November 2019

Utah Board of Pharmacy News

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Common Violations Found in DOPL Pharmacy Inspections

Whether you hate inspections, tolerate them, or like them (and yes, there are a few who like them), pharmacy inspections are a necessary part of owning and operating a pharmacy in the state of Utah. These inspections are essential in determining whether the pharmacy and its employees are compliant with state and federal laws and regulations. Utah Division of Occupational and Professional Licensing (DOPL) inspectors and investigators are frequently asked what violations are found in Utah pharmacies. The answers are consistently the same.

The following are the top things encountered as violations in a pharmacy inspection:

1. **Expired medications** on the shelves as dispensing stock or in the refrigerator.
2. **Annual controlled substance inventories** are not readily available. Pharmacies have all of the last five years' inventories together, they are not signed by the pharmacist-in-charge, and they fail to indicate the time and date when the inventory was taken. Pharmacies fail to conduct an inventory before opening or after closing a pharmacy.
3. **Records, invoices, credit returns, and inventories** are not separated per Schedule II, Schedule III-V, and legend drugs.
4. **Standard operating procedures** are not available, not complete, or not specific to your pharmacy's practice for nonsterile compounding, sterile compounding, home deliveries, or deliveries by mail.
5. **Employees are not wearing name tags** or name tags do not include licensure title or the title of supportive personnel.

Rules are found and updated on the DOPL website at *www.dopl.utah.gov.* Familiarize yourselves with Utah Code Title 58 Chapter 17b Pharmacy Practice Act and Utah Administrative Code (UAC) Rule R156-17b. Pharmacy Practice Act Rule.

New Board Member Karen Gunning

Karen M. Gunning, PharmD, BCACP, BCPS, received her doctor of pharmacy degree from the University of Utah and completed a postgraduate residency in family medicine/primary care at the University of Washington. She is currently a professor (clinical) of pharmacotherapy, associate dean of community engagement, adjunct professor of family and preventive medicine, and clinical pharmacist for the University of Utah Family Medicine Residency Program. Dr Gunning is director of the PGY2 Ambulatory Care Pharmacy residency at University of Utah Health. She has received the Teacher of the Year Award for the College of Pharmacy three times and Specialty Teacher of the Year for the Family Medicine Residency Program twice, as well as receiving the Utah Society of Health-System Pharmacists Pharmacist of the Year Award. In 2016, she received the University of Utah Distinguished Teaching Award. Dr Gunning served six years on the Board of Pharmacy Specialties (BPS) Pharmacotherapy Council, including as chair, and is now serving her second term on the Board of Directors for BPS, and is chair-elect.

Her research and teaching interests include sex and gender pharmacotherapy; curriculum development for pharmacists and medical residents regarding changing models of care delivery; medication safety in the patient-centered medical home (PCMH); the impact of pharmacists and the interdisciplinary team on costs, outcomes, and efficiency in the PCMH; and the impact of ambulatory care pharmacist engagement in transitions of care.

Dr Gunning moved to Salt Lake City, UT, 21 years ago from the Pacific Northwest and has loved every day of blue sky since moving here. She is the proud mom of a very tall basketball- and trumpet-playing 14-year-old son and a beautiful 10-year-old dancer/volleyball player daughter.

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 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.

Standing Order for Naloxone

During the July 2019 Utah Board of Pharmacy meeting, members reviewed and provided recommendations for updates to the Utah standing order for naloxone. This included language clarifications and explicit information regarding House Bill (HB) 399, requiring pharmacists to affix a warning label on opioids and to have an informational brochure at the point of sale.

During the 2016 Utah General Legislative Session, Representative Steve Eliason sponsored HB 240, the Opiate Overdose Response Act, authorizing the Utah Department of Commerce and the Utah Department of Health (UDOH) to implement a standing prescription drug order to dispense naloxone. As a result, the executive director of UDOH signed a statewide standing order allowing pharmacists to dispense naloxone without a prior prescription to anyone at increased risk of experiencing an opioid overdose. The standing order is intended to increase access to naloxone for those who might be at risk of an overdose or who might be in a position to assist somebody at risk of an overdose. Naloxone can be administered via a nasal spray (commonly known as Narcan®) or intramuscular injection. It is a safe and legal drug that can reverse heroin and prescription opioid overdoses by blocking the effects of opiates on the brain and restoring breathing in minutes. There is no potential for abuse and side effects are rare.

While not mandatory for pharmacies to participate in the Utah standing order for naloxone, those that do are encouraged to voluntarily register with the UDOH. Additionally, UAC Rule R156-17b-625 requires pharmacists dispensing naloxone under the standing order to report annually to the UDOH the total number of single doses of naloxone dispensed and the name of each naloxone product dispensed along with the total number of single doses of that particular product. In 2018, 177 pharmacies were enrolled to participate in the standing order and dispensed a total of 2,741 naloxone doses (see Table 1).

