

Submitter : Mary Ann Wagner

Date: 10/01/2007

Organization : National Association of Chain Drug Stores

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-154-Attach-1.PDF



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

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

Re: 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 National Association of Chain Drug Stores (NACDS) represents the nation's leading chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 38,000 pharmacies, employ 114,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of nearly \$700 billion. NACDS members are the primary providers of Medicare Part D prescription drugs and services, in addition to supplying Medicare Part B medications, durable medical equipment, and other supplies. We appreciate the opportunity to comment on the above referenced proposed rule requiring a \$65,000 surety bond from DMEPOS suppliers, as a condition for the issuance or renewal of their provider number.

413 North Lee Street
Alexandria, Virginia
22314

CMS has solicited comments on whether large, publicly traded chain suppliers of DMEPOS should be exempt from the rule. See 69 Fed. Reg. 42004. We believe that CMS' definition of "chain suppliers of DMEPOS" includes chain pharmacies and that they should be exempt from the surety bond rule in consideration of the licensing and regulatory requirements they already comply with. NACDS further urges that this exemption be broader than only "large" or "publicly traded" chain suppliers, and in fact, *all* state licensed chain pharmacies should be exempt from the surety bond requirement. CMS has also requested comments on whether licensed pharmacists who furnish DMEPOS items for the convenience of their patients should be exempt from the surety bond rule. See 69 Fed. Reg. 42004. We believe that *all* state licensed pharmacists should be exempt from the proposed rule, in consideration of their education and training, state licensure requirements and the integrity they bring to the DMEPOS program.

The surety bond requirement would be superfluous as applied to state licensed chain pharmacies and pharmacists given the numerous state and federal regulations they are required to comply with. More importantly, requiring surety bonds from state licensed chain pharmacies and pharmacists could jeopardize Medicare patients' access to important DMEPOS items and create severe economic hardships for community pharmacies that provide DMEPOS items to Medicare beneficiaries.

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I. All state licensed chain pharmacies should be exempt from the surety bond rule

State licensed community chain pharmacies do not pose any threat to the integrity of the Medicare DMEPOS program. First, community chain pharmacies are licensed by the states and must comply with state and federal laws regulating dispensing and delivery of pharmacy services. Second, unlike other DME suppliers, pharmacists are present in community chain pharmacies to deliver DMEPOS services and deter fraudulent practices. Finally, employees at chain pharmacies have no incentive to engage in fraudulent billing practices. These attributes are common to all community chain pharmacies, regardless of their size or whether they are “publicly traded.” NACDS therefore urges CMS to create an exception for chain pharmacies of all sizes and not just those that are “large” or “publicly traded.”

A. State licensed chain pharmacies operate in a highly regulated environment

Unlike other DMEPOS suppliers, community pharmacies are licensed by the board of pharmacy of their respective states. 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. No other type of DME supplier is required to undergo this additional layer of scrutiny. State licensed chain pharmacies currently operate more than 38,000 pharmacies. Each one of these over 38,000 stores, represented by NACDS, has satisfied strict state and board of pharmacy licensing requirements.

State licensed chain pharmacies also closely monitor the HHS Office of Inspector General (OIG) exclusion list to ensure that excluded providers are not involved in delivery of Medicare services. The OIG exclusion list provides timely information on healthcare providers that have been barred from federal healthcare programs for their failure to abide by CMS' regulations.

B. Presence of a pharmacist at the pharmacy reduces fraudulent practices and saves Medicare resources

State pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the operation of that pharmacy in compliance with the applicable laws and regulations. The state pharmacy laws, depending on the state, identify this pharmacist as the pharmacist-in-charge (PIC) or the pharmacist manager. Other non-pharmacy suppliers of DMEPOS are not required to maintain supervision by a state licensed pharmacist. Allowing continued access to DMEPOS items through a pharmacy provides this additional measure of safeguard to the Medicare program that is not available in other settings.

Further, the presence and involvement of a licensed pharmacist provides patients the chance to discuss proper use of the DMEPOS items and other drugs with their pharmacists. For Medicare beneficiaries, purchase of DME items in a pharmacy allows the benefit of having a professional healthcare provider available to assist them. Counseling with pharmacist increases patient compliance with medications and improves health outcomes. Such interactions are unique to pharmacies and the benefits of such interactions should not be taken lightly by CMS because it

leads to early awareness and treatment of diseases and translates into substantial savings for the Medicare program.

C. Chain pharmacy employees have no financial incentive to engage in Medicare fraud

Staff Pharmacists, technicians and other employees at community chain pharmacies have no financial incentive to engage in Medicare fraud because their compensation is not tied to the volume of Medicare prescriptions filled or DMEPOS items furnished. Further, chain pharmacies have very effective safeguards in place to ensure that a rogue 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 or reconciliation. These measures are highly effective in preventing Medicare fraud.

D. CMS has other means of recouping losses to the Medicare program from fraudulent suppliers

CMS states that one of the policy goals of the surety bond is to maintain a source of funds for recoupment. NACDS understands that many unscrupulous DMEPOS suppliers are insolvent, which prevents CMS from enforcing monetary penalties and recouping lost funds. Chain pharmacies, on the other hand, do not pose this problem. In the very rare occasion where a chain pharmacy is found in violation of a Medicare law, CMS can levy penalties and effectively recoup Medicare funds. Chain pharmacies have the resources available to satisfy judgments and penalties imposed by CMS. Many chain pharmacies have been in business for decades and have served beneficiaries since the inception of the Medicare program. Requiring a surety bond from chain pharmacies despite their exceptional history of compliance with fraud, waste and abuse laws, and their ability to satisfy judgments, would contradict CMS' intended goals.

Further, Medicare has made significant improvements in detecting and deterring fraud, waste and abuse in program administration. Through the use of program safeguard contractors (PSCs), the Medicare program has been able to identify numerous cases of overpayments and has referred many matters to law enforcement for prosecution. PSCs reported to CMS that, in 2005, they identified overpayments of \$54,673,571 in connection with their investigations. These efforts reveal that programs that do not unnecessarily exclude provider participation show great promise and should be pursued more vigorously. The presence of less burdensome and effective programs further reduces the need for the disruptive and exclusionary surety bond rule.

E. CMS should exempt all chain pharmacies from the surety bond rule without regard to whether they are "large" or "publicly traded"

As mentioned previously, all pharmacies are required to comply with state laws regarding corporate formation, pharmacy and pharmacist licensure, and an array of federal regulations related to delivery of services to Medicare beneficiaries. These and other measures already instituted by CMS should dispel fears of Medicare fraud arising from state licensed chain pharmacies. NACDS is encouraged that CMS appears to understand this and has considered

including chain pharmacies in the group that warrant consideration for exemption from the surety bond rule. However, NACDS is concerned that the inclusion of “large” and “publicly traded” language may prevent CMS from achieving its intended goals.

Many community chain pharmacies are neither “large” nor “publicly traded,” yet they maintain high ethical standards in their pharmacy operations. Many chain pharmacies are smaller and regionally based. Nevertheless, smaller chain pharmacies that are not publicly traded submit to the same licensing and regulatory requirements as their larger “publicly traded” counterparts and as a result, a differentiation is not appropriate.

Further, the filings and regulations pertaining to public trading are not intended to provide security to the Medicare program; rather they are designed to protect the security of investors. On the other hand, the laws and regulations pertaining to pharmacy operations are designed to protect the public at large. Therefore, NACDS urges CMS to provide exception to the surety bond rule for all state licensed chain pharmacies regardless of whether they are “large” or “publicly traded.”

II. State licensed pharmacists should be exempt from the surety bond rule

NACDS believes that the Medicare program benefits tremendously from continued participation of state licensed pharmacists in the delivery of DMEPOS services. Numerous factors such as a pharmacist’s education, licensing and registration, and continued education requirements serve as assurances of pharmacists’ reliability in participating in the Medicare program. Each of these factors is examined briefly below and deserves weighty recognition when CMS issues its final rule. NACDS also suggests that CMS use these factors as the criteria for considering an exception to the surety bond rule for pharmacists.

Further, the surety bond proposal seeks comments on whether “licensed pharmacists who furnish DMEPOS items for the *convenience of their patients*” should be exempt (*emphasis added*). We believe that CMS is correct in identifying licensed pharmacists as the subject of potential exemption from the rule. However, we request that when CMS issues its exception for pharmacists, it should exclude the extraneous language related to “convenience of their patients.”

A. State licensed pharmacists are highly educated and regulated healthcare providers

Pharmacists are among the most trusted professionals in America, and they play an important role in securing the health and wellness of all Americans. The immense confidence the public places in the pharmacist is well deserved. Patients realize that pharmacists serve as the sentinel of trends in diseases, therapy management, drug utilization, compliance and abuse. With their formal education and training, pharmacists are able to provide these services in a unique manner.

Education: Today’s pharmacists are specialists formally trained in the art of patient care. Pharmacists are highly educated to provide counseling to patients and doctors on proper use of drugs and medical devices. Pharmacists must graduate from an accredited pharmacy school and be licensed in the states where they practice pharmacy. All pharmacists are now required to graduate from a Doctor of Pharmacy degree program consisting of a minimum of six years of education,

with two years of pre-pharmacy school and four years of pharmacy school. Today's pharmacy curriculum is extensive and includes clinical training directly with patients to offer advice on their care and training. Pharmacy schools are also aware of the importance of maintaining strong ethical foundations for graduating pharmacists. Pharmacy schools' accreditation standards now require topics on professionalism to be addressed as part the school's core curriculum. The fact that pharmacists are professionals and have a strong ethical foundation should serve as an assurance of integrity for the Medicare DMEPOS program.

State licensure: After graduation from pharmacy school and prior to being licensed, pharmacists must pass the National Association of Boards of Pharmacy Pharmacist Licensure Exam ("NAPLEX"). The state board of pharmacy considers the pharmacist's prior conduct in determining whether the pharmacist should be licensed, despite the fact that the pharmacist may have fulfilled all educational requirements to be granted a degree. In addition, after graduation and licensure, many graduates enter a one- or two-year residency program, thereby making many pharmacists' education an eight-year endeavor.

As part of the pharmacist's licensure, the vast majority of states already require yearly continuing education (CE) courses to help pharmacists stay abreast of changes in the law and regulations affecting their practice, including those related to federal healthcare programs. These courses are designed to help pharmacists improve their patient care skills, recognize problem areas in their professional practice, including how to recognize, avoid and counter fraud and abuse issues. A pharmacist's failure to enroll in CE courses and document compliance with course requirements would subject the pharmacist to board review and possible revocation of their license to practice pharmacy.

State boards of pharmacy monitor pharmacists for compliance with state and federal laws. Pharmacists are given the privilege to provide healthcare services with the understanding that non-compliance with state and federal laws could serve as the basis for revocation of this privilege. The pharmacy and pharmacist licensure laws establish the disciplinary authority of the state boards of pharmacy. Pharmacists are subject to board of pharmacy disciplinary actions against their licenses for a variety of conducts, including fraudulent activities. Other unlicensed, unregulated individuals that sell DMEPOS items do not face similar consequences for violations.

Medicare beneficiaries have the right to contact the state board of pharmacy with concerns or complaints about their local retail pharmacists. As a state consumer protection agency, the state board of pharmacy holds the authority to investigate and penalize pharmacists for any wrongdoing. This consumer protection mechanism does not exist with other non-licensed DMEPOS suppliers.

