



Ohio State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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It's Time to Renew Your Pharmacist License

Pharmacist renewal notices were mailed out the last week in July to all pharmacists licensed with the Ohio State Board of Pharmacy who are eligible for renewal. If you have not received your renewal notice by August 10, you need to check with the Board office to find out what you need to do to renew your license. If your license is not renewed by September 15, 2012, you may not continue to practice as a pharmacist in Ohio until you do get it renewed.

This year's renewal is the same online process that it has been the last few years with the exception of a few things. First, you will need your National Association of Boards of Pharmacy® (NABP®) e-Profile ID number for continuing education (CE) in order to renew. To obtain your NABP e-Profile ID number, register online with NABP at www.MyCPEmonitor.net. This is needed independent of whether or not you report your CE this year. As mentioned in previous *Newsletters*, this will augment the future process that the Board will be using for CE reporting, so the Board must collect this e-Profile number now. This will be a forced field requirement during the renewal and this number will be validated with NABP, so please do not enter invalid numbers as this could be viewed as falsification of your application. The other major difference in this year's renewal process is that it will combine the license renewal with CE reporting (for those pharmacists whose license numbers begin with, "033" who report this year) into one online process which is further explained below.

Instructions for renewing your identification card online are outlined in your online renewal notice. Please follow the instructions carefully and you should have no problems. If you do run into problems or have concerns, please call the Board office. If you do not have Internet access or cannot renew online for some other reason, you will need to contact the Board office in writing (fax or e-mail are also accepted) and request a paper renewal form.

Since this is the first time the "033" pharmacists are "attesting" (reporting) their CE online, let's review a few items. First, you **no longer** have to report or enter the actual CE program numbers anywhere in this process (the Board likes this too!). You will answer "Yes" or "No" to the appropriate CE reporting questions during the online renewal process. All CE Certificates of Participation must be dated between March 1, 2009 and May 15, 2012, unless this is the pharmacist's first-ever CE reporting year (see below). Please carefully read the online renewal question titles and the actual questions. Because the Board has to take into account all CE reporting situations, it can get confusing, such as:

- ◆ the pharmacist does not report this year due to being licensed after May 30, 2012;
- ◆ the pharmacist is reporting CE for the very first time (you can use CE Certificates of Participation dated from your first license issue date through May 15, 2012);
- ◆ the out-of-state pharmacist is not working in Ohio and has a current pharmacist license in another state;
- ◆ any pharmacist with an up-to-date pharmacy practice specific specialty certification (ambulatory care pharmacy, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, poison information, oncology pharmacy, pharmacotherapy, psychiatric pharmacy) must complete 0.3 CEUs of Ohio Board-approved jurisprudence.

These questions are presented in a specific order to address each reporting situation. Again, please read the questions carefully and answer the question appropriately. You will eventually get to your CE reporting scenario!

(Note: All pharmacists who practice pharmacy in the state of Ohio, regardless of your address, **must** complete the required 6 CEUs of CE experience, of which 0.3 CEUs must be Ohio Board-approved jurisprudence. Out-of-state pharmacists who practice pharmacy in Ohio **cannot** use their other state pharmacist license to satisfy Ohio's CE requirements.)

Continued on page 4



FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.

Rethink the Vial



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 an FDA MedWatch 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.

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid pre-

scriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request Parents' Guide to Understanding Prescription Drug Abuse brochures for distribution to your patients, visit www.SafeguardMyMeds.org.

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at www.abbott.com/vicodin-consumer-alert.htm. Abbott advises that anyone who has the counterfeit ver-



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at www.safemedicines.org/resources-for-healthcare-professionals.html. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm. Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at www.fda.gov/Drugs/DrugSafety/ucm300747.htm. Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWARE_xE[®] Web site at www.awarerx.org/informedSiteMap.php.

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWARE_xE Web site at www.awarerx.org/OTCMedUse.php. The AWARE_xE consumer protection program and the National Association of Boards of Pharmacy[®] (NABP[®]) are part of the Acetaminophen Awareness Coalition.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and
Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

Pharmacists whose license numbers begin with “031” or “032” will see the same online renewal process that the Board has been using the past few years, with the exception of needing your NABP e-Profile ID. Pharmacy interns’ online renewal process is also unchanged.

The only real problem the Board generally sees is due to pharmacists who, after submitting their final information, hit the back button on their computer screen. Please do not do that. Every time you hit the back button, your credit card is charged. If you do accidentally get charged more than once, the Board will try to catch it and credit your account. Many times last year the Board caught it and fixed it before it got to the credit card company. However, if a double billing does appear on your credit card bill, please let the Board office know and the Board will try to get it fixed.

Again, you need to renew your license by September 15, 2012, if you plan to continue practicing pharmacy in Ohio after that date. If you do not wish to renew your license, please notify the Board office immediately. The Board truly appreciates all of the pharmacists and pharmacy interns who utilize the online renewal process.

