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Government & Professional Affairs

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

Docket Reference: 2007N-0356 – Behind the Counter Availability of Certain Drugs

Dear Sir or Madam:

The American College of Clinical Pharmacy (ACCP) supports the availability of certain medications without a prescription following consultation with and appropriate patient assessment and education by a pharmacist.

ACCP appreciates the opportunity to comment on several of the issues relevant to the topic of "behind-the-counter (BTC) availability" of certain medications as outlined by the Food and Drug Administration (FDA) in its October 4, 2007, request for comments. We believe that improvements in both overall public health and enhanced patient-specific medication use outcomes and quality of life would result from the greater availability of appropriate medications through the establishment of a system of availability without a prescription **when linked with the clinical care and supervision of a pharmacist.**

ACCP is a national professional and scientific society representing almost 10,000 clinical pharmacist practitioners, researchers, and educators. Our members have been among the profession's leaders for almost three decades in developing and providing clinical pharmacy services, consultation, cutting-edge clinical research, and educational programs that improve the quality of medication use in the broad range of health care settings in which they practice.

ACCP commends the FDA for exploring this issue as a means to improve public health and facilitate greater access to medications that can improve patients' health and quality of life. Studies in both community and institutional settings have demonstrated that pharmacists can positively influence safe and effective medication use and outcomes when they are actively involved in direct patient care[1].

[1] Schumock, G.T., et. al. Evidence of the economic value of clinical pharmacy services. *Pharmacotherapy* 2003; 23(1):113–132

One of the most successful and frequently cited examples in the U.S. is commonly known as the "Asheville Project"[2]. In this community- based program, which has been ongoing for almost a decade, pharmacists' clinical services and interventions, in collaboration with other health care providers, substantially improved clinical, economic, and humanistic outcomes in patients with diabetes, asthma, and lipid disorders.

We believe it is obvious, but nevertheless quite important to emphasize, that the benefit to patients and the health care system of implementing such an approach will derive not from the segregation of the medication within a facility ("behind the counter") nor from a minimalist expectation of the pharmacist as the 'gatekeeper' of products, as seen with the recent approaches at both the federal and state levels with emergency contraception and pseudoephedrine access restrictions. Rather, the value will be achieved from an expectation of and policy support for active patient-centered interaction between pharmacists and consumers to enhance their understanding and use of such medications. Evidence from other countries that utilize "pharmacist-only" systems for access to certain medications suggests that these benefits are substantial and are valued by consumers.[3]

Therefore ACCP urges the FDA in subsequent notices and rule-making activities to use the term **"pharmacist-supervised medications"** or similar terminology to describe the framework being considered by the agency. We believe this terminology would also encourage patients and consumers to seek the clinical guidance and expertise of pharmacists for other health, wellness, and disease prevention needs.

Of the 25 issues and questions raised in the October 4 notice, ACCP is specifically addressing four key areas at this time. Because we anticipate the policy discussion on this important topic to continue to unfold in the months ahead, we will continue to provide our perspective and positions as that discussion proceeds on the full range of issues that have been identified and that likely still remain to be identified as a result of the initial public hearing.

These key areas are:

- Criteria for medication availability
- Documentation and medication record issues
- Professional services and payment
- Patient safety and pharmacovigilence

Criteria for Medication Availability

The criteria that should be utilized to identify medications available as "pharmacist-supervised medications" should strike a logical and appropriate balance between the existing criteria that guide the categorization of either prescription-only or non-prescription medications in the existing regulatory framework. A key element of that balance is that the medication can be more appropriately and safely used by patients or consumers with the active involvement, support, and services of a pharmacist than without. Such a determination should be based on sound clinical evidence and information, and supported by the input of health professionals, consumers, policy

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[2] The Asheville Project: Long-Term Clinical, Humanistic, and Economic Outcomes of a Community-Based Medication Therapy Management Program for Asthma. http://www.aphafoundation.org/searchable_files/filemanager/JAPhA%5FAsthma%20Article.pdf

[3] Gilbert, A. et.al. A review of pharmaceutical scheduling processes in six countries and the effect on consumer access to medicines. *International Journal of Pharmacy Practice* 2006; 14:95-104.

analysts, and pharmaceutical companies. Existing methods to identify such medications, such as a citizen's petition, may also be appropriate to consider.

ACCP supports what it interprets to be the perspective of FDA, based on introductory comments in the October 4 notice, that these medications would usually be medications that require a prescription but which could be made available without a prescription with the appropriate intervention and services of a pharmacist. In addition, ACCP recommends that the following criteria be considered in the determination of availability under the supervision of a pharmacist:

- The medication is used for the treatment of a disease or condition that can be accurately detected and monitored by the patient, caregiver, pharmacist, or other care providers;
- The medication has a demonstrated and highly positive benefit to risk profile;
- The medication has undergone appropriate clinical testing and sufficient post-marketing surveillance as a prescription medication to have identified the true rate of occurrence of serious adverse effects;
- Evidence of effectiveness (or ineffectiveness) of the treatment should be able to be assessed by the patient and/or pharmacist during monitoring and follow up of therapy;
- Any laboratory or other tests needed to effectively monitor the patient's disease and/or therapeutic response should be available to or able to be performed by the pharmacist;
- Evidence exists to demonstrate that availability of the medication only by prescription unnecessarily restricts access to the medication due to economic or sociologic barriers.

With time and experience, additional criteria that address pharmacoeconomic and pharmacoepidemiologic issues could be developed to enhance the effectiveness and efficiency of such an approach.

