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Utah Board of Pharmacy News

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Promethazine With Codeine Robbery and Forgery Alert

The Utah Board of Pharmacy and Division of Occupational and Professional Licensing (DOPL) received reports of several pharmacies that were robbed for their supply of promethazine with codeine. In addition, pharmacies have reported an increasing number of forged prescriptions for promethazine with codeine across Utah and other states. Promethazine with codeine, a Schedule V controlled substance (CS), has been used for years as a cough suppressant. Lately, it is more commonly known as "purple drank" or "lean" among abusers of the substance. Purple drank is a combination of promethazine with codeine, often mixed with a soda pop and crushed hard candy for additional flavor.

The Board has seen continued incidents of forged prescriptions for promethazine with codeine unknowingly filled by Utah pharmacists in recent months. Pharmacists, technicians, and interns should be on alert for promethazine with codeine prescriptions and perform due diligence in confirming that the prescriptions are legitimate.

Common red flags to look for:

1. telephoned prescriptions
2. an out-of-the-area prescriber you do not recognize
3. a patient you do not recognize
4. a large quantity or exact quantity for 473 mL
5. a cash-paying patient or use of a discount phone app
6. a new patient you do not know

In addition to forged prescriptions and the recent robberies, the Board has had reports that perpetrators are jumping the pharmacy counters during open pharmacy business hours and stealing promethazine with codeine stock bottles right off the shelves. It is suspected that the perpetrators watch for ideal times of day when shift changes occur, leaving the pharmacies more susceptible with minimal staff on duty. Perpetrators may scope out the pharmacy using a smart phone to record the location of the cough syrup on the shelf to speed their entry and exit from the pharmacy.

Please be aware that all incidents of forgeries and robberies need to be reported to local law enforcement first. The Board asks that you also notify DOPL Investigations. All reports should be emailed to DOPL Investigations Supervisor Dan Briggs at dlbriggs@utah.gov.

To ensure that the Board has enough information to send out a pharmacy alert, it is imperative to add all details regarding a robbery, forgery, or doctor shopper. Your email to Investigations Supervisor Dan Briggs should include the following:

- The prescriber's name and contact information
- The name and contact information of the individual calling in the prescriptions
- The name, date of birth, address, and contact information of the patient
- An attached copy of the physical script, if available
- Attachments of still images captured from surveillance
- Completed Drug Enforcement Administration Form 106
- Your pharmacy's contact information, including the person making the report

Please continue to verify CS with the provider.

Vaccine Administration Protocol Revision

The Vaccine Administration Protocol was revised September 24, 2020. The latest version has the addition of the coronavirus disease 2019 vaccine. Please be sure to update your pharmacy protocol for compliance. You can find the Vaccine Administration Protocol by visiting DOPL's pharmacy website at *dopl.utah.gov/pharm*. Select "Related Information" on the left side of the screen, and then choose "Resources." This information is also available at *dopl.utah.gov/pharm/vaccine_administration_protocol.pdf*.

Pharmacy Technician and Intern Independent Access to the Utah Controlled Substance Database

The Utah Controlled Substance Database (CSD) is a resource created to enable prescribers and pharmacists to provide safe, effective, and appropriate care for patients. By monitoring CS prescribing and dispensing, pharmacy caregivers are better able to identify medication safety concerns, document accurate medication histories, and detect potential overutilization or abuse. The database collects information on all Schedule II-V medications dispensed in Utah, including data from retail, mail-order, institutional, and outpatient pharmacy settings. It also includes information on drug-related criminal charges and hospital records related to CS misuse, including poisoning or overdose.

continued on page 4

National Pharmacy Compliance News

November 2020

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 Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

continued from page 1

On May 12, 2020, independent access to the CSD was extended to pharmacy technicians and interns. The expansion of this access supports ongoing efforts by the Board to promote the professional development and advancement of pharmacy technicians and interns. New CSD subscribers are encouraged to educate themselves on appropriate usage of the database and the laws and rules that protect patient privacy. Information on the CSD Act can be found at *https://le.utah.gov/xcode/Title58/Chapter37F/58-37f-P2.html.*

Signing Up

1. Pharmacy technicians who had delegate access have already been granted independent access and will not need to create a new account. First-time subscribers will need to create an account with UtahID at *https://id.utah.gov.* Enter the email address where password changes and reminders should be sent, and click submit. If you see the error message, "Email already in use," call the Help Desk at 801/538-3440.
2. After verifying your email address, you will be directed to an account creation page. When finished, select the link to go to UtahID profile self-service portal and sign in.
3. You will be given an option to tour the self-service portal. After completing or bypassing the tour, you may enter your account information. This information can be updated at any time.
4. After completing your UtahID account, you may apply for access to the CSD by going to *https://csd.utah.gov.*
5. Select user type, then enter your date of birth and the last four digits of your Social Security number. At this point, a pin number will be emailed to you. You will need to enter your pin number to accept the Terms of Agreement and gain access to the database.
6. If you reach an error page, you may just need to log out and log back in. If you continue to have issues, contact the CSD at csd@utah.gov or by calling 801/530-6220.

Use of the Database

Technician and intern independent access is limited to the state of Utah. If out-of-state data is needed, the query must be run by the supervising pharmacist.

It is inappropriate to search and review actual patients solely for the purpose of training. New subscribers can train on navigating the database by searching a test patient – name: Alpha Papa; date of birth: January 1, 1921. For the most results, enter only the last name (Papa) and date of birth. Highlight each line and click View Selected. This will populate a comprehensive overview of the patient's CS history. **Note the following information:**

- Active – A green encapsulated "yes" indicates that this prescription is currently active and is based on the days supply.
- External Records – External records include hospital records and court cases related to the patient's history with CS. Court cases only include convictions and will not provide information on outstanding arrests or charges. Hospital records will include information regarding overdose details and outcomes. If a patient has recently been admitted for an overdose, the pharmacist may need to contact the prescriber before filling new scripts for CS.
- Morphine Milligram Equivalents (MME) – MME is based on **active** medication orders and will adjust as new orders are added and days supply is depleted. An MME $\leq$ 49 is considered a minor risk, 50-89 is moderate risk, and $\geq$ 90 is high risk. A pharmacist should be consulted if the patient's MME has reached an inappropriate level.

Misuse

Misuse of the database may result in charges ranging from Class C misdemeanors to third-degree felonies, and include penalties of up to $5,000 per violation. Inappropriate use of the database includes releasing information to an unauthorized individual, group, or publication – either intentionally, or due to negligence or recklessness – as well as obtaining, or attempting to obtain, information from the database through misrepresentation or fraud. CSD users should familiarize themselves with the rules and penalties associated with misuse. Information can be found at *https://le.utah.gov/xcode/Title58/Chapter37F/58-37f-S601.html.*

Patient information in the CSD is protected. Users are expected to follow all rules and laws associated with the protection of patient privacy and the use of CS. This includes the Health Insurance Portability and Accountability Act, the Utah CSD Act, and the Controlled Substances Act.

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