



Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Idaho Legislature Approves Repeal of All Board Rules and Approves a New Set

This issue of the *Idaho State Board of Pharmacy Newsletter* will detail the rule changes that are anticipated to become effective on **July 1, 2018**.

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 six pending rule chapters are as follows:

1. General Provisions;
2. Rules Governing Licensing and Registration;
3. Rules Governing Pharmacy Practice;
4. Rules Governing Pharmacist Prescriptive Authority;
5. Rules Governing Drug Compounding; and
6. Rules Governing Durable Medical Equipment (DME), Manufacturing, and Distribution.

As the Board reorganized its rules into chapters, it aimed to simultaneously eliminate outdated regulations and those that stifle the emergence of new technology or new practice models that can improve public health and safety. All told, the new rules cut the overall word count by 55%, removed 62% of the restrictions, and eliminated six categories of licensure.

While this *Newsletter* provides a descriptive summary of **some** of the more significant pending rule changes, this brief review is no substitute for reading the actual pending rule change language, which may be found on the Board's website at https://bop.idaho.gov/code_rules.

It is important to note that the new rules must be read concurrent with Idaho Code and federal law, as all licensees and registrants are expected to abide by all pharmacy laws.

Rule Chapter 1: General Provisions

The scope of **Chapter 1** is to establish the definitions and abbreviations used in subsequent chapters, specify parameters for Board investigations and inspections, and specify acts that constitute unprofessional conduct. Significant rules include:

Rule 020 specifies the Board's general approach to scope of practice. If a specific act is not expressly prohibited by law, it is generally allowable as long as the act is consistent

with the licensee's education, training, or practice experience, and if performance of the act is within the accepted standard of care.

Rule 021 allows the Board to grant temporary or permanent waivers of rules in order to test an innovative practice or service delivery model.

Rule 023 specifies acts that constitute unprofessional conduct, which now includes providing health care services that fail to meet the standard provided by other qualified licensees in the same or similar setting, or directly promoting or inducing the provision of health care services or products that are unnecessary or not medically indicated.

Rule Chapter 2: Rules Governing Licensing and Registration

The scope of **Chapter 2** is to establish the rules related to licensure and registration for both individuals and facilities and to establish a fee schedule. Significant rules include:

Rule 021.03 transitions from a June 30 license renewal deadline to a birth month renewal model, whereby most individuals would renew their license by the last day of their birth month. **The 2018 license renewal period for pharmacists and technicians will remain the same**, with licenses requiring renewal by June 30 in order to remain active. The Board will share more information on the transition to a birth month model as 2019 nears.

Rule 030.03 exempts pharmacists from having to obtain a controlled substance registration in addition to their pharmacist license. While not needing this separate registration, pharmacists are still required to maintain compliance with the Idaho Uniform Controlled Substances Act.

Rule 033 establishes that pharmacists must complete 15 hours of continuing education annually between January 1 and December 31. The Board did, however, remove specific requirements (eg, live, law, and immunizations credits). At least 12 hours must be from an Accreditation Council for Pharmacy Education-accredited provider. Up to three hours may be from continuing medical education (CME), though new requirements regarding documentation and submission of CME were established.

National Pharmacy Compliance News

March 2018



NABPF
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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 Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*, applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA’s website at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC’s *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with

prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report*, “Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015,” can be accessed on the CDC website at www.cdc.gov/mmwr/index.html in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient’s family member or close friend, which may be found in the August 2017 document, “AMA Opioid Task Force naloxone recommendations,” available on the AMA opioid microsite at <https://www.end-opioid-epidemic.org>.

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

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 in an FDA Drug Safety Communication announcement at www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015*, found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. “Some counties have 13 pharmacies per capita, while others have none,” said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit <https://doi.org/10.1371/journal.pone.0183172>. The UIC news release is available at <https://today.uic.edu/access-to-pharmacies-limited-to-some-patients>.

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they

comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA’s website may be found at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report.

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Rule 036 consolidates “externs” and “interns” into a single category named “pharmacist interns.”

Rule 041 transitions the technician-in-training registration category to a one-time registration with a two-year duration. The employer requirement is eliminated. Current technicians-in-training will not be required to renew this spring. The Board has chosen to ensure that current technicians-in-training have the same time period they would have had if they were able to complete the renewals allowed by the previous rule. Board staff will be sending notices to all those affected.

Rule 042 creates a “student technician” registration category for individuals who are enrolled in a school-supervised program and who do not otherwise meet the requirements for registration as a technician-in-training or certified technician.

Rule 050.03 creates a pathway for a temporary pharmacy license number issued prior to operation so that a pharmacy can begin establishing health plan contracts, among other things.

Rule Chapter 3: Rules Governing Pharmacy Practice

The scope of [Chapter 3](#) is to establish professional practice standards, drug outlet practice standards, rules for filling and dispensing prescription drugs, record-keeping and reporting requirements, and prescription drug monitoring program (PDMP) requirements. The Board made the most cuts to this chapter, emphasizing **what** needs to occur as opposed to **how** or **where** it occurs. Significant rules include:

Rule 101 replaces previous micromanaged rules regarding what tasks pharmacists could or could not delegate to technicians and interns. Pharmacists now retain full discretion over what tasks to delegate and to which individuals under their supervision, but they must first consider whether the task is commensurate with the education, skill, and experience of the individual and whether the unique professional judgment of the pharmacist is necessary for the task.

