to mail order suppliers, potentially further reducing the revenues that retail pharmacies would receive from selling Medicare DME. Rite Aid's wants to continue to provide Medicare beneficiaries with access to products and services. However, the increasing number of requirements in the Medicare program in order to sell DME, coupled with a potential decrease in retail-based revenues, could result in Rite Aid needing to reassess the economic feasibility of being able to absorb the additional expenses that will be incurred on a per location basis. CMS is essentially asking DME providers to bear significant increased costs to participate in the DME program, and expect providers to do so with less reimbursement and revenues under the new DME competitive bidding program.

Finally, the economic analysis in the proposed regulation recognizes that a significant number of DMEPOS supplies could leave the program as a result of this new surety bond requirement. The analysis further states that "To assist Medicare beneficiaries locate a replacement DMEPOS supplier...we would conduct an education and outreach effort to ease the transition..."

Rite Aid operates many pharmacies in rural areas, where Medicare beneficiaries already may not have many choices of providers of DME. The loss of providers in rural areas means that Medicare beneficiaries may have even fewer choices. Given that many Medicare beneficiaries in rural areas are low income and may not have the means to travel, this education campaign will mean little for a beneficiary that simply cannot travel to a very distant pharmacy to get their diabetes supplies. These individuals may find that they have fewer choices of reputable, established providers, such as Rite Aid, or may have to travel longer distances for their products, if these new requirements go into effect. This assumption in the analysis that simply directing them to another supplier will solve their problem is shortsighted, and could lead to a significant decline in beneficiary health if necessary supplies cannot be obtained.

We appreciate your interest in our views on this matter, and ask that you contact us at 703-888-0859 if we can provide additional information. Thank you.

Sincerely,

John M. Coster

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John M. Coster, Ph.D., R.Ph.
Vice President, Federal Affairs and Public Policy

Submitter : **Mrs. christa huddleston** **Date: 09/29/2007**

Organization : **South Sound Therapy Services**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

September 10, 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: Christa I Huddleston MS OTR CHT

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. I would estimate about 20 % of the overall charges to Medicare. 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. My patients are very grateful to receive the supplies, splints and orthotics where they receive the evaluation and treatment for their condition. This ensures the correct equipment is given, fitted and necessary.

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.
Respectfully submitted

Christa I Huddleston

Provisions

Provisions

see attatchment below

Submitter : Mr. JEFF COWDRY **Date:** 09/30/2007

Organization : ADVANCED TRAINING AND REHAB

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Patients are sharp consumers. Therapists are professionals trying to care for them. Please do not place another fincancial drain on my practice. Make people who have a history of abuse or fraud be required to purchase surety bonds.
Thank you for your consideration.

Impact

Impact

The proposal of requiring me to carry a 65k surety bond per NPI number puts and additonal buren on the small private practice. We already will be paying seveal thousand dollars getting accredited to make custom splints. There is no way to pass this cost along to the consumer. It is an additional tax on practices already experiencing lower and lower profit margins. It will do nothing to protect my patients. This tax should be placed on practices who have a history of fraud or abuse.

Provisions

Provisions

The estimated $2000 cost of the surety bond per NPI # in addition to the new costs of accreditation place an undo hardship on my office. My profit margin goes lower every year and has been trending down for 10 years. How am I to make up for the cost of accreditation AND the cost of a surety bond?

Submitter : Ms. Carol Napierski **Date:** 09/30/2007

Organization : New York Medical Equipment Providers Association

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-150-Attach-1.DOC

#150

Via Electronic Transmission

September 30, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
http://www.cms.hhs.gov/eRulemaking

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:

New York Medical Equipment Providers Association (NYMEP) appreciates the opportunity to provide comments on a proposed rule that would require a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to obtain a $65,000 surety bond for each of its National Provider Identification (NPI) numbers as a condition of Medicare enrollment.

NYMEP is a state association comprised primarily of 150 durable medical equipment providers (DME) and manufactures employing over 5,000. NYMEP, on behalf of our membership, is submitting comments related to the documentation and procedural issues as they relate to the implementation of the proposed rule making for Surety Bond requirement for suppliers of Durable Medical Equipment.

NYMEP is a member of American Association for Homecare (AAH) and of the MAC Jurisdiction A Advisory Council. NYMEP has reviewed and concurs with the comments submitted AAH. NYMEP's immediate concerns with the implementation of the Proposed Rule and the desired outcomes of the Final Rule and respectfully recommends the following:

- The surety bond requirement should apply to new suppliers only. Given that Congress intended the surety bond requirement to serve as a screening tool for Medicare, the value of requiring suppliers to post a bond decreases the longer a supplier has been in the program.

- CMS should not impose an inflation adjustment on the amount of the bond. The inflation adjusted bond will be 25% higher than the $50,000 bond originally contemplated by Congress. Since it appears that CMS' only rationale for increasing the bond amount is the passage of time, imposing this additional financial and administrative burden on suppliers is arbitrary.

- A final rule must include a mechanism to protect suppliers in the event the NSC or a surety mistakenly reports that a bond has been cancelled, or the surety goes out of business. At a minimum, suppliers should have notice that their billing number will be revoked and an opportunity to demonstrate that they have a bond *before* the revocation.