Today's pharmacist is uniquely qualified to serve as the medication and medical device use expert for advising and counseling Medicare patients and providing advice to other healthcare providers on the use of healthcare products. Pharmacists are ideally situated to provide Medicare patients using diabetes supplies and other DME items with counseling and important information on the proper use of these items. Such qualifications clearly differentiate pharmacists from general unlicensed, unregulated suppliers of DMEPOS. Given the layers of assurances provided by pharmacists' unique education, licensing and practice rules, requiring a surety bond from

pharmacists would be unnecessarily redundant. Thus, NACDS urges CMS to exempt *all* licensed pharmacists that furnish DMEPOS items from the proposed surety bond requirement.

B. CMS' final rule should exempt all licensed pharmacists from the surety bond requirement without the proposed rule's language regarding "convenience of their patients"

Pharmacists deliver services to their patients in many settings and geographies around the country, and always do so for the convenience of their patients. The extent of a pharmacist's DMEPOS business depends on many factors, including the locality of the services and demographics of the patients. For example, pharmacists in states with higher retiree populations may have larger DMEPOS practice than pharmacists who practice in states with lower retiree populations. Thus, whether pharmacists in states with higher retiree population furnish DMEPOS for the "convenience of their patients," or as a larger part of their business should have no bearing on their exclusion from the surety bond requirement. All pharmacists are regulated in an equally strict manner regardless of the character of their DMEPOS business. Thus, CMS should clearly exempt *all* state licensed pharmacists without any reference to the volume or nature of their DMEPOS business. As discussed earlier, pharmacists' education, licensure and practice rules provide an effective measure against fraudulent behavior. CMS' efforts to combat fraudulent activities of unlicensed, unregulated individuals in delivering DMEPOS items is warranted, however, seeking redress from state licensed healthcare providers, i.e. the pharmacists, would be misplaced.

III. Proposed rule will place tremendous burden on pharmacies *and* patients

The proposed surety bond rule stands to create tremendous financial burdens on community pharmacies that furnish DMEPOS items as they already operate on very low profit margins. The impact of the surety bond will not be limited to pharmacies, however. Medicare beneficiaries could experience significant disruptions in care if they are unable to obtain their DMEPOS supplies from their preferred pharmacy providers.

A. Proposed surety bond rule will cause severe economic hardships on community pharmacies

Many community pharmacies that do not have significant DMEPOS business may be unable to withstand the enormous surety bond requirement and may be forced to turn away Medicare patients. The amount of the surety bond required will be higher than total reimbursement realized under Medicare for many pharmacies, including those that have a sizeable DMEPOS business. NACDS understands that as a result of the surety bond requirement, many uncommitted, transient DMEPOS suppliers will choose to stop serving Medicare beneficiaries; however, it may also cause many stable, committed chain pharmacies to do the same because of the costs.

As currently proposed, the surety bond requirement will apply to all pharmacies that seek to obtain or renew their Medicare billing number or National Provider Identifier (NPI). Chain pharmacies have anywhere from a few locations to thousands of retail locations. Some of these retail locations have a more significant DMEPOS business than others; however, they provide the same access to covered DMEPOS items for the convenience of their Medicare patients. Requiring chain retail

pharmacies to pick and choose the stores for which they can afford the surety bond will create confusion for many Medicare beneficiaries, as one store of a chain may not be able to provide the same services as another store. Medicare beneficiaries will have no way to know whether any two retail outlets of a chain pharmacy can provide the same DMEPOS items. The only way to alleviate this concern would be for chain pharmacies to either stop providing all DMEPOS supplies or submit to surety bonds for all store locations and suffer tremendous losses.

B. Reducing Medicare patients' access to DMEPOS items through their preferred community pharmacy creates confusion and potential disruptions in the continuity of their care, and increases healthcare costs

According to CMS' own calculation, up to 15,000 DMEPOS suppliers (22 percent of whom are in rural areas) currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries. CMS envisions that, "most, if not all, of the Medicare business conducted by these DMEPOS suppliers would be assumed by other DMEPOS suppliers remaining in the program (for example, by mail order or via the World Wide Web)." NACDS is concerned that such a simplistic calculation does not reflect the true extent of the outcome. Many DMEPOS suppliers forced to stop providing services to beneficiaries may be pharmacies that are unable to withstand the high surety bond costs. However, the impact will not be limited to the pharmacies. Medicare beneficiaries would have their access to DMEPOS items severely limited. Further, reducing Medicare patients' access to DMEPOS items through their preferred community pharmacy could undermine patient therapy compliance and jeopardize their health.

The preference beneficiaries show for community pharmacies is rooted not only in convenience, but also in the reliable, consistent access to their medications and supplies, and pharmacists' professional counseling community retail pharmacies provide. For example, consider the needs of a diabetes patient. Currently, Medicare Part B provides beneficiaries with access to glucose monitors and test strips that are necessary for the at-home monitoring of blood glucose. Self-monitoring of blood glucose levels with glucose monitors and test strips is a critical aspect of managing both type 1 and type 2 diabetes. The proposed rule would force a patient who prefers a community pharmacy for all of his/her diabetes care needs to obtain Part B diabetes testing supplies from a mail order pharmacy and Part D insulin and/or oral diabetes drugs from the preferred local pharmacy. Requiring patients to visit and coordinate with multiple suppliers and pharmacies for their healthcare needs would cause tremendous disruptions and frustrations for patients and their providers.

By going through the mail order or on-line supplier, Medicare beneficiaries will be precluded from the opportunity to consult with a pharmacist of their choice while obtaining their DMEPOS items. Time and again, data shows that interaction with a pharmacist is critical in increasing drug therapy compliance and early detection of diseases. The surety bond rule is likely to reduce such pharmacist-patient interactions, resulting in increased patient non-compliance, delayed identification and treatment of diseases, and ultimately increased healthcare costs for everyone.

IV. Conclusion

NACDS and our member companies stand firm with CMS in our mutual goal to eliminate fraud and abuse in the Medicare program. CMS should be allowed to use innovative programs to ensure the integrity of the participants in the Medicare program. The surety bond requirement as applied to state licensed pharmacies and pharmacists, however, would not properly achieve this goal.

CMS's solicitation of comments on whether pharmacists and chain DMEPOS suppliers should be exempt from the surety bond rule suggests CMS understands the critical role pharmacists and pharmacies play in delivering Medicare Part B services to beneficiaries. We urge CMS to exempt all state licensed chain pharmacies and pharmacists from the surety bond requirement. We thank you for the opportunity to present our views on this matter. If we can provide any additional information, please feel free to contact me at 703.837.4136.

Sincerely,



Mary Ann Wagner, R.Ph.

Senior Vice President, Policy and Pharmacy Regulatory Affairs

Submitter : Ms. Linda Leone
Organization : Illinois HomeCare council
Category : Health Care Provider/Association

Date: 10/01/2007

Issue Areas/Comments

GENERAL

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See Attachment

CMS-6006-P-155-Attach-1.DOC



October 1, 2007

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

Dear Sir or Madame:

Thank you for this opportunity to comment on the proposed regulation entitled "Medicare Program: Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)" published in the Federal Register on August 1, 2007 (Vol. 72, No. 147). The Illinois HomeCare Council (IHCC) is a trade association representing approximately 220 home care providers and suppliers in Illinois. These comments were developed by IHCC's Regulatory and Reimbursement Committee in consultation with the DME Work Group.

PROVISIONS

IHCC objects to many aspects of the proposed regulation. Specific concerns and suggested alternatives are described below.

Comment: Section 424.57(c)(26)(i)(A) proposes that all DMEPOS suppliers be required to secure a surety bond valued at \$65,000. In the preamble to the regulation, CMS justifies the \$65,000 figure by stating that it was derived by applying the CPI to the previously proposed surety bond amount of \$50,000. While IHCC members recognize the difficulty CMS sometimes faces in recouping overpayments from suppliers, it seems unreasonable to expect a supplier to purchase a surety bond that far exceeds the value of the organization's annual claims. This is the case for almost half of the organizations represented in Table 2 in the proposed regulation (see page 42007).

CMS' preamble goes on to discuss the potential chilling effect that having to purchase a surety bond costing an estimated \$2,000 per year would have on a number of the suppliers currently participating in the Medicare DMEPOS program

(see page 42008). IHCC members believe that if CMS wants to reduce the number of DMEPOS suppliers they should accomplish this goal by more straightforward means than adopting a regulation that will simply drive a number of suppliers out of the market based on operating costs.

IHCC members remember CMS' efforts to implement surety bonding in the home health industry several years ago, and difficulty of identifying companies to issue the bonds. Ultimately, CMS abandoned the proposal as unworkable. IHCC members speculate that it will again be difficult to identify companies to issue surety bonds for the DMEPOS sector and wonders if the \$65,000 proposal reflects a minimum amount of coverage that the bonding industry is willing to consider offering. IHCC members wonder if bonding companies are willing to offer bonds at a level that is rationally related to CMS' overpayment experience.

Recommendations: IHCC members believe that if the surety bond requirement is designed to address one or more real problems faced by CMS, then a realistic approach to solving those problems should be proposed. IHCC suggests that CMS should require surety bonds of a limited number of suppliers and require a level of coverage that reflects experienced overpayments.

Specifically, IHCC members recommend that at a minimum CMS exempt all suppliers who billed less than \$10,000 in the prior year from the surety bond requirement. This would eliminate approximately one third of the suppliers that would currently be subject to the surety bond requirement. Suppliers who bill over 10,000 could then be stratified by billing level and experienced overpayment rates for each level could be computed. Suppliers who fall in each category could then be required to secure and maintain a surety bond at a level that actually reflects CMS' overpayment experience.

IHCC believes that one exception to this exemption should be made: all newly enrolled suppliers should be required to secure and maintain a surety bond for their first five years of participation in the Medicare program. Again, IHCC believes the amount of the bond should reflect experienced overpayment rates for this sector of suppliers.

Comments: Proposed Section 424.57(c)(26)(ii) includes several categories of suppliers for exception from the proposed surety bond requirement. IHCC members support some of the proposed exceptions and objects to others. Specifically, IHCC supports exceptions for physicians, non-physicians practitioners, and pharmacists, as well as for home health agencies and hospices, all of whom provide small amounts of DMEPOS as part of their service delivery to patients. Not only is the provision of DMEPOS to patients in these settings a convenience, it is often a component of providing quality services in a timely manner.

IHCC objects to the proposed exception for large, publicly traded chain suppliers of DMEPOS. These organizations are better able to afford and obtain surety bonding or some other type of repayment insurance than are the smaller organizations in the DMEPOS sector. In addition, these organizations also represent at least the same level of risk for inappropriate billing.

Recommendations: IHCC believes that the best way to exempt the suppliers described above is to exempt all suppliers whose revenue in the prior year was below the \$10,000 level. In this way, the identified practitioners and providers can continue to provide the equipment their patients need and can bill Medicare appropriately as suppliers for these services. IHCC also recommends that CMS abandon its proposal to accord exceptions to the surety bond requirement to large publicly traded DMEPOS suppliers.

Comments: In proposed Section 424.57(c)(26)(iii) CMS states that they will “revoke or deny a DMEPOS supplier’s billing privileges based on submission of a bond that does not reflect the requirements of this section.” (See page 42010) IHCC views this penalty as excessively harsh given the potential problems suppliers may have acquiring bonds in the market place. CMS’s regulations should recognize situations where suppliers have made a good faith effort to secure a bond that meets CMS requirements if the market place will not provide such a product.