E-Prescribing of Controlled Substances Now Occurring in Ohio

As you may know, Drug Enforcement Administration (DEA) finished their interim rule allowing e-prescribing of controlled substances (C2-C5) about two years ago. It has taken the computer system vendors some time, but finally there have been a few that have completed the certification process created by DEA. DEA is not actually “certifying” the systems, but they have approved a number of firms that do. The Board of Pharmacy is not one of these firms. It is also important to know that the Board of Pharmacy acknowledges this certification and thus this meets our state requirements for e-prescribing of controlled substances. And if the same process/method is used for non-controlled e-prescriptions, these systems also meet our requirements for e-prescribing non-controlled drugs. However, the Board has noticed some systems are using different processes and types of positive identification, depending on whether it is a controlled or non-controlled e-prescription. If the system does not use the same DEA-certified process for non-controlled e-prescriptions, the system must be approved by the Ohio State Board of Pharmacy.

Please note that **both** the sending prescriber system and the receiving pharmacy system must be certified and need to be re-certified every two years by one of the DEA-accredited firms. Currently, there are only a few prescribing and pharmacy vendors who have completed the DEA approval process for e-prescribing controlled substances. Also there is a pilot program in the Findlay, OH, area where controlled e-prescriptions are being sent and filled.

Before filling these electronic controlled prescriptions, here are some things you should know:

- ◆ You must ensure your pharmacy system has been certified to accept controlled e-prescriptions. Your company or software vendor should indicate when this approval is completed. Also, if you utilize Surescripts (an intermediary switching station that directs electronic prescriptions and claims), you can check the Surescripts Web site for your system at www.surescripts.com/about-e-prescribing/e-prescribing-of-controlled-substances.aspx, and click on “EPCS Certified Pharmacies and Pharmacy Software Vendors.”
- ◆ You must validate any e-prescriptions that fail due to a transmission error. This may involve calling the prescriber and/or calling other pharmacies.
- ◆ Part of the certification process forces these systems to print “copy,” or something to that effect, on the paper copy if the prescriber also tries to print the e-prescription for any reason. This should minimize the potential for multiple scripts from the same e-prescription.
- ◆ These controlled e-prescriptions shall **not be** e-faxed. They must be computer to computer.
- ◆ You must print these e-prescriptions for your files.
- ◆ Traditional paper controlled prescriptions and the regulations pertaining to them are still valid!
- ◆ Traditional faxed controlled prescriptions (fax-fax) and the regulations pertaining to them are still valid! The main point to remember on these prescriptions is that a “wet” handwritten signature was applied to them, not a digital computer-generated signature.

For prescriptions handled by Surescripts:

- ◆ Surescripts will ensure the prescribing systems that submit these controlled e-prescriptions are certified and will block those that are not on the certified list. Surescripts will also have on their Web site a list of all approved e-prescribing and pharmacy systems able to e-prescribe controlled substances. For more detail visit www.surescripts.com/about-e-prescribing/e-prescribing-of-controlled-substances.aspx, and click on “EPCS Certified Prescriber Software Vendors.”
- ◆ If your pharmacy does not utilize Surescripts, or you have e-prescriptions prescribed via another intermediary, please contact your company and/or IT vendor for information on how to validate the prescribing systems are certified.

Any Concerns with E-Prescribing?

The Board of Pharmacy has been actively involved with Ohio Health Information Partnership (OHIP), which is an organization whose goal is to increase the utilization of

e-prescribing and the adoption of health information exchanges in Ohio. The OHIP work groups, including Ohio Pharmacists Association and Board of Pharmacy staff, have concerns about the quality and types of errors that we are seeing in these electronic prescriptions. This group is also working on capturing the main safety issues that can go along with this change. Because as we all know even though some legibility issues may be resolved with e-prescribing, there are many other types of errors that e-prescribing may create. Potential errors include drop-down errors for wrong sig, drug, prescriber, and patient. Another common error includes free form sigs in the notes field, which may directly contradict the drop down chosen sig. If you notice these types of problems are occurring routinely, thus a system issue, please contact the Board and the Board will follow up with the vendor for corrective action.

APNs Now Prescribing C2 Prescriptions

As of June 8, you probably noticed C2 prescriptions coming into your pharmacies from advanced practice nurses (APNs). Per the last *Newsletter*, this is now legal but there are parameters spelled out for each classification of drug including opiates, sedatives/hypnotics, and stimulants. Please visit the Ohio Board of Nursing Web site for details at www.nursing.ohio.gov.

New Web Site Coming!

The Board has developed a new Web site for the Board of Pharmacy that will bring a fresh look and more intuitive functionality. Testing is going on currently, and a mass e-mail will be sent out upon going live. Look for it very soon!

Disciplinary Actions

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The agency 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

DEA – 800/882-9539, www.deadiversion.usdoj.gov

Page 5 – August 2012

The *Ohio State Board of Pharmacy News* is published by the Ohio State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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