March 2021

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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2021 Summary of Statute Changes

The following is a summary of the proposed substantive changes to the Idaho Code in the Pharmacy Practice Act, anticipated to become effective on July 1, 2021. The documents related to the Controlled Substances Act (CSA) and the Pharmacy Practice Act are available on the Idaho State Board of Pharmacy website.

- Updates the practice of pharmacy definition to remove the age restriction on patients receiving immunizations from a pharmacist. It also removes restrictions on pharmacists providing compounded and biologic products for patients.
  - ◊ These changes seek to make permanent the restrictions and prohibitions waived during the coronavirus disease 2019 (COVID-19) pandemic, to allow for continued safe access to pharmacist services. When many other providers' offices closed, pharmacies served as an important safe point of access for childhood immunizations and over-the-counter compounded drugs such as hand sanitizer.
- Streamlines the Wholesale Drug Distribution Act by removing eight pages of the outdated statute that is more restrictive than federal law. While providing no new regulatory burden, it relocates remaining necessary elements for safe wholesale drug distribution in Idaho.
- Removes repetitive and duplicative language related to the Health Insurance Portability and Accountability Act of 1996.
- Throughout the entire bill, the language streamlines previous references to both "license or registration" as now being a "certificate" for clarity. The definition of "certificate" means a license or registration issued by the Board unless specifically stated.
- Simplifies the previous allowances to make it clear that a health care professional may prescribe naloxone or epinephrine to any patient or entity.
  - ◊ This removes duplicative explanations to ensure these lifesaving medications are readily available and accessible to any Idahoan, including entities such as schools, fire departments, and police stations.
- Updates the CSA to mirror the scheduling changes made by Drug Enforcement Administration (DEA). It adds several synthetic cannabinoids to Schedule I, a fentanyl precursor to Schedule II, corrects a spelling in a Schedule IV listed drug, and adds a new agent for migraines to Schedule V. This bill also deschedules Epidiolex® from Schedule V to non-scheduled by narrowly tailoring the definition of marijuana.

Proposal to Remove X-Waiver Requirement Rescinded

On January 28, 2021, the United States Department of Health and Human Services (HHS) withdrew the proposal to remove the X-waiver. Two weeks earlier, HHS announced that it would publish new guidelines exempting physicians from certain certification requirements that were previously in place for prescribing buprenorphine. The *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder* was planned to include an exemption from certain requirements under the CSA for physicians who are licensed under state law and possess a DEA registration. Read the full article from *Addiction Professional.*

Current law requires that buprenorphine prescriptions used for medication-assisted treatment must bear the X-DEA number on the face of the prescription, and must also be submitted to the prescription drug monitoring program (PDMP) with the X-DEA number. Remember that prescriptions written for methadone to treat opioid use disorder outside of a narcotic treatment facility is prohibited by federal and state law.

COVID-19 Vaccination Update

On January 19, 2021, Governor Brad Little announced that Idaho will offer health care providers new grants to administer the safe and effective COVID-19 vaccine more quickly across the state. "The safe and efficient administration of the COVID-19 vaccine in Idaho is my number one priority," Governor Little said. "The state of Idaho ensures available doses are sent directly to health care providers, but the providers are the ones to get the shots in the arms of people who want it. We are actively working to ensure there are absolutely no resource barriers for providers in performing this critical role."

Providers must be enrolled in the vaccine program and have received the necessary training, as well as have plans in place to properly administer it. They must also administer vaccines by

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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.

DEA Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA website.

Time to End VinCRIStine Syringe Administration

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vin**CRIS**tine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vin**CRIS**tine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vin**CRIS**tine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals,* which were launched in 2014[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vin**CRIS**tine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vin**CRIS**tine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vin**CRIS**tine doses to be diluted in a minibag.

References

1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids*

What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products

This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on March 23, 2020, FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

Key Terms for Biosimilar and Interchangeable Products

- **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

What is the Purple Book?

The Purple Book database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research .

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation (eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the "Orange Book." The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA's rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

Where Can I Find Additional Resources?

- *fda.gov/biosimilars*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *fda.gov/media/135340/download*

Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, *Insanitary Conditions at Compounding Facilities Guidance for Industry,* provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

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appointment, which takes time and preparation. Organizations interested in providing the COVID-19 vaccine should send an email to IDCOVID19Vaccinators@dhw.idaho.gov for additional information.

COVID-19 vaccinations are occurring in phases in Idaho. Vaccinations for the general public are expected to be available in spring or summer. Health care workers started receiving the vaccine the week of December 14, 2020. Residents and staff of long-term care facilities started receiving vaccinations December 28, 2020. All required forms for providers and Idaho's vaccine distribution timeline can be found at *https://coronavirus.idaho.gov/covid-19-vaccine/.*

Prescription Forgeries

The number of fraudulent oxycodone prescriptions has decreased over the last few years, however, the number of fraudulent promethazine with codeine prescriptions has increased. Often, these medications are prescribed in conjunction with a non-controlled substance (CS) to give the appearance of authenticity, for example, antibiotics or a non-steroidal anti-inflammatory drug.