Recommendation: IHCC recommends that CMS add language to this section that recognizes a supplier’s good faith effort to secure a bond that meets CMS’ requirements.

Comments: Proposed Section 424.57(c)(26)(viii)(A) would require that all DMEPOS suppliers must secure a surety bond and submit it to the NSC within 60 days of CMS’ adoption of a final version of the proposed regulation. Given the volume of suppliers potentially subject to this proposed regulation and previously experienced difficulties in identifying companies willing to write surety bonds for Medicare providers and suppliers, this proposal seems quite unrealistic.

Recommendation: IHCC recommends that CMS modify the proposal to allow suppliers up to 6 months to secure the required bonds, or to submit evidence of a good faith effort to do so.

Comment: Proposed Section 424.45(c)(26)(xii) would establish revocation of billing privileges as the penalty for a supplier’s failure to obtain, maintain and timely file a surety bond. IHCC finds this penalty to be excessively harsh given the broad range of infractions that CMS is proposing it should apply to. Revocation of billing privileges should be reserved for the most flagrantly non-compliant suppliers, while others who may be out of compliance due to factors

outside their control or first-time simple negligence should be addressed with less punitive sanctions.

Recommendation: CMS should revise this section of the proposed regulation to reserve revocation of billing privileges as the penalty for flagrantly non-compliant suppliers, and should propose other, lesser penalties, for suppliers who are unable to secure the required bond or are out of compliance due to minor negligence.

Sincerely,

Linda Leone
President

Submitter : Mr. Dan Reckase
Organization : Degen Berglund, Inc.
Category : Health Care Industry

Date: 10/01/2007

Issue Areas/Comments

Impact

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EXCEPTIONS-Little rationale is given for why the exceptions should be considered other than government suppliers. Physicians have been implicated in large Medicare fraud prosecutions, though not as suppliers as far as I know, but why exclude them? Large chain suppliers have been at risk for poor financial performance and bankruptcy, so the bonds would provide an alternative source of recoupment. I represent a pharmacy, so this comment is subject to conflict of interest, but independent pharmacies with small DME departments would be likely to drop Medicare billing, limiting beneficiary access. If anything, the class you define as "Current Medicare enrolled DMEPOS suppliers that do not have any prior history of criminal, civil or administrative sanctions for billing-related problems" makes the most sense for an exception. Otherwise, you're penalizing the compliant suppliers.

UNAUTHORIZED SURETY-For a supplier who has purchased a bond from a surety that becomes "unauthorized," it is unclear if there are any ramifications. To require the supplier to obtain a replacement bond without receiving a refund of premium would penalize the wrong party.

PARAGRAPH (viii)(A)-Given the somewhat unique characteristics of these bonds, more than 60 days may be necessary to implement this program. For the sureties to develop appropriate language for the bond and the private contract called for to accommodate the appeals process and underwrite may not leave the suppliers with time to consider alternatives.

Provisions

Provisions

The cost/benefit for this proposal appears heavily weighted to the cost side. Four potential benefits are identified, but each is questionable.

LIMIT FRAUDULENT DME SUPPLIERS-For truly fraudulent individuals expecting to reap thousands or millions of dollars, \$2,000 for a surety bond will not represent much of an impediment.

ENSURE ONLY LEGITIMATE DME SUPPLIERS ARE ENROLLED-This duplicates what the National Supplier Clearinghouse is supposed to be doing already. It puts up a barrier to DME suppliers developing low volume but convenient locations. Many supplier numbers must be held by providers of other health care services, who may cease providing, however, current Medicare regulations make it quite risky to do business with customers over the World Wide Web, so this will not take up the slack.

ENSURE RECOUPMENT OF PAYMENTS-Your Paperwork Reduction Act estimates indicated that 1,000 suppliers would be asked for bond documentation. If all those required payment to Medicare from the surety (unlikely, I would guess), that only amounts to \$65,000,000, yet suppliers are being asked to potentially pay almost \$200,000,000 per year.

ENSURE BENEFICIARIES RECEIVE APPROPRIATE PRODUCTS AND SERVICES-My company has five NPI numbers. Three locations do substantial Medicare business. Another is a small one person office located between a substantial hospital and a group practice clinic that is very convenient for customers but provides less than 1% of our revenue. The final location is the only pharmacy in a town of less than 10,000. For both these locations, Medicare billing may be dropped, but the locations would not close. This would lead to products being denied to Medicare beneficiaries at these two convenient locations.

Submitter : Dr. Paul Kesselman

Date: 10/01/2007

Organization : Dr. Paul Kesselman

Category : Physician

Issue Areas/Comments

GENERAL

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See Attachment

CMS-6006-P-157-Attach-1.DOC

Paul Kesselman DPM FACFAS
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September 30, 2007

Kerry N. Weems
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Department of Health and Human Services
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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: Medicare 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:

On August 1, 2007, the Federal Register published proposed rules [CMS-6006-P] RIN 0938-AO84, Medicare Program; Surety Bond, Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Page 42004 of the August 1, 2007 Federal Register, CMS stated it was soliciting comments on whether certain practitioners should be granted an exception to the Surety Bond requirement. This included certain physicians and non-physician practitioners, such as those whom may occasionally furnish DMEPOS items for the convenience of their patients. I would like to primarily address this issue within my background as a podiatric physician with extensive expertise in the field of DMEPOS.

The Durable Medical Equipment Regional Carriers (DMERCS) established the Provider Communication Advisory Group (PCOM or SCOM). The PCOM functions as a liaison between the DMERCS and the supplier community. The PCOM interacts directly with DMERCS and CMS staff to discuss current trends and global concerns within the industry. The PCOM Advisory Group membership is open to representatives from state medical societies, state supplier associations, manufacturers, billing services, and all other appropriate supplier organizations and third party entities.

As a podiatric physician practicing in New York State I have been a member of the PCOM for Region A, C and most recently D for several years representing various manufacturers of Durable Medical Equipment (DME) equipment and providing me with the opportunity to better educate my colleagues on both clinical applications of devices for their patients and the ethics of delivering and being reimbursed for these services. This year as a member of the NYSPMA Insurance Committee, I was appointed by the New York State Podiatric Medical Association (NYSPMA) to represent its membership's interest on the PCOM Advisory Group for DMERC A. My views may not necessarily reflect the views of the NYSPMA, however they are often sought by the association in particular those concerning the provision of Durable Medical Equipment by the membership of the NYSPMA to its patients.

I therefore feel qualified to submit my comments with respect to those provisions which would require podiatric physicians to obtain a Surety Bond in order to continue to provide necessary DME to our patients.

First and foremost, the Congress did not intend surety bond requirements to apply to physicians, including podiatric physicians. For example, 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. However, 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 rather 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.

Secondly I am deeply concerned that CMS has not take into account the effect of cumulative regulations on the podiatric profession and in particular the harmful effects this will have on patient care. In particular CMS has not appreciated the negative effective this will have on the large number of patients seen by physicians who provide them with DME, especially for those patients who have urgent medical conditions. CMS failed to appreciate and analyze the economically burdensome nature of this regulation on the small suppliers (i.e. podiatric physicians).

CMS notes that, "the vast majority of DME suppliers are small entities (based on Medicare reimbursement alone)." 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. 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. CMS also admits that Medicare beneficiaries will be directly affected by small DME suppliers' decision to leave the program. 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. In all these studies, however, CMS additionally failed to take into account the potential number of physician suppliers and the untold effect this will have on their ability to provide effective and timely patient care.

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. Professional practices have other economic burdens which already are in excess of this \$2,000 fee and these are not required of non-professional or unlicensed individuals. This includes more expensive state and federal licensing requirements, educational requirements, higher malpractice insurance rates, higher economic costs of employing more technically skilful personnel and those costs associated with providing higher end DME as opposed to cheaper less effective products provided by many other profit driven suppliers. There are also other costs associated with the provision of medical services which dwarf those of the average DMEPOS supplier.

The regulation of medical practice is already highly regulated by state licensing boards. Physician specialty certification is highly regulated by certification boards with stringent training requirements and an arduous examination processes. Undergraduate educational requirements for physicians entering medical training programs are far in excess of those required for almost any other profession. The requirement for physicians to obtain a Surety Bond, will therefore have no positive influence on the medical professional's ability to provide our patients with highly effective care nor will it likely result in any positive effect for the Medicare program. The proposed regulations will only cause more of an economic burden for the physician supplier, possibly resulting in less effective medical care.

A large DME supplier with hundreds of thousands or millions of dollars in DME revenue can more easily absorb the expenses of a Surety Bond because of a much lower percentage of its overall costs in comparison to their DME generated revenue stream. For physicians who occasionally provide DME services, an additional direct economic burden cannot be so easily be absorbed. Other proposed and/or final regulations already imposed on the DME industry (e.g., competitive bidding rule and accreditation requirements), will force many podiatric physicians to reconsider their financial ability to provide necessary DME products and services. For example, a small podiatric medical practice which generates approximately \$10,000 in annual ancillary DME services to its patients would be hard pressed to justify reducing 20% of that profit to pay for the privilege of continuing the practice of providing ancillary DME services and an additional 10% (\$1,000) for the cost of annual accreditation. These percentages do not reflect those costs associated with obtaining the Surety Bond or the proposed requirements of accreditation currently (i.e. hiring additional staff, additional paper work etc). With the profit margin now reduced and the additional burdensome paper work, a significant number of physician suppliers will simply not elect to renew their supplier numbers in order to provide DMEPOS. This will transfer the burden to a higher number of patients seeking care from unlicensed and mostly unregulated suppliers.

The reduction in revenues generated from DME services and for other medical services physicians currently provide (due to the proposed cuts in physician payments), will force many podiatric physicians to forego hiring new employees and the curtailment of providing benefits for employees (including health care and retirement benefits). It may also result in many other physicians choosing either to forego Medicare assignment or force their withdrawal from the Medicare program altogether. CMS has failed to acknowledge any of these factors in any of the studies they noted in the Federal Register or those noted by the Office of Advocacy.

The single most important factor not addressed by the proposed Surety Bond regulations is the harmful effects it will have on our patients. Requiring patients who have an acute medical requirement for low cost items such as canes, crutches, ankle braces and CAM Walkers to travel, to in many cases an unlicensed and unregulated provider, is unreasonable and may often cause undue harm to the patient. This will undoubtedly result in higher medical expenditures for CMS, in exact contrast to that intended by this proposed regulation.

It is not uncommon for podiatric physicians to see patients on a daily basis requiring an immediate fitting with an immobilizing DME device such as a brace, cane or crutches. The physician cannot be expected to immobilize a patient if Medicare regulations are unduly harsh and the practice cannot economically afford to meet those burdens.

Many podiatric physicians have also incorporated the single most effective preventive program for preventing diabetic foot ulcers, The Therapeutic Shoe Program into their practices. Patients have expected podiatric physicians to both recommend and fit them with appropriate footwear in order to reduce the incidence of Diabetic Foot Ulcers (DFU). DFU and their associated infections continue to be the number one reason for in-patient admission for diabetic patients and contribute to one of the longest length of in-patient stays, often resulting in other medical complications. Many studies have indicated the positive effects therapeutic shoes have on preventing DFU, reducing the recurrence rate of DFU and reducing the more than 64,000 Lower Extremity Amputations (LEA) performed annually in the USA. With hospital admissions for DFU averaging \$45,000, and estimates that the number of LEA can easily be reduced by 50%, it seems CMS should be encouraging podiatric physicians to continue to provide DME supplies, including Therapeutic Shoes to our patients rather than introducing additional costly and burdensome regulations.

