June 2019

Idaho State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Welcome From New Executive Director

I am both humbled and honored to serve as the new executive director of the Idaho State Board of Pharmacy. I am excited to have the opportunity to work with the Board and the staff, as well as licensees, registrants, stakeholders, and others in state government on the mission of promoting, preserving, and protecting the health and safety of the public through the effective control and regulation of the practice of pharmacy. In my time serving as a Board member I had a front row seat to the shift in the model of governance for pharmacy in our state. Taking a commonsense approach to regulation and allowing room for innovative ideas and technological advances are just a few of the experiences I had on the Board that have made me proud to be a pharmacist in Idaho.

I am now focused on seeing the fruits of that labor come to harvest through the engagement of our licensees and registrants for the good of patients across Idaho. I am grateful to be supported by the agency's staff, who work incredibly hard to bring to life that which the Board sets out in rule and the legislature confers. Idaho has been a leading state in pharmacy practice and is often recognized for its progressiveness. Other states look to Idaho for assistance and ideas. I expect our agency to continue to be a resource to our colleagues across the country.

As for goals in this role, I include providing outstanding communication and transparency to our customers, continuing the tradition of working together with the legislature, and collaborating with stakeholders, all while keeping an eye on the financial side of the house. I will continue the tradition of visiting many pharmacies across the state in the coming months to hear your ideas and concerns.

Please do not hesitate to reach out at any time if you have questions or would like assistance at nicki.chopski@bop.idaho.gov or 208/334-2356.

Thank you,

Nicole "Nicki" Chopski, PharmD, BCGP, ANP

2019 License Renewal Season

Pharmacists and pharmacy technicians are among the many registrants and licensees that are required to renew their licenses and registrations by June 30, 2019, and should have already received a renewal email 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.

Following this renewal, most individual licenses will be on a birth month renewal model.

In the meantime, please renew your license by June 30, 2019, if you intend to continue to practice in Idaho or remotely into Idaho. Contact the Board at info@bop.idaho.gov or 208/334-2356 if you have any questions.

Legislation Set to Take Effect July 1, 2019

The following pharmacy-related bills were passed by the Idaho Legislature and signed into law by Governor Brad Little with an effective date of July 1, 2019.

House Bill (HB) 10

This bill creates a more mobile pharmacy license that would allow pharmacists, technicians, and student pharmacists to better practice across state lines. In recent years, similar bills have been presented and passed for nurses, physicians, and emergency medical services that have increased license mobility and portability, and those have proven to be resounding successes. Thus, consistent with these other health professions and the Idaho Licensing Freedom Act, this bill would accomplish the same for pharmacy.

Second, it would increase access to care by broadening the ability of local public health districts to dispense medications to meet local public health needs.

Third, it mirrors language from the other Idaho health professions that allows the Board to take emergency disciplinary action in accordance with the state's Administrative Procedures Act.

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National Pharmacy Compliance News

June 2019

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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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Lastly, it creates an avenue for unused and unexpired animal medications to be donated for use by other animals. The state's drug donation act only applied to humans, and this is corrected in this bill to be more consistent with other states.

HB 11

This bill provides annual housekeeping to conform Idaho's Controlled Substance Act with the federal Controlled Substances Act. Of note, this year's changes reflect Drug Enforcement Administration (DEA) changes with respect to various synthetic opioid products, like fentanyl, and reflect DEA's scheduling of Epidiolex®.

HB 12: 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 a 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 Little signed HB 12, which allows any licensed or registered health professional 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
- A person who, in the opinion of the licensed or registered health professional, has a valid reason to be in the possession of an opioid antagonist

The statutory definition of "person" is broad, and thus a licensed or registered health professional 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 licensed or registered health professional 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, those 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 Section 54-1733B.

Recently, the American Medical Association updated a guidance document encouraging prescribers to consider co-prescribing naloxone for patients at risk of overdosing or to persons who might be in a position to help someone at risk. Questions to consider for co-prescribing 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 condition or other medical condition that makes him or her more susceptible to an overdose?

As of July 1, 2018, all naloxone dispensed in Idaho or into Idaho must be reported to the prescription monitoring program. 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.

HB 182

In furtherance of the prescribing authority set forth in Idaho Code Section 54-1704(5)(e), this bill removes the necessity for the Board to specifically authorize certain drugs, drug categories, and devices that may be prescribed.

Idaho pharmacists can now prescribe any drugs that are in accordance with Food and Drug Administration-approved labeling and are limited to conditions that:

- do not require a new diagnosis;
- are minor and generally self-limiting;
- have a Clinical Laboratory Improvement Amendments-waived test that is used to guide diagnosis or clinical decision making; or
- in the professional judgment of the pharmacist, threaten the health and safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.

Controlled substances, compounded drugs, and biological products cannot be prescribed by a pharmacist.

All of the other rules and requirements around independent prescriptive authority for pharmacists remain intact. See IDAPA 27.01.04.020 for more information.

Notice of Upcoming Rulemaking

The Board has scheduled its rulemaking meetings as follows:

- June 13, 2019 – negotiated rulemaking
- October 23-24, 2019 – proposed rulemaking

Both sessions are open to the public, and comments may be made in writing in advance of the meeting or verbally at the meeting.

Of note, the Board intends to continue streamlining the rule book in accordance with Idaho's Red Tape Reduction Act, Governor Little's second executive order.

All licensees and registrants are encouraged to actively engage with the Board as it begins the process of open and collaborative rulemaking.

Help Is Available for Impaired Pharmacists Through the Idaho PRN

The Idaho State Board of Pharmacy 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. Its website is *www.southworthassociates.net.*

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is the official method of notification to licensees and registrants. Please read it carefully.

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