



Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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2018-2019 License Renewal Season

Pharmacists, pharmacy technicians, and drug outlets are among the many registrants and licensees that are required to renew their licenses and registrations by June 30, 2018, and should have already received a renewal email or form with online renewal instructions. Late fees are imposed on July 1, and if not renewed by July 31, licenses and registrations will be required to be reinstated. Reinstatement requires fingerprinting for pharmacists and technicians and takes extra time.

Idaho Code 37-2726(3) requires all pharmacists to be registered with the Idaho Prescription Monitoring Program (PMP). This requirement is now being enforced, and an active PMP registration will be required in order to renew your pharmacist license. The PMP registration is free and does not require renewal. To access registration, visit <https://idaho.pmpaware.net/login>.

In 2019, the Idaho State Board of Pharmacy will transition most individual licenses to a birth month renewal model. Detailed information on how this transition will occur will be sent in 2019. In the meantime, please renew your license by June 30, 2018, if you intend to continue to practice in or remotely into Idaho.

Contact the Board at info@bop.idaho.gov or 208/334-2356 if you have any questions.

New Board Rules Set to Take Effect July 1, 2018

As detailed in the Board's [March 2018 Newsletter](#), the Idaho Legislature approved the Board's full repeal of its existing rulebook and replaced it with six chapters of rules that are better organized around specific topics.

The rule update features a significant shift in regulation. Rather than the rules being read as an itemized checklist of what pharmacists can do, the Board has adopted an approach known as "permissionless innovation" that recognizes professionalism and allows for innovation in practice.

Rule 27.01.01.020 provides guidance to licensees as they determine whether a specific act is permissible. First, a licensee should consider whether the act is expressly prohibited by any state or federal law. If an act is not expressly prohibited, the licensee should consider whether:

- ◆ The act is consistent with the licensee's or registrant's education, training, or practice experience; and
- ◆ Performance of the act is within the accepted standard of care that would be provided in a similar setting by a

reasonable and prudent licensee or registrant with similar education, training, and experience.

Two questions that may help licensees successfully navigate this change in approach from prescriptive rules to professional judgment are as follows:

1. If someone asks why I made this decision, can I justify it as being consistent with good patient care and with the law?
2. Would this decision withstand a test of reasonableness (ie, would another prudent pharmacist make the same decision in this situation)?

Please review the *March Newsletter* and the updated rules carefully. All six updated chapters may be found on the Board's website at https://bop.idaho.gov/code_rules.

Legislation Set to Take Effect July 1, 2018

The following pharmacy-related bills were passed by the Idaho Legislature and signed into law by Governor Butch Otter with an effective date of July 1, 2018.

House Bill (HB) 339: Enables therapeutic substitution within the same therapeutic class (excluding narrow therapeutic drugs and biological products) in any practice setting if three things occur:

1. The prescriber has clearly indicated that drug product substitution is permissible by indicating "therapeutic substitution allowed" or by making a similar designation;
2. The drug product substitution is intended to ensure formulary compliance with the patient's health insurance plan or, in the case of a patient without insurance, to lower the cost to the patient while maintaining safety; and
3. The patient opts in to the drug product substitution, and the pharmacist clearly informs the patient of the differences in the drug products and specifies that the patient may refuse the substitution.

If all three of these things occur and a pharmacist makes a therapeutic substitution, he or she must also modify the prescriber's directions to allow for an equivalent amount of drug to be dispensed as prescribed and notify the original prescriber of the substitution within five business days.

HB 340: Provides long overdue housekeeping to the Uniform Controlled Substances Act. Of note, the bill places acetyl fentanyl in Schedule I and removes dronabinol in oral solution from Schedule I consistent with Drug Enforcement Administration's scheduling of the product (Schedule II).

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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.

