



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



February 2, 2009

Ms. Charlene Frizzera
Acting Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Administration Review of Medicare Regulation Requiring Surety Bond from State-Licensed Pharmacies (CMS-6006-F)

Dear Ms. Frizzera:

The Food Marketing Institute (FMI), the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) urge the Centers for Medicare and Medicaid Services (CMS) to reconsider a recently finalized regulation that creates costly, onerous requirements for community pharmacies and jeopardizes patients' access to necessary healthcare products and services.

On January 2, 2009, the Bush Administration issued a final regulation requiring suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to obtain a \$50,000 surety bond for each enrolled location that serves Medicare beneficiaries. (*See* 74 Fed. Reg. 166, Jan. 2, 2009; effective March 3, 2009). This rule was issued to address fraud and abuse in the Medicare DMEPOS program and to create a pool of funds for recovery of erroneous payments. While we agree with the need to combat fraud in the Medicare program, this rule raises serious policy and administrative concerns that must be addressed by the new CMS leadership before the rule becomes effective.

At a time when policymakers are underscoring management of chronic diseases as a cornerstone of healthcare reform, this regulation will fragment care by depriving patients of the tools necessary in disease management, which will ultimately raise federal healthcare spending. For example, if pharmacies are unable to afford the cost of the surety bonds and participate in the Medicare program, diabetic patients are likely to face difficulties in obtaining their blood glucose testing supplies and pharmacists' counseling to control their disease. Similarly, immunosuppressive patients and those taking oral anticancer drugs are likely to miss their prescribed therapy or medication counseling. According to CMS, over 25,000 DMEPOS suppliers currently enrolled in the Medicare program will stop participating due, in part, to the

cost of the surety bond. While we believe this estimate is very low, even this figure likely includes many pharmacies that would be unable to withstand the high surety bond costs, forcing many chronically ill patients to forego their doctor's recommendations.

Forbearance of physician recommendations will not only lead to deteriorating health outcomes, but it will also dramatically tax the Medicare system with additional costs. Imposing a surety bond will lead to fewer DMEPOS diabetic supplies providers, especially in rural areas. This decreased access to supplies and services, especially when combined with recent DMEPOS programs such as competitive bidding and accreditation, will lead to additional costs to the system. A Milliman study calculates that, for every 1 percent of Medicare beneficiaries that see their glycated hemoglobin (A1C) blood glucose levels¹ increase 1 percent, an additional \$52 million in downstream Medicare costs (e.g., emergency room visits, hospital days, physician visits) will arise.²

The impact of the surety bond rule is not limited to Medicare. Several state Medicaid programs require DMEPOS suppliers to be enrolled in Medicare in order to provide DMEPOS to Medicaid patients. If pharmacies in these states are unable to comply with the surety bond requirement, they will be forced to turn away Medicaid patients in addition to Medicare beneficiaries. Congress did not envision the consequences of DMEPOS surety bonds to be so extensive that they would impede the access of vulnerable populations to needed healthcare.

We question the value of implementing a sweeping surety bond upon all those that provide DMEPOS supplies, when that bond might not deter those that perpetrate fraud upon the program, yet will deter legitimate provision of DMEPOS supplies and services to needy beneficiaries by those that provide the best access to such supplies and services. The Balanced Budget Act (BBA) was enacted almost 12 years ago. In the interim, CMS has made significant improvements in the Medicare enrollment process and has made successful use of prosecutorial tools to combat fraud and abuse. These measures should be further strengthened and pursued to target fraudulent suppliers, instead of forcing the surety bond requirement on legitimate healthcare providers such as state-licensed pharmacies.

