



# Iowa Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Online License and Registration Renewals**

The Iowa Board of Pharmacy has converted its legacy licensing database to iGov Solutions, LLC's Integrated Licensing and Enforcement Management System (iLEMS). You may now log on at [https://iowa.igovsolution.com/ibop/online/user\\_login.aspx](https://iowa.igovsolution.com/ibop/online/user_login.aspx) and create a user profile. Through this portal, individuals can manage personal information online, including updating address and employment information.

A cornerstone to this solution includes the provision for licensees and registrants to renew and pay for licenses and registrations online through their respective user profiles. As of May 15, 2018, pharmacists, pharmacy technicians, and individual Controlled Substance Act (CSA) registrants are able to renew through the online portal. More license and registration categories will be added and given online renewal permissions throughout 2018. Businesses will be able to renew licenses online starting November 1, 2018.

## **Approved Activities: Technicians vs Interns**

*By Danielle Watznauer, Pharmacist-Intern*

Often there may be confusion as to what the differences are regarding what pharmacy technicians and pharmacist-interns may do within the pharmacy. The greatest difference lies within activities entailing professional judgment. Pharmacy technicians are not authorized to perform tasks requiring professional judgment. Such activities include interpreting prescription drug orders, conducting prospective drug use review, and performing final product verification, except for participation in an approved tech-check-tech program. Technicians cannot provide patient counseling, consultation, or patient-specific drug information, nor can they tender an offer of patient counseling on behalf of a pharmacist or accept a refusal of patient counseling from a patient or patient's agent. They also cannot transfer a prescription to another pharmacy or receive the transfer of a prescription from another pharmacy.

However, pharmacist-interns are allowed to perform activities requiring professional judgment. These tasks,

usually restricted to a pharmacist, may be delegated to interns registered by the Board at the discretion of the supervising pharmacist. These judgmental functions include, but are not limited to, verifying the accuracy, validity, and appropriateness of filled prescriptions, reviewing and assessing patient records, providing patient counseling, and administering vaccinations. In addition, interns may answer patient-specific drug information questions and transfer a prescription into or out of the pharmacy under the pharmacist's supervision. A licensed pharmacist on duty in the pharmacy is responsible for all actions of the intern.

## **Prescription Monitoring Program – Updated!**

*By Sharon Smith, Clerk Specialist*

On April 4, 2018, the Board, in coordination with Appriss Health, launched its new prescription monitoring program (PMP) system, PMP AWA<sub>R</sub>X<sub>E</sub>. The updated, more user-friendly software platform allows users the ability to register and submit requests online, self-manage delegate users, and reset their own password, to name a few small but convenient changes. The new advanced analytical tool, NarxCare, primarily uses PMP data to generate a patient-centered interactive report, including Narx Scores and Overdose Risk Scores, which enables prescribers and dispensers to visualize and analyze their patients' controlled substance (CS) use history. This, along with the optional integration into electronic health records and pharmacy dispensing systems, will make the PMP an even greater asset to health care professionals when determining appropriate treatment for their patients.

Additionally, dispensers can now submit data to multiple states with one PMP Clearinghouse account. On May 16, 2018, Board Rule 657-37.3(3) became effective, which requires dispensers to report dispensings to the PMP no later than the next business day.

Technical assistance provided by Appriss Health is available 24/7 at 844/442-4767. More information regarding PMP AWA<sub>R</sub>X<sub>E</sub> may be found at <https://iowa.pmpaware.net>.

# National Pharmacy Compliance News

June 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](http://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](http://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](http://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](http://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](http://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](http://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](http://www.ptcb.org).



## USP Chapters <795> and <797> Updates on Compounding Standards – Comment Period

To provide a unified approach to quality compounding, United States Pharmacopeia (USP) intends to align the timing and content of General Chapters <795>, <797>, and <800>. Chapters <795> and <797> are in the active revision process. Among other content changes in the proposed revisions, hazardous drug handling sections in Chapters <795> and <797> will reference Chapter <800>. Chapter <800> was completed and published in February 2016 and is not currently under revision.

The three chapters are anticipated to be official and aligned on December 1, 2019. It is important to note that the current published versions of United States Pharmacopeia and the National Formulary Chapters <795> and <797> are official until the revised chapters become official.

The public comment period for Chapter <795> opened on March 30, 2018, and will close on July 31, 2018. Comments may be submitted electronically at [https://usp.az1.qualtrics.com/jfe/form/SV\\_aWexhZowjRBbKnP](https://usp.az1.qualtrics.com/jfe/form/SV_aWexhZowjRBbKnP). The public comment period for Chapter <797> will open on July 27, 2018, and will close on November 30, 2018. USP will host an open microphone session on September 5, 2018. During the session, USP will highlight changes in the proposed revised standard and answer questions about the approach and methodology of the revision.

As a reminder, the Board requires adherence to USP Chapter <795> (Board Rule 657-20.3) and Chapter <797> (Board Rule 657-20.4). Questions regarding compliance standards may be directed to your assigned compliance officer.

### Legislative Update

By Dayton Trent, Pharmacist-Intern

The Iowa Legislature has adjourned its 2018 session. The Legislature passed a significant bill relating to the opioid epidemic (House File 2377, referred to as the “opioid bill”), as well as bills initiated by the Board and the Iowa Pharmacy Association (IPA). On May 14, 2018, Governor Kim Reynolds signed the opioid bill; she has also signed the Board’s and IPA’s bills.

House File 2377 was signed into law with hopes to mitigate the opioid epidemic. The bill contains several new requirements, but the information below covers only the portions that affect pharmacists and pharmacies:

**Electronic Prescriptions.** Beginning January 1, 2020, every prescription issued must be electronically transmitted to a pharmacy. There are certain exceptions identified in the bill – such as for patients residing in inpatient hospice care, long-term residential facilities, or correctional facilities – and exemptions for licensed veterinarians or practitioners who are unable to timely comply (with Board approval). A pharmacist who receives a written, oral, or facsimile prescription after January 1, 2020, will not be required to

verify that a prescription is subject to an exception and may still dispense the medication. However, a pharmacist must exercise professional judgment in identifying and reporting suspected violations to the Board or to the appropriate professional licensing board.

**PMP Reporting.** The bill requires dispensers to report to the PMP the dispensing of opioid antagonists in addition to the other CS previously required. The bill also removes a previous exemption and will require, as of July 1, 2018, the reporting of CS dispensing for inpatient hospital patients.

**CSA Registration Surcharge.** The Board may add a surcharge of not more than 25% to a CSA registration application fee to fund the PMP.

**PMP Proactive Notification/Prescriber Activity Reports.** The bill allows the Board to distribute proactive notifications to prescribers or pharmacists that will indicate when a patient may be doctor shopping or pharmacy shopping or is at risk of abusing or misusing a CS. The Board will also better educate prescribers with annual prescriber activity reports beginning by February 1, 2019.

Senate File (SF) 2298 was passed by both houses and signed by the governor on May 16, 2018. The bill modifies the composition of the Board by adding a registered, certified pharmacy technician to the Board membership. The bill also addresses the licensure of wholesale distributors to align with federal law and creates a new licensure category for third-party logistics providers.

SF 2322 was also passed by both houses and signed by the governor on May 16, 2018. The bill allows technician product verification programs to be initiated in community pharmacies and allows the establishment of statewide protocols for certain services (such as immunizations), both pursuant to the enactment of rules by the Board.

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