Dr. Edwards, the SADMERC Medical Director and I have met on many occasions. He wholeheartedly endorses the podiatric professions continuing role in the Therapeutic Shoe Program. The proposed regulations, if enacted, would effectively reduce the number of highly trained licensed podiatric physicians who fit patients with appropriate footwear. This is clearly contrary to the intent and success of the Therapeutic Shoe Program and would be a disservice to the millions of diabetic patients the podiatric profession treats annually. The potential economic toll on both the Medicare program and other socio-economic costs are unfathomable.

Transportation costs for dual eligible patients (Medicare and Medicaid patients) will also exponentially increase. Because many indigent patients are ill and require ambulette assistance to reach their health care providers, another trip financed by the taxpayers would be required to obtain their DME device. This untold un-estimated cost, would result in higher costs associated with the delivery of all DME devices for the government (whether directly or in-directly).

The Surety Bond requirement was originally proposed in order to limit the Medicare program's risk to fraudulent durable medical equipment (DME) suppliers. This need while understandable is significantly outweighed by the fact that the vast majority of fraudulent DME suppliers are unlicensed non professional suppliers and not podiatric physicians. Because no licensing is required to become a DME supplier, it is easy for dishonest non-professionals to begin billing for DME devices without any clinical knowledge or educational requirements. Most often these unscrupulous providers bill for services and products never provided. Other unscrupulous providers' bill for highly profitable items such as power operated assistive devices and wheelchairs which may not be required. For example, in Harris County, Texas, Medicare paid for more than 3,000 power wheelchairs in 2001. A year later, it paid for 31,000, reflecting an estimated \$84 million in fraudulent claims. To the best of my knowledge no podiatric physician suppliers were ever accused or indicted due to this fraudulent behavior and the vast majority of this fraudulent behavior was instigated by non-professional, unlicensed individuals. Fraudulent behavior of this extent must be investigated and those found responsible prosecuted to the full extent of the law. Implementing programs however, which are excessive and cause economic harm to professional providers and ultimately delay necessary medical care are not in the best interests of my patients or those of other podiatric physicians.

To conclude, requiring a Surety Bond for physicians, including podiatric physicians seems contrary to the original intent of the conference report language accompanying the Balanced Budget Act of 1997 (BBA). It clearly stated that **"The conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals"** [emphasis added].

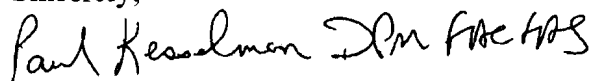
I believe there are many reasonable alternatives to this proposed regulation that would help mitigate the burdensome nature of the rule on podiatric physicians who usually provide DME products to their patients as an ancillary service, often during emergent and acute situations. I also believe that many other products and services are an integral portion of the medical services podiatric physicians provide and that the imposition of a Surety Bond on physicians, including podiatric physicians will put an undue burden on professional and licensed providers who are already highly regulated.

It is therefore my opinion that licensed professionals should not be subjected to the same requirements as non-licensed professionals as we already have met a much higher standard of practice. The NSC can easily tabulate this data in supplier applications and offer state licensing by physicians as an alternative to the posting a Surety Bond.

I respectfully request that CMS give consideration to the issues raised herein, and encourage CMS to better analyze the possible effects this regulation may have on the public health and physicians, in particular podiatric physicians.

I appreciate the opportunity to provide CMS with these comments. If you have any questions or concerns, please feel free to contact me at: (718) 338-7878 or pkesselman@pol.net

Sincerely,

A handwritten signature in black ink that reads "Paul Kesselman DPM FACFAS". The signature is written in a cursive, flowing style.

Paul Kesselman DPM FACFAS

Submitter : Mrs. Betty Kasparie
Organization : Denman Services, Inc.
Category : Other Health Care Provider

Date: 10/01/2007

Issue Areas/Comments

GENERAL

GENERAL

As a small rural provider, we ask CMS to ensure new regulatory requirements do not create an additional financial burden for compliant providers.

2. Denman Services, Inc. has had the following suspension thru no fault of their own:

The incident occurred when Denman Services, Inc. submitted a Medicare renewal application. NSC personnel misplaced the documentation, but indicated that their tracking system showed the information had had been received. However, since they were unable to locate the documents, the license was suspended for a period of time until resolution.

This situation was not the fault of the Supplier. So would it be the intent of your description above to increase the surety amount for each occurrence when the situation was not the fault of the Supplier. There needs to be some exception for these types of situations. If there is going to be a surety bond requirement, you categorize the suppliers by risk.

3. Recommendation if there is to be a surety bond requirement:

Current Medicare enrolled DMEPOS suppliers that do not have prior history of criminal, civil, or administrative sanctions for billing related problems should be excluded from obtaining the surety bond.

"New DMEPOS suppliers applicants, not new locations, that have no prior billing history with the Medicare program would be required to carry a surety bond for 5 years to establish a pattern of compliance, then they would no longer be required to carry such a bond, if there are no sanctions.

"Current DMEPOS suppliers with a prior history of sanctions for billing related problems would be required to obtain a surety bond as a part of the CIA to cover an appropriate amount per sanction. This should be required of all DMEPOS. The surety bond amount should be increased based on the amount of the dollar violation.

Impact

Impact

1. The continued addition of regulatory requirements is pushing small rural suppliers out of the market, not just the bad players. This creates a hardship for customers in the small rural markets.

2. The current language may penalize suppliers through no fault of their own.

3. Limit the cost to the higher risk providers.

Provisions

Provisions

1. Who the rule applies to 2. The statement, 'We are considering a \$65,000 increase in the surety amount for each occurrence when a DMEPOS supplier has a final adverse action as specified in section 221(g)(1)(A) of the Health Insurance Portability and Accountability Act of 1996. Examples of final adverse actions include, but are not limited to, Federal and State criminal convictions related to the delivery of health care items or service, formal or official action, such as revocation or suspension of a license, and exclusion from &'. is a concern. 3. Recommendations for categorizing surety bond requirements.

Submitter : Ms. Debbie Garza
Organization : Walgreen Co.
Category : Health Care Industry

Date: 10/01/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-159-Attach-1.DOC



Government and Community Relations Department

October 1, 2007

Submitted Via eRulemaking

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

RE: 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:

Walgreen Co. together with its home care and mail service division, Walgreens Health Services (collectively, "Walgreens"), are writing to comment on the proposed rule concerning the surety bond requirement for suppliers of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"). Through its more than 6,000 home care, mail service and retail pharmacy locations, Walgreens is a leading supplier of DMEPOS to Medicare beneficiaries, including diabetic testing supplies, crutches, canes and IV drugs requiring a pump for infusion.

Medicare 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 CMS should align its regulatory priorities in order to ensure beneficiary access to DME products while diligently protecting program resources.

Background

CMS is seeking comments on a proposed rule that would require DMEPOS suppliers 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 mandated by Congress under 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.

By 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. 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 bond 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 bond coverage.

Discussion

The Proposed Surety Bond Requirement Risks Limiting Access to DMEPOS Suppliers without Advancing CMS's Goal of Reducing Fraudulent Practices

Walgreens strongly supports all efforts to curtail fraud and abuse in the Medicare DMEPOS benefit. We are concerned, however, that the proposed rule will increase suppliers' costs and paperwork burdens without accomplishing the goal of reducing fraudulent practices – a goal shared with CMS by all legitimate DMEPOS suppliers. CMS's own analysis shows that the requirement to obtain a bond will collectively cost suppliers approximately \$198 million annually. Not surprisingly, CMS's 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's data show that in 2005 there were roughly 16,000 suppliers who billed the Medicare program less than \$1,000. There were also more than 13,000 suppliers who billed between \$1,000 and \$4,999. Given that these suppliers are not likely to recover the cost of the bond (estimated by CMS to be at least \$2,000 each) from their Medicare business, CMS believes that many of them may decide not to obtain a bond and, as a result, will lose Medicare billing privileges. In all, CMS predicts that as many as 15,000 suppliers currently enrolled in Medicare would stop serving Medicare beneficiaries, 22% of which would come from rural areas.

If these costs were likely to lead to substantial reductions in program fraud, Walgreens would wholeheartedly support them. However, we are concerned that the proposed surety bond requirement does not substantively strengthen program integrity for the DMEPOS benefit and may be duplicative of other initiatives which CMS has not fully implemented, including the requirements that suppliers meet quality standards and become accredited. Requiring suppliers to obtain a surety bond as a condition of Medicare enrollment may deter some simplistic fraudulent schemes, but it is unrealistic for CMS to expect that it will eliminate the most insidious type of fraudulent suppliers, such as those recently identified in Florida -- entities that superficially display the indicia of legitimate businesses but that in reality exist simply to bill Medicare for services that

are not actually rendered to beneficiaries. To such malevolent entities, the costs of the surety bond requirement are minimal and quickly recovered through their fraudulent billings. But to the thousands of reputable DMEPOS suppliers, the costs of the surety bond requirement could easily overwhelm the benefits of their continued participation as a Medicare supplier and force them out of the program.

CMS contends that any loss of access suffered by beneficiaries as a result of the surety bond requirement will be offset by other suppliers remaining in the program (for example by mail order or via the World Wide Web). While mail-order and web-based suppliers play an important role in the provision of DMEPOS items, CMS should not cavalierly assume that these suppliers can satisfactorily meet the needs of all Medicare patients. For example, many diabetic patients choose to obtain their testing supplies from retail community pharmacies, not only for the convenience that such locations offer but because they have decided that they can most effectively manager their condition through face-to-face consultations with pharmacists. Time and again, data shows that interaction with a pharmacist is critical in increasing drug therapy compliance and early detection of diseases for diabetic patients. Thus, by relying ever more on mail order and on-line suppliers, CMS is depriving patients of the opportunity to consult with a pharmacist while obtaining their DMEPOS items, thereby resulting in increased patient non-compliance, delayed identification and treatment of diseases, and, ultimately, increased healthcare costs for everyone.

The DMEPOS Supplier Accreditation Initiative Can Be Used to Satisfy the Goals of the Surety Bond Requirement

CMS is presently in the process of implementing a supplier accreditation program. While this program is initially mandatory only for suppliers participating in the first round of the Part B competitive acquisition program, it rapidly will expand to apply to all Part B DMEPOS suppliers. It is duplicative and costly for DME suppliers to spend a significant amount of money on accreditation and then also have to spend additional monies for a surety bond. The DMEPOS supplier accreditation process is aimed at determining whether a supplier is legitimately able to provide high quality services to beneficiaries and whether it has in place the policies and procedures necessary to comply with the programmatic requirements necessary to ensure that only valid billings are submitted for reimbursement. Thus, the accreditation program tracks the goals of the surety bond program. In the event a supplier is found to be unable to demonstrate appropriate billing controls, its accreditation – and, therefore, its Part B billing privileges – could immediately be suspended. Thus, we recommend that, at a minimum, CMS delay implementation of the surety bond requirement until the accreditation program is rolled out for all suppliers and its effects at reducing inappropriate billings can be thoughtfully analyzed.

