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News

Delaware State Board of Pharmacy

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http://dpr.delaware.gov/boards/pharmacy/index.shtml

Pharmacy Issues

2012 Continuing Education Renewal Reminder

Edited by Susan Miccio

You should have received a renewal notice about two months before your license expires on September 30. The renewal notice explains how to file an online renewal application.

The requirements for renewals and continuing education (CE) are found in 24 *Del. C.* §2512 "Issuance and Renewal of License" and Pharmacy Regulations 1.3 and 1.4. The amount of CE required depends on when your Delaware license was issued:

- If issued before October 1, 2010 – 30 credit hours.
- If issued on or after October 1, 2010 – 1.25 credit hours per month that you were licensed.

You must complete the required CE credit hours before your license expires.

A program given by a Delaware State Board of Pharmacy-approved Delaware provider or approved by the Accreditation Council for Pharmacy Education (ACPE) automatically qualifies for CE credit. If a program is not already ACPE approved, you should **promptly** file a Request for Individual Program to request the Board's approval of the program. (The form is available at *www.dpr.delaware.gov* – click on "Pharmacy" and then on "Forms.") **Do not hinge renewal of your license on approval of a last-minute application!** Note that the Board may not approve the program or may approve it for less credit than you request.

Following the renewal, a percentage of pharmacists will be selected for audit of their CE. However, please do not submit CE documentation until you receive the Audit Notice.

Only pharmacists who are registered as immunizers and who maintain their continuing competency are allowed to administer injectable medications, biologicals, and adult immunizations (Regulation 14.1.3). You will be asked a question about your registration as an immunizing pharmacist on the renewal application. If you are registered as an immunizer, it is your responsibility to take at least two hours of CE, out of the 30 hours required each licensure period, in the area of immunization. It is the responsibility of each registered pharmacist to maintain his or her current status.

If you fail to renew your Delaware pharmacist license by September 30, your license will lapse. It is illegal to continue practicing without an active license. There is no "grace period."

Regulations 3, 5, and 17 Amendments

The Delaware State Board of Pharmacy, pursuant to 24 *Del. C.* §2506(a)(1), revised its rules and regulations for pharmacy regulations 3, 5, and 17. On June 20, 2012, the Board of Pharmacy held a hearing for the above regulations during a routine Board meeting. Effective August 11, 2012, the changes create a requirement that pharmacists-in-charge complete annual self-inspections; clarifies that a cabinet is not an acceptable storage location for controlled substances; removes the requirement that the Office of Narcotics and Dangerous Drugs be notified in the event of pharmacy construction; and adds a list of crimes to those defined as substantially related to the practice of pharmacy.

For further review please visit the Board's Web site at *www.dpr.delaware.gov* and view Regulations 3.1.2.7, 3.5.3, 3.5.5, 5.1.13.5, and 17.

Should you have any questions regarding this information, please contact the Board office.

Controlled Substance Issues

Diversion and Pharmacist-in-Charge Responsibilities

The Board of Pharmacy and the Office of Controlled Substances continue to receive numerous notices of missing/theft of controlled substances from pharmacies. In some cases the sheer number of associated controlled substances missing/diverted is staggering. Pharmacists-in-charge are reminded that they are the persons responsible for reporting, for pharmacy operations, and training of personnel and for proper adherence with state laws and regulations.

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 prescriptions. 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-

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 AWAR$_X$E® 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 AWAR$_X$E Web site at *www.awarerx.org/OTCMedUse.php.* The AWAR$_X$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

Practitioner Self-Treatment or Treatment of Immediate Family Members

The Board sometimes receives calls from pharmacists regarding practitioner self-treatment or treatment of immediate family members. The following is from the American Medical Association Guidelines, Opinion 8.19, regarding this issue.

