FOOD MARKETING INSTITUTE

October 1, 2007

Via Courier

Mr. Herb B. Kuhn
Acting Deputy Administrator
The Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) in the Medicare Program; (CMS–6006–P).

Dear Administrator Kuhn:

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement a requirement that suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) furnish CMS with a surety bond (72 Fed. Reg. 42001 (Aug. 1, 2007)). Pursuant to the agency's request for comments about possible exceptions to the surety bond requirement, FMI is writing to support exceptions for licensed pharmacies and large publicly traded chain suppliers.

FMI conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies - food retailers and wholesalers - in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion - three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

FMI's retail members also operate over 19,000 in-store pharmacy departments. We estimate that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward larger store formats and the convenience of one-stop shopping, we anticipate that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

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A. Policy Overview

As we have noted in letters on related topics, FMI applauds CMS for its efforts to ensure that Medicare beneficiaries receive quality DME products and service. Likewise, FMI believes strongly in CMS' quest to reduce Medicare fraud and abuse. However, we believe that the surety bond requirement is not necessary for licensed pharmacies or for large publicly traded chain suppliers. As we discuss in greater detail below, FMI therefore strongly supports exceptions to the surety bond requirement in these two instances.

Our supermarket pharmacy members stock DMEPOS items to provide their customers with convenient access to items such as diabetic testing supplies—access which we believe is important to the health and well-being of many Medicare beneficiaries. With these comments, along with a variety of other efforts, FMI seeks to limit unnecessary requirements that could serve to limit access to DMEPOS items in supermarket pharmacies.

B. CMS Should Finalize an Exception for Licensed Pharmacy Suppliers

FMI believes that the licensure and other requirements to which the pharmacies that supply DMEPOS items are subject provide adequate protection against fraud and abuse. We believe that the imposition of a surety bond requirement on licensed pharmacies would impose unnecessary costs on these suppliers, without a corresponding benefit to the Medicare program. Indeed, the increasing costs of participation as DMEPOS suppliers could cause some pharmacies, particularly those that are small businesses, to determine that they are no longer able to provide DMEPOS items for their customers.

Consequently, FMI supports an exception from the surety bond requirement for licensed pharmacies. We note that the proposed rule discussion of possible exceptions refers to "licensed pharmacists." We assume that any exception to the surety bond requirement would be based on DMEPOS supplier numbers. We believe that CMS should clarify that an exception for "licensed pharmacists" who provide DMEPOS items for the convenience of their patients applies to "licensed pharmacies" based on DME supplier number.

FMI believes that the exception for licensed pharmacies should apply to those pharmacy suppliers that:

- Are duly licensed in their respective states;
- Have not been found to be engaged in fraud or abuse by federal or state authorities; and
- Do not have debts outstanding for more than 90 days that are based on erroneous payments for which all appeals have been exhausted.

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Pharmacies that failed to meet these requirements would then become subject to the surety bond requirement. FMI believes that an exception drafted in this manner would meet the CMS goals of mitigating fraud, enhancing the supplier enrollment process, and ensuring recovery of erroneous payments.

C. CMS Should Finalize an Exception for Large Publicly Traded Companies

Similar to the case of licensed pharmacies, FMI believes that a surety bond requirement is not necessary for large, publicly traded companies. Such companies are subject to significant regulations by the Securities and Exchange Commission (SEC) and a number of other regulatory bodies under a variety of statutory regimes, including the Sarbanes-Oxley Act. The requirements for financial auditing (both internal and external) include the billing and adjudication of DME claims, which would play a major role in preventing fraud, waste and abuse. We believe that these regulations meet the proposed rule's goals of limiting fraud, enhancing the enrollment process, and ensuring the recovery of erroneous payments.

FMI believes that an exception for large, publicly traded, chain suppliers should apply to those suppliers that:

- Have not been found to be in significant ongoing violation of SEC requirements;
- Have not been found to be engaged in fraud or abuse by federal or state authorities; and
- Do not have debts outstanding for more than 90 days that are based on erroneous payments for which all appeals have been exhausted.

D. If Appropriate Exceptions Are Not Adopted, CMS Should Adopt Single Bond Requirement for Suppliers with Multiple Locations

While FMI is optimistic that CMS will adopt appropriate exceptions for licensed pharmacies and large chain suppliers, if the agency chooses to apply the surety bond requirement to these entities, it should allow suppliers with multiple locations the flexibility and reduced expense of a single surety bond at the corporate level. We believe that requiring a full $65,000 surety bond for each location of a chain of supermarket pharmacies would represent an unnecessary expense. Per the agency's regulatory impact analysis, this expense would amount to an additional cost of $2,000 per store—or $2 million annually for a company with 1000 stores.

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E. Conclusion

We look forward to working with CMS on these issues in the future. Please feel free to contact me at 202-220-0631 with any questions you might have.

Sincerely,

/S/

Catherine M. Polley, RPh
Vice President, Pharmacy Services

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