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Legislative Update for Utah 2018 General Session

By Drew Favero, 2018 PharmD Candidate

The following are summaries of bills passed by the Utah State Legislature in the 2018 General Session.

Pharmacy

Senate Bill (SB) 184 2 Sub: Pharmacist Dispensing Authority Amendments (Senator Todd Weiler – District 23). This bill permits a pharmacist to dispense a self-administered hormonal contraceptive under a standing prescription drug order established under a licensed physician. Specifically, this bill:

- Allows a pharmacist or pharmacy intern to dispense a self-administered hormonal contraceptive when:
  - The patient is 18 years of age or older;
  - The patient has completed a self-screening risk assessment questionnaire that has been approved by the Utah Board of Pharmacy and the Utah Physicians Licensing Board and the results indicate it is safe; and
  - The duration of pharmacist or pharmacy intern dispensing does not exceed 24 months without the patient having consulted with a primary care or women's health care practitioner.
- Requires the patient to be provided written information with:
  - The importance of seeing a primary care or women's health practitioner;
  - The effectiveness and availability of long-acting reversible contraceptives;
  - The patient's completed self-assessment tool; and
  - A description of the contraceptive dispensed; or
  - The basis for not dispensing a contraceptive.
- Does not create a duty or standard of care for a person to prescribe or dispense self-administered hormonal contraceptives.
- Restricts the liability of a physician who issues the standing prescription drug order.

SB 208 4 Sub: Pharmacy Benefits Manager or Coordinator Amendments (Senator Evan Vickers – District 28). This bill requires a pharmacy benefits manager (PBM) or coordinator that uses direct or indirect remuneration fees to report related information to the contracted pharmacy or pharmacy services administration organization, and prohibits a PBM from preventing a pharmacist from disclosing cost information to a patient. Specifically, this bill:

- Requires that a pharmacy is provided with a reimbursement report that:
  - Explains the reason for any adjusted compensation; and
  - Is provided in an easily accessible format within 120 days of the request.
- Prohibits a PBM from preventing a pharmacist from:
  - Disclosing the cash price of a medication; and/or
  - Charging a patient the retail price of the medication without prescription drug coverage.

Cannabis Products

SB 130 2 Sub: Cannabidiol Product Act (Senator Vickers). This bill enacts and amends provisions related to cannabidiol products and gives the Utah Department of Agriculture related rulemaking authority. Specifically, this bill:

- Grants the Department of Agriculture rulemaking authority to:
  - Apply for a federal waiver from the Controlled Substances Act;
  - Authorize the cultivation, production, possession, and use of cannabidiol oil under certain circumstances;
  - Set a fee to register cannabidiol products;
  - Set requirements for a cannabidiol producer license;
  - Establish a cannabidiol product tax;
  - Test cannabidiol products for safety; and
  - Ensure that products have accurate labeling and anything else deemed necessary.

House Bill (HB) 195 3 Sub: Medical Cannabis Policy (Representative Brad Daw – R). This bill is a "right to try" bill that allows cannabis-based treatment for terminally ill patients. Specifically, this bill:

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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 Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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- Allows patients who have been determined by a medical provider to have six months or less to live to try cannabis-based medical treatment.
- Requires cannabis used in medical treatment to be in a medicinal dosage form.

HB 197 2 Sub: Cannabis Cultivation Amendments (Representative Daw). This bill is the "feeder bill" that deals with the cultivation, processing, and sale of cannabis within the state of Utah to provide cannabis for patients identified in 2018's HB 195 and for Institutional Review Board-approved studies identified in 2017's HB 130. Specifically, this bill:

- Authorizes the Department of Agriculture to:
  - Contract with a third party to cultivate or process cannabis;
  - Make rules associated with cannabis production within the state; and
  - Establish a state dispensary for cannabis that has been processed into a medicinal dosage form.

Controlled Substances – Opiate Abuse

HB 127 2 Sub: Controlled Substance Database Act Amendments (Representative Justin Fawson – R). This bill changes the requirements for checking the Utah Controlled Substance Database (CSD). Specifically, this bill:

- Requires prescribers to check the CSD when prescribing a Schedule II or III opiate to a patient for the first time.
- Grants the Utah Division of Occupational & Professional Licensing authority to:
  - Review the CSD to identify prescribers who may be overprescribing opioids; and
  - Offer education to prescribers.

HB 399 3 Sub: Opioid Abuse Prevention and Treatment Amendments (Representative Steve Eliason – R). This bill requires pharmacists to affix a warning label to certain opiate prescriptions and commissions and requires the Utah Department of Health to develop a pamphlet with information about opiates. Specifically, this bill:

- Requires pharmacies that dispense Schedule II and III opiates to:
  - Affix a label to all Schedule II and III opiate prescriptions that warns of the risk of overdose and addiction; and
  - Display an opiate information pamphlet developed by the Department of Health at the point of sale.

Medicaid

HB 472: Medicaid Expansion Revisions (Representative Robert Spendlove – R). This bill amends the state Medicaid program to permit an expansion of Medicaid eligibility under certain requirements. Specifically, this bill:

- Requires the Department of Health to submit a waiver to the federal government to:
  - Extend Medicaid benefits to eligible individuals who are below 95% of the federal poverty level;
  - Obtain 90% federal financial participation; and
  - Establish a work activity requirement for qualified adults.
- Sets a sunset date for the bill if federal financial participation drops below 90%.

