December 2019

Iowa Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

400 SW 8th St, Suite E • Des Moines, IA 50309-4688 • Tel: 515/281-5944
Fax: 515/281-4609 • Website: *https://pharmacy.iowa.gov*

USP <795>, <797>, and <800>

On June 1, 2019, the United States Pharmacopeial Convention (USP) published revisions to USP Chapters <795> and <797>, which were slated to become effective on December 1, 2019. USP also announced that USP Chapter <800> would become effective on December 1, 2019. Consequently, the Iowa Board of Pharmacy amended Iowa Administrative Code (IAC) 657 – 8.5(11) to require compliance with USP Chapter <800> effective December 1, 2019.

On September 23, 2019, USP announced that the effective date of the published revisions to USP Chapters <795> and <797> would be delayed, no longer becoming effective on December 1, 2019. USP maintained the December 1, 2019 effective date for USP Chapter <800>.

USP is considering the following appeal topics for USP Chapters <795> and <797>:

1. beyond-use date provisions in both chapters
2. removal of the alternative technology provision from USP Chapter <797>
3. the applicability of both chapters to veterinary practitioners

The Board recognizes that if USP's appointed appeals panel approves one or more appeals, the USP Expert Committee's review of USP Chapters <795> and <797> is not necessarily limited to the sections under appeal. In accordance with Rules 657 – 20.3 and 657 – 20.4, the proposed revisions will become effective, and enforceable by the Board, on the effective date established by USP.

The Board has received several inquiries as to how the Board intends to enforce USP Chapters <795>, <797>, and <800> in light of USP's recent announcement. On October 3, 2019, the Board convened and made the following decisions regarding enforcement.

Enforcement of USP Chapter <800>

All pharmacies are expected to be fully compliant with USP Chapter <800> beginning on December 1, 2019. This includes pharmacies that receive, store, handle, dispense, or compound hazardous drugs.

USP Chapters <795> and <797>: Current Versions Versus Proposed Revisions

- A pharmacy that has made progress toward complying with the proposed revisions to USP Chapters <795> and <797> will not be penalized for doing so. A pharmacy that is already compliant or making progress toward compliance with the proposed revisions will have a head start at achieving compliance by the new effective date, which will be established by USP.
- During this period of flux, a pharmacy may comply with either the current versions or the proposed revisions of USP Chapters <795> and <797>. A pharmacy is expected to establish and follow standard operating procedures for sterile and nonsterile compounding that identify the version of USP Chapter <795> or <797> it intends to follow. Requirements specified by USP Chapter <800> must be followed for hazardous compounding even if not specified by current versions of USP Chapters <795> and <797>, unless a delayed compliance petition has been granted.
- All compounding pharmacies will be expected to comply with the proposed revisions to USP Chapters <795> and <797> by the effective date established by USP, which has yet to be determined.

Delayed Compliance Petitions

- Board Rule 657 – 8.5(11) establishes a process whereby a pharmacy engaged in compounding of hazardous drugs may request delayed compliance for specific requirements of USP Chapter <800> pertaining to compounding in accordance with Rule 657 – 20.5. The Board has received and responded to several petitions filed under these provisions.
- A compounding pharmacy that can comply with all requirements of USP Chapter <800> by December 1,

continued on page 4

National Pharmacy Compliance News

December 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 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.

continued from page 1

2019, does not need to submit a petition for delayed compliance. A pharmacy is not eligible to receive delayed compliance for any non-compounding requirements in USP Chapter <800>.

- A compounding pharmacy that has been granted a delay in compliance will retain the delay as specified in the approval letter. The granted delay will be valid through the end date referenced in the approval letter.

Electronic Prescribing Mandate – January 1, 2020

In 2018, the Iowa Legislature passed legislation that will require all prescriptions, including controlled substances, to be electronically prescribed by prescribers and electronically received by pharmacies, beginning on January 1, 2020.

According to Surescripts data from September 2019, Iowa's e-prescribing activity is still well below the national average. Of Iowa's prescribers, 70.1% (versus 76.5% nationally) are submitting electronic prescriptions to pharmacies. A total of 68.1% of Iowa's prescribers have certified and audit-approved software that is capable of transmitting electronic prescriptions for controlled substances (EPCS). Yet, only 47.6% of Iowa's prescribers have enabled this feature within their e-prescribing software (versus 41.3% nationally).

Conversely, Iowa's pharmacies are slightly above the national average for the ability to receive electronic prescriptions (98.6% versus 98.4%, respectively) while the rate of EPCS-enabled pharmacies in Iowa hedges out the national averages by more than 2% (98.6% versus 95.9%, respectively).

The legislation requiring e-prescribing permitted several exceptions to the e-prescribing mandate. Prescriptions that are excluded from the mandate include:

1. A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.
2. A prescription authorized by a licensed veterinarian.
3. A prescription dispensed by a US Department of Veterans Affairs pharmacy.
4. A prescription requiring information that makes electronic submission impractical, such as complicated or lengthy directions for use or attachments.
5. A prescription for a compounded preparation containing two or more components.
6. A prescription issued in response to a public health emergency in a situation where a non-patient-specific prescription would be permitted.
7. A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.
8. A prescription issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location, provided that a prescription issued pursuant to this subparagraph shall indicate on the prescription that the practitioner or pharmacy is experiencing a temporary technical or electronic failure.
9. A prescription issued in an emergency situation pursuant to federal law and regulation rules of the Board.

