May 2018

Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

Published to promote compliance of pharmacy and drug law

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A Message From Secretary Schneider

Greetings,

Welcome to the May issue of the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter.*

I hope that everyone's spring season is off to a great start. I am pleased to announce that the Illinois Department of Financial and Professional Regulation (IDFPR) recently hired a new drug compliance investigator, Robert (Rob) Nelson, RPh, BCOP. Rob joins the Drug Compliance Unit with many years of experience in different settings in pharmacy. Rob is from a family of pharmacists. His uncle and father were pharmacists, his son is now a pharmacist, and one of his nephews soon will be. He graduated from Ohio Northern University in Ada, OH, where he met his wife of 28 years. His career with the IDFPR started in the Medical Cannabis Unit, providing regulatory supervision and collaboration to support the implementation of the Medical Cannabis Pilot Program.

After college, Rob started his career working at a large hospital pharmacy and filling in part-time at his family's pharmacy. While working hospital pharmacy full-time for 19 years, he gained experience in clinical pharmacy, institutional pharmacy, sterile compounding, hazardous drug compounding, and investigational drugs. He then took a position as a consultant pharmacist at a long-term care pharmacy services provider. Disease state management, monitoring drug therapy, and ensuring compliance with rules and regulations were major job responsibilities. Next, he accepted the opportunity to work in a non-traditional setting of a physician office-based infusion center at a cancer institute. Here, he was tasked with attaining United States Pharmacopeia Chapter <797> compliance, ensuring safety in all aspects of providing chemotherapy, and implementing an investigational drug and pharmacy student experiential program. He became Board-certified in oncology pharmacy in 2014. Rob's commitment to the profession of pharmacy and experience in many different settings will be a valuable addition to the Drug Compliance Unit.

Very truly yours,
Bryan A. Schneider
Secretary, IDFPR
bryan.schneider@illinois.gov, 312/793-3676

Upcoming Board Meetings

The IDFPR, Division of Professional Regulation – State Board of Pharmacy is scheduled to meet:

- May 15, 2018 (Chicago, IL)
- July 10, 2018 (Chicago)

Chicago location: 100 W Randolph Street, 9th Floor

Notice of Proposed Rulemaking

The IDFPR has proposed changes to the Rules for the Administration of the Illinois Pharmacy Practice Act, published in the December 26, 2017 issue of the *Illinois Register,* Volume 41, Issue 51 (also available through the Illinois Secretary of State). The publication of this notice began the 45-day public comment period, which ran through February 9, 2018. The IDFPR will be responding to the large volume of comments received during the public comment period before filing for Second Notice.

For more information on the Illinois rulemaking process, you may view this user-friendly guide.

Collaborative Pharmaceutical Task Force

Public Act 100-0497, the sunset reauthorization of the Pharmacy Practice Act, created the Collaborative Pharmaceutical Task Force to discuss and make recommendations on how to further advance the practice of pharmacy in a manner that recognizes the needs of the health care system, patients, pharmacies, pharmacists, and pharmacy technicians.

As a part of its discussions, the Task Force shall consider, at a minimum, the following (reformatted from the original):

- the extent to which providing whistleblower protections for pharmacists and pharmacy technicians reporting violation of worker policies; . . .

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National Pharmacy Compliance News

May 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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- requiring pharmacies to have at least one pharmacy technician on duty whenever the practice of pharmacy is conducted;
- to set a prescription filling limit of not more than 10 prescriptions filled per hour;
- to mandate at least 10 pharmacy technician hours per 100 prescriptions filled;
- to place a general prohibition on activities that distract pharmacists;
- to provide a pharmacist a minimum of 2 15-minute paid rest breaks and one 30-minute meal period in each workday on which the pharmacist works at least 7 hours;
- to not require a pharmacist to work during a break period;
- to pay to the pharmacist 3 times the pharmacist's regular hourly rate of pay for each workday during which the required breaks were not provided;
- to make available at all times a room on the pharmacy's premises with adequate seating and tables for the purpose of allowing a pharmacist to enjoy break periods in a clean and comfortable environment;
- to keep a complete and accurate record of the break periods of its pharmacists;
- to limit a pharmacist from working more than 8 hours a workday; . . .
- to retain records of any errors in the receiving, filling, or dispensing of prescriptions of any kind could be integrated into the Pharmacy Practice Act; . . .
- requiring pharmacy prescription systems contain mechanisms to require prescription discontinuation orders to be forwarded to a pharmacy;
- to require patient verification features for pharmacy automated prescription refills; . . .
- to require that automated prescription refills notices clearly communicate to patients the medication name, dosage strength, and any other information required by the Department governing the use of automated dispensing and storage systems to ensure that discontinued medications are not dispensed to a patient by a pharmacist or by any automatic refill dispensing systems whether prescribed through electronic prescriptions or paper prescriptions may be integrated into the Pharmacy Practice Act to better protect the public; . . .
- the extent to which Public Act 99-473 (enhancing continuing education requirements for pharmacy technicians) and Public Act 99-863 (enhancing reporting requirements to the Department of pharmacy employee terminations) may be relevant to the [above] issues.

The task force meets at least once per month or more frequently if deemed necessary by the Task Force Chair. The next Collaborative Pharmaceutical Task Force meeting will be held May 15, 2018, at 1:30 PM and will mark the task force's fifth meeting. The February meeting focused on the Whistleblower Act and patient safety. The National Association of Boards of Pharmacy® gave a presentation at the March meeting on the rules and regulations in other states aimed at addressing the issues above. Several guest speakers came to the April meeting to discuss e-prescribing and e-discontinuation. The meetings are held in both Chicago and Springfield, IL, via video conference and are regularly scheduled for the second Tuesday afternoon of each month. All task force meetings are open to the public and attendance is encouraged. If you are interested in following the work of the Collaborative Pharmaceutical Task Force, future meeting notices and agendas will be posted on the Board's page of the IDFPR website.

National Transportation Safety Board Report

In 2014, the National Transportation Safety Board issued a report titled "Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment." Among other things, the report highlighted the importance of routine discussions between licensed health care providers, pharmacists, and patients about the transportation safety risks associated with some diagnosed medical conditions and drugs.

As a reminder, pursuant to the Administrative Rules regarding the Pharmacy Practice Act, prior to dispensing a prescription to a new patient, a new medication to an existing patient, or a medication that has had a change in the dose, strength, route of administration, or directions for use, the pharmacist shall provide verbal counseling to the patient, which includes counseling on "[c]ommon severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur" (68 Illinois Administrative Code 1330.700).

The *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter* is published by the Illinois Department of Financial and Professional Regulation (IDFPR) 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 IDFPR unless expressly so stated.

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