July 2020

Arizona State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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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 contact information in its system is not always current and up to date. You are required to update your personal contact information and pharmacy employer within 10 days after a change pursuant to Arizona Revised Statutes §32-1926. Please use your online profile to update your contact information.

Thank You From the Board of Pharmacy

This has been a year to remember, and a year that many would not mind forgetting. We all have faced difficult challenges and, sadly, it is not over yet. Even though these times are difficult, you the pharmacists, technicians, technician trainees, and interns have stood on the front lines to be there for patients. You are the heroes ensuring that patients are getting their medications, helping find alternative treatments, answering questions about health and wellness, and providing that special something to keep hope alive. The courage and dedication displayed by pharmacy professionals is recognized and the Board would like to say **"Thank you!"**

Wholesale Distribution of Short-Dated Medication

Effective May 22, 2020, and only for the duration of the coronavirus disease 2019 pandemic:

1. Section R4-23-604(K)(e)(ii). More specifically, the requirement to quarantine and not sell or distribute "any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that has less than 120 days remaining on the expiration date."
   a. The 120-day restriction is waived to allow for distribution of short-dated inventory to facilities that administer medications in an inpatient setting, if the following circumstance are present:
      i. The medication shall still be within the expiration date when administered or consumed by the patient.
      ii. The distributor shall inform the purchaser of the short-dated product(s).
      iii. If the pharmacy does not use the medication prior to expiring, the distributor shall refund the full value for that product.
   b. The 120-day restriction is waived to allow for distribution of short-dated inventory that does not have less than a 30-day expiration date for an outpatient setting, if the following circumstances are present:
      i. The medication shall still be within the expiration date when consumed by the patient.
      ii. The distributor shall inform the purchaser of the short-dated product(s).
      iii. If the pharmacy does not use the medication prior to expiring, the distributor shall refund the full value for that product.

State-Licensed Technician Versus National Certified Technician

To become a state-licensed technician, you must take and pass the nationally certified exam through the Pharmacy Technician

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National Pharmacy Compliance News

July 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.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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Certification Board (PTCB) or the Exam for the Certification of Pharmacy Technicians (ExCPT). Simply taking and passing the national exam does not qualify you to practice. Practicing without a license is a violation of state law and would be subject to disciplinary action for the person practicing without a license, the pharmacist-in-charge (PIC), and the permit holder. The permit holder and PIC shall validate that the individual is licensed prior to allowing the individual to work as a pharmacy technician. You can use the Board website to verify a license.

Summary of Statute and Rule Changes Effective March 14, 2020

- **R4-23-110** Removes the term "graduate" intern and adds the definition for a virtual wholesaler.
- **R4-23-204** Amends the continuing education (CE) requirements for pharmacists: adds three hours of opioid-related CE to the biennial requirement; removes the three hours of pharmacy law. Newly licensed pharmacists are exempt from CE requirements between the time of initial licensure and first renewal.
- **R4-23-205** Adds fees for temporary licenses.
- **R4-23-407** Adds language waiving the red cap requirement for Schedule II opioids if dosage form or packaging prevents use of a red cap.

  Note:
  - ◊ The warning label requirements are not waived in those instances.
  - ◊ A red sticker shall be used in place of a red cap.
- **R4-23-407** Adds pharmacist prescription adaptation language for non-controlled drugs. Pharmacists may make adaptations to:
  1. Change quantity if package size prescribed is not commercially available,
  2. Change dosage form (eg, cream to ointment) or directions if change achieves the intent of the prescriber,
  3. Complete missing information on a prescription if there is evidence to support the change, or
  4. Extend the quantity of a maintenance drug for the limited quantity necessary to achieve medication refill synchronization.
- **R4-23-407** Amends the transfer rules for non-controlled drugs to allow for a transfer by fax. Removes the language allowing a controlled substance (CS) to be transferred by fax. Amends the transfer rules for CS to allow interns to transfer Schedule III through Schedule V prescriptions verbally or electronically.
- **R4-23-408** Removes the requirement to maintain hard copies of non-controlled prescriptions for 30 days for those pharmacies using an electronic imaging record-keeping system compliant with rule 408. Amends language to clarify rule does not apply to CS hard copy prescriptions. Adds language that all prescription records are to be made available within 72 hours of a Board request.
- **R4-23-411** Adds the requirement that reports to the primary care provider are to be available in the pharmacy or provided within 72 hours of a request by Board personnel. Adds the requirement that administration records are to be maintained in the pharmacy or database for seven years from date of administration. Immunization renewal is now included in the CE rule 204.
- **R4-23-607** Amends language for nonresident permits to require both an Arizona and a nonresident permit for distribution of drugs or devices into Arizona.
- **R4-23-1103** Includes PTCB and ExCPT as the approved technician examinations. Amends a valid trainee license to 36 months per statute changes in 2017.
- **R4-23-1106** Amends the CE requirements for technicians: removes the two hours of pharmacy law. Newly licensed technicians are exempt from CE requirements between the time of initial licensure and first renewal. (Reminder: technicians are to have three hours of opioid-related CE per renewal period – see changes in 2018 and 2019.)

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/open?id=1wCy-V-EI4NaAFXOOHaxrcdgWVTYCA4es.*

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