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Delaware State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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

Pharmacy Issues

Mandatory Duty to Report

As a Delaware-licensed health care provider, you have mandatory duties to report under Delaware law. The purpose of this information is to explain the mandatory duties to report that apply to your profession. Delaware law **mandates** you to report, in writing, within 30 days of becoming aware of information that you reasonably believe indicates that **any health care provider,** including (but not limited to) any practitioner certified and registered to practice medicine in Delaware or licensed by the Board of Mental Health and Chemical Dependency Professionals, who:

- ♦ has engaged or is engaging in conduct that would constitute grounds for discipline under his or her licensing laws; or
- ♦ may be unable to practice with reasonable skill and safety to the public by reason of mental illness or mental incompetence; physical illness (including deterioration through the aging process or loss of motor skill); or excessive abuse of drugs (including alcohol).

You must file your report with the Division of Professional Regulation within 30 days of becoming aware of the information. The law imposes a $10,000 to $50,000 fine for noncompliance. The law also allows the division to keep your identity confidential and affords immunity from civil or criminal prosecution for good faith reporting.

The sections of Delaware law that explain your duties are 24 Del. C. §3018, 24 Del. C. §1730, 24 Del. C. §1731, and 24 Del. C. §1731A.

For information on filing a report, visit the division's website at *www.dpr.delaware.gov* and click on "Report Healthcare Provider" under "Services."

Delaware law also **mandates** you to make an immediate oral report to the Department of Services for Children, Youth and Their Families when you know of or suspect child abuse or neglect under Chapter 9 of Title 16 of the **Delaware Code** and to follow up with any requested written reports (16 Del. C. §903).

You may report child abuse or neglect by calling the department's 24-hour child abuse and neglect hotline at 800/292-9582. The department will notify the Division of Professional Regulation of child abuse allegations.

Delaware law also **mandates** you to **self-report** when:

- ♦ your license to practice as a pharmacist in another jurisdiction has been subject to discipline or has been surrendered, suspended, or revoked; or
- ♦ you have been convicted of a crime that is substantially related to the practice of pharmacy (24 Del. C. §2515 (a)(8)).

For information on filing a report, visit the division's website at *www.dpr.delaware.gov* and click on **"Report Healthcare Provider"** under "Services."

Should you have any questions regarding this information, please contact the Delaware State Board of Pharmacy office.

Delaware Prescription Monitoring Program Update

The Delaware Prescription Monitoring Program (PMP) started collecting data from pharmacies on March 1, 2012. The Delaware PMP is a tool created to prevent and detect prescription drug misuse and diversion, as well as enable better coordination of patient care. It is another tool clinicians can add to their toolkit for preventing and intervening against misuse and diversion of prescription drugs.

The Delaware PMP maintains a database of **all** transactions for controlled substances (CS) dispensed in the state of Delaware. The data is reported on a daily basis by Delaware-licensed pharmacies and prescribers who dispense CS. This database is available online to

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Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

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 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.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

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 medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

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prescribers and dispensers and is a free service through the Office of Controlled Substances (OCS) in the Division of Professional Regulation. Delaware-licensed prescribers are encouraged to register to request patient reports. These patient reports, and the automatically sent threshold reports, enhance the ability of health care providers to coordinate care. The database is searchable online and is available 24/7 with full mobile device access. Prescribers can use the program to check the history of a new patient and to monitor ongoing treatment.

The Delaware PMP is to be used for health care purposes only. The Delaware Prescription Monitoring Act (16 Del. C. §4798) authorizes the OCS to establish, maintain, and monitor the Delaware PMP and to reduce misuse of CS in this state while promoting improved professional practice and patient care. The OCS does not warrant any report to be accurate or fully complete and expressly disclaims liability for errors and omissions in the contents of this report. Records on this report should be verified before any clinical decisions are made or actions are taken. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and all confidentiality and non-disclosure provisions of Delaware law cover the information contained in this database. All users must comply with HIPAA Privacy Rule requirements when using this system. Reports from the Delaware PMP database **may not** be distributed to the patient. Failure to abide by all applicable federal HIPAA and state privacy laws could lead to disciplinary sanctions, which may include fines and/or criminal prosecution. The Delaware PMP commenced interstate PMP data sharing through the National Association of Boards of Pharmacy® (NABP®) PMP InterConnect® in November 2013. NABP, through grants, funded the implementation and two years of interstate sharing maintenance, which were costs incurred from the state's PMP vendor. NABP will continue to fund the separate costs for data transmission through NABP InterConnect through June 30, 2016.

For additional information and questions, please e-mail the Delaware PMP at delawarepmp@state.de.us.

Delaware State Board of Pharmacy Newsletter Updates

Notifications about the *Delaware State Board of Pharmacy Newsletter* are available only by e-mail. To ensure that you receive future *Newsletter* notices, you must keep your e-mail address in the Division of Professional Regulation's database up to date. You can update your e-mail and other contact information online at *www.dpr.delaware.gov.* Click on "Change Contact Information" on the left and follow the instructions for logging in.

Newly Licensed Pharmacists

31 Issued from October 1, 2013 to December 31, 2013

Nancy T. Duong – A1-0004505; Thomas Austin McLean – A1-0004506; Khushbu Patel – A1-0004507; Pamela A. Gagliardi – A1-0004508; Adeshola A. Olubode – A1-0004509; Rickey Tang – A1-0004510; Celeste A. Meanix – A1-0004511; Amanda Lauren Yosslowitz – A1-0004512; Shiven Bhardwaj – A1-0004513; Sheila N. Arrington – A1-0004514; Jenna L. Murray – A1-0004515; Desta Kamala – A1-0004516; Jay C. Patel A1-0004517; Shannon M. Tryon – A1-0004518; James J. Xu – A1-0004519; Natalie E. Hemphill – A1-0004520; Abduselam M. Suleyman – A1-0004521; Diane M. Pascu – A1-0004522; Ogboo Sosi – A1-0004523; Joohee Lee – A1-0004524; Susan M. Sincavage – A1-0004525; John N. Wallner – A1-0004526; Melissa Miller-Beaty – A1-0004527; Harlan J. Smith – A1-0004528; Etsegenet H. Menji – A1-0004529; Maria D. Seeke – A1-0004530; Nicholas J. Carini – A1-0004531; Kyle R. Mason – A1-0004532; Jennifer L. Reyes – A1-0004533; Patricia A. Owusu – A1-0004534; Kristi Ann Kubosh – A1-0004535.

Distributor Permits

11 Issued from October 1, 2013 to December 31, 2013

Cardinal Health 200, LLC – A4-0002029; DUSA Pharmaceuticals, Inc – A4-0002030; Alson Laboratories, Inc – A4-0002031; Diplomat Pharmacy Services – A4-0002032; Gulf South Medical Supply, Inc – A4-0002033; Grifols USA, LLC – A4-0002034; Cooper Surgical, Inc – A4-0002035; Cardinal Health 200, LLC – A4-0002036; Reliance Wholesale, Inc – A4-0002037; Turning Point Logistics, LLC – A4-0002038; Fagron Holding, LLC, dba B&B Pharmacy – A4-0002039.

In-State Pharmacy Permits

Four Issued from October 1, 2013 to December 31, 2013

Delaware CVS Pharmacy #10222, LLC – A3-0000959; Delaware CVS Pharmacy #10296, LLC – A3-0000960; Walgreens #13823 – A3-0000962; Atlantic Apothecary Middletown – A3-0000963.

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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