

Written Statement of the Food Marketing Institute

Submitted to the

**HOUSE COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT**

**“COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT:
WILL SMALL SUPPLIERS BE ABLE TO COMPETE?”**

OCTOBER 31, 2007



The Food Marketing Institute (FMI) would like to thank the Subcommittee on Investigations and Oversight for holding this important hearing on the structure of the competitive acquisition program for Durable Medical Equipment, Orthotics and Supplies (DMEPOS). We believe that the program is being implemented in ways that could be harmful to small businesses and to the Medicare beneficiaries these businesses serve. FMI offers the following comments about the DMEPOS program, focusing particularly on the burden of the program on small business as well as the importance of retail access to diabetic testing supplies.

FMI is an association that 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.

Supermarket Pharmacies have an Important Role in the Health and Wellness of Consumers

FMI's retail members also operate over 19,000 in-store pharmacy departments. FMI estimates 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, the association anticipates 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.

Supermarket pharmacies have a unique ability to focus on health care issues in a holistic way. By providing healthy foods, pharmacy access and other on-site health care services, FMI's supermarket pharmacy members meet the health and wellness needs of their customers. In addition to wholesome foods, preventative health items and prescription medications, many of these stores offer durable medical equipment to Medicare beneficiaries, diabetic testing supplies in particular.

The Impact of Competitive Bidding for DMEPOS on Small Businesses

When it mandated that competitive bidding for DMEPOS be implemented, the Congress ordered the agency to consider the impact of the program on small businesses, and to provide special protections for these businesses. FMI does not believe that the CMS protections for small businesses are adequate. The program CMS has designed will produce in most cases perhaps one or two small business suppliers per category in each competitive bidding region. The expenses of accreditation and even the bid process itself will be prohibitive for many small businesses, and a number of the programs CMS is considering (such as the national or regional mail-order program

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for diabetic testing supplies) seem designed to raise the bar against small business entry to the DMEPOS marketplace even higher. The subcommittee will hear important testimony today about the impact of the DMEPOS competitive bidding program on small businesses, and FMI—which represents supermarket and mass-merchant companies from the very small to the very large—wishes to echo these concerns.

The Importance of Retail Access to Diabetic Testing Supplies

FMI was encouraged earlier this year when CMS decided that diabetic testing supplies sold in a retail setting would not be included in the first round of competitive bidding. While these supplies will be subject to competitive bidding in the ten competitive bidding areas when delivered via mail-order, Medicare beneficiaries in these areas will still be able to acquire supplies at retail store if they wish. FMI believes that it is particularly important for Medicare beneficiaries to have continued access to diabetic testing supplies through the retail pharmacies of their choice. The CMS decision to restrict competitive bidding to mail-order is an important step in preserving this access. Furthermore, because Medicare beneficiaries tend to form relationships with individual pharmacies, which can contribute to positive health outcomes for Medicare beneficiaries, FMI believes that it is important for beneficiaries with diabetes to be able to maintain these relationships with their local pharmacy. The policy to limit competitive bidding to mail-order for diabetic testing supplies should be permanent. A competitive bidding program which results in only one or two suppliers in a region providing diabetic testing supplies would prevent many, and perhaps a significant majority of Medicare beneficiaries, from receiving diabetic testing supplies in their chosen retail pharmacies. Accordingly, FMI would urge the subcommittee to encourage CMS to adopt policies which maintain full retail access nationwide as the agency continues to implement competitive bidding.

FMI was particularly concerned by language in the CMS proposed rule implementing competitive bidding suggesting that the agency was considering the potential for “mail only” access to diabetic testing supplies under a national or regional competitive bidding program beginning in 2010. While the agency appeared to back away from this language in its final rule, FMI would urge the subcommittee to carefully oversee the implementation of a national or regional competitive bidding program to ensure that beneficiaries continue to have access to diabetic testing supplies through their neighborhood pharmacies.

Furthermore, FMI believes that any proposed national or regional mail-order program will be of special concern to the subcommittee, since such a program would by definition tend to favor larger businesses.

