August 2016

Utah Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

PO Box 146741 • Salt Lake City, UT 84114-6741
www.dopl.utah.gov/licensing/pharmacy.html

Legislative Update for 2016 General Session

The following are summaries of House Bills (HBs) passed by the Utah State Legislature in the 2016 General Session.

Controlled Substances – Opiate Overdose

HB 240: Opiate Overdose Response Act – Standing Orders and Other Amendments. This bill renames the Emergency Administration of Opiate Antagonist Act as the Opiate Overdose Response Act and authorizes the use of a standing prescription drug order issued by a physician to dispense an opioid antagonist.

HB 238: Opiate Overdose Response Act. This bill renames the Emergency Administration of Opiate Antagonist Act as the Opiate Overdose Response Act, amends civil liability provisions, authorizes an overdose outreach provider to furnish an opiate antagonist without civil liability, requires an overdose outreach provider to furnish instruction on how to recognize and respond appropriately to an opiate-related drug overdose event, exempts an overdose outreach provider from licensure under the Utah Pharmacy Practice Act, and specifies that the prescribing or dispensing of an opiate antagonist by a dentist is not unprofessional or unlawful conduct.

HB 192 3 Sub: Opiate Overdose Response Act – Pilot Program. This bill renames the Emergency Administration of Opiate Antagonist Act as the Opiate Overdose Response Act, amends liability provisions, creates the Opiate Overdose Outreach Pilot Program within the Utah Department of Health, authorizes the Department to make grants through the program to persons who are in a position to assist an individual who is at increased risk of experiencing an opiate-related drug overdose event, and specifies how grants may be used.

Controlled Substance Database

HB 239: Access to Opioid Prescription Information via Practitioner Data Management Systems. This bill requires the Utah Division of Occupational & Professional Licensing to make opioid prescription data information in its Controlled Substance Database accessible to an opioid prescriber or pharmacist via the prescriber's or pharmacist's electronic data system. It also limits access to and use of the information by an electronic data system to a prescriber or a pharmacist in accordance with rules established by the Division. It also requires the Division to periodically audit use of the information and amends Controlled Substance Database Act penalty provisions.

HB 150: Controlled Substance Prescription Notification. This bill amends the Controlled Substance Database Act to allow a person for whom a controlled substance (CS) is prescribed to designate a third party who is to be notified when a CS prescription is dispensed to the person.

HB 114: Controlled Substance Reporting. This bill amends the requirement for a general acute hospital to report admissions for poisoning or overdose involving a prescribed CS to the Division and requires courts to report to the Division certain violations of the Utah Controlled Substances Act.

HB 375 3 Sub: Prescription Drug Abuse Amendments. This bill amends the Controlled Substance Database Act to promote utilization of the Controlled Substance Database to prevent opioid abuse, requires a dispenser to contact the prescriber if the Controlled Substance Database suggests potential prescription drug abuse, and limits liability for prescribers and dispensers who contribute to and use the Controlled Substance Database.

HB 149 2 Sub: Reporting Death Involving CS Amendments. This bill requires a medical examiner to provide a report to the Division when the medical examiner determines that a death resulted from poisoning or overdose involving a prescribed CS. It also requires the Division to notify each practitioner who may have written a prescription for the CS involved in the poisoning or overdose, allows probation and parole officers to obtain information in the Controlled Substance Database without a warrant, and allows the Division to provide information to law enforcement officers engaged in specified types of investigations.

Pharmacy

HB 236 3 Sub: Charitable Prescription Drug Recycling Program. This bill creates a charitable prescription drug recycling program that allows certain pharmacies to accept and dispense donated unused prescription medications to certain individuals.

Administrative Rule Writing Topics

The Division and the Utah Board of Pharmacy have recently started a second monthly meeting to draft administrative rule. The meetings are held at 8:30 AM on the first Wednesday of each month and are held in the North Conference Room of the Division building, the Heber M. Wells Building (160 E 300 S, Salt Lake City, UT). The meetings are open to the public, and interested

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More Selected Medication Safety Risks to Manage in 2016

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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parties are encouraged to attend. The following is a list of topics that are in the rule drafting process.