Surety Bond Requirements Should Be Tailored to Apply Only to Suppliers at Higher Risk of Engaging in Inappropriate Billing

While we believe that the surety bond requirement should be delayed in its entirety pending review of the effects of the DMEPOS supplier accreditation program, should CMS decide to move forward with that requirement sooner, we strongly recommend that it be targeted through a “risk-based” system so that only those suppliers that are likely to cause inappropriate billings must obtain surety bonds. With this in mind, we recommend that the surety bond requirement be implemented with the following characteristics:

1. Suppliers that have no prior history with the Medicare program should be required to secure a surety bond

Because these suppliers are unknown to Medicare, prudence dictates that they be subject to submitting a surety bond. However, it is important for CMS to recognize that many “new” suppliers are in reality additional locations for existing large suppliers. For example, Walgreens, like many chain suppliers, opens many new retail pharmacies and other home care locations every month and each location requires its own supplier number. However, because all such locations are subject to Walgreens policies and procedures, they should not be treated as “new” suppliers.

2. Suppliers that have engaged in material questionable billing practices in the past should be required to secure a surety bond

Requiring surety bonds from providers that have engaged in questionable billing practices best ensures that CMS will have the ability to recoup future losses resulting from improper payments. Moreover, it is fundamentally fair to subject a supplier that has not demonstrated appropriate compliance with Medicare billing requirements to the additional costs and burdens of securing a surety bond. We caution, however, that in determining the materiality of any billing practice, CMS must take into account the overall size of the supplier and the total number of supplier locations it operates. What might be a significant error for a smaller provider, and evidence of a significant breakdown in its internal controls, could be a relatively insignificant and isolated error for a much larger, chain supplier. CMS should calibrate its criteria for identifying questionable billing practices to take into account these differences in supplier scope.

3. Publicly traded chain suppliers should be exempt from the surety bond requirement

Large, publicly traded suppliers generally can be expected to have adequate resources to refund any Medicare payments they receive in error. In addition, such suppliers are already heavily regulated by virtue of the fact that they are subject to the laws and regulations surrounding publicly traded companies.

4. Suppliers licensed as pharmacies should be exempt from the surety bond requirement

DMEPOS suppliers that are licensed as pharmacies (together with the pharmacists that work in their facilities) are already subject to numerous, rigorous federal and state standards, including:

- licensure requirements for state boards of pharmacy, which permit the denial or revocation of a license for an entity not capable of providing services in a satisfactory manner
- state pharmacy board rules of conduct, which permit the imposition of serious discipline for violation of state fraud, waste, and abuse laws
- Drug Enforcement Administration requirements regulating the issuance of permits to dispense controlled substances

The oversight provided by these agencies -- which extends uniquely and only to licensed pharmacies -- provides assurance to CMS that pharmacy DMEPOS suppliers are operating in compliance with Medicare billing requirements that is much more effective than the proposed surety bond requirement. Indeed, the remedies available to state boards of pharmacy and the Drug Enforcement Administration can effectively force a supplier out of business if it engages in fraudulent activity. In effect then, these agencies work as adjuncts to CMS in the enforcement of Medicare program requirements relating to licensed pharmacies. This additional scrutiny to which licensed pharmacies alone are subject obviates the need for them to obtain surety bonds.

In addition, the thousands of individual pharmacists that work for chain pharmacies have no incentive to overcharge Medicare or commit fraud and abuse. Such pharmacists' compensation is not tied to the volume of Medicare prescriptions filled or DMEPOS items furnished. And their own licenses to practice pharmacy, and with them their livelihoods, would be jeopardized by engaging in fraudulent billing practices. Thus, these pharmacists, who actually are incentivized to detect and prevent fraud and not to commit it, also act as front-line, anti-fraud personnel for CMS.

Because of these safeguards, DMEPOS suppliers that are licensed pharmacies should be exempt from the surety bond requirement.

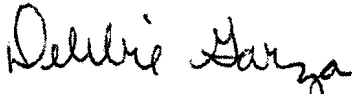
Conclusion

Walgreens stands ready to work with CMS and all interested parties in preventing fraud, waste, and abuse from diluting the scarce resources needed to provide care for our country's senior citizens. However, we urge CMS not to apply bluntly a surety bond requirement to all DMEPOS suppliers. The costs of such an action -- in terms of lost supplier capacity and the resulting patient disruption -- far outweigh the limited benefits that might result from the surety bond requirement. Accordingly, we first urge CMS to

delay implementation of the surety bond requirement until it has had an opportunity to assess the effectiveness of the new, comprehensive accreditation requirement for DMEPOS suppliers. Following that, if CMS believes that a surety bond requirement is necessary, we urge the application of that requirement only to those suppliers that do not have an established, clean track record with respect to Medicare billings and that are not subject to other regulatory requirements that will otherwise provide assurance of compliance.

We appreciate the opportunity to comment on these important matters.

Very truly yours,

A handwritten signature in cursive script that reads "Debbie Garza".

Debbie Garza, R.Ph.
Vice President, Government and Community Relations
202-393-0414
debbie.garza@walgreens.com

Submitter : Mrs. Laraine Forry
Organization : Air Products Healthcare
Category : Other Health Care Provider

Date: 10/01/2007

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

Submitter : Mr. Eric Sokol
Organization : Power Mobility Coalition
Category : Health Care Provider/Association

Date: 10/01/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachement.

CMS-6006-P-161-Attach-1.TXT

The Power Mobility Coalition

WORKING TOGETHER FOR FREEDOM AND INDEPENDENCE

#161

October 1, 2007

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

RE: CMS-6006-P

Dear Administrator Weems:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of suppliers and manufacturers of power mobility devices (PMDs), we are writing in response to the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) in the August 1, 2007 Federal Register entitled *Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)*. 72 Fed. Reg. 42001-42011. This proposed rule would implement Section 4312 of the Balanced Budget Act of 1997 (BBA) (P.L. 105-33) by requiring that each Medicare enrolled DMEPOS supplier obtain a surety bond for each National Provider Identifier (NPI) from an authorized surety. The surety bond or government security must be in the amount of \$65,000.

CMS has issued this proposed rule to (i) limit the Medicare program risk to fraudulent DME suppliers; (ii) 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; (iii) 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 (iv) help ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DME suppliers. 72 Fed. Reg. 42001.

The PMC supports efforts to strengthen program safeguards and eradicate fraud and abuse from the Medicare program. Toward this end, the PMC has long advocated mandatory accreditation and increased supplier standards to be imposed on suppliers who do business with the federal government. A surety bond requirement, if implemented correctly, will add an additional layer of accountability and provide a further deterrent to nefarious actors who are only interested in ripping off the Medicare program and perpetuating fraud on American taxpayers.

The PMC supports a surety bond requirement and offers the following comments to further protect the Medicare program and honest, law abiding suppliers.

Bond Amounts Should Not be Forfeited until Final Determination of Supplier Liability

DMEPOS suppliers are subject to several different types and levels of scrutiny including prepayment and post payment audits. This often involves questions of medical necessity, lack of documentation or some other procedural issue. In a vast majority of these cases, initial denials are overturned during the appeals process. Underwriters should not be required to reimburse CMS for any overpayment until the supplier appeal rights under the law have been exercised, supplier liability for the claim is firmly established, and the supplier is past due on repayment.

Small Suppliers Should Have Access to SBA Loans to Help Secure a Surety Bond

Small suppliers are vital to ensure beneficiary access to quality DME, especially in rural and underserved areas. Yet the costs and burdens associated with obtaining a surety bond fall disproportionately on small suppliers with limited revenues, high costs and lower patient volumes. To ensure small supplier participation with the bond requirement, the PMC recommends that CMS work with the Small Business Administration (SBA) to extend low or no interest loans to qualified small DMEPOS suppliers for the exclusive purpose of obtaining a bond.

CMS Must Meet with Underwriters Prior to Implementation to Ensure they Will Issue Bonds

CMS has tried several times to implement a bond requirement on Medicare partners with limited success. An effort taken several years ago to bond home health agencies (HHAs) was deemed unenforceable after sureties refused to underwrite bonds for any HHAs regardless of payment history. To ensure underwriter participation, CMS must vet bond requirements with the sureties prior to implementation and make any revisions necessary so that DME suppliers can qualify for bonds at the market rate which, according to the proposed rule, should be 2-3% of the forfeiture amount.

Adverse Actions under the Bond Requirement Needs to be Specifically Defined

CMS needs to specifically list all actions that will result in an increased bond amount. Even the most scrupulous suppliers can be subject to overpayments, federal investigation or corporate integrity agreements. On their face, these may seem like “adverse actions,” yet many lawful

suppliers, with sound payment and repayment histories, are subject to these determinations. To ensure that lawful suppliers are not unfairly penalized, CMS must list (with an opportunity for public comment) all instances deemed as “adverse actions” that will subject the supplier to elevated bond payments.

PMD Industry Standards Require In-Home Assessment

CMS declared the following in the proposed rule:

We estimate that as many as 15,000 DMEPOS suppliers, or 23 percent of the 65,984 entities, and 15 percent (or 17,471) of the 116,471 individual suppliers currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries if this proposed rule is implemented. We believe that approximately 22 percent of the 15,000 DMEPOS suppliers are located in rural areas. We further believe that most, if not all, of the Medicare business conducted by these DMEPOS suppliers would be assumed by other DMEPOS suppliers remaining in the program (for example, by mail order or via the World Wide Web).

72 Fed. Reg. 42008.

The assumption of business by mail order suppliers is inappropriate with regard to the power mobility industry. Suppliers of PMDs are already required to conduct an in-home assessment, thereby making internet or nationwide mail order suppliers a non-viable substitute for PMD suppliers, as contemplated by the proposed rule.

CMS Needs to Fully Implement Mandatory Accreditation

As part of the Medicare Modernization Act, Congress passed a number of provisions designed to eradicate fraud in the Medicare DME benefit and to specifically strengthen the supplier enrollment process. It has been close to a year since CMS has finalized these DME quality standards and named the nationally recognized accreditation bodies. Yet, CMS has not yet required that suppliers need to be accredited by a date certain. Instead, CMS is requiring just those suppliers who are submitting bids for the initial round on competitive bidding to be accredited, leaving a majority of DME suppliers with no accreditation requirement.

At a minimum, the PMC feels that CMS should immediately require all DMEPOS suppliers to be accredited as a condition of the issuance or renewal of a Medicare supplier number. An accreditation mandate will make sure that suppliers are legitimate players before they are given a supplier number and allowed to bill the Medicare program.

As always, the PMC thanks you for the opportunity to submit comments and looks forward to working with CMS and all interested stakeholders on these important issues.

Sincerely,

Eric W. Sokol
PMC Director

Stephen M. Azia
PMC Counsel

Submitter : Mr. Ronald Grousby

Date: 10/01/2007

Organization : Mayo Clinic

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-162-Attach-1.DOC

September 28, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6006-P
P.O. Box 8017
Baltimore, Maryland 21244-8017
<http://www.cms.hhs.gov/eRulemaking>.

We appreciate the opportunity to comment on the Proposed Rule of August 1, 2007 regarding Surety Bond Requirements for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

The following comments are offered for your consideration

Provisions

We agree that establishing a surety bond requirement for DMEPOS suppliers with an adverse history who pose a risk to the Medicare program would help to prevent risk of fraudulent activity and potential overpayments due to abusive billing practices. CMS should not require surety bonds for suppliers who do not pose any risk to the Medicare program. We believe that proof of current DMEPOS accreditation status or a clean history of billing activities should warrant a provider in good standing and eliminate the need for this burdensome and costly requirement. We also encourage CMS to establish an exception for rural DMEPOS suppliers. Many rural suppliers are furnishing items to patients in rural locations who would otherwise not be able to obtain such items or services.

