



PHARMACY
SOCIETY OF
WISCONSIN

*'Leading Our Profession
in a Changing
Health Care Environment'*

The Honorable David Obey
Washington DC Office
2314 Rayburn Building
Washington, DC 20515-4907

Dear Congressman Obey,

We are writing to request your immediate attention to a rapidly developing situation that will negatively affect every community in your Congressional district.

The bad news is that a problem exists. The good news is that a solution also exists. The best news, given the nation's economic difficulties, is that the solution will not cost any money.

But immediate action is necessary or pharmacy businesses in every community will be required to spend thousands of dollars unnecessarily or discontinue providing services to Medicare recipients.

The attached paper provides detailed background information on the situation that concerns us and we believe should concern you. The bottom line is that unless immediate action is taken, pharmacy providers will be required to become accredited to provide medical supplies to their patients beginning in 2009. Accreditation programs are charging pharmacies \$4,000 - \$6,000 to become accredited, plus renewal fees costing thousands of dollars each year. These are fees that must be paid by every pharmacy in order to sell supplies such as diabetic test strips, canes and wheel chairs—medical supplies that pharmacies already provide every day to their patients—without problem!

Congress exempted licensed health professionals from this new federal accreditation requirement. However, for some reason, pharmacists and pharmacy providers were not included in the long list of health professionals that have been exempted. Pharmacists and pharmacies are licensed by the state that they reside and they are heavily regulated. State pharmacy regulations are far more extensive than other health professional regulations. An additional accreditation program will not enhance the regulation of these pharmacies; it simply is an additional cost and new administrative burden.

We understand that CMS has had some problems with "pharmacies" that operate as mail order suppliers of medical equipment—companies like Liberty Mutual that advertises on television. However, traditional pharmacies should not be penalized because of questionable practices of these national mail order businesses that are purportedly doing business as pharmacies.

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Most traditional pharmacies provide medical supplies as a supplement to their primary business of providing medications. It is a complementary service and they are complementary products that patients (regular people) need. However, in many cases, especially in small communities, a pharmacy does not make enough money providing these products to warrant the cost, let alone the administrative burden, of becoming accredited. In these cases, the only prudent business choice will be for the pharmacy to discontinue providing the products. Surely, it is not the intent of Congress to reduce access to medical supplies, especially in rural communities where access to health care services is already threatened.

We believe the solution is simple: Exempt pharmacy providers from the accreditation requirement, just like all the other licensed health care providers are exempted, in the next appropriations bill. If necessary, and perhaps as a way to address the mail order “pharmacies”, accreditation could be required of pharmacy providers when over 10% of their gross revenues are derived from providing medical equipment. Such a bright-line test would be easy to separate the pharmacy providers that provide medical supplies as a complement to their business, rather than as their business.

Time is of the essence. Many pharmacies are already unsure of how to proceed. Some have already taken steps and incurred costs to become accredited. We are requesting your leadership in the resolution of this issue.

Sincerely,



Christopher J. Decker
Executive Vice President & CEO

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DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES (DMEPOS) ACCREDITATION FACT SHEET

Overview

The Centers for Medicare & Medicaid Services (CMS) issued guidance regarding Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) furnished by certain health care professionals and persons. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required all DMEPOS suppliers to meet quality standards for Medicare accreditation by September 30, 2009. In addition, MIPPA stated that certain professionals and persons do not have to meet this deadline unless quality standards are developed specific to these professionals and persons.

Background Information

Section 302 of the Medicare Modernization Act of 2003 (MMA) added a new paragraph 1834(a)(20) to the Social Security Act (the Act). This paragraph required the Secretary to establish and implement quality standards for suppliers of DMEPOS. All suppliers that furnish such items or services set out at subparagraph 1834(a)(20)(D) as the Secretary determines appropriate must comply with the quality standards in order to receive Medicare Part B payments and to retain a supplier billing number. Pursuant to subparagraph 1834(a)(20)(D) of the Act, the covered items and services are defined in section 1834 (a) (13), section 1834 (h) (4) and section 1842 (s) (2) of the Act. The covered items include:

- DME
- Medical supplies;
- Home dialysis supplies and equipment;
- Therapeutic shoes;
- Parenteral and enteral nutrient, equipment and supplies;
- Transfusion medicine; and
- Prosthetic devices, prosthetics, and orthotics.

The quality standards are published on the CMS website at:
<http://www.cms.hhs.gov/medicareprovidersupenroll>

Guidance on the Medicare Improvements for Patients and Providers Act of 2008

The MIPPA, section 154(b), added a new subparagraph (F). This subparagraph states that eligible professionals and other persons (defined below) are exempt from meeting the **September 30, 2009** accreditation deadline unless CMS determines that the quality standards are specifically designed to apply to such professionals and persons. CMS will work in collaboration with the medical and professional groups to develop specific quality standards. Those providers that were accredited prior to the enactment of MIPPA will not have to undergo a re-accreditation process.

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The eligible professionals (as defined in section 1848(k)(3)(B)) include the following practitioners:

- Physicians (as defined in section 1861(r) of the Act),
- Physical Therapists,
- Occupational Therapists,
- Qualified Speech-Language Pathologists,
- Physician Assistants,
- Nurse Practitioners,
- Clinical Nurse Specialists,
- Certified Registered Nurse Anesthetists,
- Certified Nurse-Midwives,
- Clinical Social Workers,
- Clinical Psychologists,
- Registered Dietitians, and
- Nutritional professionals.

Additionally, section 154(b) of MIPPA allows the Secretary to specify "other persons" that are exempt from meeting the accreditation deadline unless CMS determines that the quality standards are specifically designed to apply to such other persons. At this time, "such other persons" are only defined as the following practitioners:

- Orthotists,
- Prosthetists,
- Opticians, and
- Audiologists.

MIPPA also states that CMS may exempt such professionals and persons from the quality standards based on their licensing, accreditation or other mandatory quality requirements that may apply. At the present, CMS is not exercising their statutory authority to exempt suppliers based on their licensing, accreditation or other mandatory quality requirements

Accreditation Deadlines for DMEPOS Suppliers

Existing DMEPOS suppliers, with the exception of those eligible professionals and other persons mentioned above, that are enrolled in the Medicare program are required to obtain and submit proof of accreditation to the National Supplier Clearinghouse (NSC) by **September 30, 2009**. The NSC will revoke a DMEPOS supplier's billing privileges on **October 1, 2009**.

The accreditation process may take up to 9 months to complete for an enrolled DMEPOS supplier that submits a complete application to the Accreditation Organizations (AOs) and has no deficiencies to correct post onsite-survey. Therefore, all enrolled DMEPOS suppliers, except those eligible professionals and other persons mentioned above, will need to submit a complete accreditation application to the accreditation organizations (AOs) by **January 31, 2009**. This is to ensure that the DMEPOS supplier will receive an accreditation decision (provided that they meet the all the accreditation requirements) by **September 30, 2009**.

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If an enrolled DMEPOS supplier does not submit a complete accreditation application to the AOs by **January 31, 2009**, CMS cannot ensure that the AOs will be able to accredit them by the **September 30, 2009** deadline.

Since March 1, 2008, new DMEPOS suppliers submitting an enrollment application to the NSC (excepting those eligible professionals and other persons mentioned above) must be accredited prior to submitting the application. The NSC will not approve any DMEPOS supplier's enrollment application if the enrollment package does not contain an approved accreditation upon receipt or in response to a developmental request. The NSC shall reject the enrollment application unless the DMEPOS supplier provides supporting documentation that demonstrates that the supplier has an approved accreditation.