March 2020

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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2020 Summary of Pharmacy Administrative Rule Changes

The following is a summary of some of the rule changes that are anticipated to become effective on *sine die* (when the legislature adjourns), which is expected to be mid-to-late March. You may read the complete pending rule changes on the Idaho State Board of Pharmacy's website.

Traditionally, the administrative rules are reauthorized at the conclusion of the legislative session. However, the 2019 legislative session ended without the reauthorization taking place. Governor Brad Little then reprinted the rules as both temporary and proposed to ensure existing administrative rules remained in effect. At that time, changes that had been considered at two separate negotiated rulemaking sessions were wrapped into omnibus rulemaking. In line with the Red Tape Reduction Act, these edits were made in an effort to simplify current rules, combine five chapters of rules into one chapter, and remove unnecessary barriers and restrictions to licensure/registration in Idaho. Highlights of the changes include:

- Streamlining of definitions and removal of terms no longer used in rule
- With the exception of compounding, removal of the administrative burden of policy and procedures as a matter of law (Use of policy and procedures remains a best practice)
- Added flexible staffing and eased administrative burden for remote dispensing sites
- Permitted expiration of controlled substance (CS) prescriptions to match Drug Enforcement Administration (DEA)
- Standardized labeling requirements for all prescription types
- Removed outdated temporary scheduling language
- Removed unnecessary language due to the passage of House Bill 182 during the 2019 session

After additional open public meetings, the Board submitted further language changes as part of omnibus proposed rulemaking, summarized below:

- Collapses categories of technicians into just two: pharmacy technician and certified technician. Upon the effective date of the rule, anyone currently registered as a grandfathered technician, a technician in training, or student technician will be converted to a pharmacy technician registration automatically. Current certified technicians will remain certified technicians. This rule change eliminated the requirement to become a certified technician after two years. The Board values technicians and encourages ongoing education and certification as evidenced by the expanded duties permitted over the past three years that are commensurate with the education, training, and experience of the technician to which the tasks are delegated. The Board views certification as an employer decision, not a matter of law.
- Enables pharmacists to use alternatives to the continuing education (CE) requirement, such as Board certification, to renew their licenses. This new language provides a pathway for a pharmacist to substitute a current certification by a nationally accredited pharmacy practice-specific specialty certification program in lieu of CE credits.

New CPE Cycle Begins With the New Year

The transition year for continuing pharmacy education (CPE) has now passed. For this year (January 1 - December 31, 2020), pharmacists will need to complete 15 hours of Accreditation Council for Pharmacy Education (ACPE)-accredited CPE that is reported to CPE Monitor®. Up to three hours of continuing medical education credit will be accepted as long as it meets the requirements of Rule 213.02. If you are not familiar with Rule 213, now is the time to review it.

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National Pharmacy Compliance News

March 2020

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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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Need help tracking your CPE progress? There is an app for that. Check out the National Association of Boards of Pharmacy® (NABP®) e-Profile app for a seamless experience using CPE Monitor. Logging in to CPE Monitor directly from the NABP website is also available using this link.

During the last license renewal cycle, you may have noticed that the Board no longer requires you to attest to completion of the required CE upon license renewal. This is due to the complete severing of the tie between the CPE cycle and license renewal.

As a reminder, your individual license must be renewed by the last day of your **birth month.** Use the "Verify a License" function on the Board's website to check the expiration of your license.

Upcoming CPE Opportunities

Please note that ACPE-accredited CPE is granted to attendees of the conferences or conventions listed below. Presentation times are subject to change.

Idaho State University CPE Spring Seminars

- **When:** March 15, 2020, Law CPE, 8:30 AM
  Where: Idaho College of Osteopathic Medicine, 1401 E Central Drive, Meridian, ID
- **When:** March 29, 2020, Law CPE, 8:30 AM
  Where: Best Western Plus Coeur d'Alene Inn, 506 W Appleway Ave, Coeur d'Alene, ID

For more information, visit *https://isu.edu/pharmacy/outreach--services/continuing-education/cop/live-programs.*

Idaho Society of Health-System Pharmacists' Spring Conference

- **When:** April 26, 2020, Law CPE, 11:30 AM
  Where: St Al's Regional Medical Center, Boise, ID

For more information, visit *https://ishp.wildapricot.org/page-1863690.*

Reporting Controlled Substances to the PDMP

The Board would like to remind licensees of the following rule related to reporting CS to the prescription drug monitoring program (PDMP). Per IDAPA 27.01.01.600, specified data on CS **must** be reported by the end of the next business day by all drug outlets that dispense CS in or into Idaho and prescribers who dispense CS to humans. Though drug outlets 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:

- **Expired prescriber DEA numbers –** Rules 400 and 401 both reference the responsibility of the pharmacist to ensure that the DEA number is valid. Verifying the expiration date of the prescriber's DEA number is part of determining validity. Pharmacies are encouraged to check with the software vendor to determine if there is functionality within the program to monitor or maintain the DEA expiration dates.
- **X-DEA selection –** Prescriptions for buprenorphine for medication-assisted treatment should be submitted with the prescriber's X DEA number. As a reminder, both the prescriber's DEA registration and unique identification numbers must appear on the prescription. When prescriptions are phoned in, pharmacists must have both numbers on the prescription record. Practitioners must provide these numbers if they are not already on file. Pharmacists should visit the Buprenorphine Pharmacy Lookup to verify a practitioner's certification for buprenorphine. All other CS should be submitted with the prescriber's standard DEA number. Please be sure to select the correct DEA number for the prescription being filled. Review the settings within your software to ensure compliance. Contact your software vendor for assistance, if needed. As many prescribers have the same or similar names, pharmacists must also ensure that the correct prescriber is selected.
- **Addressing error reports from Appriss –** Appriss is the provider that maintains the data in the database. When a drug outlet's submission contains errors, a report is generated and sent to the email address on file for the drug outlet's account. The expectation is that these reports are reviewed, the necessary corrections are made, and the data is resubmitted. Please ensure that the corrections are being completed in a timely manner. If your outlet uses a third party to report PDMP data, follow up with them to ensure the corrections are being completed in a timely manner. Ultimately, the correction of the errors is the responsibility of the outlet, not a third-party vendor. The error correction emails will continue to be sent to the email address on file for the account every 24 hours until the error is corrected, or for 30 days.

In addition to being a violation of law, incorrect data in the PDMP can be a detriment to patient care. If you need assistance, contact the Board office at 208/334-2356.

Attention: CS Registrants – PDMP Delegate List Review

Is your delegate list up to date? The new year is an opportunity to ensure that the delegates assigned by you are still active and accurate. The delegate review is to ensure that delegate users of the Idaho PDMP are still authorized to

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perform searches on their supervisor's behalf. As a supervisor, you are responsible for activities performed within the system by your delegate(s). **Please take a moment to perform the delegate review by doing the following:**

1. Log in to your Idaho PDMP account.
2. From your dashboard, click on "View All Delegates."
3. Review delegates listed.
4. If delegates are correct, take no further action. If a delegate should be removed, continue to step five.
5. Select any delegate to remove.
6. Click on "Remove."
7. Click on "Reject."
8. Repeat steps five, six, and seven until all unwanted delegates have been removed from the Delegate Management view.

Thank you for your attention in this important matter.

Licensing System Updates Now Live

A number of system upgrades have been made to the agency's licensing system. Updates to e-Gov include:

- License cards for all license types can now be printed online. To do so, when logged into e-Gov there will be a hyperlink that says "Print" next to the active license. Only active licenses can be printed.
- Individuals with the following license types can update their "Licenses in other States" via License Update: manufacturer, out-of-state mail service, outsourcing drug outlet, wholesaler distributor, wholesaler of legend medical devices, and wholesaler of over-the-counter products. Please verify your record and update as needed.
- Individuals with the following license types can update their "Business Hours" via License Update: community pharmacy, institutional pharmacy, durable medical equipment, limited service, prescriber drug outlet, and remote dispensing. Please verify your record and update as needed.

Per Rule 501.02 – Individual Information Changes, it is the responsibility of the licensees and registrants to notify the Board of any changes to information required on the initial or renewal application. **This includes contact information, email address, and employment changes.** Please verify that the contact information on file is current and make any necessary changes online. Alternate methods of submission are no longer reviewed and will be rejected. Of note, email is the primary method by which the Board communicates with its licensees and registrants. Please be thoughtful in the choice of email address on file with the Board.

Confirmation of Validity of a License

"Verify a License" is the most accurate way to confirm that a license or registration is in good standing. When hiring new employees to work in the pharmacy, use the "Verify a License" tool on the Board's website. It is updated and maintained daily. A printed license is only as accurate as the day it was printed.

Help Is Available for Impaired Pharmacists Through 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.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and controlled substance registrants licensed and/or registered by the Board. Please read it carefully.

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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