



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

<https://dpr.delaware.gov/boards/pharmacy>

Pharmacy Issues

Letter From the Board – Avoiding Rule Violations

The Delaware State Board of Pharmacy and Delaware Division of Professional Regulation are concerned about the frequency of certain recent rules violations. This article alerts you to the violations and explains how to avoid them.

Pharmacist-in-Charge Responsibilities

The Board's Rules and Regulations (Section 3.1) assign specific responsibilities to pharmacists-in-charge (PICs). Violations related to some of these responsibilities occur often.

- ◆ If you are named as a PIC but have never held the position before, you must appear before the Board for an interview within 90 days after you take the position. Even if the position is “acting” PIC, the interview is still required if your tenure will last more than 90 days.
- ◆ When a pharmacy's PIC changes, the outgoing PIC must notify the Board within 10 days. In addition, the new PIC must complete a **self-inspection report** within 30 days of taking the role and, after that, every year on February 1. Forms for these reports are available at <https://dpr.delaware.gov/boards/pharmacy/forms>.
- ◆ If you are leaving your PIC position, you **and** the incoming PIC together must inventory all controlled substances (CS). Send a copy of the inventory to the Delaware Office of Controlled Substances and keep a copy on the premises.

The Rules and Regulations are available online at the following links:

- ◆ Board Rules and Regulations: <http://regulations.delaware.gov/AdminCode/title24/2500.shtml>
- ◆ Uniform Controlled Substances Act Regulations: <http://regulations.delaware.gov/AdminCode/title24/Uniform%20Controlled%20Substances%20Act%20Regulations>

Loss or Theft of Controlled Substances

CS registrants must file immediate reports when a theft or significant loss of CS occurs, as follows:

- ◆ Notify the Office of Controlled Substances as soon as the loss is discovered. Also, complete the required federal forms and send them to the Office of Controlled Substances.
- ◆ Notify the Drug Enforcement Administration (DEA) Field Division Office in the area, in writing, within one business day of discovery of the loss. Also, file a DEA Form 106, Report of Theft or Loss of Controlled Substances, and send a copy of it to the Office of Controlled Substances. The current DEA Form 106 is available at https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.

Newly Licensed Pharmacists

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Constance L. Smith – A1-0005140; Eric V. Nguyen – A1-0005141; Jagadishkumar N. Rabadia – A1-0005142; Steven Andersen – A1-0005143; Timothy John Derose – A1-0005144; Aaron M. Gehring – A1-0005145; Joel L. Copper – A1-0005146; Jessica Paulistin Marcelin – A1-0005147; Chandni Chintan Thakkar – A1-0005148; Lisa Anne Heisey – A1-0005149; Ethel A. Fomundam – A1-0005150; Akash Verma – A1-0005151; Blaid Kapiamba Mbiyangandu – A1-0005152; Gregory C. Hayes – A1-0005153; Yekaterina E. Mutilin – A1-0005154; Hyun Jung Shim – A1-0005155; Sumit H. Bhalodia – A1-0005156; Kyle Zenon Rajkowski – A1-0005157; Christina Ly – A1-0005158; Erin Nicole Barton – A1-0005159; Laura Michelle Watkins – A1-0005160; John K. Price – A1-0005161; Nazaree Hines-Starr – A1-0005162; Ashley E. Payne – A1-0005163; Thomas Andrew Madej – A1-0005164; Katherine Michelle Gibison – A1-0005165; Rebecca Anne Straub – A1-0005166; Aviva Y. Bodek – A1-0005167; Kelly Ann Alexander – A1-0005168; Edwin K. Langat – A1-0005169; Heather Tyas – A1-0005170; Thanh T. Ngo – A1-0005171; Darshna P. Patel – A1-0005172; Jonette Lee Vagts – A1-0005173; Capri J. DiGiovanni – A1-0005174; Michael Torosian – A1-

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National Pharmacy Compliance News

April 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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0005175; Jennifer Amirhamzeh – A1-0005176; Alicia R. Vickers – A1-0005177; Ronald Joseph Zaycer – A1-0005178; Sonia R. Darley – A1-0005179; Jenny R. Liu – A1-0005180; Mi Jang – A1-0005181; Sandy Lim – A1-0005182; Ryan A. Ung – A1-0005183; Michael Lee Nguyen – A1-0005184; Kevin Patrick Gallagher – A1-0005185; Andrew M. Nye – A1-0005186; Mayur Indravadan Patel – A1-0005187; Twillow R. Rhodes – A1-0005188; Hannah Mary McGuigan – A1-0005189; Karen Gordon – A1-0005190; Andrea J. Samuels-Smith – A1-0005191; Sharon F. Rosal – A1-0005192; David S. Bourgeois – A1-0005193; Irene Toth – A1-0005194; Jacquelin S. Braner – A1-0005195; Linda K. Raleigh – A1-0005196; Samantha L. Landolf – A1-0005197; William Todd Kautz – A1-0005198; Yunju Lee – A1-0005199; Collin Wofford Runyon – A1-0005200; Jamie R. Beever – A1-0005201; Peter P. Anley – A1-0005202; Robert M. Gosner, Jr – A1-0005203

Distributor Permits

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In-State Pharmacy Permits

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Christiana Care Pharmacy – A3-0000701; Aerenson Road Pharmacy, LLC – A3-0001015

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