Transfer Legend Drugs

By Carrie Dunford, MBA, PharmD, BCPS

The Board has recently been asked to clarify the communication methods that may be used when transferring a prescription from one pharmacy to another. In the Utah Pharmacy Practice Act Rules, **R156-17b-612(5) – Operating Standards - Prescriptions** indicates the required information that must be communicated to the receiving pharmacist, pharmacy intern, or designated medical practitioner (DMP) transferring the prescription. Based on a concern for transcription errors, the Board was asked if it was appropriate to communicate the required information via fax machine. After the initial conversation takes place between pharmacists, pharmacy interns, or DMPs, the information regarding the transferred prescription may be communicated to the receiving pharmacy via fax machine. It is important that the information be communicated clearly so the total number of authorized refills is not exceeded. The required information for transfer is outlined in the rule below:

> (a) the transfer shall be communicated directly between pharmacists, pharmacy intern, or DMP or as authorized under Subsection R156-17b-613(9);
>
> (b) both the original and the transferred prescription drug orders shall be maintained for a period of five years from the date of the last refill;
>
> (c) the pharmacist, pharmacy intern, or DMP transferring the prescription drug order shall void the prescription electronically or write void/transfer on the face of the invalidated prescription manually;
>
> (d) the pharmacist, pharmacy intern, or DMP receiving the transferred prescription drug order shall:
>
> (i) indicate on the prescription record that the prescription was transferred electronically or manually; and
>
> (ii) record on the transferred prescription drug order the following information:
>
> (A) original date of issuance and date of dispensing or receipt, if different from date of issuance;
>
> (B) original prescription number and the number of refills authorized on the original prescription drug order;
>
> (C) number of valid refills remaining and the date of last refill, if applicable;
>
> (D) the name and address of the pharmacy and the name of the pharmacist, pharmacy intern, or DMP to whom such prescription is transferred; and
>
> (E) the name of the pharmacist, pharmacy intern, or DMP transferring the prescription drug order information;

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(e) the data processing system shall have a mechanism to prohibit the transfer or refilling of legend drugs or controlled substance prescription drug orders that have been previously transferred; and

(f) a pharmacist, pharmacy intern, or DMP may not refuse to transfer original prescription information to another pharmacist, pharmacy intern, or DMP who is acting on behalf of a patient and who is making a request for this information as specified in Subsection (12) of this section.

Most Common Errors the Utah CSD Receives From Pharmacies

In March 2017, the Utah CSD adopted the American Society for Automation in Pharmacy (ASAP) 4.2 Format for data submissions. The CSD requires pharmacies to report all data segments/elements of the 4.2 standard. In addition, Utah's CSD requires pharmacies to submit additional and specific data segments/elements found in Utah Law §58-37f (Controlled Substance Database Act) and Rule R156-37f (Controlled Substance Database Act Rule).

When some pharmacies report, they continue to omit required data segments/elements, make preventable human data entry errors, and not report in a timely manner. According to §58-37f-203(1)(a), in-state and out-of-state pharmacies, as defined by §58-17b-102, must meet the same data submission requirements.

Below are specific data elements that continue to be problematic for some pharmacies when reporting to the CSD.

Utah-Specific Data Elements

- Must provide either NCPDP/NABP provider ID (identifier assigned to pharmacy by the National Council for Prescription Drug Programs) (PHA02) or Drug Enforcement Administration (DEA) registration number (PHA03). CSD prefers PHA02 to be reported for auditing purposes.
- Date sold (DSP17). This is a must, as it represents the date the prescription left the pharmacy to be used by the patient, not the date it was filled.
- ID-issuing jurisdiction (AIR03). Code identifying the jurisdiction that issues the ID contained in AIR05; reference Appendix A from the ASAP 4.2 guide or ask the CSD for a copy.
- ID qualifier of person picking up prescription (AIR04). Code indicating the type of ID in AIR05; reference ASAP 4.2 guide for code.
- ID number of person picking up prescription (AIR05). ID number from AIR05 code type.
- Last name of person picking up prescription (AIR07).
- First name of person picking up prescription (AIR08).
- Last name or initial of pharmacist (AIR09). Last name or initial of the pharmacist dispensing the medication.
- First name of pharmacist (AIR10). First name of the pharmacist dispensing the medication.
- If submitting PAT01, PAT02, and PAT03, or if submitting PAT04, PAT05, and PAT06, all three elements are required as a group in either of these data element sets.

Missing Data Elements

- DEA number (PRE02). Identifying number assigned to a prescriber.
- Some elements are blank or not included in the submission.
- First name of pharmacist (AIR10). First name of the pharmacist dispensing the medication.
- Some elements are blank or not included in the submission, but AIR09 has initials or last name.
- If submitting data in AIR03, AIR04, or AIR05, all three are required as a group.

Common Human Errors

- DEA number (PRE02). Pharmacist needs to confirm that the DEA number submitted is the actual number associated with the prescriber on the prescription. The CSD checks this against DEA's national database.
- Transposing the first two alphabetic characters.
- Too short – does not contain all nine characters.

For questions about any of these data elements, please contact the Utah CSD at 801/530-6220.

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