December 2019

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

Considering Possessing, Selling, Wholesaling, or Distributing CBD in Idaho?

The Idaho State Board of Pharmacy receives many inquiries concerning the legality of cannabidiol (CBD) products in Idaho. Idaho's statutory definition of marijuana encompasses any substance that contains any amount of tetrahydrocannabinol (THC), per Idaho Code §37-2701. Both THC and marijuana (marihuana) are classified as Schedule I controlled substances (CS), per Idaho Code §37-2705(d)(19) and (27).

The Board cautions anyone intending to possess or sell any product that may contain any amount of THC. Some manufacturers of CBD or hemp products may claim their products are 100% THC free. However, that may not always be accurate, and a manufacturer's representation may not protect you from criminal, civil, or administrative penalties.

Publicly available resources regarding CBD and hemp products in Idaho include:

- The Idaho Office of Drug Policy
  - ◊ *https://odp.idaho.gov/cannibidiol*
- 2015 Idaho Attorney General Informal Opinion Letter to Elisha Figueroa, former administrator for the Idaho Office of Drug Policy
  - ◊ See page 130, *www.ag.idaho.gov/content/uploads/2017/12/2015.pdf*
- Office of the Attorney General, Counsel for the State Podcast, Episode 3: CBD and Hemp in Idaho
  - ◊ *https://www.ag.idaho.gov/office-resources/counsel-for-the-state*

The Board recommends that any questions concerning the legality of any particular CBD or hemp product be discussed with private legal counsel, addressed directly with local law enforcement, or both. CBD and hemp are controversial topics, and criminal enforcement may vary among local jurisdictions.

Common Compliance Issue: CS Registrants' Reporting Requirements

Recently, the Board has found several instances involving inaccurate addresses on file for CS registrants. There are a variety of scenarios where this information comes into play.

- A prescriber updates his or her address with Drug Enforcement Administration (DEA) but fails to update his or her address with the Board. Failure for the controlled substance registration (CSR) address to match the address DEA has on file results in a cancellation of the Idaho CSR, thereby invalidating all prescriptions, storage, and dispensing.
- A wholesaler can only legally distribute CS to the registered address. The prescriber can only store CS at the registered address. Again, the address on the CSR must match the address with DEA and be the location at which the CS are stored, administered, and dispensed.
- A pharmacy selling small quantities of CS to a prescriber must verify the prescriber has a valid DEA registration and a current Idaho CSR prior to the sale. The addresses of these documents should be the same and be the location at which the CS are delivered and stored.
- For emergency medical services (EMS) providers, the medical director should hold a DEA registration and an Idaho CSR with the address of the location of the EMS station.

Per IDAPA 27.01.01.501.02, changes to information provided on or with the initial or renewal application must be reported to the Board within 10 days of the change. **This includes address changes.** To verify the address on file

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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.

USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and

Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

Pharmacists Invited to Participate in NAPLEX Pharmacy Practice Survey

The National Association of Boards of Pharmacy® (NABP®) sent email invitations to randomly-selected pharmacists in all areas of practice encouraging them to participate in the NAPLEX Pharmacy Practice Analysis Survey. Analysis of the survey results is used to evaluate the North American Pharmacist Licensure Examination® (NAPLEX®) competency statements.

The analysis of practice supports the relevance of the NAPLEX competency statements, which define the content for the examination. This analysis helps ensure that competency statements, otherwise known as the examination "blueprint," are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. In addition, the review supports the NABP mission to protect the public health by providing the state boards of pharmacy with a reliable means of assessing competency that assists them with licensure decisions to support safe and effective practice.

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with the Board or to update the address on file, please visit *https://idbop.mylicense.com/eGov/Login.aspx*.