CMS proposes to establish elevated risk and elevated bond amounts by classifying DMEPOS suppliers into the categorical approach noted below. We support the need for a surety bond for category 3, and agree "adverse history" of criminal, civil, or billing problems warrants an elevated amount of required surety. However, we do not agree with categories 1 and 2 falling into an elevated risk category. Category 2 suppliers should be excluded from a bond requirement. In addition, Category 1 suppliers should not be subject to a bond requirement when anticipated revenue does not cover the cost of the bond.

Category 1: New DMEPOS supplier applicants that have no prior billing history with the Medicare program

Category 2: Current Medicare enrolled DMEPOS suppliers that do not have any prior history of criminal, civil or administrative sanctions for billing-related problems

Category 3: Current Medicare enrolled DMEPOS supplier with a prior "adverse history" of criminal, civil or administrative sanctions for billing-related problems

We are concerned about the current timeframe for submission of the bond. The proposed rule states enrolled DMEPOS suppliers that do not meet the criteria for exceptions must submit an initial surety bond no later than sixty days following the publication date of the final rule. Due to the fact many suppliers have multiple DME locations and multiple supplier billing numbers, the sixty days may not be adequate timeframe to obtain and submit multiple surety bonds. CMS should extend the timeframe to secure and submit the surety bond to six months following the publication of the final rule which will allow suppliers to perform internal analysis to determine whether or not to obtain the surety bond or to cease enrollment as a DMEPOS supplier.

Impact

According to the proposed rule, CMS anticipates that many DMEPOS suppliers will elect to cease their enrollment in Medicare business because the bond costs could exceed profits from billing for Medicare-covered items. It was noted in the proposed rule that the average bond cost is approximately \$2000. We believe many small suppliers furnish items occasionally for convenience of their patients. These small suppliers, particularly those located in rural areas may not be able to remain in business because the costs would exceed the dollar amount billed to Medicare annually. In addition, all DMEPOS suppliers are also required to enlist accrediting agencies to accredit the DMEPOS supplier. The cost of the surety bond and the accreditation costs will surely eliminate most, if not all, small or rural DMEPOS suppliers.

While we agree surety bonds could help to ensure the government recoups money from DME suppliers who default on their obligations to the Medicare program, we do not believe the surety bonds are needed for Medicare enrolled suppliers that have not had prior history of criminal, civil or administrative sanctions for billing related problems. The burden associated with the requirements, time and effort obtaining and submitting the bonds as well as the costs for purchasing the bonds are unnecessary burdens on businesses that have not posed risk to the Medicare Trust Fund.

Thank you for the opportunity to comment. We sincerely appreciate your consideration of these comments. Please contact either Mollie Brooks (480) 301-4090 or me at (507) 284-4627 if you have any questions.

Very truly yours,

Ronald Grousky
Medicare Coordinator
Mayo Clinic

cc: M. Brooks

Submitter : Mr. Matthew Rowan
Organization : Health Industry Distributors Association
Category : Other Association

Date: 10/01/2007

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment

CMS-6006-P-163-Attach-1.DOC



HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

Serving Medical Products Distributors Since 1902

October 1, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6006-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Surety Bond Requirement for DMEPOS Suppliers; File Code CMS-6006-P

Dear Administrator Weems:

Thank you for the opportunity to comment on your proposed rule regarding surety bonds for DMEPOS suppliers. I am writing to you on behalf of the Health Industry Distributors Association (HIDA) and its 200 member companies. Our members handle over 80 percent of the medical products distributed through the healthcare supply chain. HIDA member distributors fill an essential role in delivering vital healthcare products and services to almost 20,000 long term care facilities.

HIDA supports efforts to protect the Medicare program from fraud and ensure that beneficiaries receive appropriate products and services from legitimate suppliers. However, surety bonds are not necessary and would add another layer of burden and cost to suppliers already struggling to meet additional CMS requirements. A summary of HIDA members' concerns follows:

1. Suppliers in established good standing with Medicare should not be required to provide a surety bond.

CMS should include grandfathering provisions for suppliers that meet the Medicare Part B DMEPOS Competitive Bidding Program requirements or that have no prior adverse history with Medicare. CMS and its contractors have already vetted these suppliers before issuing billing numbers. These suppliers have already demonstrated the desire and ability to serve Medicare beneficiaries by providing reasonable and necessary medical products and services.

2. DMEPOS Competitive Bidding accreditation and financial standards requirements already serve the type of purpose the proposed rule seeks to accomplish. The surety bond requirement is a duplicative measure.

Many HIDA members have achieved accreditation, submitted their bids for the Competitive Bidding Program, and are now subject to potential additional costs without knowing if they are going to be awarded a contract as a winning supplier. Financial standards for the Competitive Bidding Program are already a significant burden for suppliers. In order not to place undue hardships on DMEPOS suppliers, both of these initiatives should be analyzed, coordinated, and reconciled prior to implementation.

3. The impact of a surety bond requirement, when combined with accreditation and financial standards requirements, is an anti-competitive barrier to entry for small businesses.

As CMS essentially laid out in the proposed rule, both the proposed surety bond requirement and competitive bidding are designed to "thin the herd" of DMEPOS suppliers:

- As of April 2007, CMS indicated there were 116,471 individual DMEPOS suppliers with only 65,984 unique billing numbers – this was before competitive bidding started.
- CMS believes that most of the 13,836 suppliers with allowed charges between \$1,000 and \$4,999 would not recoup their bond costs from Medicare business.

- In addition, in 2005, approximately 15,800 suppliers billed Medicare for less than \$1,000 – CMS believes that almost all of those suppliers would cease enrollment in Medicare because their bond cost would exceed their profit.
- In the end, CMS believes that 32-33,000 suppliers will cease providing DMEPOS items to Medicare beneficiaries as a result of this rule, including many in rural areas. CMS stated that it believes that mail orders and internet orders could cover the loss of suppliers.

Generally speaking, larger companies will be able to secure bonds at more favorable rates than smaller companies. Additionally, the larger the volume a company does, the easier it is for them to amortize the cost of the bond over the units of goods sold. The net effect of this would be to provide a competitive advantage to larger companies.

In addition, it may be extremely difficult for many smaller suppliers to secure bonds. The average HIDA member is a small, local business with annual revenues of between \$3-5 million. **We share the concerns that the Small Business Administration expressed in its September 13, 2007 letter to Administrator Weems and CMS (see http://www.sba.gov/advo/laws/comments/cms07_0913.html).** **We are especially troubled by the lack of analysis of the proposed rule's impact on small suppliers and Medicare beneficiaries.**

4. Requiring a surety bond is a change in scope that will increase the cost of doing business for DMEPOS Suppliers.

CMS should not create a competitive bidding environment and then separately impose additional requirements that increase costs to suppliers without compensating them. If surety bonds are required, the cost should be factored in with the Competitive Bidding Program; in some cases, it is too late to do this.

CMS should either (1) delay further expansion of the Competitive Bidding Program until this issue is determined so that bidders may adjust their prices accordingly, or (2) allow provisions so that bidders who have submitted bids prior to the implementation of the bonding requirement may have their prices adjusted accordingly when the bonding requirement is implemented.

5. CMS must use methods currently in place to inspect, audit and monitor suppliers.

CMS should focus on effectively using current methods that are already in place to detect fraud and abuse. The primary responsibility of Program Safeguard Contractors is to detect and deter fraud and abuse in the Medicare program – they should be held accountable. The National Supplier Clearinghouse, which is responsible for distributing Medicare supplier numbers, must do a better job of determining which companies are legitimate and should be issued a supplier number. In addition, current and upcoming accreditation and financial standards requirements of the Competitive Bidding Program will also help weed out unscrupulous suppliers.

In conclusion, HIDA strongly supports targeting fraud and abuse and preventing fraudulent suppliers from entering the market, but there are better ways to accomplish such a goal. Some measures are currently in place and need to be reexamined for effectiveness. This proposed rule is one more step that will make it more difficult for DMEPOS suppliers that have been serving Medicare beneficiaries for years to continue to do so. We urge CMS to take a close look at the totality of recent efforts and proposals and evaluate which methods are meaningful and cost-effective to best serve Medicare patients.

Sincerely,



Matthew J. Rowan
President & CEO

Submitter : Mary Ann Wagner
Organization : National Association of Chain Drug Stores
Category : Health Care Professional or Association

Date: 10/01/2007

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-6006-P-164-Attach-1.DOC

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

Re: 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 National Association of Chain Drug Stores (NACDS) represents the nation's leading chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 38,000 pharmacies, employ 114,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of nearly \$700 billion. NACDS members are the primary providers of Medicare Part D prescription drugs and services, in addition to supplying Medicare Part B medications, durable medical equipment, and other supplies. We appreciate the opportunity to comment on the above referenced proposed rule requiring a \$65,000 surety bond from DMEPOS suppliers, as a condition for the issuance or renewal of their provider number.

CMS has solicited comments on whether large, publicly traded chain suppliers of DMEPOS should be exempt from the rule. *See* 69 Fed. Reg. 42004. We believe that CMS' definition of "chain suppliers of DMEPOS" includes chain pharmacies and that they should be exempt from the surety bond rule in consideration of the licensing and regulatory requirements they already comply with. NACDS further urges that this exemption be broader than only "large" or "publicly traded" chain suppliers, and in fact, *all* state licensed chain pharmacies should be exempt from the surety bond requirement. CMS has also requested comments on whether licensed pharmacists who furnish DMEPOS items for the convenience of their patients should be exempt from the surety bond rule. *See* 69 Fed. Reg. 42004. We believe that *all* state licensed pharmacists should be exempt from the proposed rule, in consideration of their education and training, state licensure requirements and the integrity they bring to the DMEPOS program.

The surety bond requirement would be superfluous as applied to state licensed chain pharmacies and pharmacists given the numerous state and federal regulations they are required to comply with. More importantly, requiring surety bonds from state licensed chain pharmacies and pharmacists could jeopardize Medicare patients' access to important DMEPOS items and create severe economic hardships for community pharmacies that provide DMEPOS items to Medicare beneficiaries.

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I. All state licensed chain pharmacies should be exempt from the surety bond rule

State licensed community chain pharmacies do not pose any threat to the integrity of the Medicare DMEPOS program. First, community chain pharmacies are licensed by the states and must comply with state and federal laws regulating dispensing and delivery of pharmacy services. Second, unlike other DME suppliers, pharmacists are present in community chain pharmacies to deliver DMEPOS services and deter fraudulent practices. Finally, employees at chain pharmacies have no incentive to engage in fraudulent billing practices. These attributes are common to all community chain pharmacies, regardless of their size or whether they are “publicly traded.” NACDS therefore urges CMS to create an exception for chain pharmacies of all sizes and not just those that are “large” or “publicly traded.”

A. State licensed chain pharmacies operate in a highly regulated environment

Unlike other DMEPOS suppliers, community pharmacies are licensed by the board of pharmacy of their respective states. 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. No other type of DME supplier is required to undergo this additional layer of scrutiny. State licensed chain pharmacies currently operate more than 38,000 pharmacies. Each one of these over 38,000 stores, represented by NACDS, has satisfied strict state and board of pharmacy licensing requirements.

