February 2020

Arizona State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

1616 W Adams St, Suite 120 • Phoenix, AZ 85007 • Website: *https://pharmacy.az.gov*
Email: kgandhi@azpharmacy.gov

The Board Is on Facebook

Follow the Arizona State Board of Pharmacy for the latest news and updates at *https://www.facebook.com/Arizona-State-Board-of-Pharmacy-396869467321193.*

Update Your Profile

In an effort to communicate more effectively with its licensees and permittees, the Board noticed that some contact information in its system is not current and up to date. Please use your online profile to update your contact information.

New Dengue Vaccine

Food and Drug Administration has approved the dengue vaccine, Dengvaxia®, for people nine through 16 years of age to protect against dengue serotypes 1-4. The Board does not expect Dengvaxia to be available in Arizona in the near future. However, when it is, the Arizona Department of Health Services plans to go through the regulatory process to add it to the list for which a pharmacist would require a prescription in order to administer it (Arizona Administrative Code (A.A.C.) R9-6-1301), and the Board will let you know when it does so. People who are seronegative for dengue are at increased risk for severe dengue when they are vaccinated with Dengvaxia and later infected with a dengue virus. Therefore, Dengvaxia should only be given to people who have been documented to have previously had a dengue infection **and** who live in areas where dengue is endemic. In addition, it should not be given to immunocompromised people since the vaccine is created by using a live, attenuated yellow fever backbone for the dengue antigens.

The Duties of a Pharmacist-In-Charge

By Ann Shangraw, PharmD Candidate, Class of 2020, University of Arizona College of Pharmacy

"Would you like to become the pharmacist-in-charge (PIC)?" You might hear this question someday, whether it comes as a surprise or is a goal you have been working to achieve. This is an exciting opportunity, and you may feel yourself inclined to say yes without much thought. The title of PIC may come with added benefits, such as a pay increase. However, along with potential benefits, the title of PIC definitely comes with a larger responsibility load. The goal of this article is to explain and further expand on what it truly means to be a PIC by defining what a PIC is and describing some of the required duties.

As a pharmacist, you have numerous tasks you must perform to effectively complete your job. By assuming the role of a PIC, you will not only be accountable for your current responsibilities, you will also be adding new duties to your daily routine. When you become the PIC, you become the individual who is responsible to the Board for ensuring that the establishment is in compliance with the laws and administrative rules of Arizona and the federal government (Arizona Revised Statutes (A.R.S.) §32-1901). Not only are you responsible for the management of your pharmacy, but you are also responsible for other pharmacists, interns, and technicians in your pharmacy (A.A.C. R4-23-610). In other words, as a PIC you become responsible for your pharmacy and all your pharmacy employees in it.

Once you become the PIC, you become the channel of communication between the pharmacy and the Board. Once you have assumed the role of PIC, you must immediately tell the Board office staff when you start. Additionally, should your role as PIC for that facility come to an end, this information must immediately be relayed to the Board. As stated previously, due to your responsibility for all pharmacy employees, you must inform the Board if a pharmacist, intern, technician, or technician trainee has been terminated due to actions by the individual that suggest they are or may be professionally incompetent, guilty of unprofessional conduct, or mentally or physically unable to safely perform their permitted duties or roles based on their license. Along with informing the Board, you must provide it with a general statement of the reason(s) why the pharmacy terminated the individual. Another way you might be conversing with the Board is if the Board or its compliance officers request information. If requested, you must also communicate to the Board and its compliance officer(s) the necessary records and documents within the allotted time frame. The time frame will be dependent on what information they are requesting. These are just some of the ways you will be conversing with the Board.

In addition to being the line of communication to the Board, you will also be making sure that your pharmacy and its employees are following the law. For instance, you must make sure that prescription records are kept as described by the A.R.S., the A.A.C., and the Code of Federal Regulations (CFR). Not only do you have to keep records, but you must also create and update manuals on policies and procedures for various equipment and processes in the pharmacy, such as the computer system or the use of an electronic imaging record-keeping system. Another duty you have as a PIC is to ensure that the pharmacy is set up properly with the correct area requirements for the pharmacy workspace and the necessary equipment. Examples of

Continued on page 4

National Pharmacy Compliance News

February 2020

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.

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

necessary equipment include an adequate refrigerator, a current hard copy or access to a current electronic copy of the Arizona Pharmacy Act and administrative rules and Arizona Controlled Substances Act, and a professional reference library. When it comes to the pharmacy employees, you must check that individuals are licensed before they work in your pharmacy. These are just a few examples of the required duties of a PIC.

When you become the PIC, you will end up having to wear many hats in your new role. You will continue your normal daily tasks, but you will also be held accountable by the Board for your pharmacy and your pharmacy team. This is an amazing opportunity and experience, but make sure that you are well prepared by understanding what it truly means to be a PIC. When you are performing your PIC duties to the fullest, you will have a compliant pharmacy and pharmacy team. This will allow you to provide patient care to the fullest!

