



State of Ohio Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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From the Director's Desk

Dear Ohio Pharmacist,

Effective December 1, 2019, Rule 4729:1-4-02 of the Ohio Administrative Code (OAC) requires Ohio-licensed pharmacists to report to the State of Ohio Board of Pharmacy certain types of conduct of which the licensed pharmacist has knowledge.

The new rule requires pharmacists to report the following to the Board:

- ◆ Conduct indicating that an individual licensed or registered by the Board is addicted to or is suspected to be abusing alcohol, drugs, or other chemical substances, or is impaired physically or mentally to render the individual unfit to carry out his or her professional duties
- ◆ Violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Ohio Revised Code (ORC) Chapters [4729](#) (Pharmacy Practice Act), [4752](#) (Home Medical Services), [3715](#) (Pure Food and Drug Law), [3719](#) (Controlled Substances), [3796](#) (Medical Marijuana Control Program), [2925](#) (Drug Offenses), and [2913](#) (Theft and Fraud) or any rule adopted by the Board under those provisions by an individual or entity licensed or registered by the Board
- ◆ Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern, or pharmacist that constitutes unprofessional conduct or dishonesty

A pharmacist is not required to report an error in dispensing or a prescription error except when the error is the result of reckless behavior or unprofessional conduct per the National Coordinating Council for Medication Error Reporting and Prevention's *Index for Categorizing Medication Errors*. Per Section [4729.23](#) of the ORC, the identity of the pharmacist making a report in accordance with this rule will remain confidential.

The rule also requires a pharmacist to self-report to the Board any of the following:

- ◆ Any criminal conviction within 10 days after the date of conviction, except for minor traffic violations, or if the pharmacist is convicted of, plead guilty to, or is subject to a judicial finding of eligibility for intervention in lieu of conviction. The conviction must be reported regardless of whether the case has been expunged or sealed or the equivalent thereof.
- ◆ Entry into a diversion program, deferred prosecution program, or equivalent within 10 days after the individual is granted entry into a program.
- ◆ Any arrest for a felony within 10 days after the arrest.
- ◆ Any disciplinary licensing or registration action taken by another state against the licensee within 10 days of the notice action.

For more information on duty to report, visit www.pharmacy.ohio.gov/PharmReport. If you have any questions, please do not hesitate to contact the Board via contact@pharmacy.ohio.gov or 614/466-4143.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

Reminder: Law Review Presentation

The Board offers a [law review presentation](#) to learn about the latest developments in pharmacy laws and rules. Presentations take place across the state. Space is limited so early registration is recommended. The law review presentation qualifies for two hours (0.2 CEUs) of Board-approved jurisprudence continuing education. More information and registration instructions can be found on the Board's [Continuing Education web page](#).

National Pharmacy Compliance News

November 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.

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 psychotherapeutics 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.

Reminder: Notice on the Enforcement of USP Compounding Chapters for Pharmacies

This notice only applies to pharmacies.

The Board is aware of [United States Pharmacopeial Convention's \(USP's\) announcement](#) that was released on September 23, 2019, pertaining to the effective dates of revised USP Chapters <795>, <797>, and <825>. The Board has received multiple inquiries as to how this announcement will affect the Board's enforcement of USP Chapter <800> when it becomes effective on December 1, 2019.

Please be advised that the Board will **not** begin enforcing USP Chapter <800> on December 1, 2019.

Rather, the Board will be discussing the effective date of updated compounding rules that require adherence to USP Chapter <800> for all drugs listed in Table 1 of the [National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings](#) at its November 2019 meeting. More information will be provided following the meeting.

To view the complete notice on the implementation of USP Chapter <800>, visit www.pharmacy.ohio.gov/Compound800.

Pharmacist CS Registration

Pharmacists with a controlled substance (CS) registration issued by the Board (see paragraph (C)(6) of Rule 4729:1-6-02) are permitted to obtain a mid-level Drug Enforcement Administration (DEA) CS registration.

Before applying for a mid-level DEA registration, a pharmacist working under a consult agreement authorizing the prescribing or management of CS must obtain a CS registration issued by the Board.

More information can be found at www.pharmacy.ohio.gov/consult.

Drug Repository Rules

The new drug repository rules have been finalized and became effective on October 15, 2019. The online guidance has been modified to reflect the new rules.

Please be advised that the general operation of a drug repository program has not changed substantially in OAC 4729:5-10. However, Rule 4729:5-10-04 does expand the type of drugs that may be collected by a repository to include the following:

- ◆ Orally administered cancer drugs that are not in original sealed and tamper-evident unit dose packaging. "Orally administered cancer drug" means either of the following: (1) an orally administered

dangerous drug that is used to treat cancer or its side effects; or (2) an orally administered dangerous drug that is used to treat the side effects of a dangerous drug used to treat cancer. Orally administered cancer drugs do not include CS or drugs that require refrigeration, freezing, or storage at a special temperature.

- ◆ CS in a long-acting or extended-release form used for the treatment of opioid dependence or addiction.

The new guidance can be found [here](#).

Verification of Licensure

As a reminder, before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor is required by Ohio law to verify either of the following:

- ◆ The seller is licensed to engage in the sale of dangerous drugs in accordance with Section [4729.52](#) of the ORC (ie, the seller is licensed in Ohio as a manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs).
- ◆ The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with [OAC 4729:5-3-09](#).

Verification of licensure requirements for terminal distributors can be found in [OAC 4729:5-3-04](#).

Change in Responsible Person

The Board has received questions about change of responsible person. OAC 4729:5-2-01 requires all locations licensed as a terminal distributor to have a responsible person at all times. When there is a change of responsible person, the licensees must notify the Board within 10 days of the effective date of the appointment of the new responsible person.

The change in responsible person must be made using the [eLicense system](#). While it is the responsibility of the terminal distributor or drug distributor to notify the Board, the person who is leaving his or her role as responsible person should verify that he or she is no longer listed on the license.

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