Documentation and Medication Record Issues

The successful implementation of a system of "pharmacist-supervised medications" must include a requirement for consistent and accurate documentation of both the pharmacist-patient clinical encounter and a record of the dispensing of the medication to the patient. In that regard, the documentation procedures for dispensing of a "pharmacist-supervised medication" should generally be of the same order of rigor as a prescription-only medication. Adaptation of existing medication profile systems to include documentation of the dispensed medication itself should be relatively straightforward, requiring only minor adaptation of a few selected data elements (e.g., the authorized prescriber, the numbering or tracking system, etc.) to accurately document the transfer of the medication to the patient.

Documentation of the clinical encounter should generally meet established standards for health care provider services. For example, concise notations in the patient's medication record that document the subjective and objective data, the assessment of the patient, and suggested plan of care (i.e., SOAP notes) relative to the "pharmacist-supervised medication" should be consistently recorded and retrievable to facilitate follow-up and or referral activities that may be required.

Such an approach is essential to adequately serve patients and to derive maximum benefit from such a system of expanded access. The procedures currently employed for the very limited number of

existing products that are sometimes characterized as "behind the counter", such as emergency contraception and pseudoephedrine, require only proof of age from a government-issued photo ID. ACCP believes this technique is clearly insufficient for a system of "pharmacist-supervised medications."

As experience is gained, efforts should be directed toward the development of a standardized electronic system that is effectively integrated with the patient's prescription medication profile and that is available to other health care providers whom the patient wishes to grant access. Such a system could also facilitate more effective medication reconciliation processes as patients move from one setting of care to another, and can more readily support the detection of adverse reactions, interactions, and over- or under-utilization of medications at both the patient and population level.

Professional Services and Payment

The professional services of pharmacists that should accompany the provision of a "pharmacist-supervised medication" would generally include all of the activities described in the October 4 notice, including patient assessment and interview, laboratory test review and/or performance, patient counseling and education concerning the medication and any associated devices necessary for its proper use, monitoring and follow up activities to determine therapeutic success, and, when appropriate, communication with the patient's other primary care providers. The nature and intensity of the services required by patients will inevitably vary based on their overall health status, age, and utilization of other medications, to name only three variables. Service intensity also may vary because of the particular medication being considered for use.

ACCP believes that the professional services that would accompany the provision of a "pharmacist-supervised medication" are just that – professional services. What we envision, and what the health care system should expect with this approach, is a pharmacist-patient clinical encounter rather than a "policed" commercial transaction.

Therefore, these services are clearly appropriate for payment by patients and public and private payers of health care services. The recent approval of permanent Category I Current Procedural Terminology (CPT) codes by the AMA CPT Editorial Panel for pharmacists' face-to-face medication therapy management services (CPT codes 99605, 99606, and 99607) provide a standardized and HIPAA-compliant framework for billing and documentation of these services.

Patient Safety and Pharmacovigilence

Any decision to develop and implement a system of "pharmacist-supervised medications" must have as a central tenet a firm commitment to patient safety and enhanced and targeted pharmacovigilence activities that support examination of both the positive and negative clinical outcomes associated with the use of these medications.

In order to effectively monitor, research, evaluate, and document the nature and extent of adverse drug reactions associated with such medications, the MedWatch program, the FDA's Safety Information and Adverse Event Reporting Program, should be both expanded and adapted to support more structured pharmacovigilance of medications that might be available through such a system. ACCP urges the utilization of this mechanism not only for voluntary reporting of adverse drug reactions but also as a valuable source of data and information to investigate the association between

exposure and clinical outcomes from the use of such medications in patients. Through this mechanism, better data and understanding of the true safety and efficacy of a system of "pharmacist-supervised medications" could be more readily demonstrated.

Finally, pharmacists should be fully and actively involved in regulatory and advisory panels that may direct the development, implementation and ongoing operation of a system of "pharmacist-supervised medications." Their knowledge, perspective, and experience as the providers most affected by such a system will be essential to its success.

In summary, ACCP believes that the creation of a system of "pharmacist-supervised medications" can result in enhanced access to medications and can promote better patient care and improved medication use outcomes for the American public. Pharmacists are uniquely educated health professionals, possessing the clinical skills and competencies necessary to assist patients in the more effective use of all types of medications. Key issues that should be addressed include the following:

- The term "pharmacist-supervised medications" or similar terminology should be used to more accurately describe the approach being contemplated and to demonstrate the expectation that the system supports effective pharmacist-patient interaction and clinical services to enhance safer and more effective medication use;
- Appropriate criteria for identification of medications to be included in a system of pharmacist-supervised medications must be utilized;
- Accurate and complete documentation of the professional services and intervention provided by the pharmacist, together with a dispensing record that is integrated with the other prescription medication records of the patient, must be assured;
- The scope of professional services should be appropriate to the needs of the patient receiving care, and payment for those services should be an expectation of patients and third party payers;
- A system of "pharmacist-supervised medications" must have as a basic premise a firm commitment to patient safety and enhanced pharmacovigilence activities.

ACCP and its members are committed to working closely with FDA and other stakeholders to examine the feasibility, structure, processes, and desired outcomes of a system of "pharmacist-supervised medications." We believe that such a system holds great promise for enhanced access to and improved outcomes from the use of medications.

Sincerely,

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Executive Director

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Director, Government & Professional Affairs

cc: ACCP Board of Regents