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Department of Government & Professional Affairs

July 6, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Dear Sir or Madam:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to comment on ways to improve Food and Drug Administration's (FDA) Medication Guide (MedGuide) program, which requires the distribution of FDA-approved patient information for selected prescription drugs that pose a serious or significant public health concern.

ACCP is a national professional and scientific society representing more than 9,000 clinical pharmacist practitioners, researchers and educators. Our members have been among the profession's leaders for almost three decades in developing and providing professional services, consultation, cutting-edge clinical research, and education programs that improve the quality of medication use in the health care settings in which they practice.

ACCP members are committed to improving health outcomes and managing health care costs through the safe and appropriate use of medications. ACCP members - participating in programs such as Medication Therapy Management (MTM) under Medicare Part D or in state-regulated Collaborative Drug Therapy Management (CDTM) - already provide care and services to help patients better manage their medications.

Medication Guides (MedGuides) are just one tool that pharmacists use to provide patient information on the relative risks and benefits associated with certain prescription products. ACCP recognizes the value of this information to patients, but has noted a number of areas where improvements could be made to the current MedGuide program.

ACCP Recommendations

1. Electronic Dissemination of MedGuides

Currently, MedGuides are supplied by manufacturers exclusively in print format. Pharmacists have reported a number of problems associated with this paper-copy only approach, including difficulties ensuring that manufacturers provide an adequate supply of MedGuides, problems reordering MedGuides when needed and a number of workflow issues resulting from these administrative challenges.

To address this, FDA should encourage the development of systems that allow electronic rather than paper dissemination of MedGuides. This may include streamlining the MedGuide program to allow

pharmacy software vendors greater flexibility to integrate MedGuide information with the patient information automatically printed with each prescription.

To facilitate this shift towards electronic dissemination, FDA should consider ways to integrate MedGuides into other patient information - including Package Inserts (PI) and Consumer Medication Information (CMI) – to enhance patient understanding of their medications while simultaneously enhancing pharmacy workflow.

Where electronic MedGuides are not available or not appropriate, ACCP recommends that the Agency establish a central telephone number and web site to simplify the process by which pharmacists order MedGuides.

Finally, pharmacists should be permitted to distribute MedGuides electronically (by e-mail) to patients who request this format and distribution approach.

2. Improving Medication Guide Content

Efforts to improve the production and dissemination of MedGuides are important and commendable, but it is also vital to ensure that the information provided is properly read and understood by patients and actually helps patients better understand their medicines. ACCP therefore recommends reviewing the substance and formatting or layout of MedGuides to ensure that they are more consumer-friendly and accessible to those with limited reading skills.

While patients should have access to all necessary or relevant information, it is important that MedGuides are not so lengthy that patients are discouraged from reading them. Patients should also receive a balanced analysis of the relative risks **and benefits** associated with a medication, rather than simply a list of all the risks.

Due to concerns over patients being overwhelmed by the volume of printed information they receive with their prescription and a general lack of understanding among patients of the risks associated with prescription medications, ACCP recommends that the FDA standardize the information that must be provided in the MedGuide and require a consistent format, look, and feel to MedGuide information to help patients better understand the purpose and significance of MedGuides.

3. Improving Opportunities for Patient Care

MedGuides serve an important function in providing key information to patients on prescription drugs that pose a serious public health concern. However, this printed information should not be considered a substitute for direct interaction between patients, prescribers and pharmacists to help ensure safe medication use.

Given various reports that MedGuides – in their current form – can be cumbersome and are not user-friendly, ACCP recommends that time spent by pharmacy staff administering the MedGuide program could be better spent working directly with patients to review and discuss their medication regimen.

Due to the risks associated with certain medications and the challenges in effectively conveying these risks to patients, we strongly recommend that FDA actively promote direct access to pharmacist-provided Medication Therapy Management (MTM) services for patients that are on medications that require a MedGuide as part of the MedGuide program.

ACCP also recommends exploring ways to improve interaction between pharmacists and prescribers to help ensure safe medication use. Greater efforts should be made to make prescribers aware of which products require MedGuides and to allow MedGuides to also be provided at the point of

prescribing. Prescribers should also encourage their patients to work with pharmacists to review their medication regimen and so better understand the risks and benefits of the medications they take.

Finally, ACCP recommends that FDA undertake a public awareness campaign to help patients understand the purpose of MedGuides, the importance of being educated about the relative risks and benefits of any medication, and the roles that prescribers and pharmacists can play in providing this education.

In Conclusion

The FDA MedGuide program plays a vital role in providing important information to consumers on the risks associated with selected prescription medications. However, due to the fragmented and outdated process for the production and distribution of MedGuides, their effectiveness has been significantly diminished.

There are clearly inherent problems associated with paper MedGuides - administering the process of disseminating paper MedGuides has proven detrimental to workflow processes for many pharmacists and there are significant concerns that paper MedGuides are not being adequately supplied by manufacturers.

Finally, by placing so much emphasis on providing written MedGuides to patients, an important opportunity to encourage effective interaction and discussion between health care professionals and patients on the risks and benefits of prescription medications is being missed. We hope that FDA will consider opportunities to make better use of the MedGuide program to encourage improved interaction between patients, prescribers, and pharmacists.

ACCP thanks FDA for holding a public meeting and soliciting stakeholder comments on ways to improve this important program. Please feel free to follow up with us at any time if the College and its members can be of assistance in this effort.

Sincerely,



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Executive Director



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Director, Government & Professional Affairs

Cc: ACCP Board of Regents

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