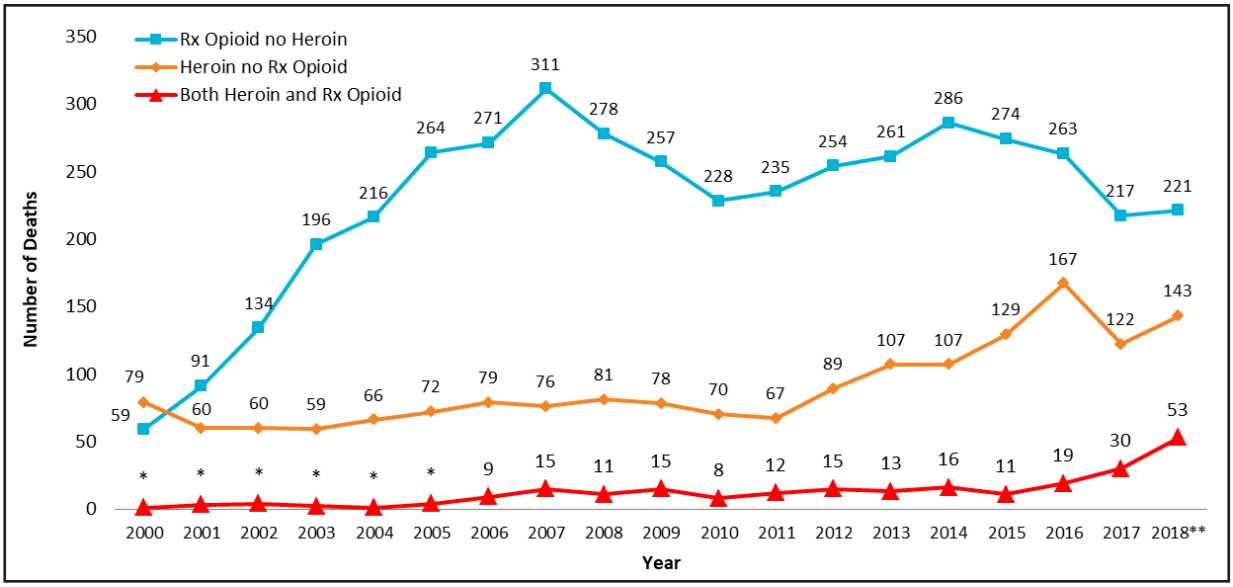
Table 1: Number of naloxone doses disseminated through the Utah standing order for naloxone by geographic location and type of naloxone, Utah 2018

Naloxone Type	Urban	Rural	Frontier	Total
Nasal spray	1,638	490	28	2,156
Pre-filled luer lock syringe	415	29	31	475
Auto-injector	12	7	0	19
Vial	78	13	0	91
Total	**2,143**	**539**	**59**	**2,741**

From 2017 to 2018, there was an observed increase in the number of opioid-related deaths in Utah. The number of prescription opioid overdose deaths excluding heroin increased by 1.8%. The number of heroin overdose deaths excluding prescription opioids increased by 17.2%. The number of deaths involving both prescription opioids and heroin increased by 76.7% (see Figure 1 below). By participating in the Utah standing order for naloxone,

continued on page 5

Figure 1: Number of occurrent opioid overdose deaths by category, Utah 2000-2018***



*Data is suppressed. Counts <5.

**Counts from 2018 are preliminary and subject to change as additional toxicology results become available.

***Occurrent deaths include individuals who died in Utah, whether or not they were residents of Utah.

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pharmacies can provide ready access to naloxone, which is key for saving lives.

To learn more about naloxone, find educational materials for patients, and participate in the standing order, visit *https://naloxone.utah.gov.* To learn more about opioids, visit *https://www.opidemic.org.*

Name and Address Changes

Have you moved, changed your name, or chosen another email address? Did you know that DOPL needs to be notified about changes to your name and mailing address within 10 business days? Failure to update your name or address with DOPL is considered unprofessional conduct.

R156-17b-502. Unprofessional Conduct.

(4) failing to provide the Division with a current mailing address within a 10 business day period of time following any change of address;

(23) failing to update the Division within seven calendar days of any change in the email address designated for use in self-audits or pharmacy alerts;

- Simply log in to *www.dopl.utah.gov/pharm*
- Open the Licensing tab
- Select "Change Your Name/Address"

For name changes, you must verify the change by submitting a copy of a marriage certificate, divorce decree, court order, driver's license, or social security card to the Division. If you desire a reprint of your license reflecting the name change, you must also submit a $10 reprint fee with the request.

Send the required information via email to doplweb@utah.gov or via mail to DOPL, PO Box 146741, Salt Lake City, UT 84114-6741.

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