The Board recommends reviewing the A.R.S., the A.A.C., and the CFR to become familiar with all the duties associated with being a PIC. You can find the A.R.S. and the A.A.C. in the Law Book under the "Resources" tab on the Board's website at *pharmacy.az.gov.*

Universal Licensure in Arizona

Recently, House Bill 2569 was passed into law in Arizona, allowing for licensed professionals to reciprocate their licenses to Arizona to work. The Board has been receiving many questions on this subject. The most common question is, "How does this change the current reciprocity process of the Board?" The answer is that it does not impact the Board very much. Prior to this new law, the Board already had in place a reciprocity process. There have been some minor adjustments; for instance, the Board will now recognize California licenses issued prior to 2004 (prior to California adopting the North American Pharmacist Licensure Examination®) and allow those licensees to reciprocate to Arizona. Also, keep in mind, the new law is only applicable if the person is moving to Arizona to work in the state.

2020 Legislative Session

The new legislation season is getting started. There will be several bills being proposed that will involve the profession of pharmacy. Below is a link to the Arizona Legislature's website to monitor and see what bills are being introduced. More information on these bills can be found here. If you have any questions, please call the Board office.

Arizona Controlled Substances Prescription Monitoring Program – EPCS FAQs

Beginning January 1, 2020, a Schedule II controlled substance (CS) that is an opioid may be dispensed only with an electronic prescription order as prescribed by federal law or regulation.

This is a statutory mandate to all pharmacies receiving Schedule II opioid prescriptions, with the exception of federal facilities (Indian Health Service (IHS), Department of Veterans Affairs (VA), and Department of Defense (DOD)), as they are not subject to state law.

Dispensers' Frequently Asked Questions (FAQs):

Q. What is EPCS?

A. EPCS stands for Electronic Prescribing of Controlled Substances and may also be referred to as e-prescribing of CS.

Q. What does EPCS-certified mean?

A. In 2010, Drug Enforcement Administration (DEA) issued regulations permitting prescribers to write prescriptions for CS electronically. A practitioner is able to issue electronic CS prescriptions only when the electronic prescription or electronic health record system the practitioner is using is EPCS-certified. In order to be EPCS-certified, the system must meet strict DEA requirements for credentialing, software certification, and dual factor authentication.

Q. What is the difference between e-prescribing and EPCS?

A. Electronic prescribing, or e-prescribing, allows health care providers to enter non-CS prescription information into a computer device and securely transmit the prescription to pharmacies using a special software program and connectivity to a transmission network. EPCS-certified systems allow health care providers to submit electronic prescriptions for Schedule II-V CS. EPCS-certified systems are specialized systems that must meet strict DEA requirements for credentialing, software certification, and dual factor authentication.

Q. Is it true that all Arizona pharmacies must be able to receive CS prescriptions electronically?

A. Beginning **January 1, 2020,** a Schedule II CS that is an opioid may be dispensed only with an electronic prescription order as prescribed by federal law or regulation. This is a statutory mandate to all pharmacies receiving Schedule II opioid prescriptions, with the exception of federal facilities (IHS, VA, and DOD), as they are not subject to state law.

Q. Is there a waiver for pharmacies that are currently unable to accept electronically submitted Schedule II opioid prescriptions?

A. No, there is not a waiver available for Schedule II opioid EPCS. Pharmacies must have EPCS-certified systems by **January 1, 2020,** in order to receive electronic prescriptions for Schedule II CS that are opioids.

Q. Do Schedule II opioid prescriptions from out-of-state prescribers need to be electronically submitted?

A. Per A.R.S. §36-2525(D), ". . . a pharmacy may sell and dispense a Schedule II [CS] prescribed by a medical practitioner who is located in . . . another state if the prescription was issued to the patient according to and in compliance with the applicable laws of the state of the prescribing medical practitioner and federal law."

Q. Can I fill a written prescription for a Schedule II opioid if the provider's electronic prescribing system or my pharmacy management system is not operational?

A. Yes. As per A.R.S. §36-2525(D)(1), "If the electronic prescribing system or a pharmacy management system is not operational or available, the pharmacist may dispense a prescription order that is written for a Schedule II [CS] that is an opioid. The pharmacist must maintain a record, for a period of time prescribed by the [B]oard, of when the electronic prescribing system or pharmacy management system is not operational or available in a timely manner."

Q. Can outpatient pharmacies fill handwritten prescriptions from federal facilities?

A. Yes. As per A.R.S. §36-2525(D)(2), a pharmacist may dispense a prescription order if "The prescription order for a Schedule II [CS] that is an opioid is in writing and indicates that the medical practitioner who issued the prescription order provided care for the patient in a veterans administration facility, a health facility on a military base, an [IHS] hospital or other [IHS] facility, or a tribal-owned clinic."

Q. What are the next steps for pharmacies if compliance is not met with becoming EPCS capable?

A. The Board will enforce provisions through the opening of and receiving of complaints.

Q. If a Schedule II opioid prescription is handwritten in 2019, but still has valid dating, can that handwritten prescription be filled in 2020?

