

July 22, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

RE: Docket No. 98N-0222

The Academy of Managed Care Pharmacy is pleased to submit comments on the Proposed Rule: *Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices*, published in the June 8, 1998 Federal Register.

The Academy of Managed Care Pharmacy is the national professional society dedicated to the concept and practice of pharmaceutical care in managed health care environments. AMCP's mission is to promote the development and application of pharmaceutical care in order to ensure appropriate health care outcomes for all individuals. Its sole purpose is to represent the views and interests of managed care pharmacy. The Academy has more than 4,500 members nationally who are part of more than 600 health care organizations that provide comprehensive coverage to the millions of Americans served by managed care.

AMCP generally applauds the efforts of the Food and Drug Administration (FDA) to draft this rule to implement Section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). This section of FDAMA is clearly intended to make information regarding new and unapproved (off-label) uses of pharmaceutical, biologics, and devices more readily available to healthcare professionals.

AMCP supports off-label use of FDA-approved drugs when medically appropriate. The Academy believes each pharmaceutical agent on the market should be used only in accordance with generally accepted medical practices. Therefore, the Academy's official position is that managed care organizations consider defined criteria before deciding whether to provide coverage of FDA-approved drugs for certain off-label uses. The criteria are:

- Whether the drug has been proven effective and accepted for the treatment of the specific medical condition for which it has been prescribed according to the current edition of the United States Pharmacopoeia Dispensing Information, Volume I, or the American Hospital

98N-0222

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Formulary Service Drug Information compendium.

- Whether the drug is recommended for the particular condition involved, and has been proven to be safe and effective for that condition according to formal clinical studies, the results of which have been published in peer-reviewed professional medical journals.

The Federal Register notice description of the proposed rule states that “it is essential that this information be provided only to persons who have the education, training, and experience to interpret its meaning and relevance.” Since this was clearly the intent of Congress, AMCP members have expressed great concern that pharmacists are excluded from the list of recipients of this essential information. AMCP believes that it is essential for optimal drug utilization and improved patient outcomes that pharmacists are included as potential recipients of this information.

Pharmacists receive extensive in-depth training in pharmacology, kinetics, dosage estimates, drug interactions, available products, and drug therapy management. This training in appropriate medication use makes the pharmacist uniquely qualified to interpret the meaning and relevance of this information. Ready access to information about new and unapproved uses of drugs, biologics, and devices is critical for the pharmacist in his or her role as consultant to other health care providers.

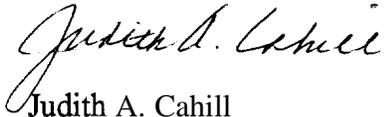
In Section 4401 of the Omnibus Budget Reconciliation Act (OBRA) of 1990, Congress recognized the ability of pharmacists to improve quality of care and lower costs of medical care by detecting potential problems with drug therapy and promoting rational outcomes. Under this provision of OBRA 1990, pharmacists are mandated to perform proactive drug utilization review to ensure that patients receive appropriate medications. Pharmacists systematically review each drug regimen’s therapeutic use, potential for drug-drug, drug-food, and drug-disease interactions, and adverse drug reactions. This drug utilization review helps patients avoid duplicate therapy, contradicted uses of a drug, and undesirable outcomes. Pharmacists also counsel patients on how to properly use medications in order to increase patient compliance and help improve patient health status. The ability of pharmacists to more freely access all relevant information about a drug would greatly enhance their ability to fulfill their obligations under the provisions of this Act while greatly enhancing the pharmacist’s ability to improve patient health status.

Furthermore, pharmacists play a key role in the collection, analysis, and interpretation of scientific studies relevant to addition or removal of drugs from health plan formularies. Pharmacists routinely prepare evaluations of available clinical information and drug company product literature for Pharmacy and Therapeutics (P&T) Committee consideration. Access to all relevant information about drug products is essential so that the P&T committee can evaluate not only the safety and efficacy of the drugs being reviewed, but the effect of adding or removing individual drugs on the health plan membership and the cost implications of their decisions.

Considering the positive impact of pharmacists in optimizing drug therapy and patient outcomes, AMCP respectfully requests that pharmacists be added to the list of Recipients of Information enumerated in Section 99.105.

AMCP would welcome the opportunity to meet with FDA staff to discuss this matter.

Sincerely,

A handwritten signature in black ink that reads "Judith A. Cahill". The signature is written in a cursive style with a large initial "J".

Judith A. Cahill
Executive Director