July 2020

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board Members and Staff

20.15 Clarification of the Board's Notification Requirement

All licensees and registrants are required to notify the Oklahoma State Board of Pharmacy of any change in address, phone number, employment, etc, within 10 days of the change. Although the online renewal system allows changes to be entered for pharmacists and technicians, this is not considered an official notification. In order to satisfy this requirement, the notification must be submitted in writing – by fax, email, or mailed in – within 10 days of the change. Emails are received at pharmacy@pharmacy.ok.gov and faxes should be sent to 405/521-3758.

20.16 Changes to Payment Methods Beginning January 1, 2021

Beginning January 1, 2021, the Board office will only accept payments made through its online store. Accepted forms of payment are Visa, Mastercard, and electronic funds transfer. The Board will no longer accept any form of payment in the office or via mail.

20.17 New and Reinstatement Applications Must Accompany Proper Identification

All new and reinstatement applications for technicians and interns must be accompanied by a copy of a driver's license, state ID, or copy of a work authorization card. While a color copy is preferred, it is not required as long as the picture and information are legible. Any application received and deemed incomplete will be returned by the Board office to the mailing address listed on the application.

20.18 From the Inspector's Desk

OTC Compounding or Pharmacy-Generated Preparations

Effective immediately, all sales of compounded **over-the-counter (OTC) preparations** must **stop/cease** unless the pharmacy obtains a valid patient-specific prescription from a prescriber and the medication is dispensed by prescription only. After consultation with Food and Drug Administration (FDA), the Board has been informed that all compounding must be dispensed/sold by a valid patient-specific prescription from a prescriber, based on **21 United States Code (USC) §353a.** FDA considers all compounded preparations as **unapproved new drugs** that have not gone through the approval process with the agency. FDA allows a pharmacy to dispense a compounded preparation based on a valid patient-specific prescription without having to satisfy **21 USC §355. This makes all the Board rules in**

Continued on page 4

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.*

Continued from page 1

Oklahoma Administrative Code (OAC) 535:15-10-11 invalid, and they will be removed from the law book in the next rulemaking action.

20.19 Reporting Disciplinary Action From Another State

If you receive any type of sanction in another state, you are not **required** to report it to the Board until it is time to renew your Oklahoma license. However, the Board strongly encourages you to report any action taken against you as soon as possible. There is a chance your renewal may be delayed while running the appropriate background checks and information verifications, which could cause your license to expire and any appropriate fees to be assessed. Reporting disciplinary actions early gives the Board the opportunity to perform all of the administrative verification prior to your license expiration date.

20.20 COVID-19 Waivers

As a reminder, if you have obtained a waiver from the Board during the coronavirus disease 2019 (COVID-19) pandemic, these waivers are only valid until the requestor or the Board executive director deems them unnecessary. The Board will send notifications to all requestors upon the expiration of any waiver currently issued.

20.21 Storage of Prescriptions

Prescription records should be stored in completely separate files. Whether in a box, bin, folder, etc, they should be separated as follows:

- Schedule II prescriptions
- Schedule III-V prescriptions
- Non-controlled prescriptions

For more information regarding the specific requirements for the storage of prescriptions, please refer to OAC 475:25-1-4(d)(2).

20.22 Oklahoma Pharmacists Beware

In the August 2019 *Alabama State Board of Pharmacy Newsletter,* a story was published regarding Alabama investigators seeing an increasing number of fraud cases in pharmacies, and a few scenarios were outlined that pharmacists should be aware of. Oklahoma has now begun to see these same types of fraud cases in our state. If, at any time, you feel like there is a reason to be concerned about actions being taken at your pharmacy, please do not hesitate to contact the Board office or your compliance officer directly. You can read the full story in the Alabama Board's August 2019 *Newsletter.*

20.23 Training Documentation

Pharmacy technicians are required to have their initial pharmacy technician training and exam from the Board on file, as well as annual training. If employed in a compounding pharmacy, all compounders are required to have an initial compounding training and competency exam on file, in addition to the required annual training. To expedite and streamline inspections, it would be very helpful if the pharmacy maintained a separate file that is easily retrievable, for technicians and compounders, that only contains the following documentation:

1. Initial technician Board training and exam for each technician
2. Yearly training for each technician
3. Initial competency training and exam for each compounder (only for compounding pharmacies)
4. Yearly training for each compounder (only for compounding pharmacies)

20.24 Disciplinary Actions

February 2020

James Sutterfield, DPh #9810 – Case 1577: License is indefinitely suspended with the suspension being stayed. Immunization certificate is permanently revoked. Respondent will permanently refrain from dispensing or participating in the dispensing of any prescription drugs and from conducting any patient immunizations. Respondent shall attend an eight-hour law seminar in addition to the required 15 hours of continuing education (CE) during the calendar years of 2020 and 2021. All CE hours for 2020 and 2021 must be live. Respondent neither admits nor denies guilt on counts 1-39, including failure to establish and maintain effective controls to prevent prescription errors or misfills. **Fined $23,400.**

Jennifer Bierd, Technician #6068 – Case 1580: Guilty on four counts, including theft. **Revoked.**

Shelly Decker, Technician #25478 – Case 1581: Guilty on four counts, including theft. **Revoked.**

Cindy Riggs, Technician #12633 – Case 1582: Guilty as charged, including violating registrant conduct. **Revoked.**

Richard Dandridge, DPh #12894 – Case 1584: Guilty on three counts, including violating rules of professional conduct. **Revoked. Fined $9,000.**

Calendar Notes

- **Upcoming Holidays:** The Board office will be closed on September 7, 2020, for Labor Day.
- **Upcoming Board Meeting:** The Board is scheduled to meet on July 15, 2020. All meetings begin at 8:30 AM.

Change of Address or Employment?

Please be diligent in keeping your information up to date and, if possible, remind your coworkers and employees. Failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are **not** accepted as official notification. Emailed notifications can be sent to pharmacy@pharmacy.ok.gov or faxed to 405/521-3758.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574 ext 5773. All calls are confidential.

This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website. [74 O.S. §3105 and 65 O.S. §3-114]

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

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