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Delaware State Board of Pharmacy News

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Pharmacy Issues

Year 2014 Continuing Education Renewal Reminder

Edited by Susan Miccio

You will receive a renewal notice about two months before your license expires on September 30. The renewal notice will explain 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. Please remember that as per Regulation 1.4.1.1, at least two hours of CE per biennial licensure period must be in the area of medication safety/errors.

The amount of CE required depends on when your Delaware license was issued:

- If issued before October 1, 2012 – 30 credit hours.
- If issued on or after October 1, 2012 – 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 Board- or ACPE-approved, you should **promptly** file a Request for Individual Program Approval form to request the Board's approval of the program (The form is available on *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."

Controlled Substance Regulation Amendments

Effective April 11, 2014, pursuant to 29 *Del. C.* §10118, Controlled Substance Rules and Regulations were amended. The amendments re-organize the rules for greater clarity and expand the rules to incorporate pertinent provisions from Chapter 47 of Title 16. Rule 8.0 is added to address dispensing by practitioners. Rule 3.0 was amended to require initial and biennial credits of controlled substance (CS) CE to enhance practitioner competence for greater protection of the public. The rules pertaining to security in dispensing, now set forth in Rule 7.0, are amended for greater public protection. They include, but are not limited to, Regulation 7.1.2, which states that unless otherwise authorized by the Office of Controlled Substances, all CS storage area or areas shall be provided with electronic intrusion detection equipment to all sections of the said area or areas where CS are stored, so as to detect four-step movement. Four-step movement is the movement of a person walking not more than four consecutive steps at a rate of one step per second. Such four-step movement shall constitute a "trial," and a sufficient number of detection units shall be installed so that, upon test, an alarm will be initiated in at least three out of every four consecutive "trials" made moving progressively through the protective area. Electronic intrusion detection equipment shall be installed using equipment that must be UL approved and listed. The said system must be capable of transmitting a local alarm to an outside audible device that shall comply with UL Standards. Rule 7.1.3 requires that the immediate area in a pharmacy remodeled or newly constructed after July 31, 2011, containing dispersed, controlled drugs must be secured in a manner approved by the Office of Controlled Substances that will prevent entry by unauthorized persons. Such a manner includes, but is not limited to, the implementation of a floor to ceiling physical barrier limiting access to the pharmacy area, motion detectors, strategically placed surveillance cameras, and back-up alarm systems.

For further review, please see the Controlled Substance Rules and Regulations on the Board's website at *www.dpr.delaware.gov.* Should you have any questions regarding this information, please contact the office.

New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding*. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

Controlled Substance Issues

Diversion and Pharmacist-in-Charge Responsibilities

The Board and the Office of Controlled Substances continue to receive numerous notices of missing/theft of CS from pharmacies. In some cases, the sheer number of associated CS 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.

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

20 Issued from January 1, 2014 to March 30, 2014

Jayshree R. Shingala – A1-0004536; Sheetal Dixit – A1-0004537; Elyse L. Rabin-Tepper – A1-0004538; Ronald R. Sansone – A1-0004539; Joseph P. Waters – A1-0004540; Hamedat Okanlawon – A1-0004541; Anthony B. Roane – A1-0004542; Joseph V. Tinelli – A1-0004543; Tanaya N. Hampton – A1-0004544; Emily K. Schlueter – A1-0004545; Lucinda M. Jimenez – A1-0004546; Jasmine L. Mencia – A1-0004547; Lawrence J. Lubonski – A1-0004548, Chia-Chi Lee – A1-0004549; Prince Jain – A1-0004550; Daniela B. Regalado – A1-0004551; Barbara D. Mensah – A1-0004552; Nicholas Barkley – A1-0004553; Safak Duru Paker-Leggs – A1-0004554; Carrie F. Connahan – A1-0004555.

Distributor Permits

41 Issued from January 1, 2014 to March 30, 2014

Vaxserve, Inc – A4-0001152; Technomed, Inc – A4-0001781; Calvin Scott & Company, Inc – A4-0002040; PSS World Medical, Inc – A4-0002041; Atlantic Biologicals Corp – A4-0002042; McKesson Medical-Surgical Inc – A4-0002043; Exel, Inc – A4-0002044; Exel, Inc – A4-0002045; Exel, Inc – A4-0002046; Exel, Inc – A4-0002047; Exel, Inc – A4-0002048; Exel, Inc – A4-0002049; Exel, Inc – A4-0002050; The Harvard Drug Group, LLC dba Expert Med, First Veterinary Supply – A4-0002051; Pernix Therapeutics, LLC – A4-0002053; Merz Aesthetics, Inc – A4-0002054; Exel Inc – A4-0002055; Discus Dental, LLC – A4-0002056; Cardinal Health 200, LLC dba Cardinal Health – A4-0002057; Cardinal Health 200, LLC – A4-0002058; Clinical Solutions Wholesale, LLC – A4-0002059; Exel Inc – A4-0002061; Amneal Institutional, LLC – A4-0002062; The Compounding Center, Inc – A4-0002063; Septodont, Inc – A4-0002064; PSS World Medical, Inc – A4-0002065; Emerson Ecologics, LLC – A4-0002066; St Mary's Medical Park Pharmacy, Inc – A4-0002067; McKesson Corporation dba McKesson Drug Company – A4-0002068; McKesson Corporation – A4-0002069; Asclemed USA, Inc – A4-0002070; Exel, Inc – A4-0002071; Exel, Inc – A4-0002072; Axiom Marketing, Inc – A4-0002073; Patterson Dental Supply, Inc – A4-0002074; INO Therapeutics, LLC – A4-0002075; TheraCom, LLC – A4-0002076; ECR Pharmaceuticals Company, Inc – A4-0002077; RGH Enterprises, Inc – A4-0002078; Professional Hospital Supply, Inc – A4-0002079.

In-State Pharmacy Permits

Two issued from January 1, 2014 to March 30, 2014

Rite Aid #1294 – A3-0000481, ShopRite Pharmacy #538 – A3-0000533.

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™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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