April 2018

Nevada State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

431 W Plumb Lane • Reno, NV 89509 • Phone: 775/850-1440 • Fax: 775/850-1444
http://bop.nv.gov

Board Members

Leo Basch, PharmD, RPh, Las Vegas ..... President
Kirk Wentworth, RPh, Carson City ..... Treasurer
Jason Penrod, PharmD, RPh, Reno .....Board Member
Kevin Desmond, RPh, Reno .....Board Member
Melissa Shake, PharmD, RPh, Las Vegas...Board Member
Darla Zarley, PharmD, RPh, Henderson.....Board Member
Robert Sullivan, Reno ..... Public Member

Contraceptive Prescriptions

Assembly Bill (AB) 249 and Senate Bill (SB) 233, which make changes to some contraceptive prescriptions, became effective on January 1, 2018, as did many other bills. This law requires a pharmacist to dispense up to a 12-month supply of drugs for contraception if:

1. The patient has previously received a three-month supply of the same drug;
2. The patient has previously received a nine-month supply of the same drug or a supply of the same drug for the balance of the plan year in which the three-month supply was prescribed, whichever was less;
3. The patient is insured by the same health insurance plan; and
4. A provider of health care has not specified in the prescription that a different supply of the drug is necessary.

Prescription Readers

As mentioned in the October 2017 *Nevada State Board of Pharmacy Newsletter,* SB 131 requires a retail pharmacy to provide a prescription reader at the request of a patient **or** directions or advice on obtaining a prescription reader. In an effort to assist you in meeting this requirement, please note the following:

- To the Board's knowledge, there are two electronic digital audio prescription readers readily available:
  1. ScripTalk by En-Vision America, Inc: 800/890-1180; *www.envisionamerica.com*
  2. optaPHONIC by Accessamed: 855/669-4223; *www.accessamed.com*

What Pharmacists Need to Know About AB 474

By Ciera Nielsen, PharmD Candidate 2018, Idaho State University College of Pharmacy

AB 474 produced many changes to the requirements for a controlled substance (CS) prescription. The bill became effective on January 1, 2018, and the Board has identified some frequently asked questions regarding what a pharmacist needs to know before filling a CS prescription.

In addition to the requirements currently listed in Nevada Administrative Code 453.440, each prescription for a CS must now also include the practitioner's Drug Enforcement Administration (DEA) number, the patient's date of birth, the days supply of the CS, and the *International Classification of Diseases, Tenth Revision* (ICD-10) code that corresponds to the diagnosis for which the CS is prescribed.

Days supply is defined as "The fewest number of days necessary to consume the quantity of the controlled substance dispensed . . . if the patient consumes the maximum dose of the controlled substance authorized by the prescribing practitioner" (AB 474, Section 7). The prescriber may choose to assign a days supply that is of longer duration than what is calculated based simply off the definition. For example, a prescription that says "take 2 tablets every 6h prn pain #24" would have a days supply of three if the patient took the maximum authorized. However, a provider can notate "must last 30 days," which then replaces the calculated days supply of three. A pharmacist can add or change the days supply after obtaining approval from the practitioner who issued the prescription.

Continued on page 4

National Pharmacy Compliance News

April 2018

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.*

Continued from page 1

These new requirements apply to all CS Schedules II through V. A veterinarian must put his or her DEA number on the prescription, but the law clarifies that the remaining requirements only apply to a CS being dispensed for human consumption. The new requirement that prescriptions contain ICD-10 codes cannot apply to prescriptions from veterinarians, since ICD-10 is used to code and classify mortality and morbidity data for the human population.

A pharmacist is **not** authorized to add or change the DEA registration number of a practitioner on a prescription for any CS.

A pharmacist is **not** authorized to add or change the following to a prescription for a CS listed in Schedule II:

- Name of the patient, and
- Name of the CS, except in the case when the pharmacist is changing the name to reflect the generic name of the CS prescribed.

A pharmacist may, however, add or change the following to a prescription for a CS listed in Schedule II after obtaining approval from the practitioner who issued the prescription:

- Strength, quantity, and directions for use of the drug;
- Date prescription was issued can be corrected, if written in error, but not changed;
- Days supply;
- ICD-10 code; and
- Date of birth of the patient.

Pharmacists should also be aware of some prescribing limits on an initial prescription for a CS. An initial prescription is defined as "a prescription . . . for a new patient of a practitioner . . . or a new prescription to begin a new course of treatment for an existing patient" (AB 474, Section 51). These limits are for an initial prescription of a CS listed in Schedule II, III, or IV for the treatment of acute pain and are as follows:

- Must be intended to be used for no more than 14 days, and
- Must not exceed 90 morphine milligram equivalents (MMEs) daily for opiate naive (never received an opioid prescription or most recent course was completed more than 19 days prior to initial prescription).

A conversion chart for MMEs can be found at *https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.*

Prescribe 365 *(Prescribe365.nv.gov)* was developed to help provide more information to health care providers and the public. Within AB 474, a practitioner should not prescribe in any given 365-day rolling period a higher quantity of a CS than the patient needs to follow the prescriber's instructions. The practitioner may choose to prescribe a larger quantity than the patient needs for the treatment period, so long as the practitioner documents his or her reasoning in the patient's medical record. This is not meant to be a restriction to the prescribers, but rather, it is intended to help facilitate a conversation between prescribers and their patients concerning the ongoing use of CS.

Overdoses associated with opioids is a very real problem, and every health care provider should be proactive in becoming aware of the issue. Pharmacists should also make an effort to educate and assist the public in the safe and appropriate use of opioids and other CS.

The *Nevada State Board of Pharmacy News* is published by the Nevada State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Larry Pinson, PharmD, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager