No. 969 National Standardized Examination for Pharmacy Technician Certification

The Washington State Board of Pharmacy adopted rule changes at its public hearing on May 29, 2008. The amended rules result in new requirements for certification as a pharmacy technician. Effective January 1, 2009, all technician applicants must pass a national standardized examination. In addition, all applicants are still required to complete a Board-approved technician training program. Individuals who have obtained a pharmacy technician credential before January 1, 2009, will not be required to meet the new standards.

In the next few months, the Board will be developing the criteria for a Board-approved examination. The plan for applying the rule includes adopting examination standards and identifying which examination(s) are Board-approved. The rule changes also require updates to the basic standards for Board-approved training programs. It is expected that these activities will be further defined at the July 17, 2008, business meeting.

For updates, please visit the Board’s Web page at https://fortress.wa.gov/doh/hpqa1/hps4/Pharmacy/default.htm.

(WAC 246-901-030 & 060)

No. 970 New Preceptor Certifications

If you have renewed your pharmacist license recently, you may have noticed some changes. With the implementation of the new licensing system, your preceptor certification no longer appears on your pharmacist license. A separate license is now issued to pharmacists with active preceptor certifications.

During the implementation of the new system, we discovered that the issue and expiration date of several active preceptor certifications were not correctly transferred from the old system. We are working on correcting this matter and plan to issue replacement preceptor certifications. Please note: Board staff can access past preceptor license history for verification when a pharmacy intern submits hours while under your supervision.

A certificate of participation is mailed to all original and renewed preceptor licensees. Participation in this program will earn the licensee 0.3 continuing education credits. Preceptor certification expires on the licensee’s birthday and is issued for no more than five years from the activation date.

When applying for a new or renewing a pharmacist preceptor certification, please use the new application form found on the Board’s Web site.

No. 971 Frequently Asked Questions

Q. How should prescriptions from Canada be handled?

Prescriptions from a Canadian province that shares a common border with Washington can be dispensed here. Currently, British Columbia is the only province that qualifies.

Prescriptions from Canada for Food and Drug Administration-approved legend drugs can be filled if written by one of the following practitioners licensed in Canada:

- physician licensed to practice medicine and surgery;
- physician licensed to practice osteopathic medicine and surgery;
- dentist licensed to practice dentistry;
- podiatric physician and surgeon licensed to practice podiatric medicine and surgery;
- veterinarian licensed to practice veterinary medicine. (RCW 69.41.030)

In addition, all state and applicable federal requirements for prescriptions must also be met.

Prescriptions for Schedule II through V medications cannot be filled in Washington if written in Canada.

Q. Where can I find information on practitioners’ prescriptive authority?

You can find information on the Board of Pharmacy’s Web site under the site directory titled “Prescribing Authority.” The chart lists the professions that have prescribing authority and notes any restrictions or limitations. The relevant state laws and rules are also noted.

The list includes professions that can administer medications under a prescriber’s order. The section on “General Limitations” contains information on prescribing, such as not prescribing controlled substances for yourself*, and which out-of-state practitioners you can accept prescriptions from, etc. Lastly, there is a section that lists professions whose scope does not allow prescribing, administering, or dispensing of medications.

Continued on page 4
A Community Pharmacy Technician’s Role in Medication Reduction Strategies

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ISMP Medication Safety Alert! Community/Ambulatory Edition by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr; Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy condition information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person’s medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription. New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not “bother” the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as confirmation bias. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA’s Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI review (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, meet the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

FDA’s Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA’s review of the applicant’s labeling ensures that health care professionals and patients have the information necessary to understand a drug product’s risks and its safety and efficacy. Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.
Enforcement Priorities
Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled “Marketed Unapproved Drugs – Compliance Policy Guide” (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at www.fda.gov/cder/guidance/6911fnp.pdf) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency’s risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- Drugs with potential safety concerns
- Drugs that lack evidence of effectiveness
- Fraudulent drugs
- Drugs with formulation changes made as a pretext to avoid enforcement
- Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Table 1: Examples of FDA Actions Regarding Unapproved Drugs

<table>
<thead>
<tr>
<th>Drug Product Description</th>
<th>FDA Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extended release combination drug products containing guaifenesin (marketed with approved products)</td>
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</tr>
<tr>
<td>Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)</td>
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<tr>
<td>Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)</td>
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<tr>
<td>Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)</td>
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<tr>
<td>Carbinoxamine drug products (associated with 21 infant deaths)</td>
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<tr>
<td>Colchicine injectables (50 reports of adverse events, including 23 deaths)</td>
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Importance to Pharmacists
FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient’s previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA’s Unapproved Drug Initiative can be found on its Web site: www.fda.gov/cder/drug/unapproved_drugs/.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site
On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as “not recommended.” NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the “not recommended” list. The hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as “recommended.”

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, “Internet Pharmacy Public Safety Awareness,” in which the Association pledged to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft
Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at www.rxpax.com/videos.asp by clicking on “Pharmacy Safety – Robbery.”

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients’ access to life-sustaining medicines.
Continued from page 1

You may also link to other professions’ Web sites by selecting “Profession Links (A-Z)” for the site directory.


Q. When do ancillary personnel utilization plans need to be updated?

New or amended utilization plans must be submitted to the Board office for approval. The plans should be tailored specifically to the needs and practice situation of your individual pharmacy. Sample Ancillary Personnel Utilization Plans are available on our Web site through the “Forms/Applications” page under the “Forms” section. The pharmacy technician plan also includes a section on the requirements for approval of specialized functions. Visit https://fortress.wa.gov/doh/hpqal/HPS4/Pharmacy/forms.htm.

No. 972 Treating Partners of Patients with Sexually Transmitted Diseases

Recently, the Board provided input to the MQAC on a special prescribing protocol for partners of patients with sexually transmitted chlamydia and gonorrhea. Adequate treatment of these sexually transmitted diseases has long been a difficult public health issue. A study by Dr Mathew Golden of Public Health Seattle and King County (PHSKC) demonstrated success with the use of the special prescribing protocol in treating partners. In the protocol, antibiotic treatment is provided by public health staff and pharmacies to partners through use of prepackaged “partner packs.” The MQAC urges practitioners to use all reasonable efforts to ensure that appropriate information and advice is made available to the absent partner or partners. Absent partners are advised to seek a medical evaluation for sexually transmitted disease.

Contact your local Public Health clinic for more specific information on the special prescribing protocol. To view MQAC’s policy, please visit its Web site at https://fortress.wa.gov/doh/hpqal/HPS4/Pharmacy/forms.htm.

No. 973 Are Your ADDDs Approved?

ADDDs are not extra-hyper druggists, but automated drug distribution devices. These devices may also be known as automated cabinets or automated dispensing systems. Used as drug storage devices in many health care settings, ADDDs provide access, security, and accountability in the use of medications. The use of all ADDDs must be approved by the Board and is restricted to those facilities listed in the rule. The rule also describes the responsibilities of the pharmacy and the facility. To request approval, pharmacies must send policies and procedures to the Board office for review. For more information, visit the Board’s Web site at https://fortress.wa.gov/doh/hpqal/HPS4/Pharmacy/default.htm for the application form and applicable rules.

No. 974 Welcome New Board Member

Governor Chris Greigoe has appointed Albert Linggi to the Board of Pharmacy. Mr Linggi’s four-year term began on March 10, 2008.

Mr Linggi is a graduate of the University of Washington. He has an executive masters in business administration from Fuqua School of Business at Duke University. Mr Linggi has over 30 years of experience in the pharmaceutical industry. His positions include appointments as administrative director of pharmacy for St Joseph, regional director for Franciscan Health Systems, and vice president for McKesson Corporate Business Development. We look forward to Al bringing his expertise and willingness to serve the people of Washington through his Board appointment.

No. 975 Fifty-year Certificates

We would like to acknowledge and congratulate the following pharmacists for 50 years of licensure in Washington State. The honorees were recognized at the Northwest Pharmacy Conference in June of this year. Harold E. Bennett, Seattle, WA; John A. Benson, Bellingham, WA; Elwin H. Blair, Bellevue, WA; Walter G. Davison, Port Angeles, WA; Ann C. Donnelly, Tucson, AZ; Ronald D. Gilbert, Portland, OR; Robert J. Grady, Whitefish, MT; Ralph N. Herbison, Spokane, WA; Donald L. Kelly, Wenatchee, WA; Michael D. Lyon, Prosser, WA; John S. McCluskey, Naches, WA; Laverne F. Moore, Pendleton, OR; Daniel J. Nault, Lynnwood, WA; Charles E. Nunn, Buckley, WA; Joan C. Skalabrin, Port Orchard, WA; Donald A. Stoebner, Anacortes, WA; James C. Wright, Gig Harbor, WA; Marvin L. Wheeler, Harrison, ID.

No. 976 Upcoming Board of Pharmacy Meetings

The Board of Pharmacy is encouraging all pharmacists to mark their calendars with the following meeting dates.

July 17, 2008 .................................................. Tumwater
September 4, 2008 ......................................... Yakima
October 30, 2008 ............................................. Kent
December 11, 2008 ....................................... Kent

Board meetings are open to the public and pharmacists and auxiliary staff are encouraged to attend. Pharmacists are able to earn up to three contact hours (0.3 CEUs) of continuing education credit each license renewal period for attending a Board meeting. While the meetings have a formal structure, there are often public comment periods for the agenda items. If you are interested in receiving the meeting agenda, please contact WSBOF@listserv.wa.gov. This is a great opportunity to help the profession progress.