December 2018

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

2019 Board Meeting Schedule Is Set

Idaho State Board of Pharmacy meetings play an important role in the regulation of pharmacy practice in Idaho. The Board extends an open invitation to all pharmacists, technicians, and other interested parties to attend and actively participate in these meetings. Your feedback and engagement can help ensure that public health and patient safety are optimized in our state.

- February 7 – Boise, ID
- April 11-12 – Boise
- June 13– Boise
- July 11 – Conference Call
- August 15 (Negotiated Rulemaking) – Boise
- August 29 (Negotiated Rulemaking) – Conference Call
- October 23-24 (Proposed Rulemaking) – Boise

Visit the Board's website for information prior to each meeting. There you will find meeting agendas, minutes, and public meeting materials. Public meeting materials are typically available for download 48 hours prior to each meeting.

Licensees or members of the public seeking to be on the agenda may contact the Board's executive director, Alex Adams, at alex.adams@bop.idaho.gov or 208/334-2356.

The deadline to request to be on the agenda is posted for each meeting on the Board's website and is typically six weeks prior to the meeting date.

Free Online Continuing Education on Opioid Abuse and the Idaho PMP

The Idaho Department of Health and Welfare, in collaboration with the Idaho Board of Medicine, the Idaho State Board of Pharmacy, and the Idaho State Board of Dentistry, has produced a free online training video to help health care providers gain a deeper understanding of the Idaho Prescription Monitoring Program (PMP) and the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain.

This activity provides tips on utilizing the Idaho PMP and implementing the CDC guideline into your practice and overcoming challenges. At the conclusion of this activity, participants will be able to:

- Describe the opioid epidemic within the state of Idaho
- Integrate PMP use into provider/clinic workflows
- Create and interpret PMP data reports
- Utilize patient prescription history to inform clinical decision making
- Identify warning signs of medication misuse
- Discuss safe prescribing of opioids and alternative treatments for pain

Registration is free for any pharmacist, physician, or other practitioner. To access the course, visit *https://app.keysurvey.com/f/1345299/12f1.*

Common Compliance Issue: Removing Expired Drug Products

Recently, the Board has issued disciplinary orders for an increasing number of pharmacies that carry outdated medications on their shelves. Per Rule 27.01.01.023.10, it is considered unprofessional conduct for licensees or registrants to fail to remove expired drugs from stock.

Any expired drug must be removed from its stock and sequestered for return or destruction. Further, Rule 27.01.03.201.06 notes that expired controlled substances "must be properly disposed of through the services of a DEA-registered reverse distributor or another method permitted by federal law."

It is not a defense to allege that the pharmacy, "would never dispense that expired product," or to simply proclaim that the outdated drugs are a "historical pharmacy display."

In resolving the recent disciplinary cases, the Board has imposed a fine of $2,000. Moving forward, the Board will consider the volume as well as the product's use for compounding as escalating factors. Pharmacies are encouraged to review their policies and procedures in terms of identifying and removing expired drugs from stock, and use this opportunity to refresh all pharmacy staff on expectations.

New Pharmacist Prescribing Rules: Frequently Asked Questions

Rule 27.01.04 – Rules Governing Pharmacist Prescriptive Authority, took effect on July 1, 2018. The rules set forth a list of drug and device categories that pharmacists may independently prescribe in accordance with the general requirements set forth in Rule 020 of this document, as well as the applicable standard

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National Pharmacy Compliance News

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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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of care. Board staff has received the following questions on the new rules.

Why is naloxone not listed in the independent prescribing rules? Rule 020 states, "In addition to all nonprescription drugs and devices *and the statutorily authorized drug products and categories* set forth in Section 54-1704, Idaho Code…" (Emphasis added)

Section 54-1704 of Idaho Code notes that pharmacists can independently prescribe:

- Dietary fluoride supplements when prescribed according to the American Dental Association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States Department of Health and Human Services' recommended concentration;
- Agents for active immunization when prescribed for susceptible persons six years of age or older for the protection from communicable disease;
- Opioid antagonists pursuant to Section 54-1733B of Idaho Code;
- Epinephrine auto-injectors pursuant to Sections 54-1733C and 54-1733D of Idaho Code;
- Tobacco cessation products pursuant to Section 54-1733E of Idaho Code; and
- Tuberculin purified protein derivative products pursuant to Section 54-1733F of Idaho Code.

Thus, pharmacists can indeed prescribe opioid antagonists like naloxone. The Board chose not to reiterate these authorities in the rule as the Board did not want the general requirements to impose additional burdens on pharmacists' long-standing prescribing authority.

Naloxone co-prescribing to high-risk patients is strongly encouraged by the Board. Pharmacists wishing to learn more about naloxone prescribing and overdose prevention are encouraged to seek any of the free online training programs, such as the following training, which is offered by Boston University, *https://www.opioidprescribing.com/naloxone_module_1-landing.*

What happens if the patient does not have a primary care provider? Rule 020.06 states that the "pharmacist must inquire about the identity of the patient's primary care provider, and, **if one is identified by the patient,** provide notification within five business days following the prescribing of a drug." (Emphasis added)

The intent of the rule is to ensure coordinated team-based care by notifying that patient's identified primary care provider. If no primary care provider is identified by the patient, no notification is required under the rule.

If feasible, the Board does encourage pharmacists to work with medical providers in their local community to provide a list of primary care providers who are enrolling new patients, when appropriate.

Does the Board have any limits on prescribing to family members? The Board specified high standards for pharmacist prescribing as part of its general requirements (Rule 020). If a specific topic is not covered in these general requirements, the Board's intent was for pharmacists to assimilate into the existing practices expected of other prescribers. For example, Rule 27.01.03.300.05 specifies, "A prescription drug order written for a prescriber's family member is invalid if inconsistent with the scope of practice and prescriptive authority of the prescriber's profession." On this issue, and similar matters, pharmacists are held to the same requirements of any other prescriber authorized under Idaho law.

Does the Board have any resources available for pharmacist prescribers? As a reminder, the Board has provided template protocols for several of the drug categories included in the independent prescribing rules. The template protocols were developed collaboratively by pharmacists, physicians, lawyers, and government agency staff. They may be accessed by visiting *https://bop.idaho.gov/code_rules/2018_04_13_final%20bop%20protocol%20packet.pdf.*

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 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.

The *Idaho State Board of Pharmacy News* is published by the Idaho State Board of Pharmacy 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 Board unless expressly so stated.

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