

September 13, 2007

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

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

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

Dear Administrator Weems:

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

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

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<sup>1</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. §612(a).

<sup>2</sup> Exec. Order No. 13,272 § 1, 67 Fed. Reg. 53,461 (Aug. 13, 2002).

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

In the rule's preamble, The Centers for Medicare and Medicaid Services (CMS) states that the public policy underlying this regulation's requirement for surety bonds, among other reasons, is to limit the Medicare program's risk to fraudulent durable medical equipment (DME) suppliers.<sup>5</sup> CMS also notes that, "the vast majority of DME suppliers are small entities (based on Medicare reimbursement alone)."<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> CMS also admits that Medicare beneficiaries will be directly affected by small DME suppliers' decision to leave the program.<sup>9</sup> 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.<sup>10</sup>

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

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<sup>3</sup> E.O. 13272, at § 2(c), 67 Fed. Reg. at 53,461.

<sup>4</sup> *Id.* at § 3(c), 67 Fed. Reg. at 53,461.

<sup>5</sup> The rule was published in the *Federal Register* at 72 Fed. Reg. 42001 (August 1, 2007).

<sup>6</sup> *Id.* at 42007.

<sup>7</sup> *Id.* at 42008.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

## I. CMS's Regulatory Impact Analysis Needs Improvement

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

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

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

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

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<sup>11</sup> 5 U.S.C. §§ 601, et. seq.; Northwest Mining Association v. Babbitt, 5 F. Supp. 2d 9, (D.D.C. 1998).

<sup>12</sup> 5 U.S.C. § 603(a).

<sup>13</sup> 5 U.S.C. § 603(c).

<sup>14</sup> CMS does certify that this rule will not have a significant economic impact on a substantial number of small rural hospitals. 72 Fed. Reg. 42007.

<sup>15</sup> Id.

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

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

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

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

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

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

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

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

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

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

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

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

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<sup>17</sup> 72 Fed. Reg. 42004.

<sup>18</sup> 72 Fed Reg. 42008.

<sup>19</sup> Section 424.57(c)(26)(i)(c) specifies that a DME supplier seeking to enroll a new location must obtain a new surety bond for this new location since this new location is also required to be enumerated with a unique national provider identifier (NPI).

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

3. CMS alleges a benefit to replacing 66,000 TIN numbers, the basic identification element for a DME supplier, with 99,000 NPI (national provider identifier) numbers. However, CMS does not adequately provide the reasoning behind the transition from TIN to NPI and does not analyze the impact of the decision on the DME industry. For example, does the move to NPI actually increase the costs of the regulation because multi-site businesses must now acquire multiple surety bonds?
4. Small DME providers are concerned that the requirements of this regulation may result in increasing costs to small suppliers and reducing costs for large suppliers. According to industry sources, the 1998 proposed DME surety bond rule provided for a sliding-scale approach to the bond for DME suppliers. The surety bond started at \$50,000 and rose to 15% of reimbursements (capped at \$3 million). Advocacy believes that an alternative, a tiered system, will improve the percentage of small suppliers remaining in the market without compromising the public policy objective. CMS should analyze whether a \$50,000 surety bond for small suppliers and \$65,000 for other suppliers would meet its regulatory objective. As a result of this change a more equitable percentage of small suppliers will remain in the market.
5. Some industry representatives note that the proposed rule requires that annual “audited” financial statements be obtained by each organization. Many companies have an external auditing firm provide annual financial statements; and the industry representatives are concerned that the costs associated with obtaining “audited” statements is exorbitant and, they believe far in excess of the government’s intention with the original legislation. They ask that CMS consider that annual financial statements not have the additional requirement of being “audited” statements. This alternative should be analyzed by CMS.

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

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

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<sup>20</sup> 72 Fed. Reg. 42005.

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

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

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

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

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

“HCFA has imposed conditions that go beyond the standard in the surety bond industry. Some of the biggest problems include cumulative liability, a short period of time in which to pay claims, and bond values of 15 percent of the previous year's Medicare revenues with no maximum, the letter said. ‘The cumulative effect is that many surety companies are opting not to offer bonds to Medicare [home health agencies] at all,’ the letter said. ‘Those companies which are offering the bonds are doing so at a cost which is prohibitive, or with demands for collateral or personal guarantees that HHAs cannot provide.’

The letter said Congress enacted the surety bond requirement to keep risky agencies out of the Medicare program. However, HCFA's rule seems to use the bonds as security for overpayments to providers, the letter said.

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<sup>21</sup> 63 Fed. Reg. 10,730 (March 4, 1998).

‘We simply doubt that it is realistic to expect bonding companies to embrace a role as guarantors for overpayments from HCFA,’ the senators wrote.”<sup>22</sup>

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

### Conclusion

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

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

Sincerely yours,

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

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