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Accreditation Issues for Retail Pharmacies

One requirement facing entities wishing to participate in the competitive bidding program is a costly accreditation process. While accreditation will eventually be required of all Medicare suppliers, so far CMS has only set a deadline for suppliers participating in the first round of competitive bidding.

Our members' recent experiences in considering whether to participate in the first phase of the DME competitive bidding program have highlighted the prohibitively expensive and unnecessary accreditation requirements that CMS is imposing on retail pharmacies, first under the competitive bidding program and later as a part of Medicare supplier quality standards. We believe that these requirements could affect Medicare beneficiaries' access to certain categories of DME, particularly diabetic testing supplies.

FMI strongly supports the efforts of Congress and CMS to ensure that Medicare beneficiaries receive quality DME products and services that are not tainted by fraud and abuse. We believe that the quality standards that apply to DME suppliers are important and that a reasonable accreditation system is a sensible way to ensure that these standards are met. However, the current accreditation requirements being applied to retail pharmacies are duplicative and unreasonable. In order to meet the accreditation standards, retail pharmacies are required to undergo extensive site visits and accredit every store in their chains, regardless of whether that store provides DME. The costs of accreditation are especially egregious when compared to the marginal added value of the accreditation. The accreditation requirement duplicates the requirements of state licensure and other government program requirements that apply to licensed pharmacies and thus produces little, if any, extra information for CMS to use in determining whether the pharmacies will meet the "basic good business practices" reflected in the standards.

The accreditation requirements include documentation of appropriate financial, human resource, and information management; evidence of product safety measures; and standards for product preparation and delivery, and beneficiary education. But these requirements simply duplicate requirements that pharmacies must meet to maintain their state pharmacy and Drug Enforcement Agency licenses and to participate in other Medicare programs, such as Part D. For instance, the accreditation process requires that pharmacies be licensed, maintain complex record keeping systems to track activity, customer history and dispensing activity, and operate under the Board of Pharmacy, DEA and other health agency rules and regulations. All of these requirements must be met in order for a pharmacy to receive a state license. Likewise, the DMEPOS accreditation requirement that personnel be licensed matches state licensure requirements that all pharmacists be licensed in the state in which they are practicing.

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Given the high cost of accreditation and the marginal benefit that accreditation brings, FMI urges Congress and CMS to modify the accreditation standards for pharmacies. FMI strongly believes that CMS has the authority and discretion under Section 1834(a) (20) (A) of the Social Security Act, and Section 302(a) (1) of the Medicare Modernization Act of 2003, to exempt licensed pharmacies from the DMEPOS accreditation requirements. However, CMS has stated that it does not agree with our interpretation of these laws.

Therefore, FMI believes that a clarification of the quality standards to exempt pharmacies and licensed healthcare providers is appropriate. FMI has also proposed a compromise to CMS that will continue to promote the aims of the accreditation requirements, namely ensuring quality health care services for Medicare beneficiaries, while reducing some of the accreditation cost burden on licensed pharmacies. FMI has proposed that all suppliers, including pharmacies, continue to be accredited by a CMS-deemed accrediting organization. However, for licensed health care providers, such as pharmacies, the accreditation standards would be modified so that a smaller sample of store locations would be required to undergo site visits, essentially to confirm the work that has already been done by pharmacy licensure organizations. If the accrediting organization finds that the accrediting standards are not being met, a larger sample of stores would then be subject to site visits. Additionally, only those stores that would provide DME items would be required to be accredited. This compromise would allow CMS to ensure that the accrediting standards are met and that Medicare beneficiaries receive quality health care services and products. It also relieves some of the financial burden that accreditation brings, particularly to small businesses.

Conclusion

FMI thanks the subcommittee for holding this important hearing. We are hopeful that Congress and CMS can design a competitive bidding program that provides better protection for DMEPOS suppliers that are small businesses. The current program will undoubtedly reduce the number of small businesses among the ranks of DMEPOS suppliers—both in its general design and through the workings of accreditation requirements that are unnecessarily onerous, particularly for pharmacies and other licensed health care providers.

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