Physicians generally should not treat themselves or members of their immediate families. Professional objectivity may be compromised when an immediate family member or the physician is the patient; the physician's personal feelings may unduly influence his or her professional medical judgment, thereby interfering with the care being delivered. Physicians may fail to probe sensitive areas when taking the medical history or may fail to perform intimate parts of the physical examination. Similarly, patients may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the physician is an immediate family member. This discomfort is particularly the case when the patient is a minor child, and sensitive or intimate care should especially be avoided for such patients. When treating themselves or immediate family members, physicians may be inclined to treat problems that are beyond their expertise or training. If tensions develop in a physician's professional relationship with a family member, perhaps as a result of a negative medical outcome, such difficulties may be carried over into the family member's personal relationship with the physician.

Concerns regarding patient autonomy and informed consent are also relevant when physicians attempt to treat members of their immediate family. Family members may be reluctant to state their preference for another physician or decline a recommendation for fear of offending the physician. In particular, minor children will generally not feel free to refuse care from their parents. Likewise, physicians may feel obligated to provide care to immediate family members even if they feel uncomfortable providing care.

It would not always be inappropriate to undertake self-treatment or treatment of immediate family members. In emergency settings or isolated settings where there is no other qualified physician available, physicians should not hesitate to treat themselves or family members until another physician becomes available. In addition, while physicians should not serve as a primary or regular care provider for immediate family members, there are situations in which routine care is acceptable for short-term, minor problems. Except in emergencies, it is not appropriate for physicians to write prescriptions for controlled substances for themselves or immediate family members.

When faced with the above issue, pharmacists should speak to the practitioner about their concerns focusing on the patient's care. While it is difficult to confront other health care professionals about their prescribing, patient safety is paramount.

Newly Licensed Pharmacists

Twenty-Two Issued from April 1, 2012 to June 30, 2012

Haneefah Jamiu – A1-0004273; Akua Asare – A1-0004274; Unmil Rana – A1-0004275; Mahesh Tickley – A1-0004276; Monica Pobee – A1-0004277; Neelima Koduru – A1-0004278; Benjamin Lopchinsky – A1-0004279; Amanda Dacey – A1-0004280; Sean Whalen – A1-0004281; Emma Collina – A1-0004282; Muzit Iyassu – A1-0004283; Kristy Casale – A1-0004284; Ying Chow – A1-0004285; James Woznicki – A1-0004286; George Shehata – A1-0004287; Satyam Patel – A1-0004288; Sandra Mihalick – A1-0004289; Cheryl Krempa – A1-0004290; Lakshmi Kandula – A1-0004291; Karen Alesch – A1-0004292; Vinaykumar Prajapati – A1-0004293; Chetana Patel – A1-0004294.

Distributor Permits

Twenty Issued from April 1, 2012 to June 30, 2012

Exel, Inc – A4-0001896; Slate Pharmaceuticals, Inc – A4-0001897; Anda Pharmaceuticals, Inc – A4-0001898; Boehringer Ingelheim Vetmedica, Inc – A4-0001899; Linde Gas North America LLC – A4-0001900; Exel, Inc – A4-0001901; AMD Pennsylvania, LLC – A4-0001902; Physicians Total Care, Inc – A4-0001903; Dixon Shane LLC dba R+S Northeast LLC – A4-0001904; Emergency Medical Services & Preparedness Section – A4-0001905; Vedco, Inc – A4-0001906; Eye Supply USA, Inc – A4-0001907; Safecor Health, LLC – A4-0001908; Fibrocell Technologies, Inc – A4-0001909; UPS Supply Chain Solutions, Inc – A4-0001910; MWI Veterinary Supply Co. – A4-0001911; APL Logistics WMS, Inc – A4-0001912; Teleflex Medical Incorporated – A4-0001913; Teleflex Medical Incorporated – A4-0001914; Fisher Clinical Services, Inc – A4-0001915.

In-State Pharmacy Permits

Three Issued from April 1, 2012 to June 30, 2012

The Corner Apothecary – A3-0000931; HomeTown Drugs – A3-0000932; Cure Pharmacy – A3-0000933.

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The *Delaware State Board of Pharmacy News* is published by the Delaware 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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