



Ohio State Board of Pharmacy

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Terminal Distributor Renewals

By the time this *Newsletter* is published, renewal notices for terminal distributor licenses will have been sent out by the Ohio State Board of Pharmacy and should have been received by all licensees. If you have not yet received yours, please contact the Board office as soon as possible. If you are the responsible person on the license, please remember that you are responsible for seeing that the license is renewed before January 1, 2011.

This year's process for renewal is similar to last year's renewal process. The Board will be accepting online terminal distributor renewal applications with payment by a credit card for most licensed sites. Please note that only terminal distributors with **unlimited** licenses will be able to renew online this year. Also, a terminal distributor license cannot be renewed online if any of the following applies: change of address, change of responsible person, change of business name, change of business ownership, and/or change of drug category of the license. This is all explained on both the renewal application and the online renewal screens, which give directions on how to handle these situations. For ordinary renewals, however, the process should be as easy and painless as possible, **if you read and follow the directions contained in your renewal packet and on the renewal screens. Please also note – do not hit the “back” button after you authorize payment with your credit card!** This will cause your credit card to be charged again, each time you hit the back button. The last few years, the Board has had several pharmacists whose cards were charged multiple times because they were not patient enough to wait for the card processing to occur. In other words, if that happens, it is because you hit the back button, not because the system had a problem. The Board tries to catch those mistakes before they get posted to your card, but is not always successful. If it does occur, please contact the Board office so the extra charges can be reversed.

Proposed New and Changed Rules Filed

On September 30, 2010, the Board filed several proposed new and changed rules for public notice. The public hearing on these rules was scheduled for November 1, 2010, at 1:30 PM. Pharmacists interested in reviewing the rule changes proposed by the Board may view them on the Board's Web site under "What's New" prior to the Board making a final determination on their status ([www.pharmacy.ohio.gov/Proposed-](http://www.pharmacy.ohio.gov/Proposed-Rule-Changes-Nov-2010-text-showing-changes.pdf)

[Rule-Changes-Nov-2010-text-showing-changes.pdf](http://www.pharmacy.ohio.gov/Proposed-Rule-Changes-Nov-2010-text-showing-changes.pdf)). After the Public Rules Hearing, there will also be a hearing before the Joint Committee on Agency Rule Review. After that hearing, the Board will make a final determination on implementation and on the effective date of those rules that are given final approval. Notice of that decision and copies of all new and changed rules will be placed on the Board's Web site and, on the effective date, the changes will be incorporated into the Administrative Code rules posted on the Web site.

Electronic Prescribing of Controlled Substances

As discussed in the August 2010 *Newsletter*, Drug Enforcement Administration (DEA) published an interim final rule, effective on June 1, 2010, allowing prescribers and pharmacies who wish to engage in the electronic transmission of controlled substance prescriptions (including Schedule II prescriptions) to do so, **but only after the prescribing and pharmacy systems can meet the requirements set forth in the rule.**

In order to show that the system has met the requirements, each system must undergo an independent (third party) audit by either of the following:

1. A person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit.
2. A Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.

As the Board understands, many of the major financial auditing firms are able to offer the required audits. One important note to make is that it is **not** the responsibility of the individual prescriber or pharmacy to obtain this audit. It is the responsibility of the e-prescribing system vendor and the pharmacy system vendor to have an audit conducted. Once it is conducted, the system vendors are responsible for notifying their clients.

The bottom line is this – until you receive notice that your pharmacy computer system has successfully completed the DEA required audit, you may **not** accept electronically transmitted controlled substance prescriptions, even if the prescribing system has been successfully audited.

At the time of the writing of this article, no prescribing system and no pharmacy system had undergone a successful audit.

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FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.

FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm.

FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for

those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm.

Safeguards to Implement with 'High Alert' Medications



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA Med-Watch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag



check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

Comparison to prescriber's order:

- ◆ Is this the prescribed drug?
- ◆ Is this the prescribed dose/strength/rate and route of administration?
- ◆ Is this the right patient (use two patient identifiers)?
- ◆ Is this the prescribed frequency?

Additional cognitive checks:

- ◆ Does the drug's indication correspond to the patient's diagnosis?
- ◆ Is this the right drug formulation?
- ◆ Are dose calculations correct?
- ◆ Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- ◆ Is the prescribed dose/frequency/timing appropriate for this patient?
- ◆ Is the route of administration safe and proper for this patient?
- ◆ Has patient been educated on appropriate monitoring?

ASCO/FDA Program Provides Information on Expanded Access for IND Applications

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- ◆ A thorough explanation of all expanded access programs available
- ◆ Links to key references and resources that are relevant to the slide content
- ◆ Selected virtual meeting presentations from ASCO Annual Meetings
- ◆ Helpful resources to use with patients

The program is available at <http://university.asco.org/ExpandedAccess> and participants may earn a certificate of participation or completion.

Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admis-

sions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at www.samhsa.gov/newsroom/advisories/1007140544.aspx.

USP Recommends Patient-Centered Standards for Prescription Labels

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at <http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d>.

Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- ◆ Recommendations: AMA Scope of Practice Data Series: Pharmacists, www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm.
- ◆ Response Letter: AMA Scope of Practice Data Series: Pharmacists, www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149.
- ◆ Scope of Contemporary Pharmacy Practice, www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150.

Therefore, there should be no electronic controlled substance prescriptions being transmitted or accepted.

Pharmacy Technician Issues

The Board is still receiving a large number of calls from or about technicians. Please remember that, in Ohio, technicians are **not** required to be licensed, registered, or certified. However, employers must ensure that technicians are “qualified” to compound drugs or to package or label any drug. In order to be a qualified pharmacy technician, a person must be 18 years of age or older, a high school graduate (exceptions are made for technical school students for the age and graduation requirements), must have cleared a Board-defined background check, and must have passed a Board-approved examination. Technicians who were employed on or before April 8, 2009, were required to meet those criteria by October 7, 2010. They should all be qualified by now or they should not be performing any duties of a qualified technician. Technicians hired after April 8, 2009, were given 12 months from the date of hire to meet the criteria. During that 12-month period, the technicians may perform qualified technician duties even though they do not yet meet the requirements. At the end of the 12-month period after the date of hire as a pharmacy technician, they must meet the legal requirements or stop performing the duties of a qualified technician. The rules for the background checks and the approved examinations may be found on the Board’s Web site under “What’s New” if you need more information. As always, if you have specific questions that are not answered on the Web site, please call the Board office.

OPDATF Releases Final Report

The Ohio Prescription Drug Abuse Task Force (OPDATF) provided its final report to the governor on October 1, 2010. The complete text of the report may be viewed on the Ohio Department of Health’s (DOH) Web site at www.odh.ohio.gov. Once on the DOH’s Web site, click on the “Task Force” button on the left of the screen. Once on the Task Force page, there is a link to the full report.

The task force accomplished a great deal in the six months of its existence. The report includes 20 main recommendations on legislative reform, increased funding and education, and facilitating proper disposal of prescription medication. It also recommends establishing new and supporting existing coalitions to address the prevention of prescription drug misuse, abuse, and overdose. The recommendations cover a wide range of issues from enforcement to treatment to prevention. It became obvious very early on that focusing on one aspect of the problem while ignoring the others would not result in a long lasting solution. In other words, if the Board focused on the supply (law enforcement) but ignored the demand (treatment/prevention), the Board would never see an end to the problems.

Suggestions that might be of particular interest to pharmacists include:

1. Setting standards for pain management clinics that would include standards by the State Medical Board of Ohio and licensing by the Ohio State Board of Pharmacy. It was suggested that ownership of the pain clinics should be limited to prescribers only.

2. Limiting the dispensing of controlled substances by prescribers to a short-term supply (ie, 72 hours), thereby requiring a prescription to be filled by a pharmacy for longer terms of therapy.
3. Support funding and improvements to the Board of Pharmacy’s Ohio Automated Rx Reporting System program.
4. Encourage increased initial and continuing education on pain management and drug abuse.
5. Identification of best practices for managing acute and chronic non-malignant pain and disseminate and promote those best practices.
6. Facilitate the proper disposal of prescription medications.
7. Provide population specific education related to the risks of prescription drug abuse.

These are only seven of the 20 recommendations, but they are recommendations that would be better accomplished with active participation by pharmacists. They are not, however, all things that can be done from behind the prescription counter. Some of them will require pharmacists to contact their state legislators to promote passage of legislation. To assist in the implementation of other recommendations, please take an interest in your communities and get involved in outreach to your local schools and organizations. Pharmacists are some of the best qualified people to teach the public about the benefits and risks of prescription drugs. Everyone is becoming aware of the problems with prescription drugs, but leadership is needed. Pharmacists are in a unique position to provide some of that leadership for their communities.

Disciplinary Actions

Anyone having a question regarding the license status of a particular prescriber, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, www.dental.ohio.gov

State Medical Board – 614/466-3934, www.med.ohio.gov

State Nursing Board – 614/466-3947, www.nursing.ohio.gov

State Optometry Board – 614/466-5115,
www.optometry.ohio.gov

State Pharmacy Board – 614/466-4143,
www.pharmacy.ohio.gov

State Veterinary Medical Board – 614/644-5281,
www.ovmlb.ohio.gov

Drug Enforcement Administration – 800/882-9539,
www.deadiversion.usdoj.gov

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