- ♦ Charitable prescription drug recycling program
- ♦ Veterinary pharmaceutical facilities
- ♦ Methadone clinics
- ♦ Third-party logistics providers
- ♦ Volunteer health care continuing education (CE)
- ♦ CE
- ♦ Central processing
- ♦ Name, ownership, and location change
- ♦ Positive identification
- ♦ Medication therapy management
- ♦ Nuclear pharmacy
- ♦ Prescription misfills
- ♦ Hospice facilities

News From the Compounding Task Force

Changes are coming to United States Pharmacopeia (USP) Chapter <797>, and a new USP Chapter <800> will enter the compounding arena. Embrace the changes and additions, as they will not only bring higher standards but will also allow for improved patient safety and overall higher-quality compounded products.

The USP Compounding Expert Committee published the proposed revisions to USP Chapter <797> on September 25, 2015, and the public comment session ended on January 31, 2016. Expect to see this chapter published and released late 2016 or early 2017. Once the chapter is finalized, the changes likely will require more resources and focus devoted to quality assurance and control activities to ensure pharmacies are achieving and maintaining a proper state of control and can prove it. Some of the major changes that will be seen are moving three risk levels to two categories, requirements for quarterly personnel monitoring, beyond-use dating and storage times (45 days maximum regardless of sterility testing), and monthly requirements for viable air sampling and surface sampling.

USP Chapter <800> will become official and effective on July 1, 2018, and the Board will adopt this chapter into its rules as it incorporated USP Chapters <795> and <797>. The backbone of the chapter highlights containment strategies and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection. The majority of the chapter concentrates on facilities and engineering controls, which will prove to be the biggest challenges as well as the most expensive for pharmacies. Get ready now and utilize the gap analysis created by the *International Journal of Pharmaceutical Compounding* at *www.compoundingtoday.com*.

Compounding labeling requirements have been updated to mirror more closely USP Chapters <795> and <797> and became effective in rule on April 21, 2016. These changes start at Utah Administrative Code (UAC) R156-17b-614a(3)d. It may be helpful to make a list of items that should be included in the master formulation and compounding records. Division investigators/inspectors have indicated not all items are accounted for during their inspections. Also, it is imperative you meet all the requirements with the duplicate label and that all pertinent sample labeling information such as active ingredients, beyond-use date, storage conditions, and lot number are provided on the final product given to the patient.

Minutes from the Compounding Task Force meetings can be found on the Division website (lower right-hand corner), and meetings are open to attend. The task force's next meetings are scheduled for August 16 and November 15 in the North Conference Room of the Division building from 7 to 9 AM.

Pharmacy Inspectors Information

Division inspectors/investigators are frequently asked in Board meetings what are the problems or violations they find in pharmacies on random inspections. Sadly, it consistently seems to be some of the same issues. Please look over the following areas in your pharmacy to make sure that you are compliant with the Utah Pharmacy Practice Act and Pharmacy Practice Act Rule.

Expired Medication in Dispensing Stock

UAC R156-17b-605(1) states that "[a]ll out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label."

The Board suggests that you implement what works for your pharmacy, whether it is tagging soon-to-expire medication or assigning shelves for which individual employees are to be responsible. Additionally, if your pharmacy compounds, examine the expiration dates for your compounding stock.

Annual Inventories of CS

Refer to UAC R156-17b-605(2)(a)(b)(c)(d)(e)(f)(g)(h)(i)(j). Familiarize yourself and staff with these general requirements for inventory of CS. Some of the requirements that Board staff find in noncompliance during inspections are: the required five years are filed in multiple places or filed in storage that is not readily available to inspect; Schedule II and Schedule III-V CS are not inventoried or listed separately; not documenting when the inventory is conducted by time, date, and opening or closing of business; or without signatures.

Compounding Nonsterile and Sterile

Master Worksheet Documentation

[UAC R156-17b-614a(3)(e)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii)(A-D)(ix)(A-D)(x)(xi)(xii)(xiii)]

Preparation Worksheet Documentation

[UAC R156-17b-614a(3)(e)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii)(ix)(x)(xi)(xii)(A-D)(xiv)(A-D)(I-III)(xvii)(xviii)(xix)]

Documentation on both Master Worksheets and Preparation Worksheets require many items to be compliant with USP Chapters <795> and <797>. Review your current Preparation Worksheets and Master Worksheets to see if additional information needs to be included to be compliant.

These are the most common violations that staff is currently finding. Please address these areas with your facility.

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