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Utah Board of Pharmacy News

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Three Common Problems Found in Submissions to the Utah Controlled Substance Database (In No Particular Order)

By Jeff Henrie, Utah Controlled Substance Database

Name of the Patient

Common errors involve the correct order of the patient's first and last name, using a pet's name when the owner's name should be used, and not submitting a last name or a first name when both are required by the American Society for Automation in Pharmacy Version 4.2 Standard for Prescription Monitoring Programs. Also know that no other notations or symbols should be included with the patient's name, as this will affect future patient matching.

The Additional Information Reporting (AIR) Fields

Since October 2017, Utah has required that the following data be collected and submitted from the person picking up the prescription. Check with your vendor to make sure your pharmacy is compliant.

- AIR03 – Identification-issuing jurisdiction – The state or providence that issued the verified identification
- AIR04 – Identification qualifier – The type of verified identification, submitted as a two-digit code (eg, 06 = driver's license)
- AIR05 – Identification of the person picking up the prescription – The number from the verified identification (This should most likely be a driver's license or state-issued identification card.)
- AIR07 – Last name of the person picking up the prescription
- AIR08 – First name of the person picking up the prescription
- AIR09 – Last name or initials of the dispensing pharmacist
- AIR10 – First name of the dispensing pharmacist

Incorrect DEA Number for the Provider

The dashboard and the practitioner notification system need to be provided with correct Drug Enforcement Administration (DEA) numbers so that the right information concerning patient activity is reported to prescribers.

Common errors include transposing the two letters (eg, GM vs MG); not matching the second letter to the provider's last name (There are some providers with legal name changes but 99% should match); and common number errors such as entering 2 instead of 7, or the letter O instead of 0 (zero). Please take the extra few seconds to ensure all data is entered correctly.

CBD in Utah

By Melissa Ure, Utah Department of Agriculture and Food

After years of largely unregulated and unofficial sales in Utah, rules governing the processing, product registration, and labeling of cannabidiol (CBD) products are about to go into effect and standardize the industry. During the 2018 legislative session, the Utah Legislature passed, and the governor signed, two bills that address industrial hemp and CBD specifically. Utah Code 4-41-402 allows for the "sale or use" of a CBD product provided it is registered with the Utah Department of Agriculture and Food (UDAF). The law specifies that CBD products must be in one of the following medicinal dosage forms: capsule, tablet, concentrated oil, sublingual, liquid suspension, or transdermal preparations. Additionally, the law allows UDAF to establish labeling and testing requirements for CBD products.

Hopefully, the following information will help answer many of the questions about the over-the-counter sale of CBD oils that UDAF has received over the past few

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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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months. UDAF has been working to establish the rules governing the sales and labeling requirements of CBD products. Since many in the industry are already advertising the products as dietary supplements, UDAF determined that they should be labeled as such. Therefore, the rule requires that labels for CBD products meant for human consumption follow the federal guidelines for the labeling of dietary supplements, including the usage of a supplement facts panel and not a nutrition facts panel. Additionally, the label should include a barcode or QR code, which will link to the certificate of analysis (COA) performed for that specific batch of product. The rule does not allow medical claims to be made.

UDAF requires that these products undergo third-party testing. These third-party tests must establish and show the cannabinoid profile and test for residual solvents, pesticide residue, heavy metals, and microbials. A copy of the COA for each product must be attached to the label with the product being registered with UDAF. UDAF will periodically check these products against the COA filed with the product to check the accuracy of the labels and the COA.

It is the responsibility of retail owners to ensure that the products in their stores are registered. Once the rule is final and registration is open, UDAF anticipates giving a grace period for companies to have their labels corrected. UDAF is committed to educating retailers about the rules before issuing citations. However, UDAF will take all steps available, as needed, to protect the public from harmful substances.

The public comment period for these rules concluded on October 1, 2018. UDAF is currently reviewing all comments received. Barring the need to make any substantive changes, UDAF anticipates product registration to begin around November 1.

Expanding Technician Roles

By Alicia Moran, CPhT, Utah Board of Pharmacy Member

There is currently a lot of attention throughout the country focused on expanding the roles of pharmacy technicians. Expanding these roles not only provides technicians with excitement and opportunity, but also allows pharmacists to step into a more clinical role and focus on patient care.

In the last six months, the Utah Board of Pharmacy conducted a work group discussing the top technician roles the profession would like to see expanded. The most prominent topic was allowing technicians to administer vaccines. Last year, Idaho became the first state to implement new rules allowing pharmacists to delegate vaccine administration to a certified technician who has completed training in appropriate immunization administration techniques and holds certification in basic life support for health care professionals. Alex J. Adams, PharmD, MPH, executive director of the Idaho State Board of Pharmacy, focused on three main points for advanced delegation:

1. Supervision – A task must be delegated under the supervision of a pharmacist.
2. Education, skill, and experience – The task must be appropriate for the level of training and education of the individual.
3. Professional judgement restriction – Even if state law does not prohibit delegation of a specific task or function to a technician, a pharmacist may use his or her professional judgement to decide not to delegate a specific task to a specific technician.

Removing prohibitions on technicians will allow the roles to continue to expand in a growing profession. The Board wants to create new roles and career opportunities for technicians and encourage them to grow and develop. In doing so, the Board can increase workflow efficiency and give pharmacists the opportunity to safely explore their clinical roles.

Expanding technician roles will be a focus for the Board over the next year and the Board hopes to engage technicians in that conversation. Look for Utah to change rules to allow for vaccinations by technicians in the near future.

Utah DOPL Funds a USP <800> Study

By Carl Trip Hoffman III, PharmD, Utah Board of Pharmacy Chair

The Board provides support to the Division of Occupational and Professional Licensing (DOPL) mission to protect the public health and support commerce. United States Pharmacopeia (USP) General Chapter <800> is a set of guidelines written by USP regarding the handling of hazardous drugs. Additional data is needed to assist the executive and legislative branches of Utah's government as well as the Board's USP <800> task force in drafting and implementing policy to protect the public and health care providers who handle hazardous drugs.

The Board has a compounding task force that makes recommendations for compounding laws and rules to ensure the safety of compounders and patients. The task force is in need of a summary of published scientific literature that will be used to direct an evidence-based approach to the practice of compounding.

A comprehensive search of available literature would need to be done that describes the safety and occupational hazards related to human or animal exposure to hazardous

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substances (eg, drugs, active pharmaceutical ingredients, and medications) listed in Group 2 and Group 3 of the National Institute for Occupational Safety and Health (NIOSH) list. Such products from the NIOSH list include estradiol, medroxyprogesterone, progesterone, testosterone, methimazole, finasteride, fluconazole, oxytocin, tretinoin, clonazepam, colchicine, spironolactone, zonisamide, and zidovudine.

The focus of this analysis is to guide the task force in drafting policy recommendations regarding the risk of exposure and best practices for handling the above hazardous drugs for compounding.

The study will be conducted by Intermountain Healthcare's Drug Information Service and led by Whitney Mortensen. The review will be completed in early December, so stay tuned for details on USP General Chapter <800> to be released in early 2019. It is crucial to remember the implementation of USP General Chapter <800> is set for December 1, 2019.

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