Additionally, a practitioner, medical group, or pharmacy that is unable to timely comply with the electronic prescribing requirements may petition the Board for an exemption based on economic hardship; technical limitations that the practitioner, medical group, or pharmacy cannot control; or other exceptional circumstances. The Board may grant exception requests for a period of time that may not exceed one year, which may be renewable with Board approval. Exemption petition forms and additional information regarding the e-prescribing mandate can be found on the Board's website.

After the mandate becomes effective on January 1, 2020, a pharmacist who receives a written, oral, or faxed prescription that is otherwise legitimate **will not be required to verify that the prescription is subject to an exception listed above and may dispense the prescription.** However, a pharmacist must exercise professional judgment in identifying and reporting suspected violations of the e-prescribing mandate to either the Board or the appropriate professional licensing board of the practitioner.

A prescriber who violates this mandate is subject to an administrative penalty of $250 per violation, up to a maximum of $5,000 per calendar year. The administrative penalty assessed by the prescriber's primary licensing board will not be considered a disciplinary action or reported as discipline. A practitioner may appeal the assessment of the administrative penalty, which will initiate a contested case proceeding. The administrative penalties collected will be deposited into the drug information program fund to further support and enhance the state's prescription monitoring program.

Statewide Protocols

The Board's statewide protocols for naloxone, nicotine replacement products, and immunizations went into effect on April 5, 2019. Pharmacists acting under the statewide protocol may need to obtain a national provider identification (NPI) number in order to properly bill the prescriptions to third-party payers.

Additionally, the Iowa Legislature postponed the sunsetting of the physician-approved immunization

continued on page 5

continued from page 4

protocols from July 1, 2019, to July 1, 2020. The legislature recognized that additional time may be necessary to ensure that Iowa Medicaid recognizes the pharmacists' NPI number on the claims being submitted for immunizations under the statewide protocol.

Technician Product Verification Programs

The Board adopted final rulemaking to rescind Chapter 40, "Tech-Check-Tech Programs" and adopt the new Chapter 40, "Technology-Assisted Technician Product Verification Programs." During the 2018 session of the Iowa Legislature, the IAC was amended to allow technician product verification (TPV) programs in community pharmacies. Previous programs were called tech-check-tech programs and only authorized the practice in a hospital pharmacy or community pharmacy providing care for facility patients when another licensed health care practitioner would be administering the medications. Under the new rules, which became effective June 26, 2019, a pharmacy may establish a TPV program that is intended to redirect pharmacist time to increased clinical services (such as medication therapy management, collaborative practice, statewide protocols, and immunizations). In a pharmacy using a TPV program, **pharmacist hours shall not be reduced but shall be redistributed to clinical pharmacy services to improve patient care and health outcomes.**

Additional TPV program requirements include:

- ♦ appropriate scanning technology to ensure that each product is accurately filled and verified
- ♦ no more than three checking technicians per pharmacist involved in the prescription-filling process (institutional settings are exempt)
- ♦ advance notice to the Board of program implementation
- ♦ minimum qualifications for checking technicians
- ♦ quality assurance process
  - ◊ quarterly verification
  - ◊ quarterly reports
- ♦ record keeping

The Board did not authorize "grandfathering" of any previously existing tech-check-tech programs, so pharmacies are expected to be compliant with the revised rules in Chapter 40, unless the pharmacy has received a waiver. The complete chapter is available on the Board's website.

Want to Know What Rules Are Changing?

The Board establishes the minimum standards for the practice of pharmacy and lays out those standards in rules. Changes to rules are initiated by a variety of triggers:

- ♦ legislation or legislative mandates
- ♦ overall review of rules, required every five years
- ♦ a suggestion from a licensee, compliance staff member, or stakeholder
- ♦ following the receipt of a number of waivers to a rule

The Board encourages all licensees and registrants to be aware of rulemaking undertaken by the Board and appreciates licensee participation through the open comment opportunities.

Throughout the rulemaking process, each rulemaking is available for review by interested individuals. When the Board is considering rulemaking, the documents to be voted on are available on the Board's website. From the home page, select "Board," then "Meetings," then the meeting date of interest, and scroll to the bottom of the page for the "Meeting Materials" section where all the proposed rulemaking documents will be attached.

Following approval from the full Board on a rulemaking, the rules are filed and published in the Iowa Administrative Bulletin. This is published every two weeks and includes all rulemaking in Iowa. Rulemaking filings can also be found at *rules.iowa.gov.* Another resource for reviewing all the rulemaking underway by the Board is the Rules Tracker. On this site, choose to search rulemakings by "Agency." In the "Select an Agency" drop-down list, scroll down to "Public Health Department," under which you should select "Pharmacy Board" to view a list of rulemaking documents. Finally, the Board recommends subscribing to its email distribution list to receive notice when rulemaking is approved. You can sign up for this from the Board's home page in the "Social Media" area.

The *Iowa Board of Pharmacy News* is published by the Iowa 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.

Andrew Funk, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager