May 2016

News

Delaware State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

Cannon Building • 861 Silver Lake Blvd, Suite 203 • Dover, DE 19904

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

Pharmacy Issues

Address and Name Changes

The 2016 renewal for pharmacists is fast approaching. Renewal notices will be mailed in July. Please be sure that your mailing address is correct so that you will receive the renewal notice. You can check and update your address online at *www.dpr.delaware.gov;* click Online Services for Licensees.

If your name has changed since your last renewal, submit a Request for Name Change form. Enclose a copy of the legal document that changed your name (eg, marriage certificate) with the form. The form is available at *www.dpr.delaware.gov;* click Guide to Information, then Name Change under Report Information.

Continuing Education Reminders

Edited by Susan Miccio

Your license expires on September 30. The renewal notice the Delaware State Board of Pharmacy sends you 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 at least two hours of CE in each two-year license period must be in the area of medication safety/errors (Regulation 1.4.1.1). Controlled substance (CS) CE credit is **not** required for your 2016 renewal.

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

- If issued before October 1, 2014, 30 credit hours.
- If issued on or after October 1, 2014, 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 Board-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 Approval form 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 request!** 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 two-year license 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.

Get Involved With the Board

Get involved! Pharmacists, students, interns, and technicians are invited to attend regularly scheduled meetings of the Board. With the exception of July and December, the Board meets monthly to discuss pharmacy business as well as to preside over any disciplinary matters. The meetings will routinely be held on the third Wednesday of each month at 9:30 AM. These meetings are open to the public, except when the Board might enter into executive session. The Board welcomes your attendance and

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FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

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 Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc*. 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med*. 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc*. 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

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contributions. The Board calendar and meeting agenda can be accessed at *https://egov.delaware.gov/pmc/#agency94*.

Controlled Substance Issues

Diversion and PIC Responsibilities

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

Refilling CS Prescriptions Early

The Board office has recently had numerous calls related to the early refilling of CS prescriptions. There is no easy way to determine how early a CS refill may be filled. Delaware patients have a whole host of events that would require early refills, including but not limited to vacations, medication loss, and waste. However, when the request for an early refill begins to be repeated and becomes a routine, the pharmacist should contact the practitioner to alert him or her of the patient's reasoning for early filling and to ensure practitioner knowledge of the repeated event. Documentation of the practitioner contact should be kept on file. A pharmacy written policy and procedure including proper documentation of the handling of the early refill is suggested.

Newly Licensed Pharmacists

28 Issued From January 1, 2016, to March 31, 2016

A1-0004894 – Thanh Hien Thi Wang; A1-0004895 – Latrina Denise Melton; A1-0004896 – Warren L. Hill; A1-0004897 – Rekha Rao; A1-0004898 – Deborah P. Hanson; A1-0004899 – Falak A. Thaker; A1-0004900 – Zoya Shub; A1-0004901 – Arin R. Passmore; A1-0004902 – Ryan T. Albano; A1-0004903 – Patricia A. Morris; A1-0004904 – Clay Addison Parkel; A1-0004905 – James A. Hannon; A1-0004906 – Melinda A. O'Shaughnessy; A1-0004907 – Hiba Z. Cheetany; A1-0004908 – Elon R. Jacobs; A1-0004909 – Pamela Sing; A1-0004910 – Saurin Chandrakant Modi; A1-0004911 – Kanchan A. Mirchandani; A1-0004912 – Amakoe Lene Ajavon; A1-0004913 – Alfreda T. Morris; A1-0004914 – Joanna L. Ochana; A1-0004915 – Jeannine Anne Hipp; A1-0004916 – Mahjabeen S. Majeed; A1-0004917 – Ashley R. Schappell; A1-0004918 – Makda Getachew; A1-0004919 – Suebang D. Kenmatio; A1-0004920 – Yomile A. Gebremariam; A1-0004921 – Christy M. Cosmano

Distributor Permits

19 Issued From January 1, 2016, to March 31, 2016

A4-0001721 – BioRidge Pharma, LLC; A4-0001782 – Owens & Minor Distribution, Inc; A4-0002273 – Reckitt Benckiser, LLC; A4-0002274 – Dsquared Pharmaceuticals, Inc; A4-0002275 – Dendreon Pharmaceuticals, Inc; A4-0002276 – MD Logistics, Inc; A4-0002277 – Omnicare Distribution Center, LLC; A4-0002278 – ZO Skin Health, Inc; A4-0002279 – Med-Pro Distributors, LLC; A4-0002280 – Trigen Laboratories, LLC; A4-0002282 – PharMEDium Services, LLC; A4-0002283 – Sunstar Americas, Inc; A4-0002284 – Dendreon Pharmaceuticals, Inc; A4-0002286 – Mallinckrodt Nuclear Medicine, LLC; A4-0002287 – J. Knipper & Company, Inc; A4-0002288 – McKesson Medical-Surgical, Inc; A4-0002289 – Haemonetics, Corporation; A4-0002290 – QuVa Pharma, Inc; A4-0002291 – VistaPharm, Inc

In-State Pharmacy Permits

Five Issued From January 1, 2016, to March 31, 2016

A3-0000997 – Delaware CVS Pharmacy, LLC; A3-0000998 – Kmart Operations, LLC, Kmart Pharmacy #7725; A3-0000999 – Atlantic Apothecary; A3-0001000 – Express Discount Pharmacy, LLC; A3-0001001 – Unioncare Pharmacy

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