May 2019

Utah Board of Pharmacy News

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Self-Search in the CSD Is Illegal

Everyone has a legal right to his or her own prescription data stored in Utah's Controlled Substance Database (CSD), but searching for your own records is not legally allowed. For those who have access to search CSD records, it might seem reasonable to simply search for your own data; however, statute and rule do not allow for it. CSD personnel have identified a growing number of just such instances. While most are likely innocent in intent, any attempt to search for your own records in this way is illegal and could carry with it civil, criminal, and administrative penalties. Depending on the circumstances, a self-searcher could face as much as criminal felony charges, a civil fine of up to $5,000 for each instance, and administrative action on his or her license.

Utah Code 58-37f, Part 3: Access and Utilization, and Utah Administrative Rule R156-37f-301: Access to Database Information, not only limit access and use of the CSD to specific people, but also only allow use of the CSD for very specific purposes for each role. In Utah Code 58-37f-301(k), these purposes are described for pharmacists and pharmacy technicians.

Utah Code 58-37f-301-(2) and Utah Code 58-37f-301(2)(k)

(2) The [Utah Division of Occupational and Professional Licensing (DOPL)] shall make information in the database and information obtained from other state or federal prescription monitoring programs by means of the database available only to the following individuals:

(k) a licensed pharmacist having authority to dispense a controlled substance to the extent the information is provided or sought for the purpose of:

(i) dispensing or considering dispensing any controlled substance; or

(ii) determining whether a person:

(A) is attempting to fraudulently obtain a controlled substance from the pharmacist; or

(B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled substance from the pharmacist;

Any other use of the CSD by a pharmacist beyond the two purposes of considering to dispense a controlled substance (CS) and to combat individuals fraudulently obtaining CS, is illegal. DOPL recognizes that this may not be widely understood, and will work to notify and educate licensees, where appropriate, who innocently stray outside of these restrictions. Repeated infractions or any other indicators of intentional misuse of the CSD will result in administrative, civil, or criminal action.

The process to obtain one's own CSD records is detailed in Utah Code 58-37f-301(q)(r) and in Rule R156-37f-301(7).

For the legal method to obtain a copy of your own CSD record, contact the CSD via email at csd@utah.gov, or by phone at 801/530-6220.

Utah 2019 General Session Legislative Update

By Sara Whitt, 2019 PharmD Candidate

The 2019 general session was full of excitement and holds the record for the number of bills passed in a session at 574. There was a lot of progress made in the areas of CS and health care transparency. Here is a summary of a few bills that relate to the practice of pharmacy and health care.

Senate Bill 170: Pharmacy and Pharmaceuticals Amendments

Chief sponsor: Senator Evan Vickers
House sponsor: Representative Brad Daw

This bill amends provisions relating to the practice of pharmacy. The first change that was made to this bill was

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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.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWAR$_X$E® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWAR$_X$E program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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amending the definition of a closed-door pharmacy to include pharmacies that engage exclusively in the practice of telepharmacy and do not serve walk-in retail customers.

The definition of the practice as a licensed pharmacy technician was also amended to remove the definition of a licensed pharmacy technician's scope of practice, so it can be defined in rules, and so licensed pharmacy technicians have the ability to adapt more easily to the changing field of pharmacy.

Next, aripiprazole lauroxil was added to the list of long-acting injectable medications that can be administered intramuscularly by a properly trained pharmacist.

This bill also reschedules certain drugs that are Food and Drug Administration-approved and contain a certain component of cannabis. These drugs will be scheduled to reflect the federal Controlled Substances Act (CSA) and to be in accordance with Drug Enforcement Administration.

The final change that was made in this bill was to add board-certified urologists to the list of individuals who are qualified to be dispensing medical practitioners. They are now authorized to dispense cancer drug treatment regimens.

House Bill (HB) 251: Drug Diversion Reporting Requirements

Chief sponsor: Representative Steve Eliason
Senate sponsor: Senator Curtis Bramble

This bill makes it a class B misdemeanor for a practitioner to knowingly fail to report a known or suspected drug diversion of a significant amount to law enforcement. The term "drug" in this bill is defined as a Schedule II or Schedule III CS, and a "significant amount" is defined as an aggregate amount greater than or equal to 500 morphine milligram equivalents. Reporting the loss of a significant amount to law enforcement is required unless reporting it would violate the Health Insurance Portability and Accountability Act.

HB 370: Pharmacy Benefit Manager Amendments

Chief sponsor: Representative Paul Ray
Senate sponsor: Senator Evan Vickers

This bill amends provisions and creates requirements for pharmacy benefits managers (PBMs). This bill requires the Utah Insurance Department to license entities that act as PBMs in the state of Utah. The PBM license that is required to practice in Utah is valid for one year. This bill also creates operating and reporting requirements for PBMs pertaining to their rebates and administrative fees. These reporting requirements are to be reported to the Utah Insurance Department, and certain values that are reported to the Utah Insurance Department will be published on an annual basis to help establish and maintain some transparency and regulation.

HB 449: Controlled Substances Amendments

Chief sponsor: Representative Paul Ray
Senate sponsor: Senator Allen Christensen

This bill amends the CSA and the Controlled Substance Database Act. Under the provisions of this bill, tramadol has been rescheduled from Schedule V to Schedule IV. This bill also allows for a list of non-CS to be created by DOPL in collaboration with the Utah Controlled Substance Advisory Committee.

Pharmacy Alert: Utah Department of Health

Talk to Your Pharmacist Month

Each May in Utah, the Utah Board of Pharmacy encourages pharmacists to spend additional time talking with each customer to whom they dispense an opioid medication. By placing a warning label on an opioid medication, providing an educational brochure, hanging up posters, and using talking points, you can educate and warn patients of the dangers of opioids.

The Talk to Your Pharmacist Tool Kit gives talking points that would be very helpful to provide to your pharmacists. The tool kit can be found at *http://health.utah.gov/vipp/pdf/RxDrugs/TalkToYourPharmacistToolkit.pdf.*

HB 399: Opioid Abuse Prevention and Treatment Amendments

HB 399 requires warning labels and the opioid education brochure. Other helpful materials that are available and encouraged for the month of May are warning label stickers, posters, naloxone-specific brochures, and talking point assistance for pharmacists and pharmacy technicians.

Naloxone Standing Order

As of December 2016, a pharmacy may dispense naloxone under a statewide standing order. If a pharmacy dispenses naloxone under the statewide standing order, it is required to enroll in the standing order at *https://naloxone.utah.gov* and report annually.

Helpful Links

- Opioid material order form: *http://health.utah.gov/vipp/pdf/RxDrugs/OpioidMaterialRequestForm.pdf*
- HB 399: *https://le.utah.gov/~2018/bills/static/HB0399.html*
- Opioid brochure pdf: *http://health.utah.gov/vipp/pdf/RxDrugs/OpioidPrescriptionBrochure.pdf*
- Naloxone website: *https://naloxone.utah.gov*

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- Naloxone standing order: *https://dopl.utah.gov/docs/NaloxoneStandingOrder.pdf*
- Naloxone standing order in Utah Code: *https://le.utah.gov/xcode/Title26/Chapter55/26-55-S105.html?v=C26-55-S105_2016051020160510*

If you have any questions regarding the requirements or accessing materials, please call the Violence and Injury Program of the Utah Department of Health at 801/538-6864 or email vipp@utah.gov.

Continuing Education

License renewals for pharmacists and pharmacy technicians are due September 30, 2019. Please ensure you have completed your continuing education (CE). Do not send in completed CE to DOPL unless you receive a letter asking you to do so.

The *Utah Board of Pharmacy News* is published by the Utah 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, the State of Utah, or the Board unless expressly so stated.

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