

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

September 2, 2003

Barrett Toan, Chair
Chairman & CEO
Express Scripts, Inc.

Mark Merritt
President & CEO

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: PCMA Comments on FDA Docket No: 03N-0168, “Current Status of Useful Written Prescription Drug Information for Consumers”

Dear Madam or Sir:

On behalf of the members of the Pharmaceutical Care Management Association (PCMA), we appreciate the opportunity to provide comment on the status and usefulness of written prescription drug information provided to consumers.

PCMA is the national trade association for America’s pharmacy benefit managers (PBMs). PCMA member companies administer prescription drug plans for health plans, employers, unions, and public purchasers that provide coverage for 200 million Americans. PCMA member companies provide consumers with access to affordable medicines by negotiating discounts from drug manufacturers, establishing discount networks of retail pharmacies, and through the direct dispensing of prescriptions through home-delivery pharmacy services.

Of the four questions raised in the Agency’s request for comment, PCMA is specifically interested in helping to shed some light on an area where the private sector is successfully providing information that meets the FDA’s goals and in offering guidance on how the Agency can help promote “best practices” across all pharmacies.

What is the Private Sector Doing to Improve Written Drug Information?

According to IMS Health, prescriptions dispensed through home-delivery pharmacies currently account for approximately 13 percent of US prescription drug sales in 2003. Home delivery pharmacies offer consumers numerous advantages. By one estimate, these pharmacies can save consumers as much as 53 percent below the average cash price paid at retail

pharmacy.¹ For patients with limited mobility or special needs, home delivery can be far more convenient than a trip to a retail pharmacy. Rural consumers also find that home delivery services expand their pharmacy options. As well, telephone consultations available through home delivery services may afford consumers more privacy than otherwise is available in a retail setting.

PBM-operated home delivery pharmacies provide extensive written information that is useful to consumers when prescriptions are dispensed from their licensed facilities. This information also comports with the goals outlined by the Keystone Center and accepted in 1997 by the HHS Secretary. In providing information to consumers, PBM-operated pharmacies rely upon scientifically-based clinical information provided by respected independent sources. This information is typically unbiased in tone and content and includes important consumer protections and directions. This information is routinely updated and represents the best available medical science. PBMs typically provide patients with the following type of information:

- Information identifying the medication being received, along with a description of the medication, the instructions, and possible warnings, interactions, etc.
- A label with the patient information, the medication information, and doctor's instructions, that often includes other information indicating when the medication can be refilled, when the prescription and/or medication expires, etc., and
- Information specific to the order. For example, if the order is a partial order, a letter is sent to the patient indicating that the order is a partial fulfillment and that the balance of the order will be filled later. Information is also often provided related to a switch that occurred – for example, if a higher cost brand was filled with a lower cost one. PBMs will let the member know that a switch occurred and explain why.

In addition to written information, home delivery pharmacies routinely also provide consumers with information via oral communications and the Internet. For example, patients receiving prescriptions dispensed through a

¹ “Federal Employees’ Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees and Pharmacies,” General Accounting Office, January 2003. Page 4.

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home delivery pharmacy have access to a pharmacist hotline that is available 24 hours per day/7 days a week. With respect to information available through the Internet, written materials usually include the URL for the manufacturer's website. These sites contain information on the prescribed product as well as databases that allow for review of potential drug interactions. Internet-based information may also include information on drug comparisons, side-effects and treatment options.

PCMA strongly believes that information is the cornerstone to improving health care quality throughout the system and to empowering patients to make informed health care decisions. For this reason, we are very troubled by a recent Food and Drug Administration-sponsored survey finding that consumers found that only 50 percent of the drug information they receive when filling a new prescription at the retail pharmacy counter is useful. Given that at least 90 percent of outpatient prescriptions are filled at the retail pharmacy counter, these data could indicate a serious impediment to maximizing the effectiveness of prescription drugs, improving quality, and reducing overall health care costs.

In response to these data, some of our members conducted evaluations of the PPIs provided to consumers through home delivery pharmacies – based on the same research criteria used in the “expert” component of the analysis conducted for the FDA. This research found that across the four PPIs reviewed in the FDA analysis, the home delivery PPIs substantially exceeded the mean scores of those PPIs reviewed in the study conducted for the FDA. These findings provide an important example of industry best practices and could provide a pathway for improving the utility of prescription drug information provided to consumers.


What Role Should the FDA Play?

PCMA strongly encourages the FDA to examine the distinguished record of home delivery pharmacies in providing consumers with useful written information when contemplating further guidance in this area. A strict one-size-fits-all approach to consumer information could have the unintended consequence of consumers being provided *less*, not more, useful information. Conducting an industry-wide analysis of “best practices” in this area could help establish a series of voluntary guidelines for written drug information. These guidelines could be an important step in further improving useful written information provided to consumers across all pharmacies.

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Please do not hesitate to contact PCMA at (202) 207-3610 if you have any questions or if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Merritt". The signature is written in a cursive, slightly slanted style.

Mark Merritt