A large percentage of the prescriptions bear the name and DEA number of out-of-state prescribers. It is highly recommended that promethazine with codeine prescriptions be verified by calling the prescriber, using a source other than the prescription. The CSA Registration Validation Tool is also useful in these situations.

If you receive a forged CS prescription, contact DEA's Tactical Diversion Squad at 208/386-2100.

Compliance — CS Inventory

Because of a recent uptick in noncompliance, the Board is reminding registrants of the annual CS inventory requirements. IDAPA 24.36.01.500.03 states:

> Inventory Records. Each drug outlet must maintain a current, complete, and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed, or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An annual inventory must be conducted at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. Drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. Additional inventories are necessary when required by federal law.

Federal law states that an "inventory" is a complete and accurate list of all stocks and forms of CS in the possession of the registrant as determined by an actual physical count for Schedule II drugs. With respect to inventories of Schedule III-V drugs, the registrant may, with respect to an open bottle that contains no more than 1,000 tablets, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents must be made. See 21 Code of Federal Regulations (CFR) 1304.11(e)(6)(i) and (ii).

In addition, the inventory records of Schedule II CS must be kept separate from all other records of the drug outlet. The inventory records of Schedule III-V CS must be maintained either separately from all other records of the drug outlet or in such form that the information required is readily retrievable from ordinary business records of the drug outlet. Under 21 CFR Part 1300, the inventory shall include:

1. The date of the inventory
2. Whether the inventory was taken at the beginning or close of business
3. The name of each CS inventoried
4. The finished form of each of the substances (eg, 10 mg tablet)
5. The number of dosage units or volume of each finished form in the commercial container (eg, 100 tablet bottle or three mL vial)
6. The number of commercial containers of each finished form (eg, four 100 tablet bottles)
7. The total on-hand count of the substance

Neither white-out nor negative numbers should appear in the CS inventory.

News From the Licensing Team

The licensing team is comprised of three employees with a combined total of 20 years of licensing experience. These three employees are responsible for the review of all individual and facility applications for 27 different license/registration types. On any given day, the licensing team has between 500 and 600 pending applications to process. The standard turnaround time is three to six weeks, depending on the license/registration type.

As of July 2018, the Board converted to an online application system called MyLicense e-Government. This online system has revolutionized how applications are processed. Prior to the implementation of the online system, all applications were submitted on paper, and all renewal notices and licenses were printed and sent through the US Postal Service.

The licensing team maintains working relationships with several external sources such as the National Association of Boards of Pharmacy® (NABP®), DEA's Diversion Control Division, the Idaho State Police, pharmacy schools, national certification boards (Pharmacy Technician Certification Board and National Healthcareer Association), and resident and nonresident state licensing agencies. The team also coordinates information with the Board's compliance and PDMP staff.

Applicants create their own licensing accounts and submit applications online. Board staff utilizes complex reporting systems to track and review applications. Licensees/registrants can update their records with important changes such as employment, mailing address, and email address. This enables staff to communicate in a timely manner, licensees and

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registrants are required to report changes to contact information within 10 days, this included email addresses. Proof of license/registration can be printed through your account or by utilizing the Verify a License option available on the Board website. The Board's website is a Primary Source Verification.

The Board website has several sources to assist in submitting applications and updating existing records. For example, from the website menu, clicking on Licensing allows you to access overall general information (eg, how to create an individual or facility account), new application walkthrough and renewal videos, written license verification requests, and how to print license/registration cards.

For specific license/registration information, there are dedicated pages with application instructions and other useful information for established licensees/registrants. To access a specific page, hover over Licensing, then click on the specific type of license/registration.

Updates and changes to the Board website to improve the application and access process are ongoing. Recent changes include video instructions on how to complete an application for a license/registration.

Board staff is always looking for ways to improve the website and help applicants complete their applications, decrease the number of deficiencies, and improve overall application processing time. If you have suggestions for improvements, please send them to info@bop.idaho.gov.

Please review the Board website prior to emailing or calling, as you will likely find the answer to your question. Licensing staff has a dedicated email address, info@bop.idaho.gov, for more information. This email address is the best way to submit inquiries regarding applications and existing licenses/registrations. Staff may also be contacted via phone at 208/334-2356.

Continuing Education

Though the Board updated the continuing education (CE) requirements for pharmacists effective July 1, 2018, there continues to be confusion. CE is no longer tied to the renewal of a pharmacist license. Idaho pharmacists are required to complete 15 hours of CE **each calendar year.**

Board staff uses NABP's CPE Monitor® service to conduct audits. NABP has an e-Profile app, which ties into CPE Monitor. Pharmacists can also log in to CPE Monitor directly from the NABP website. If you have not started your CE for 2021, now is the time to get to it!

Idaho State University is offering immunization technique-based training events this year. You can find more information by visiting Immunization Training.

The Idaho Society of Health-System Pharmacists (ISHP) Spring Conference was held virtually and offered 10.5 hours of CE for pharmacists and seven hours for technicians. View the ISHP Spring Program.

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 CS registrants licensed and/or registered by the Board. Please read it carefully.

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