Continued on page 5

Continued from page 4

A. Yes, a pharmacist may dispense a prescription if the prescription order is handwritten for a Schedule II CS that is an opioid if the date written is prior to January 1, 2020. All other state and federal prescription requirements have not changed.

Q. If a patient presents a pharmacist with a hard copy of a Schedule II opioid prescription that does not indicate the EPCS system was down when they were given the prescription, can the pharmacist call the prescriber to confirm that the EPCS system was down and record that on the hard copy of the prescription?

A. Yes. Pursuant to A.R.S. §36-2525(B), "The pharmacist must document on the original prescription order the changes that were made pursuant to the verbal authorization and record the time and date the authorization was granted."

The pharmacist must speak with the prescriber for authorization and cannot speak with a prescriber's representative.

Q. If the strength, directions, or quantity of medication is incorrect on a Schedule II opioid prescription sent by way of EPCS, can a pharmacist call the prescriber to correct?

A. Yes. Pursuant to A.R.S. §36-2525(A), "if authorized verbally by the prescriber, the pharmacist may make changes to a written or electronic Schedule II [CS] prescription order, except for any of the following:

1. The patient's name
2. The prescriber's name
3. The drug name

B. The pharmacist must document on the original prescription order the changes that were made pursuant to the verbal authorization and record the time and date the authorization was granted."

The pharmacist must speak with the prescriber for authorization and cannot speak with a prescriber's representative. The EPCS prescription should be electronically annotated with the prescriber-authorized changes (see 21 CFR §1311.200 (f)).

Q. If I receive a handwritten prescription for a compounded medication that includes a Schedule II opioid, can I fill it?

A. The proposed language regarding compounded medications is as follows:

A pharmacist may dispense a Schedule II opioid CS from a written rather than electronically transmitted prescription order if the prescription order is written for a medication that requires compounding two or more ingredients.

This exception is currently undergoing the rulemaking process, but has not yet been enacted. Please continue to check administrative codes and the EPCS FAQs on the Board's website for further updates.

Q. If I receive a handwritten prescription for a Schedule II opioid that is not currently in the prescriber's EPCS database, can I fill it?

A. The proposed language regarding medications not in the EPCS database is as follows:

A pharmacist may dispense a Schedule II opioid CS from a written rather than electronically transmitted prescription order if the prescription order is written for a medication that is not in the e-prescribing database. The pharmacist is not required to verify whether the medication is not in the e-prescribing database.

This exception is currently undergoing the rulemaking process, but has not yet been enacted. Please continue to check administrative codes and the EPCS FAQs on the Board's website for further updates.

Q. What steps should I take if I believe a prescriber's EPCS system has been down for an extended period of time?

A. If you believe that a prescriber does not have an EPCS system or the prescriber's system has been down for an extended period of time, please fill out the form found here.

The Board will collect the information and share it with the prescriber's respective licensing board.

Q. If I receive a faxed prescription order for a Schedule II CS that is an opioid for a patient enrolled in hospice care, can I still fill it?

A. Yes. Pursuant to A.R.S. §36-2525(F)(3), a patient's medical practitioner or the medical practitioner's agent may transmit to a pharmacy by fax a prescription order written for a Schedule II CS, including opioids, if the prescription order is, ". . . For a patient who is enrolled in a hospice care program that is certified or paid for by Medicare under title XVIII or a hospice program that is licensed by this state. The medical practitioner or the medical practitioner's agent must note on the prescription that the patient is a hospice patient."

Q. If I receive a faxed prescription order for a Schedule II CS that is an opioid for a patient registered to a long-term care facility (LTCF), can I still fill it?

A. Yes. Pursuant to A.R.S. §36-2525(F)(2), a patient's medical practitioner or the medical practitioner's agent may transmit to a pharmacy by fax a prescription order written for a Schedule II CS, including opioids, if the prescription order is for a resident of an LTCF.

Q. Is a skilled nursing facility (SNF) considered an LTCF?

A. Yes. During the September 26, 2019 Board meeting, the Board moved to better define LTCF to include SNF.

Q. If I receive a handwritten prescription for a Schedule II CS that is an opioid written by a veterinarian, can I fill it?

A. Yes. As per A.R.S. §36-2525(R), veterinarians are currently exempted from the EPCS requirements, "until the Arizona state veterinary medical examining board determines that electronic prescribing software is widely available for veterinarians and notifies the [Board] of that determination."

Disciplinary Actions and Updates – Health Boards

Disciplinary actions for the Arizona State Board of Pharmacy, Arizona Medical Board, Arizona Naturopathic Physicians Medical Board, Arizona Board of Osteopathic Examiners, and Arizona Regulatory Board of Physician Assistants can be found at *https://drive.google.com/file/d/0ByEE-sGueI9GcnlhNVFzb2ozVVFSQkdzYkpFbXF4eWlMQ3hJ/view.*

The *Arizona State Board of Pharmacy News* is published by the Arizona 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.

Kamlesh "Kam" Gandhi, PharmD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Sanchez - Communications Manager