Grant Funding Available for Gateway Integration Into Pharmacy Information Systems and Electronic Health Records

Through a federal grant, the Board has funding to provide for the integration costs and the first year of license fees for hospitals and pharmacies to integrate with PMP Gateway. The Board officially launched PMP Gateway, operated by Appriss Health, the Idaho prescription drug monitoring program (PDMP) vendor, in 2016. This program enables the integration of PDMP data directly into electronic medical records and pharmacy dispensing systems. This integration allows instant access of PDMP data for prescribers and pharmacists without logging in to a separate web portal. The Board has heard complaints regarding the time associated with logging in to its current PDMP. Integration with PMP Gateway will streamline access and eliminate the time burden on end users. The Board believes this is a terrific tool to assist providers in the fight against opiate abuse.

In addition, the federal grant provided the means for the Board to implement NarxCare into the Idaho PDMP website. NarxCare is a platform that provides a more comprehensive platform to identify, prevent, and manage CS use. The NarxCare report includes a patient's Narx Scores, Predictive Risk Scores, Red Flags, Rx Graph, and access to resources. Locations already subscribing to and paying a license fee for NarxCare will no longer be charged. Please note that some pharmacy software vendors may have an alternative report similar to NarxCare. Pharmacies should check with their vendor for details.

For more information on the impact PMP Gateway integration has had on data sharing, visit *https://www.pdmpworks.org/index.html*. For additional information about funding availability and the integration process, contact Teresa Anderson at the Board at 208/334-2356 or teresa.anderson@bop.idaho.gov, or Ellen Mitchell at ellen.mitchell@bop.idaho.gov.

Time Frame of Transition Year for CPE Requirements Nears End

As previously published, the link between license renewal and continuing pharmacy education (CPE) completion has been severed. CPE hours must be obtained each calendar year between January 1 and December 31. What does this mean for this year of transition? 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.

Per IDAPA 27.01.01.213, the Board of Pharmacy's rules for CPE requirements are as follows:

> 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 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.

Facility Renewals Due December 31, 2019

As a reminder, courtesy renewal notices for facilities have been sent out to the email address of record. Please ensure the facility license/registration is renewed before the end of the year. As part of the renewal process, please ensure all contact information for the facility is current. Per IDAPA 27.01.01.501.02, changes to information provided on or with the initial or renewal application must be reported to the Board within 10 days of the change. **This includes email addresses.** Failure to receive a courtesy reminder is **not** an acceptable reason to not renew a facility license/registration in a timely manner.

2020 Board Meeting Schedule Is Set

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

- February 6
- April 9
- June 11 (negotiated rulemaking)
- July 9 (negotiated rulemaking) – conference call

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- August 6
- August 27 – conference call
- October 22 (proposed rulemaking)

All meetings will be held in Boise, ID. Please visit the Board's website for information prior to each meeting. There you will find meeting agendas, locations, minutes, and public meeting materials. Public meeting materials are typically available for download 48 hours prior to each meeting. Licensees or members of the public seeking to be on the agenda may contact the Board's executive director, Nicki Chopski, at Nicki.Chopski@bop.idaho.gov or 208/334-2356. The deadline to request to be on the agenda is posted for each meeting on the Board's website and is typically six weeks prior to the meeting date.

Free Resource Materials Available for Prescription Opioid Misuse Prevention

The Idaho Opioid Overdose and Misuse Workgroup is excited to share **free educational materials** with your pharmacy. Leftover prescriptions are responsible for much of Idaho's opioid misuse. Ensuring that patients are properly educated about the potential risks and proper disposal of opioids is a top priority for the workgroup.

The workgroup has developed several items that can assist in educating your patients to dispose of unused or expired prescription medications:

- Counter and window clings to be placed on pharmacy counters and drive-thru windows
- Pill bottle cap stickers to be used on prescription vials
- Prescription bag stickers to be used as an alternative to stapling bag
- Informational rack cards, brochures, and posters

The materials also direct patients to the website with the location of the nearest drug take-back site. Visit the Office of Drug Policy website at *https://prevention.odp.idaho.gov/order-resource-materials-prescription-opioid-misuse-prevention* to order today.

Idaho Opioid Misuse and Overdose Workgroup (Goal Group 1B–Patient Education) appreciates your dedication to creating a community of safe prescription opioid use and patient-centered care.

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.

Nicki Chopski, PharmD, BCGP, ANP - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Sanchez - Communications Manager