

03N-0342_emc-000003.txt

From: Marissa Schlaifer [mschlaifer@amcp.org]
Sent: Wednesday, July 14, 2004 6:01 PM
To: fdadockets@oc.fda.gov
Cc: 'Judy Cahill (E-mail)'
Subject: Docket No. 2003N-0342

Thank you for the opportunity to provide comments on the addition of a statement for reporting adverse events (Docket No. 2003N-0342). Attached are the comments from the Academy of Managed Care Pharmacy. For questions or additional information, please contact Judy Cahill at (703) 683-8416 x313 or jcahill@amcp.org.

Thank you,

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July 16, 2004

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

Re: Docket 2003N-0342

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Food and Drug Administration (FDA) on the addition of a statement on both over-the-counter and prescription drug products for reporting adverse events.

AMCP is a professional association of pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy through the application of managed care principles. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to over 200 million Americans served by managed care.

The Academy supports the addition of a statement on both over-the-counter and prescription drug products that includes a toll-free number for reporting of adverse events and supports the proposal to use the MedWatch system for such reporting.

However, AMCP requests that the FDA reconsider the proposed language for the statement. The proposed language "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088," fails to mention the most accessible and qualified medical professional available to discuss medication side effects. The Academy recommends that the statement should be amended to read: "Call your doctor *or pharmacist* for medical advice about side effects."

Pharmacists who know their patients and have their medication profiles on file will be aware of possible harmful drug interactions or allergies to certain drugs. The pharmacist will be able to provide advice on whether a patient should stop taking a medication, seek additional medical attention or merely modify the dose, time or combination of other medications being utilized. The pharmacist also will be able to discuss the cause of the side effects; what foods, drinks, or activities that should be avoided while on a medication; and a wide range of other helpful information.

The Academy supports the decision to utilize the term "side effect" rather than "adverse event" because of concern that some consumers may not understand the meaning of the term "adverse event."

AMCP appreciates the opportunity to comment on this important issue. If you have any questions, please contact me at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,

Judith A. Cahill, CEBS
Executive Director

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