The 2007 proposal requested comments on whether pharmacists who furnish DMEPOS for the convenience of their patients and if publicly traded DMEPOS suppliers should be exempt from the surety bond requirement. Although CMS used its discretion in exempting several providers, it did not exempt state-licensed pharmacists and pharmacies despite receiving several comments in support of such an exemption. CMS' justification that exemption of pharmacists and pharmacies is not supported by congressional intent lacks merit. Congress intended surety bonds to be targeted toward suppliers that pose serious risk to the Medicare program, and not legitimate healthcare providers. This principle is implicit in the authority granted to CMS to exempt providers. Unlike unscrupulous suppliers for whom this rule was intended, pharmacies are state licensed healthcare providers who are subject to disciplinary actions from their state boards of pharmacy for engaging in fraudulent behavior, in addition to prosecutions by state and federal authorities. In this regard, pharmacies are no different than physicians, non-physician

¹ Glycated hemoglobin (A1C) is a measure of the average blood glucose control for the past 2 to 3 months.

² Milliman Consultants and Actuaries. CY 2004 spending estimates based on the 2004 Medicare 5% sample files.

practitioners, and others who received an exemption in the final rule. Therefore, we urge CMS to verify whether the previous administration weighed relative risks posed by Medicare providers before imposing on them the surety bond requirement.

In addition to these policy concerns, we urge the new CMS leadership to consider critical administrative issues raised by the final regulation. The rule as finalized is vastly different from the proposals issued by CMS in 1998 and in 2007 to implement the same provision of the BBA. For example, the 1998 proposed rule would have required a surety bond on the basis of a supplier's taxpayer identification number (TIN). In the 2007 proposal and the final rule, however, CMS is requiring that suppliers obtain surety bond for each enrolled NPI. The differences in these two approaches are not merely procedural. Rather, they have significant economic and beneficiary access consequences that must be adequately considered. As TIN was the standard for supplier enrollment in 1997, it is also highly unlikely that Congress would have endorsed the NPI approach.

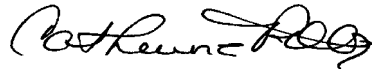
CMS also failed to adequately assess the difficulties that covered entities and the surety bond market are likely to face in complying with the rule. Requiring suppliers with multiple locations to obtain multiple bonds in the amount of \$50,000 will cause many of them to reach their risk ratings for surety bonds. The DMEPOS surety bond would essentially exhaust the company's bonding ability. As a result, many companies will be unable to secure bonds for other aspects of their business, such as performance bonds to streamline and secure new store construction or bonds needed to make other infrastructure or operational expansions. As DMEPOS is a small part of an average pharmacy's business, these burdens are unjustified barriers to pharmacies' ability to remain competitive and serve their patients. As the President seeks to stimulate the economy, these unjustifiable costs will make it exceedingly difficult for pharmacies to expand business, hire more staff or continue providing services to patients. Moreover, it is unclear whether enough capacity exists in the surety bond market to implement a \$50,000 per location bond as required by the final rule. These critical issues were not given sufficient consideration by the former administration to justify moving forward with the regulation.

On January 20, 2009, the White House directed all heads of executive departments and agencies to conduct a review of all new and pending federal regulations. In particular, for regulations that had been published in the Federal Register, but had not yet taken effect, department heads were directed to "consider extending for 60 days the effective date of the regulation... for the purpose of reviewing questions of law and policy raised by those regulations." Subsequently, the Office of Management and Budget (OMB) advised department heads that, in making their determination, they should consider several factors for regulations that had been published but that had not yet taken effect. Among them, OMB advised that agencies should consider whether the rule reflected proper consideration of all relevant facts and the agency's statutory and legal obligations, as well as whether the rule was based on a reasonable judgment about the legally relevant policy considerations.

As discussed more fully above, the surety bond rule is not supported by sound policy and administrative justifications, rendering it ripe for a thorough review by the new administration.

Thus, we urge CMS to reopen the notice and comment period and seek additional views from the public about the impact of this rule on Medicare beneficiaries and legitimate suppliers.

Sincerely,



Cathy Polley
Vice President
Pharmacy Services
FMI



Julie Khani
Vice President
Federal Healthcare Programs
NACDS



John M. Coster
Sr. Vice President
Government Affairs
NCPA

cc: Peter Orszag
Director, Office of Management and Budget