- Suppliers should not forfeit the bond except in the case of an assessment imposed after a finding that the supplier engaged in fraudulent or abusive billing practices.

- The bond amount should not be forfeited until there has been a *final* determination that a supplier is liable for an assessment or other penalty and the time to appeal the determination has expired. There is no valid rationale to impose forfeiture at an earlier date given that the surety is a third-party guarantor of the funds (up to the amount of the bond) necessary to pay the assessment or penalty.

Each of these issues will be discussed in greater detail in our comments below.

I. Comments

Since surety bonds are issued based on a company's financial strength, a facility that commits fraud may have strong financial statements rendering it easier for such a company to obtain surety bonds. Whereas an organization that follows all CMS documentation and accreditation rules may have higher costs associated with doing so, financials that reflect higher costs and difficulty obtaining Surety Bonds. These two instances prove to have an opposite effect of the primary reason for obtaining Surety Bonds in the first place.

A. CMS Should Use the Tools to Fight Fraud Currently at Its Disposal

New suppliers should also be subject to more scrutiny in the claims process. We suggest that CMS implement a coordinated program with the DMEPOS Medicare Program

Safeguard Contractors (PSC), Medicare Administrative Carriers (MACs), and the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) to monitor a new supplier's billing during the initial term of its Medicare billing number (i.e., three years). This type of monitoring can promptly identify questionable billing and can be implemented relatively quickly since the mechanisms to do it are already in place. It is our understanding that in jurisdictions where there have been high rates of fraudulent billing CMS and other oversight agencies are engaging in this kind of concerted claims monitoring effort. Close monitoring of new suppliers' billing patterns circumvents the "pay and chase" scenario that has characterized the activities of these fraudsters. Applying this heightened scrutiny to new suppliers is not unlike the process used by some professional credentialing bodies where individuals granted first-time privileges may be subject to an initial period of supervision. This type of monitoring, coupled with a second on-site inspection, would facilitate quick action if fraudulent activity is identified.

NYMEP concurs that all DMEPOS suppliers who want to bill Medicare must comply with quality standards and get accredited. Requiring suppliers to get accredited in order to begin billing the Medicare program removes the incentives that make the Medicare program attractive to fly-by-night operators because the supplier must operate as a legitimate business to pass accreditation. Currently, only suppliers in competitive bidding areas that want to submit bids are required to be accredited. We strongly encourage CMS to make this an across-the-board requirement for all suppliers.

When the GAO reviewed CMS' surety bond regulation for HHAs, it concluded that conditioning the bond on the refund of overpayments is likely to increase the cost of the bond because instances of overpayments may occur more frequently than findings of fraudulent or criminal behavior. Sureties issuing financial guarantee bonds are more likely to review a supplier's books and might request audited financial statements. Because most small suppliers do not have audited financial statements, this requirement could pose a serious hurdle to their compliance. Sureties are also more likely to ask for collateral to secure the issuance of a financial guarantee bond. The cost of the collateral will vary depending on its liquidity. Sureties will likely favor highly liquid collateral such as letters of credit which will require suppliers to incur an additional expense. We believe that this type of review is sensible when it is applied to suppliers that are new to the Medicare program. We do not believe there is added value in imposing these additional costs and paperwork burdens on suppliers that have undergone two Medicare enrollment cycles and are thus established in the program.

Established suppliers, those that have undergone two enrollment cycles, should not have to post a bond because the deterrent value of the surety's scrutiny will be small compared to the financial and administrative burden imposed on the supplier. Similarly, established suppliers opening new locations and acquisitions of established suppliers should not require bonds. Again, the value to Medicare of the surety's screening criteria in these cases will be small compared to the burden imposed on suppliers. It would be inadequate for CMS to rely exclusively on surety bonds to accomplish the program integrity goals CMS has identified in the proposed rule. Instead, we recommend that CMS combine the

surety bond requirement with enhanced monitoring and oversight of new suppliers as we described above.

B. CMS Has Not Stated an Adequate Rationale for Applying an Inflation Adjustment to the Value of the Bond

The proposed rule would require suppliers to obtain a surety bond for $65,000, an inflation- adjusted amount from the $50,000 bond called for under §4312 of the BBA. It appears that CMS' primary rationale for making an upwards adjustment of 25% in the value of the bond is the time that has lapsed since the enactment of the BBA. Although CMS acknowledges that the additional costs imposed under its proposal will drive smaller suppliers away from the program, CMS makes no effort to explain how this added financial burden to suppliers achieves the program integrity goals of the proposed rule. As the Small Business Administration (SBA) Office of Advocacy states in its comments on the proposed rule, CMS has an affirmative obligation under the Regulatory Flexibility Act to consider the effects of their regulations on small entities.[2] In this case, using CMS' own estimates of the proposed rule's economic impact, increasing the bond amount to $65,000 increases the financial impact of the bond from roughly $150 million to $198 million. Adding to the economic impact of the bond for all suppliers, but especially for small suppliers, is that sureties may require suppliers to furnish audited financial statement or post collateral for the bond. As we noted above, these requirements will increase all suppliers' costs to post a bond, but will be especially onerous for smaller suppliers.