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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HB 351: This bill updates and modernizes provisions of the Idaho Pharmacy Practice Act related to licensure and registration. The bill specifically eliminates two categories of registration: non-pharmacy retail outlets (eg, retail outlets that sell nonprescription drugs) and certain veterinary drug outlets. Elimination of these registration categories does not mean these activities cannot occur; it simply removes the need for registration prior to engaging in these activities. The bill updates the annual renewal dates for licenses and registrations. Most individual licenses will renew by the end of the licensee's birth month, and facilities will renew by December 31 annually.

HB 354: Starting July 1, 2018, all controlled substances and opioid antagonists as defined in section 54-1733B of the Idaho Code will be required to be reported to the Idaho PMP. This requirement includes all naloxone dispensed in or into Idaho.

Pharmacist Prescriptive Authority for Naloxone

Prescription drug abuse is the fastest growing drug problem in the United States. Opioid antagonists, such as naloxone, are an increasingly important tool in combating drug overdoses. When administered during an overdose, naloxone blocks the effects of opioids on the brain and restores breathing.

It can be given as an injection into a muscle (via syringe or auto-injector) or as a nasal spray. According to the Centers for Disease Control and Prevention, the use of naloxone administered by laypersons has resulted in over 26,000 drug overdose reversals between 1996 and 2014.

In an effort to facilitate greater access to opioid antagonists, Governor Otter signed HB 108 into law in 2015, which allows Idaho pharmacists to **independently** prescribe an opioid antagonist to the following individuals:

- ◆ A person at risk of experiencing an opiate-related overdose;
- ◆ A person in a position to assist a person at risk of experiencing an opiate-related overdose;
- ◆ A person who, in the course of his or her official duties or business, may encounter a person experiencing an opiate-related overdose; or
- ◆ A person who in the opinion of the prescriber or pharmacist has valid reason to be in the possession of an opioid antagonist.

The **statutory definition** of "person" is broad, and thus an Idaho pharmacist could use his or her judgment to prescribe an opioid antagonist to nearly any person or entity, including first responders. **Board rule** allows opioid antagonists to be labeled in the name of a facility or entity as appropriate.

Further, a pharmacist acting in good faith and exercising reasonable care may administer an opioid antagonist directly to another person who appears to be experiencing an opiate-related overdose. Under Idaho law, pharmacists who prescribe or administer opioid antagonists shall not be liable in a civil or administrative action or subject to criminal prosecution. For more information, see **Idaho Code 54-1733B**.

Recently, the American Medical Association updated a **guidance document** encouraging prescribers to consider coprescribing naloxone for patients at risk of overdose or to persons who might be in a position to help someone at risk. Considerations for coprescribing **include:**

- ◆ Is the patient receiving a high dose of opioids?
- ◆ Does the patient also have a prescription for a benzodiazepine?
- ◆ Does the patient have a history of substance use disorder?
- ◆ Does the patient have an underlying mental health or other medical condition that makes him or her more susceptible to overdose?

As of July 1, 2018, all naloxone dispensed in or into Idaho will be reported to the PMP. If you identify a high-risk patient for whom naloxone is clinically appropriate, you will be able to see if the patient already has an unexpired supply on hand. If you identify a gap, please consider discussing the benefits of naloxone with your patients.

Help Is Available for Impaired Pharmacists Through the Idaho PRN

The Board subsidizes the state's Pharmacist Recovery Network (PRN). The primary function of this program is to assist the impaired pharmacist in every aspect of recovery from chemical dependence, including intervention, consultation, monitoring, advocacy, education, and support. If you need confidential help – or know an associate who does – please contact the program's vendor, Southworth Associates, by phone at 866/460-9014 or visit www.southworthassociates.net for more information.

Know a Pharmacist in trouble with drugs/alcohol or mental health problems?

Please contact the Pharmacist Recovery Network for help.
www.SouthworthAssociates.net 800.386.1695

CONFIDENTIAL Toll free Crisis Line
24 HOUR 866.460.9014



Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read it carefully. The Board encourages you to keep the *Newsletters* filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book*, for future reference.

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