



Delaware State Board of Pharmacy

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Impact of USP Chapter <800> in the Retail Setting

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Are you prepared for United States Pharmacopeia (USP) Chapter <800>?

The implementation of USP Chapter <800> will impact all types of pharmacy practice including retail, long-term care, hospital, and compounding pharmacies. The purpose of USP Chapter <800> is to detail practice and quality standards for handling hazardous drugs (HDs) in health care settings. This will help promote patient safety, employee safety, and environmental protections.

USP is a scientific organization that sets standards for quality and purity of medicines. USP standards are recognized in various provisions of the Federal Food, Drug, and Cosmetic Act and in laws, regulations, and policies promulgated by individual states. The majority of states, including Delaware, require full compliance with USP general chapters that pertain to drug compounding.

A number of regulatory bodies will have enforcement roles after the implementation of USP Chapter <800>. These include the US Environmental Protection Agency (EPA), state environmental protection agencies, the Occupational Safety and Health Administration, Food and Drug Administration, and the Delaware State Board of Pharmacy.

What do you need to do?

You will first need to obtain the National Institute for Occupational Safety and Health (NIOSH) *List of Anti-neoplastic and Other Hazardous Drugs in Healthcare Settings*. This list can be found at <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>. The drugs on the list have been divided into three different sets of tables.

- ◆ Table 1 – antineoplastic drugs
- ◆ Table 2 – non-antineoplastic drugs

- ◆ Table 3 – non-antineoplastic drugs that primarily have adverse reproductive effects

Pharmacists should refer to this list to properly identify all HDs in their pharmacy. First, all of the HDs must be inventoried. Then an HD inventory list should be created. This list should contain the name of the drug, the dosage form, and the NIOSH table number. The list should also indicate if the drug needs to be reconstituted and whether or not the drug is stored in the manufacturer's packaging.

After completing the inventory and creating the list, a facility should segregate these drugs. Placing the drugs on a shelf in a section separate from the regular stock is a good practice. As you perform the segregation, you will want to mark the area or shelves with an HD sign or label.

After the drugs are arranged in the segregated area and labeled appropriately, certain procedures must be followed. Employees must use separate counting tools and latex gloves to dispense these products. Additionally, no drugs in Table 1-3 are permitted to be used in an automated counting device such as a Kirby Lester or Parata. Currently, the manufacturers of automated counting devices are working hard to engineer changes so these devices can be USP Chapter <800>-compliant.

Each drug must have an assessment of risk form, which is to be completed and kept in a binder. You can find a template at www.ncpa.co/pdf/assessment-of-risk-template-blank.docx.

Each drug must also have a safety data sheet (SDS). The SDS was formerly known as the material safety data sheet. An SDS for a particular drug can be retrieved from the NIOSH list website or is available by request from your drug wholesaler. These should also be kept together.

Disposal – HDs that have expired, whether they are on the shelf as full or partial bottles, are considered hazardous waste. These drugs must be quarantined and segregated as **“hazardous waste.”** Hazardous waste must be disposed of

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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.

Continued from page 1

in accordance with the EPA's Resource Conservation and Recovery Act. A pharmacy's return company may offer the best solutions for disposal of expired HDs.

USP Chapter <800> Compliance for Retail Pharmacies Assessment of Risk and Other Helpful Links

This informational material is **for pharmacies that do not compound with hazardous medications.**

Step 1: Identify all HDs in stock

- ◆ Identify other HDs that may not be on the NIOSH List
- ◆ Develop a system of evaluating new drug inventory
- ◆ HD risk acknowledgement form

Step 2: Use the assessment of risk tool to evaluate the handling of HDs in your pharmacy during the following activities. An example of an assessment of risk form may be found at www.ncpa.co/pdf/assessment-of-risk-template-blank.docx.

- ◆ Receiving
- ◆ Transportation
- ◆ Storage
- ◆ Dispensing
- ◆ Waste

Step 3: Develop policies and procedures that address handling and containment strategies for:

- ◆ Receipt of HDs
- ◆ Occupational safety program
- ◆ Storage of HDs
- ◆ Dedicated HD area

- ◆ Hand hygiene and personal protective equipment (PPE) based on activity
- ◆ Dispensing of hazardous medication
- ◆ Proper disposal of HDs
- ◆ Deactivation, decontamination, cleaning, and disinfection
- ◆ Spill control for HDs
- ◆ Hazard communication

Step 4: Develop a pharmacy-specific training program for all employees who handle HDs based on their job functions, which must include:

- ◆ Overview of the pharmacy's HD list and its risks
- ◆ Review of the pharmacy's standard operating procedures related to the handling of HDs
- ◆ Proper use of PPE
- ◆ Proper use of equipment
- ◆ Response to known or suspected HD exposure
- ◆ Spill management
- ◆ Proper disposal of HDs and trace contaminated material

Page 4 – November 2019

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