March 2019

Idaho State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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2019 Pharmacy Administrative Rule Changes

This issue of the *Idaho State Board of Pharmacy Newsletter* will summarize **some** of the rule changes that are anticipated to become effective in early April during the 2019 Idaho Legislature. You can read the complete pending rule changes on the Board's website at *https://bop.idaho.gov/code_rules.*

Rule Chapter 1: General Provisions

Some definitions are added or updated in Chapter 1.

- **Limited service outlet** has been expanded to include mobile pharmacies.
- **Standard of care** now encompasses acts or omissions within the practice of pharmacy, "which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting."

Rule Chapter 2: Rules Governing Licensing and Registration

Chapter 2 is updated so that the Idaho-based Multistate Pharmacy Jurisprudence Examination® is no longer a requirement for licensure. This change is consistent with nearly every other Idaho health profession.

Rule Chapter 3: Rules Governing Pharmacy Practice

For in-state drug outlets, the requirement by the Board to designate a pharmacist-in-charge has been removed from Chapter 3.

Prescription Drug Order: Validity

- There is no longer a specified expiration date for prescription orders on non-controlled substances.
- Digital image prescriptions may now be accepted, but not for a controlled substance (CS) or if the patient intends to pay cash for the drug in whole.

Prescription Drug Order: Minimum Requirements

- For a non-controlled substance, a prescriber may omit the required drug information and directions if the prescriber makes a clear indication that the pharmacist is to finalize the patient's drug therapy plan.

Filling Prescription Drug Orders: Drug Product Substitution

- **Any** institutional facility may participate in drug product substitution using a formulary created by its quality assessment and assurance committee.
- Prescriber-authorized substitution is added under this section. A prescriber must clearly indicate that substitution is allowed by indicating "therapeutic substitution allowed" or a similar designation. The substitution must benefit the patient and is made to either comply with the patient's insurance formulary or to reduce the patient's cost. The patient must opt-in and be informed of the substitution. Notification to the patient's prescriber of the substitution must be given within five business days of dispensing the prescription. Drugs exempt to substitution are biological products, narrow therapeutic index drugs, and psychotropic drugs.

Filling Prescription Drug Orders: Adaptation

Updates have been made under changes in quantity pertaining to non-controlled substances. Biological products and compounded drugs are also excluded.

- The change is intended to dispense up to the total amount authorized by the prescriber including refills.
- The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program.

A pharmacist must be acting in good faith, with reasonable care, and have patient consent to make any of the changes outlined in the adaptation rule.

Rule Chapter 4: Rules Governing Pharmacist Prescriptive Authority

Pharmacist Prescribing for Minor Conditions

There are new minor ailments listed that pharmacists can independently prescribe for when following the parameters indicated in Chapter 4.

- Allergic rhinitis: Prescribing is limited to intranasal drugs only.
- Mild acne: Prescribing is limited to topical drugs only.
- Mild cough: Only benzonatate may be prescribed for cough suppression.

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National Pharmacy Compliance News

March 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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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Prescribing for these conditions must be in accordance with the general requirements specified in **Rule 020** Pharmacist Prescribing: General Requirements. The Board has published template protocols for pharmacists to use as a starting point for allergic rhinitis and mild acne. The template protocols were developed in an open, public meeting and can be found at *https://bop.idaho.gov/code_rules/2018_12_12_final-bop-protocol-packet.pdf.*

In addition to the new protocols, some changes were made to the urinary tract infection (UTI) template based on public comment, such as removing post-menopause as an exclusion criterion. Please review the updated protocol if you intend to prescribe for UTIs.

Pharmacist Prescribing for Clinical Gaps in Care

Pharmacist statin prescribing is further clarified to include only those who have been diagnosed with diabetes instead of the previous requirement for a current prescription for a drug for diabetes.

Pharmacist Prescribing to Supplement an Infusion Order

Items have been added to include:

- Agents for catheter occlusion
- Additional supplemental drugs: methylprednisolone, hydrocortisone, diphenhydramine, epinephrine, and normal saline

Rule Chapter 5: Rules Governing Drug Compounding

Change was made to Chapter 5 under **Rule 101.02** Dosage Forms Requiring Sterility. Previously, sprays intended to treat bronchial mucosa were exempt from sterile compounding. This has been changed to exempt only sprays and irrigations intended to treat **nasal** mucosa.

The requirement for gloved fingertip sampling has been updated to reflect United States Pharmacopeia Chapter <797>. It is required every six months for personnel who compound high-risk sterile preparations and annually for those who compound only low- and medium-risk sterile preparations.

Rule Chapter 6: Rules Governing Durable Medical Equipment, Manufacturing, and Distribution

This chapter will be eliminated in an ongoing effort to simplify the administrative rules. Much of Chapter 6 duplicated other state laws, and what remained necessary was added to other chapters.

Updated CPE Requirements and Transition Plan

(Previously Reported on in the September 2018 Newsletter)

Among the updates to the Board's rules was a streamlining of continuing pharmacy education (CPE) requirements. Per Rule 27.01.02.033:

Each pharmacist applicant for license renewal must complete fifteen (15) CPE hours each calendar year between January 1 and December 31.

01. ACPE. At least twelve (12) of the CPE hours obtained must be from programs by an ACPE provider that have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. ACPE credits must be reported to and documented in CPE Monitor in order to be accepted.
02. CME. A maximum of three (3) of the hours may be obtained from CME, if the credits are:
    a. Obtained from an ACCME accredited provider; and
    b. A certificate is furnished that identifies the name of the ACCME accredited provider and a clear reference to its accreditation status, the title of the CME program, the completed hours of instruction, the date of completion, and the name of the individual obtaining the credit. All CME certificates must be submitted to the Board between December 1 and December 31.

There are several items of note in the new rule.

First, all the specific requirements from previous years were **removed.** No longer must a pharmacist complete a minimum number of live, law, immunization, or sterile compounding credits as a matter of law. That is not to say that pharmacists cannot or should not receive live, law, immunization, or sterile compounding credits; it is just not a legal mandate to do so. As self-directed, lifelong learners, pharmacists should choose the most relevant CPE programs for their professional development and maintenance of competence.

Second, a minimum of 12 hours must be obtained from Accreditation Council for Pharmacy Education (ACPE)-accredited programs, and the Board will **only** accept ACPE-accredited CPE credits reported to the CPE Monitor® service, which is accessible through the National Association of Boards of Pharmacy® website.

Third, a maximum of three hours may be obtained from continuing medical education (CME) and only if the course meets specific documentation requirements. No longer will attendance sheet-based documentation be accepted.

Lastly, the link between license renewal and CPE completion is severed, and 15 CPE hours must be obtained each **calendar year between January 1 and December 31.** So, what does this mean for the transition year? Initially, the Board will accept 15 credits obtained between July 1, 2018, and December 31, 2019. The Board will fully transition to a calendar year audit in 2020.

Birth Month Renewal

As you are aware, the Board is going to birth month renewal. Those pharmacists who renewed on or before June 30, 2018, will renew one more time on or before June 30, 2019. Communication will follow via email later this year informing you of what steps you have to take to register and complete your online renewal. Those pharmacists licensed or registered since July 1, 2018, are already set for birth month renewals. To verify which renewal cycle you are currently in, please consult the expiration date on your license/registration.

Reporting CS to the PDMP

The Board would like to remind licensees of the folowing rule related to reporting CS to the PDMP. Per IDAPA 27.01.03.500 Controlled Substances: PDMP:

> Specified data on controlled substances must be reported by the end of the next business day by all drug outlets that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. Data on controlled substance prescription drug samples does not need to be reported. (7-1-18)

Though many pharmacies are reporting "by the end of the next business day" as required, the Board is finding a multitude of errors. Errors include, but are not limited to:

- **Incorrect national drug codes (NDCs) –** Listing the incorrect NDC can cause the prescription to **not** show on the patient profile.
- **Wrong prescriber –** Listing the incorrect prescriber can be a detriment to patient care. If a patient gets a prescription from Dr George and it is attributed to Dr Green, not only is the information on the prescription label wrong, when Dr George searches the prescription drug monitoring program (PDMP) he does not see the prescription he wrote, but one from a different doctor. This same error has an impact on the Board's unsolicited reports.
- **Hospital as a prescriber –** Listing the hospital as a prescriber is the same as the wrong prescriber.

Please be sure to check your error reports and submit corrections in a timely manner. If your submission is rejected due to errors, it is considered "not reporting," which can trigger disciplinary action. If you need assistance, contact the Board office at 208/334-2356.

Dr Alex J. Adams Departs as Executive Director of the Board

Alex J. Adams, PharmD, MPH, resigned as the executive director of the Board, effective January 4, 2019, as he accepted an appointment by newly elected Governor Brad Little to serve as the administrator of the Division of Financial Management for Idaho. Alex was hired by the Board to run day-to-day operations in 2015. In addition to many other accomplishments during Alex's tenure at the Board, pharmacists received substantial increases in independent prescriptive authority, and technician duties were expanded to include vaccination administration and accuracy verification in all settings.

Alex oversaw a complete repeal and replacement of the rulebook, which included a transition to a standard-of-care based model of regulation, a first for pharmacy in the country. This included an overall reduction of 55% of the rules with an elimination of 62% of the restrictions previously established. Online PDMP access increased exponentially, and a corresponding decrease in opioid prescriptions resulted under his leadership. While Alex served as the executive director, the Board received the 2018 Fred T. Mahaffey Award for contributions to the regulation of the practice of pharmacy and efforts to develop procedures for the profession that advance public health and safety. Fortunately, Alex remains an Idaho resident and an advocate for pharmacy. The Board wishes Alex well in his new endeavors. The profession will benefit from his impact well into the future!

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.

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