



Food and Drug Administration
Public Meeting November 14, 2007

American Society of Health-System Pharmacists
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Behind the Counter Medications: Health-System Pharmacists Are Ready

ASHP represents pharmacists who practice in hospitals and in health-system settings, including outpatient pharmacies and ambulatory-care clinics. Pharmacy practice in these institutional environments is characterized by collaboration with multidisciplinary patient care teams, pharmacist access to patients' health records, and compliance with quality-enhancing practice standards such as those of The Joint Commission. Pharmacists in hospitals and health systems use pharmacy technicians and computer technology extensively to increase their productivity and give them more time for patient care. Pharmacists in this setting are in a good position to contribute to the public health success of a Behind-the-Counter category of medicines, and we appreciate this opportunity to share our views on the issue.

Outpatient care is a major part of what hospitals do today. There were nearly 700,000 outpatient visits in hospitals in 2006. Nationwide, 28% of general and children's medical-surgical hospitals have an outpatient pharmacy. Among hospitals with more than 400 beds, 55% have an outpatient pharmacy. Many of these pharmacies serve a large number of patients. For example, the outpatient pharmacies at one large health system in the southeast have 500,000 patient visits and dispense 1.6 million prescriptions per year.

I will discuss four topics: (1) ASHP's official policy on a Behind-the-Counter category of medicines, (2) our views on the optimal features of pharmacist-enabled access to Behind-the-Counter medications, (3) ASHP's emerging policy on criteria for selecting medications for Behind-the-Counter status, and (4) a suggestion for moving the public policy discussion on this issue forward.

ASHP Policy

Since 1985, ASHP official policy has supported the establishment of an intermediate, or Behind-the-Counter, class of drug products that would not require a prescription, but would be available only from a pharmacist or a licensed health care professional authorized to prescribe medications.

ASHP believes that Behind-the-Counter availability of certain medications that are currently prescription-only and that have unmet potential for improving health status would be in the public interest. It has been shown that reclassification of some prescription medications to nonprescription products resulted in increased patient autonomy and health care knowledge, as well as improvements in self-care behavior. However, from a safety perspective, some medications that may be potential candidates for nonprescription status may not be ready for widespread sale in any retail outlet. For such medications, consumers should be able to draw on the education, training, and experience of pharmacists to help them assess their need for the medication, and, if use of the medication is appropriate, to learn how to take it and monitor its effects.

Additional points in our policy specify that:

1. Drug products appropriate for this intermediate category would be identified through the advice of physicians, pharmacists, and other health professionals on the basis of medical conditions to be treated and potential adverse effects.
2. Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-reaction reporting would be collected to help determine a product's eventual movement to nonprescription status, or return to prescription-only status, or continuation in the intermediate category.

In 2005, ASHP opposed the proposed transition of a statin to nonprescription status. Although the estimated public health benefit of increased patient access to this medication was immense, ASHP did not support the switch because of the lack of safeguards and oversight that would have prevailed with the medication as a nonprescription product. However, ASHP supports statin availability in an intermediate category of drug products that is designed consistent with our policy.

Optimal Features of Pharmacist Practice Related to BTC Medications

Based on best practices in hospitals and health systems, we believe that the pharmacist's practice when providing these therapies should optimally include the following features:

1. An initial assessment of the patient, using a standardized protocol such as might be developed by professional pharmacy associations, to determine appropriateness of the medication;
2. Obtaining required patient health information, such as laboratory data, to aid in the assessment;

3. Counseling the patient about proper medication use, at the patient's literacy and comprehension level;
4. Maintaining a standardized record of Behind-the-Counter medications provided and the accompanying professional services;
5. With the consent of the patient, informing his or her primary care provider of any Behind-the-Counter medication provided; and
6. Ongoing monitoring for effectiveness and safety.

The overall role of the pharmacist here is one of clinical intervention and consultation, and that role should be recognized by appropriate payment beyond the retail price of the medication.

Criteria for Selecting Medications for Behind-the-Counter Status

ASHP is currently developing a policy statement under the direction of our Council on Therapeutics that will outline detailed criteria for determining if a medication is appropriate for Behind-the-Counter availability. We are currently seeking public comment on this document, and the policy will be finalized early next year. The current draft says that medications for Behind-the-Counter status should:

1. Have a well-established benefit-to-risk ratio and a high safety margin,
2. Have been marketed as a prescription product for a sufficient length of time and been used in sufficient numbers of patients,
3. Have evidence of effectiveness and safety at the dose and regimen recommended for the Behind-the-Counter formulation,
4. Be used to treat a disease, symptom, or condition that can be readily detected or diagnosed by the patient or pharmacist,
5. Be associated with measures that can be used to assess the effectiveness of the medication as well as signs and symptoms of potential toxicity that can be reliably detected and interpreted by the pharmacist or patient, and
6. Not be an anti-infective agent to which emergence of resistance is a concern.

A Suggestion

As FDA further examines the potential for a Behind-the-Counter category, some important questions about its appropriateness and practicality may well go unanswered. The United States has no experience base to answer some of these questions. For that reason, we suggest that there may be merit in Behind-the-Counter demonstration projects for one or more medications in selected markets, with FDA oversight and systematic data collection. The experiences documented in such projects would help answer the public policy questions in the context of conditions here in the United States.

Among the settings selected for such demonstration projects (in addition to community pharmacies) should be some outpatient pharmacies in hospitals and health systems that are well integrated with patients' overall health care services. ASHP would welcome the opportunity to help design such a study.

Conclusion

ASHP believes that a Behind-the-Counter category of medications would be in the public interest. It would give the public greater access to medications that have potential for yielding immense gains in health status. It would allow manufacturers and the FDA to assess the safety of moving such medications to even more widespread access as nonprescription products. And it would tap the expertise of a health professional who is well prepared to help people make the best use of medicines in this category.