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Utah Board of Pharmacy News

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Pharmacist Counseling of Patients

A Message From Senator Evan Vickers, RPh

One of the important, if not the most important, duties of the pharmacy profession is professional medication counseling. The opportunity to work with a patient and/or caregiver one-on-one to provide them with the knowledge they need to understand how to take their medication, side effects to look for, cautions, etc, is very important.

I want to make my pharmacy colleagues aware of a very alarming issue that I have faced during my tenure in the state legislature. As you all know, I am the only pharmacist in the legislature, which puts me in a unique position to advocate for our profession. I want you to know that I diligently advocate for the value our profession brings to the health and welfare of our citizens, whether we are discussing traditional medication treatment or cannabis medication treatment. Here is the alarming situation: I cannot tell you how many times that I have been in a discussion with other legislators and/or lobbyists and have mentioned the importance of a pharmacist counseling a patient on his or her medication needs and had those individuals respond with **"my pharmacist never counsels me on my medications."** I cannot tell you how disheartening and embarrassing this is. All I can say is that if you are a pharmacist who does not counsel your patients, **shame on you!**

I implore each of you to commit that you will take every opportunity to counsel your patients in the future. If we want to preserve and promote our profession, we have to establish what value we bring to the health care challenge.

Sign Up for Bill Tracking Service

Would you like to track bills during the 2020 legislative session? You may sign up to receive emails when a bill is changed, updated, or when a committee meeting is scheduled. To sign up, visit *le.utah.gov/tracking/trackingLogin.*

Utah Controlled Substance Database and Rx Monitoring Program

Amendments to R156-37f – Utah Controlled Substance Database (CSD) Act Rule – Division of Administrative Rules File No. 44120 – effective December 9, 2019. This is to notify you that amendments to the rule noted above became effective on December 9, 2019. The following is a summary of the amendments.

In accordance with 2019 House Bill (HB) 449, as recommended by the Controlled Substance Advisory Committee, this filing amends Rule R156-37f to have the CSD track the prescription non-controlled substance (CS) drug 1-(Aminomethyl)-cyclohexaneacetic acid (gabapentin). The filing also makes clarifications to the rule as recommended by the Division. New Subsection R156-37f-203(7) requires the Utah CSD to track the non-CS prescription gabapentin. New Subsection R156-37f-203(8) clarifies that the Utah CSD tracks derivatives of barbituric acid (butalbital). New Subsection R156-37f-301(15) clarifies that a designating practitioner or other person who employs a designee must submit a notice of disassociation of designee to the Division after the designee ceases employment or is otherwise no longer designated.

Beginning April 1, 2020, the Division will require all pharmacies dispensing the prescription gabapentin to report the dispensing and sale transaction to the CSD. If a pharmacy system has the ability to submit gabapentin prescription data to the CSD at the time of this notice, it may do so.

Pharmacies that do not possess a CS license, but dispense gabapentin, will be required to report to the CSD at each dispensing and sale of the prescription gabapentin, as outlined in the CSD Act; Utah Code Annotated § 58-37f-203.

For general questions and technical assistance in reporting electronic data to the CSD for a non-CS,

continued on page 4

National Pharmacy Compliance News

February 2020

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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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

continued from page 1

pharmacies should contact CSD staff for assistance at 801/530-6220, Monday – Friday, between 8 AM and 5 PM.

Gabapentin can be prescribed and dispensed without a CS license or a Drug Enforcement Administration (DEA) registration. Pharmacies are encouraged to contact CSD staff for assistance with the reporting requirements, due to potential prescriber and dispenser DEA data limitations, to receive clarification on how to report data in the absence of a DEA registration number.

Can Pharmacists in Utah Provide Emergency Refills?

A 36-year-old Ohio man with diabetes, Kevin Houdeshell, died in January 2014 as a result of diabetic ketoacidosis when he ran out of insulin and was unable to refill his expired prescription. His parents have worked to create "Kevin's Law" (HB 188) in Ohio to prevent another patient from being placed in a similar predicament that led to Kevin's death. In short, it was a holiday weekend and Kevin's prescription had expired and attempts to contact the prescriber were not successful.

In Utah, we already have a law and rule in the Pharmacy Practice Act Rule to allow a pharmacist to provide a three-day supply of medication to patients who may find themselves in a situation similar to Kevin Houdeshell. Read more about Kevin here.

R58-17b-608 Emergency Refills

(1) In the interest of the patient's health, a pharmacist or pharmacy intern may, in an emergency, refill a prescription for a patient, but only if the prescribing practitioner is not available promptly to authorize the refill and only if in the professional judgment of the pharmacist or pharmacy intern the prescription should be refilled.

(2) Only sufficient medication as necessary in the emergency may be furnished by the pharmacist or pharmacy intern, not to exceed a three-day supply.

(3) The practitioner shall be contacted as soon as possible for further instructions concerning the emergency.

Pharmacists and technicians, please familiarize yourself with the details about how to provide emergency refills in the Pharmacy Practice Act Rule R156-17b-612 (11). To summarize the rule, the pharmacist may exercise professional judgment in providing patients a refill of a non-CS medication if it could result in an interruption of therapy or cause the patient to suffer, and the pharmacist is unable to contact the practitioner for any reason, including natural disaster. The quantity supplied may be up to a 72-hour supply or one single dose unit (eg, insulin and inhalers) if the product is packaged in a greater quantity.

For example, if he or she comes to the pharmacy and does not have enough insulin to treat his or her diabetes, and has no refills of insulin, the pharmacist may dispense an emergency refill if he or she:

- attempts to contact the patient's prescriber to obtain refills and documents the attempt
- determines in his or her professional judgment that the patient would likely have an interruption of therapy that could create patient suffering
- dispenses one vial of insulin to the patient to allow treatment to continue and notifies the patient that this refill is being provided as an emergency refill that will require contact with a prescriber for more medication in the future
- documents all of the above information and provides the insulin to the patient

An emergency refill can also be provided if a patient presents to the pharmacy a container label, receipt, or document that contains all required information to fill a prescription from another pharmacy.

The beauty of this statute is that it allows the pharmacist to use professional judgment to continue care and prevent patient harm in the event of a natural disaster, or if the patient has simply run out of refills.

Rule Updates

The Pharmacy Practice Act Rules went into effect November 25, 2019.

The proposed substantive amendments in the filing are as follows:

- **Section R156-17b-102:** Adds definitions for the terms "Area of need," "Mail service retail pharmacy," "MPJE," "Remote Dispensing Pharmacist in Charge"/"RDPIC," "Remote dispensing pharmacy," "Retail Pharmacy," "Supervising pharmacy," and "Telepharmacy system."
- **Section R156-17b-106:** Clarifies the use of "shall" or "may" as used in the rule. Although these conventions are understood for Utah laws and rules, adding this special clarification to the pharmacy rule is important because there are other standards that apply in the pharmacy profession when using the terms shall and may.
- **Section R156-17b-203:** Creates an Advisory Pharmacy Compounding Education Committee. The Committee shall be composed of seven members, diversified between retail pharmacy, hospital pharmacy, and other pharmacy specialties deemed pertinent by the Division in collaboration with the Utah Board of Pharmacy.

continued on page 5

continued from page 4

- **Section R156-17b-302:** Clarifies that Class A pharmacies include retail pharmacies, mail service retail pharmacies, and remote dispensing pharmacies, and that a Class A pharmacy needs a pharmacist-in-charge or an RDPIC.
- **Section R156-17b-303a:** Clarifies that an applicant may prove current college admission by written verification from "a" dean of the college.
- **Section R156-17b-303c:** Clarifies that a pharmacist applicant will need to take the Utah Multistate Pharmacy Jurisprudence Examination® (MPJE®).
- **Section R156-17b-304:** Clarifies that a temporary pharmacist will need to submit evidence of having secured employment in Utah conditioned upon issuance of the temporary license, and that the employment is under the direct, on-site supervision of a pharmacist with an active, non-temporary Utah license that includes a CS license.
- **Section R156-17b-305:** Clarifies licensure by endorsement requirements for a pharmacist.
- **Section R156-17b-309:** Updates the continuing education (CE) topics and requirements for pharmacists and pharmacy technicians, including requiring two CE hours in immunizations or vaccine-related topics for pharmacy technicians who engage in the administration of immunizations or vaccines.
- **Section R156-17b-402:** Replaces all administrative penalty subsections with a fine schedule.
- **Section R156-17b-502:** Formats certain provisions to fit with the new fine schedule, and adds to the definition of unprofessional conduct "failing to comply with the operating standards for a remote dispensing pharmacy as established in Section R156-17b-614g."
- **Section R156-17b-601:** Clarifies the scope of practice for pharmacy technicians and pharmacy technician trainees. In particular, this amendment will allow pharmacy technicians to administer vaccines and emergency medications pursuant to delegation by a pharmacist under the Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications adopted March 26, 2019, if the pharmacy technician completes certain required initial training and CE, and is under direct, on-site supervision by the delegating pharmacist.
- **Section R156-17b-610:** Clarifies that patient counseling may be provided through a telepharmacy system.
- **Section R156-17b-612:** Minor wording changes were made in this section regarding prescription operating standards.
- **Section R156-17b-614a:** Clarifies that a remote dispensing pharmacy may dispense a prescription drug or device to a patient if a pharmacist or designated medical practitioner is physically present and immediately available in the facility, or supervising through a telepharmacy system.
- **Section R156-17b-614g:** This new section establishes and clarifies the qualifications and operating standards for a remote dispensing pharmacy.
- **Section R156-17b-615:** Clarifies that a Class C pharmacy may be located in the same building as a separately licensed Class A, B, D, or E third-party logistics provider.
- **Section R156-17b-617g:** This new section establishes operating standards for a third-party logistics provider.
- **Section R156-17b-621:** Allows pharmacy interns and pharmacy technicians to administer immunizations and emergency medications pursuant to delegation by a pharmacist under the March 26, 2019 Vaccine Administration Protocol, and establishes and clarifies the required training for pharmacists, pharmacy interns, and pharmacy technicians who will be engaging in the administration of a prescription drug or device, or engaging in the administration of vaccines.
- **Section R156-17b-623:** Clarifies the drugs that may be dispensed by a dispensing medical practitioner in accordance with Subsection 58-17b-802(1) and Section 58-17b-803.

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