State licensed chain pharmacies also closely monitor the HHS Office of Inspector General (OIG) exclusion list to ensure that excluded providers are not involved in delivery of Medicare services. The OIG exclusion list provides timely information on healthcare providers that have been barred from federal healthcare programs for their failure to abide by CMS’ regulations.

B. Presence of a pharmacist at the pharmacy reduces fraudulent practices and saves Medicare resources

State pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the operation of that pharmacy in compliance with the applicable laws and regulations. The state pharmacy laws, depending on the state, identify this pharmacist as the pharmacist-in-charge (PIC) or the pharmacist manager. Other non-pharmacy suppliers of DMEPOS are not required to maintain supervision by a state licensed pharmacist. Allowing continued access to DMEPOS items through a pharmacy provides this additional measure of safeguard to the Medicare program that is not available in other settings.

Further, the presence and involvement of a licensed pharmacist provides patients the chance to discuss proper use of the DMEPOS items and other drugs with their pharmacists. For Medicare beneficiaries, purchase of DME items in a pharmacy allows the benefit of having a professional healthcare provider available to assist them. Counseling with pharmacist increases patient compliance with medications and improves health outcomes. Such interactions are unique to pharmacies and the benefits of such interactions should not be taken lightly by CMS because it

leads to early awareness and treatment of diseases and translates into substantial savings for the Medicare program.

C. Chain pharmacy employees have no financial incentive to engage in Medicare fraud

Staff Pharmacists, technicians and other employees at community chain pharmacies have no financial incentive to engage in Medicare fraud because their compensation is not tied to the volume of Medicare prescriptions filled or DMEPOS items furnished. Further, chain pharmacies have very effective safeguards in place to ensure that a rogue 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 or reconciliation. These measures are highly effective in preventing Medicare fraud.

D. CMS has other means of recouping losses to the Medicare program from fraudulent suppliers

CMS states that one of the policy goals of the surety bond is to maintain a source of funds for recoupment. NACDS understands that many unscrupulous DMEPOS suppliers are insolvent, which prevents CMS from enforcing monetary penalties and recouping lost funds. Chain pharmacies, on the other hand, do not pose this problem. In the very rare occasion where a chain pharmacy is found in violation of a Medicare law, CMS can levy penalties and effectively recoup Medicare funds. Chain pharmacies have the resources available to satisfy judgments and penalties imposed by CMS. Many chain pharmacies have been in business for decades and have served beneficiaries since the inception of the Medicare program. Requiring a surety bond from chain pharmacies despite their exceptional history of compliance with fraud, waste and abuse laws, and their ability to satisfy judgments, would contradict CMS' intended goals.

Further, Medicare has made significant improvements in detecting and deterring fraud, waste and abuse in program administration. Through the use of program safeguard contractors (PSCs), the Medicare program has been able to identify numerous cases of overpayments and has referred many matters to law enforcement for prosecution. PSCs reported to CMS that, in 2005, they identified overpayments of \$54,673,571 in connection with their investigations. These efforts reveal that programs that do not unnecessarily exclude provider participation show great promise and should be pursued more vigorously. The presence of less burdensome and effective programs further reduces the need for the disruptive and exclusionary surety bond rule.

E. CMS should exempt all chain pharmacies from the surety bond rule without regard to whether they are "large" or "publicly traded"

As mentioned previously, all pharmacies are required to comply with state laws regarding corporate formation, pharmacy and pharmacist licensure, and an array of federal regulations related to delivery of services to Medicare beneficiaries. These and other measures already instituted by CMS should dispel fears of Medicare fraud arising from state licensed chain pharmacies. NACDS is encouraged that CMS appears to understand this and has considered

including chain pharmacies in the group that warrant consideration for exemption from the surety bond rule. However, NACDS is concerned that the inclusion of “large” and “publicly traded” language may prevent CMS from achieving its intended goals.

Many community chain pharmacies are neither “large” nor “publicly traded,” yet they maintain high ethical standards in their pharmacy operations. Many chain pharmacies are smaller and regionally based. Nevertheless, smaller chain pharmacies that are not publicly traded submit to the same licensing and regulatory requirements as their larger “publicly traded” counterparts and as a result, a differentiation is not appropriate.

Further, the filings and regulations pertaining to public trading are not intended to provide security to the Medicare program; rather they are designed to protect the security of investors. On the other hand, the laws and regulations pertaining to pharmacy operations are designed to protect the public at large. Therefore, NACDS urges CMS to provide exception to the surety bond rule for all state licensed chain pharmacies regardless of whether they are “large” or “publicly traded.”

II. State licensed pharmacists should be exempt from the surety bond rule

NACDS believes that the Medicare program benefits tremendously from continued participation of state licensed pharmacists in the delivery of DMEPOS services. Numerous factors such as a pharmacist’s education, licensing and registration, and continued education requirements serve as assurances of pharmacists’ reliability in participating in the Medicare program. Each of these factors is examined briefly below and deserves weighty recognition when CMS issues its final rule. NACDS also suggests that CMS use these factors as the criteria for considering an exception to the surety bond rule for pharmacists.

Further, the surety bond proposal seeks comments on whether “licensed pharmacists who furnish DMEPOS items for the *convenience of their patients*” should be exempt (*emphasis added*). We believe that CMS is correct in identifying licensed pharmacists as the subject of potential exemption from the rule. However, we request that when CMS issues its exception for pharmacists, it should exclude the extraneous language related to “convenience of their patients.”

A. State licensed pharmacists are highly educated and regulated healthcare providers

Pharmacists are among the most trusted professionals in America, and they play an important role in securing the health and wellness of all Americans. The immense confidence the public places in the pharmacist is well deserved. Patients realize that pharmacists serve as the sentinel of trends in diseases, therapy management, drug utilization, compliance and abuse. With their formal education and training, pharmacists are able to provide these services in a unique manner.

Education: Today’s pharmacists are specialists formally trained in the art of patient care. Pharmacists are highly educated to provide counseling to patients and doctors on proper use of drugs and medical devices. Pharmacists must graduate from an accredited pharmacy school and be licensed in the states where they practice pharmacy. All pharmacists are now required to graduate from a Doctor of Pharmacy degree program consisting of a minimum of six years of education,

with two years of pre-pharmacy school and four years of pharmacy school. Today's pharmacy curriculum is extensive and includes clinical training directly with patients to offer advice on their care and training. Pharmacy schools are also aware of the importance of maintaining strong ethical foundations for graduating pharmacists. Pharmacy schools' accreditation standards now require topics on professionalism to be addressed as part the school's core curriculum. The fact that pharmacists are professionals and have a strong ethical foundation should serve as an assurance of integrity for the Medicare DMEPOS program.

State licensure: After graduation from pharmacy school and prior to being licensed, pharmacists must pass the National Association of Boards of Pharmacy Pharmacist Licensure Exam ("NAPLEX"). The state board of pharmacy considers the pharmacist's prior conduct in determining whether the pharmacist should be licensed, despite the fact that the pharmacist may have fulfilled all educational requirements to be granted a degree. In addition, after graduation and licensure, many graduates enter a one- or two-year residency program, thereby making many pharmacists' education an eight-year endeavor.

As part of the pharmacist's licensure, the vast majority of states already require yearly continuing education (CE) courses to help pharmacists stay abreast of changes in the law and regulations affecting their practice, including those related to federal healthcare programs. These courses are designed to help pharmacists improve their patient care skills, recognize problem areas in their professional practice, including how to recognize, avoid and counter fraud and abuse issues. A pharmacist's failure to enroll in CE courses and document compliance with course requirements would subject the pharmacist to board review and possible revocation of their license to practice pharmacy.

State boards of pharmacy monitor pharmacists for compliance with state and federal laws. Pharmacists are given the privilege to provide healthcare services with the understanding that non-compliance with state and federal laws could serve as the basis for revocation of this privilege. The pharmacy and pharmacist licensure laws establish the disciplinary authority of the state boards of pharmacy. Pharmacists are subject to board of pharmacy disciplinary actions against their licenses for a variety of conducts, including fraudulent activities. Other unlicensed, unregulated individuals that sell DMEPOS items do not face similar consequences for violations.

Medicare beneficiaries have the right to contact the state board of pharmacy with concerns or complaints about their local retail pharmacists. As a state consumer protection agency, the state board of pharmacy holds the authority to investigate and penalize pharmacists for any wrongdoing. This consumer protection mechanism does not exist with other non-licensed DMEPOS suppliers.

Today's pharmacist is uniquely qualified to serve as the medication and medical device use expert for advising and counseling Medicare patients and providing advice to other healthcare providers on the use of healthcare products. Pharmacists are ideally situated to provide Medicare patients using diabetes supplies and other DME items with counseling and important information on the proper use of these items. Such qualifications clearly differentiate pharmacists from general unlicensed, unregulated suppliers of DMEPOS. Given the layers of assurances provided by pharmacists' unique education, licensing and practice rules, requiring a surety bond from

pharmacists would be unnecessarily redundant. Thus, NACDS urges CMS to exempt *all* licensed pharmacists that furnish DMEPOS items from the proposed surety bond requirement.

B. CMS' final rule should exempt all licensed pharmacists from the surety bond requirement without the proposed rule's language regarding "convenience of their patients"

Pharmacists deliver services to their patients in many settings and geographies around the country, and always do so for the convenience of their patients. The extent of a pharmacist's DMEPOS business depends on many factors, including the locality of the services and demographics of the patients. For example, pharmacists in states with higher retiree populations may have larger DMEPOS practice than pharmacists who practice in states with lower retiree populations. Thus, whether pharmacists in states with higher retiree population furnish DMEPOS for the "convenience of their patients," or as a larger part of their business should have no bearing on their exclusion from the surety bond requirement. All pharmacists are regulated in an equally strict manner regardless of the character of their DMEPOS business. Thus, CMS should clearly exempt *all* state licensed pharmacists without any reference to the volume or nature of their DMEPOS business. As discussed earlier, pharmacists' education, licensure and practice rules provide an effective measure against fraudulent behavior. CMS' efforts to combat fraudulent activities of unlicensed, unregulated individuals in delivering DMEPOS items is warranted, however, seeking redress from state licensed healthcare providers, i.e. the pharmacists, would be misplaced.

III. Proposed rule will place tremendous burden on pharmacies *and* patients

The proposed surety bond rule stands to create tremendous financial burdens on community pharmacies that furnish DMEPOS items as they already operate on very low profit margins. The impact of the surety bond will not be limited to pharmacies, however. Medicare beneficiaries could experience significant disruptions in care if they are unable to obtain their DMEPOS supplies from their preferred pharmacy providers.

A. Proposed surety bond rule will cause severe economic hardships on community pharmacies

Many community pharmacies that do not have significant DMEPOS business may be unable to withstand the enormous surety bond requirement and may be forced to turn away Medicare patients. The amount of the surety bond required will be higher than total reimbursement realized under Medicare for many pharmacies, including those that have a sizeable DMEPOS business. NACDS understands that as a result of the surety bond requirement, many uncommitted, transient DMEPOS suppliers will choose to stop serving Medicare beneficiaries; however, it may also cause many stable, committed chain pharmacies to do the same because of the costs.