C. The Final Rule Must Include Procedural Protections for Suppliers

The proposed rule requires a bond to guarantee refunds on overpayments assessed for reasons other than fraud. Specifically, the bond amount is forfeited as soon as CMS or the OIG makes a demand for payment on the basis of an overpayment or other assessment. The proposed rule goes so far as to require payment under the bond as soon as the overpayment is identified without regard to whether the supplier has the right to seek a review. We believe that the conditions of the bond as currently crafted are overreaching and inconsistent with Congress' intent when it passed §4312. the In other words, a default on the bond should be based on a finding of wrongdoing, not merely on the existence of debt which may be disputed and subject to appeals. The surety's liability should be triggered only when there has been a ***final*** determination of an assessment for fraud or other misconduct against a supplier and the time to file an appeal has expired. There is noationale to impose liability under the bond before a final determination is entered because the bond, by its terms, guarantees payment of the assessment.

Importantly, the final rule must include procedural protections for suppliers incase the surety fails or the NSC has incorrect information about the supplier's bond. The consequences for not having a bond are severe and suppliers should not suffer penalties unless they have been notified of a problem and an opportunity to correct a deficiency.

We understand that CMS is finalizing a rule on appeals of Medicare enrollment determinations. CMS should clarify in the final surety bond regulation that existing review procedures apply to adverse determinations concerning bonds.

Conclusion

NYMEP appreciates the opportunity to submit these comments and remain available to discuss them with you in greater detail.

For further information contact:

Carol Napierski
New York Medical Equipment Providers Association
27 Elk Street
Albany, New York 12207
Telephone: 518-436-9637
E-Mail: NYMEP@NYMEP.org

Respectfully Submitted,

Carol Napierski

Executive Director

Submitter : **Mrs. Sue Dahl-Popolizio** **Date: 09/30/2007**

Organization : **The CORE Institute**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

September 10, 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: Sue Dahl-Popolizio, OTR/L, CHT
6769 W. Rowel Rd.
Peoria, AZ 85383

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. 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 during, or immediately following their treatment to maintain improvements achieved from recent surgery (i.e. post-op splinting), and improve on gains made in therapy. The importance of our continued ability to fabricate orthoses and make timely adjustments cannot be underestimated. As therapists working with immediately moldable material, we can accommodate changes in the pt. (i.e. changes in edema, contractures, etc.). If these changes are not addressed immediately, there are risks to the pt s condition that are irreparable.

Impact: I feel that this rule may affect my ability to fabricate and supply orthoses. As I don t work full time, 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 practice. 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. I think if will decrease competition in the market, which will result in less incentive for ethical job performance, not more. I also strongly believe that the people to suffer most from practitioners like myself being pushed out of the market are the patients.

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

Submitter : **Ms. Susan Stockdell** **Date: 09/30/2007**

Organization : **Southwest Therapy Specialists, P.C.**

Category : **Occupational Therapist**

Issue Areas/Comments

Provisions

Provisions

September 29, 2007
Re: CMS-6006-P-1

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

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. I have significant concerns re: the effect of this rule on my practice and patients. I employ both physical therapists and occupational therapists, and my practice is an independent outpatient occupational therapy practice.

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 affect movement, protect joints from injury pre-operatively and/or post-operatively, support structures and joints, and improve independent Activities of Daily Living 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 woman-owned business, the estimated $2200 cost of the surety bond per NPI # in addition to the new costs of accreditation would be an undo hardship on my ability to make ends meet as a practice. 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. All this will do is cause a financial burden on the accredited provider already hit by decreased reimbursement through the years, and push the independent practice owner to make cuts on the already hard-hit budgets.

Thank you for the opportunity to comment of this proposed rule, and please do not allow the surety bond to be required when other accreditation measures are in place to make sure the practice and practitioners are exceeding community standards.

Susan Stockdell, OTR/L, CHT
President
Southwest Therapy Specialists, P.C.
7540 N 19th Ave., Ste. 101
Phoenix, AZ 85021

Submitter : **Mr. eric belusko** **Date: 10/01/2007**

Organization : **albany area hand therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

September 10, 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: Eric Belusko MHS, OTR/L, CHT
Albany Area Hand Therapy
711-D N. Westover Blvd
Albany, GA 31707

To Whom It May Concern:

I would like to take time to comment on the proposed rule CMS-6006-P-1 am an Occupational Therapist in private practice, specializing in the treatment of the upper extremity patient and have 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. Take for example an individual with RA who just had her MCP joints replaced. On a frequent basis we assess the orthodic device's effect on the hand. We may simply need to alter the pull of the outriggers or add additonal compentry to the device to correct any errant deviation of the digits. Should motion loss develop in flexion, an adjunct splint may be needed for a period of time during the day. This translates to more functional use of the hand when final ROM is achieved.

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. Prefabicated DMEPOS available from non-therapists or practitoners should fall in a different catagory as therapists continually assess all splints during the concurrent administration of therapy. 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

Sincerely,

Eric Belusko, MHS, OTR/L, CHT