Rule 202 specifies the five steps that must occur, unless exempted, when dispensing a prescription drug: 1) obtain a valid prescription drug order; 2) perform prospective drug review; 3) affix a label meeting specific requirements; 4) verify dispensing accuracy; and 5) counsel the patient.

Rule 203 allows each of the activities in Rule 202 to be performed off site if specific parameters are met. Granular technology requirements are omitted.

Rule 303 broadens emergency refill authority. A pharmacist may refill a prescription for a non-controlled drug one time in a six-month period for the quantity on the most recent fill or a 30-day supply, whichever is less.

Rule 400.06 allows any record to be stored and maintained electronically if also in compliance with federal law.

Rule 402 removes some reporting requirements for pharmacists-in-charge.

Rule Chapter 4: Rules Governing Pharmacist Prescriptive Authority

The scope of [Chapter 4](#) is to specify which drugs, drug categories, and devices pharmacists may independently prescribe and to establish rules related to collaborative pharmacy practice agreements and statewide protocol agreements.

Rule 020 specifies the general requirements that must be met in order for a pharmacist to independently prescribe drugs, drug categories, and devices specified in this chapter. Pharmacists are encouraged to review this section carefully. In particular, **Rule 020.03** requires a pharmacist to use a patient assessment protocol for each drug he or she intends to prescribe. The protocol must be based on current clinical guidelines, when available, or evidence-based research findings and must specify patient inclusion and exclusion criteria, as well as explicit medical referral criteria. The Board is currently developing template protocols for drug categories that were of most interest to our medical colleagues. In addition, **Rule 020.06** requires the pharmacist to notify the patient’s primary care provider of any drug prescribed within five business days.

Rules 021 through 026 specify the actual drugs, drug categories, and devices that pharmacists may independently prescribe and the limitations placed on such authority. Pharmacists are encouraged to carefully review these limitations.

Conditions for which pharmacists can prescribe within certain parameters include:

- ◆ Lice;
- ◆ Cold sores;
- ◆ Motion sickness prevention;
- ◆ Uncomplicated urinary tract infections;
- ◆ Influenza (based on Clinical Laboratory Improvement Amendments (CLIA)-waived test or for chemoprophylaxis); and
- ◆ Group A streptococcal pharyngitis (based on CLIA-waived test).

Devices that pharmacists can prescribe within certain parameters include:

- ◆ Inhalation spacers;
- ◆ Nebulizers;
- ◆ Diabetes blood sugar testing supplies;
- ◆ Pen needles; and
- ◆ Syringes for patients with diabetes.

Pharmacists may also prescribe the following drug categories within certain parameters:

- ◆ Statins for patients who have a previous diagnosis of diabetes;
- ◆ Short-acting beta agonists (SABAs) to patients who had a previous SABA and who have a current prescription for a long-term asthma control medication;

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- ◆ Travel medications in accordance with the Centers for Disease Control and Prevention's *Health Information for International Travel*, also known as the "Yellow Book";
- ◆ Antimicrobials for the prevention of Lyme disease;
- ◆ Supplements to an infusion order (eg, adding a heparin flush, a rate control device, or a local anesthetic for intravenous port access to a valid infusion order); and
- ◆ Drugs for a short-term emergency while emergency medical services are on the way (ie, diphenhydramine, epinephrine, and SABAs).

This chapter does not add any new requirements to the drug categories that pharmacists can already prescribe independently as authorized in [statute](#):

- ◆ Immunizations;
- ◆ Dietary fluoride supplements;
- ◆ Opioid antagonists;
- ◆ Epinephrine auto-injectors;
- ◆ Tobacco cessation products; and
- ◆ Tuberculin-purified protein derivative products.

Lastly, this chapter maintains the rules regarding collaborative pharmacy practice agreements and statewide protocol agreements, which are additional vehicles for pharmacist prescriptive authority. These agreements were exempted from the general requirements specified in **Rule 020**.

Rule Chapter 5: Rules Governing Drug Compounding

The scope of [Chapter 5](#) is to establish rules related to compounding drug products, sterile product preparation, hazardous drug preparation, outsourcing facilities, and labeling of distributed compounded drug products. No substantive changes were made to these rules relative to the current compounding rules. The Board intends to explore updates to this chapter in 2018.

Rule Chapter 6: Rules Governing DME, Manufacturing, and Distribution

The scope of [Chapter 6](#) is to establish DME outlet standards, rules related to drug distribution, wholesaler standards, and drug manufacturer standards. No substantive changes were made to these rules relative to the current compounding rules. The Board intends to explore updates to this chapter in 2018.

Access to Oregon PDMP

The Board is pleased to announce that as of January 1, 2018, Idaho Prescription Monitoring Program (PMP) users may now query the Oregon PDMP through the Idaho PMP AWAR_XE. Idaho PMP users will now find Oregon listed under the PMP InterConnect Search section of the Patient Request page. With the addition of Oregon, the Idaho PMP is connected to the following border states: Montana, Nevada, Oregon, and Utah.

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

24 HOUR CONFIDENTIAL Toll free Crisis Line
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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