As currently proposed, the surety bond requirement will apply to all pharmacies that seek to obtain or renew their Medicare billing number or National Provider Identifier (NPI). Chain pharmacies have anywhere from a few locations to thousands of retail locations. Some of these retail locations have a more significant DMEPOS business than others; however, they provide the same access to covered DMEPOS items for the convenience of their Medicare patients. Requiring chain retail

pharmacies to pick and choose the stores for which they can afford the surety bond will create confusion for many Medicare beneficiaries, as one store of a chain may not be able to provide the same services as another store. Medicare beneficiaries will have no way to know whether any two retail outlets of a chain pharmacy can provide the same DMEPOS items. The only way to alleviate this concern would be for chain pharmacies to either stop providing all DMEPOS supplies or submit to surety bonds for all store locations and suffer tremendous losses.

B. Reducing Medicare patients' access to DMEPOS items through their preferred community pharmacy creates confusion and potential disruptions in the continuity of their care, and increases healthcare costs

According to CMS' own calculation, up to 15,000 DMEPOS suppliers (22 percent of whom are in rural areas) currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries. CMS envisions that, "most, if not all, of the Medicare business conducted by these DMEPOS suppliers would be assumed by other DMEPOS suppliers remaining in the program (for example, by mail order or via the World Wide Web)." NACDS is concerned that such a simplistic calculation does not reflect the true extent of the outcome. Many DMEPOS suppliers forced to stop providing services to beneficiaries may be pharmacies that are unable to withstand the high surety bond costs. However, the impact will not be limited to the pharmacies. Medicare beneficiaries would have their access to DMEPOS items severely limited. Further, reducing Medicare patients' access to DMEPOS items through their preferred community pharmacy could undermine patient therapy compliance and jeopardize their health.

The preference beneficiaries show for community pharmacies is rooted not only in convenience, but also in the reliable, consistent access to their medications and supplies, and pharmacists' professional counseling community retail pharmacies provide. For example, consider the needs of a diabetes patient. Currently, Medicare Part B provides beneficiaries with access to glucose monitors and test strips that are necessary for the at-home monitoring of blood glucose. Self-monitoring of blood glucose levels with glucose monitors and test strips is a critical aspect of managing both type 1 and type 2 diabetes. The proposed rule would force a patient who prefers a community pharmacy for all of his/her diabetes care needs to obtain Part B diabetes testing supplies from a mail order pharmacy and Part D insulin and/or oral diabetes drugs from the preferred local pharmacy. Requiring patients to visit and coordinate with multiple suppliers and pharmacies for their healthcare needs would cause tremendous disruptions and frustrations for patients and their providers.

By going through the mail order or on-line supplier, Medicare beneficiaries will be precluded from the opportunity to consult with a pharmacist of their choice while obtaining their DMEPOS items. Time and again, data shows that interaction with a pharmacist is critical in increasing drug therapy compliance and early detection of diseases. The surety bond rule is likely to reduce such pharmacist-patient interactions, resulting in increased patient non-compliance, delayed identification and treatment of diseases, and ultimately increased healthcare costs for everyone.

IV. Conclusion

NACDS and our member companies stand firm with CMS in our mutual goal to eliminate fraud and abuse in the Medicare program. CMS should be allowed to use innovative programs to ensure the integrity of the participants in the Medicare program. The surety bond requirement as applied to state licensed pharmacies and pharmacists, however, would not properly achieve this goal.

CMS's solicitation of comments on whether pharmacists and chain DMEPOS suppliers should be exempt from the surety bond rule suggests CMS understands the critical role pharmacists and pharmacies play in delivering Medicare Part B services to beneficiaries. We urge CMS to exempt all state licensed chain pharmacies and pharmacists from the surety bond requirement. We thank you for the opportunity to present our views on this matter. If we can provide any additional information, please feel free to contact me at 703.837.4136.

Sincerely,



Mary Ann Wagner, R.Ph.

Senior Vice President, Policy and Pharmacy Regulatory Affairs

Submitter : Ms. Kate Romanow
Organization : The Orthotic and Prosthetic Alliance
Category : Health Care Provider/Association

Date: 10/01/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6006-P-165-Attach-1.DOC

October 1, 2007

Submitted Electronically To:
<http://www.cms.hhs.gov/eRulemaking>

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS 6006-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: Comments on the Provisions of the Proposed Surety Bond Requirement for DMEPOS Suppliers

Dear Acting Deputy Administrator Kuhn:

The Orthotic and Prosthetic Alliance (the "O&P Alliance") appreciates this opportunity to submit comments on the provisions of the proposed surety bond requirement for suppliers of durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS").

The O&P Alliance is a coalition of four of the primary organizations representing the field of orthotics and prosthetics. The four organizations include the American Academy of Orthotists and Prosthetists ("AAOP"), the National Association for the Advancement of Orthotics and Prosthetics ("NAAOP"), the American Orthotic & Prosthetic Association ("AOPA"), and the American Board for Certification in Orthotics, Prosthetics, and Pedorthics ("ABC"). The O&P Alliance represents the professional, scientific, research, business, and quality improvement aspects within the fields of orthotics and prosthetics (i.e., orthopedic braces and artificial limbs).

On August 1, 2007, the Centers for Medicare and Medicaid Services ("CMS") published in the Federal Register a proposed rule for a surety bond requirement for DMEPOS suppliers (the "Proposed Rule"). 72 Fed. Reg. 42001. CMS proposes to require DMEPOS suppliers that want to enroll in Medicare to obtain a surety bond in the

amount of \$65,000 for each National Provider Number (“NPI”). CMS is proposing this requirement in part to:

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

Id. CMS is also soliciting comments on whether exceptions should be made in certain situations, such as for rural DMEPOS suppliers.

The O&P Alliance supports CMS’s ongoing efforts to prevent and minimize fraud and abuse, and wants to ensure that Medicare beneficiaries have access to high quality orthotic and prosthetic care. This is why the O&P Alliance has encouraged CMS for several years to adhere to the statutes that Congress and the President have already enacted, and link Medicare payment for O&P care to the qualifications of the practitioner and/or supplier. In fact, the O&P Alliance has submitted to CMS a blueprint for action in this area, with delineated levels of complexity of orthotic and prosthetic care being linked to qualifications of practitioners and suppliers.

This paradigm reflects the intent of Congress in Section 427 of the Benefits Improvement and Protection Act of 2000 (“BIPA”), a law that limits payment of certain custom fabricated orthotics and all prosthetics to qualified practitioners and qualified suppliers. It also reflects the underlying intent of Section 302 of the Medicare Modernization Act of 2003 (“MMA”) which calls for quality standards and accreditation for suppliers of durable medical equipment and supplies, as well as orthotics and prosthetics.

Unfortunately, CMS has never issued regulations or implemented Section 427 of BIPA, despite statutory directives that mandate CMS to issue regulations within one year of enactment. In addition, CMS has set the quality standards mandated under the MMA law so low for orthotics and prosthetics that we believe the actual outcome of this law will completely contradict the intent of Congress to limit payment to only those O&P suppliers who are truly qualified to provide such care.

The O&P Alliance believes that this approach—the linking of provider qualifications with the ability to bill Medicare for certain levels of complex O&P care—is far preferable to imposition of a surety bond; an approach that simply imports a durable medical equipment (“DME”)-based, blunt tool to a field of health care that is materially different from the DME field. The provision of orthotics and prosthetics is highly clinical and service-oriented. The training and expertise necessary to provide quality

O&P care differ dramatically from the provision of DME, which usually requires little more than the opening of a store front and securing a Medicare supplier number.

O&P practitioners undergo formal education, extensive hands-on training, clinical residency, and national standardized examinations in order to be designated as qualified by the premier certification and accreditation body in the field. The provision of O&P care requires a clinical setting, patient evaluation and gait assessment facilities, biomechanical laboratories, and often close working relationships with other members of the rehabilitation team.

There is very limited, if any, evidence that the fraudulent and abusive practices that have been uncovered in the DME industry over the years are present in the O&P profession. If anything, recent instances where prosthetic limbs or orthopedic braces have been the subject of fraudulent or abusive activities have been the result of criminal enterprises preying on the O&P benefit, without the involvement of legitimate O&P suppliers. And thwarting these types of criminals can be much better accomplished with implementation of payment edits that deny payment to any supplier that does not meet O&P accreditation certification or state licensure requirements. The payment edits would deny payment in the first place, rather than relying on a surety bond to reimburse the Medicare program after the fact for the first \$65,000 of losses it may pay to unscrupulous "providers." The irony of this is that adequate laws already exist on the books to specifically address this issue and CMS has simply not implemented them. Furthermore, CMS has issued its own publication, Transmittal 656, to articulate that it will not pay any claim filed by O&P practitioners who have not met any applicable state licensure statute in their jurisdiction. However, CMS is still not enforcing Transmittal 656. We strongly believe that if CMS enforced its own Transmittal 656, and implemented existing laws, there would be no need to institute surety bond requirements for orthotics and prosthetics.

Therefore, the O&P Alliance opposes imposition of a surety bond requirement on the O&P field because there are other, more effective, mechanisms at CMS's disposal to accomplish what CMS seeks to achieve through imposition of a surety bond requirement. In fact, these mechanisms generally do not impose additional financial burdens on O&P suppliers as the surety bond requirement does.

The O&P Alliance, therefore, formally requests CMS to exempt O&P suppliers from the proposed surety bond requirement and, instead, implement long-overdue regulations that will impose payment edits on practitioners and suppliers of O&P care such that only qualified providers are permitted to be reimbursed for the provision of O&P services and devices under the Medicare program. CMS is already aware of the unique nature of the practice of orthotics and prosthetics as it has exempted all prosthetics and custom-fabricated orthotics entirely (and off-the-shelf orthotics until 2009) from competitive bidding.

While the O&P Alliance strongly opposes the surety bond requirement for qualified O&P suppliers, we clearly recognize the value of such a requirement for both DME suppliers and non-accredited providers of O&P services that bill Medicare under

the HCPCS “L-Codes,” the codes used to describe orthotics and prosthetics. One of CMS’s reasons for proposing a surety bond is to ensure that the “Medicare program recoups erroneous payments that result from fraudulent or abusive billing practices.” *Id.* To the extent that these providers are submitting claims for O&P care when they do not possess independent validation (i.e., O&P accreditation certification or state O&P licensure) that they are qualified to provide such services, a surety bond requirement is one way to ensure that there is a basic level of protection to the Medicare program.

We recommend that CMS does not require surety bonds for accredited and/or state licensed O&P suppliers. However, if CMS decides to apply the surety bond requirement to all DMEPOS suppliers, it should uniformly apply the requirement to all suppliers, including rural suppliers, physician and non-physician practitioners that occasionally supply DMEPOS, and chain suppliers. If the intent of the surety bond requirement is to ensure a basic level of integrity, quality care, and reliability of DMEPOS under the Medicare program, we fail to see a credible rationale for exempting any supplier that submits claims for orthotics and prosthetics from this requirement.

Thank you for the opportunity to comment on this important issue. As always, the members of the O&P Alliance are available to provide further information or to answer questions. If you have any questions or comments, please contact our counsel, Peter W. Thomas, Esq. at 202-466-6550.

Sincerely,



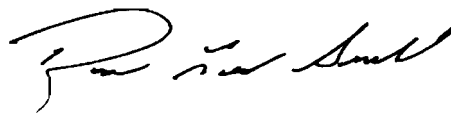
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Date: 10/01/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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