August 2020

News

Alabama State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Updates and Reminders From the Board of Pharmacy

2020 is a renewal year for pharmacists' licenses. Licenses may be renewed online starting September 15, 2020. Please note that licenses expire at midnight on December 31, 2020. **Simply submitting your renewal by December 31, 2020, does not guarantee that your renewal will be processed and that your license will be active on January 1, 2021.** The Alabama State Board of Pharmacy highly encourages completing the renewal as early as possible to ensure that there is time for the Board office to complete the renewal review and processing, and for the pharmacist to receive the updated license. No pharmacist should assume his or her renewal is processed and approved unless the pharmacist has received the renewed license by mail. Failure to have a renewed license and continuing to practice pharmacy may result in disciplinary action.

It is the responsibility of the supervising pharmacist to ensure that all pharmacists employed in the location of oversight by the supervising pharmacist have a renewed/updated pharmacy license.

In addition to timely renewal of the license, the Board encourages all pharmacists to review their personal information online. Discrepancies in personal data (mailing address, email address, etc) may slow receipt of the updated license.

Effective December 15, 2019, continuing education (CE) requirements for pharmacists were amended. The changes are reflected below:

680-X-2-.36 Continuing Education for Pharmacists

(1) Pharmacists shall complete thirty (30) hours of continuing education each renewal cycle as a condition of licensure renewal. By submitting the biennial renewal, a pharmacist is representing their compliance with this requirement by the end of the relevant renewal cycle.

(2) In order to receive credit for continuing education, the continuing education shall be previously approved by the Board. Any requests for approval of continuing education shall be submitted to the Board no less than thirty (30) calendar days prior to offering of the continuing education. A condition of approval shall be that the continuing education is pertinent to the practice of pharmacy. However, this requirement shall not apply to ACPE or ACCME approved continuing education courses for which a program number is available.

(3) Continuing Education may be completed by either attendance or by distance-based program, video or by publications; however, a pharmacist must complete at least six (6) hours of live continuing education through attendance at a course(s), within the renewal cycle.

The changes allowed for the 30 required hours, including the required six live hours, to be attained at any point during the two-year renewal cycle. The change also eliminated the prior ability to carry over hours from previous years.

It is the responsibility of the pharmacist to maintain records of his or her completed CE for validation by the Board should the pharmacist be audited. Any pharmacist not completing the required hours during the renewal period may be subject to disciplinary action by the Board.

In June 2019, **680-X-2-.12 Supervising Pharmacist** was amended to clarify reporting changes in and to address a temporary absence of supervising pharmacist. The changes became effective August 4, 2019, and are defined in sections (8) and (9) of 680-X-2-.12:

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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 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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(8) If the permit holder's supervising pharmacist will be or is no longer employed or no longer desires to act as a supervising pharmacist, the permit holder shall notify the Board within ten (10) days by the submission of an action plan for the designation of another supervising pharmacist. This plan shall not exceed ninety (90) days before the permit holder is in violation of operating a pharmacy without a supervising pharmacist at which time the Board may require closure of the pharmacy until such time as a supervising pharmacist assumes his/her duties.

(9) In the event of a temporary absence by supervising pharmacist of greater than 30 days, the permit holder shall designate a temporary supervising pharmacist with notification to the Board of the name of the temporary supervising pharmacist and the period of time during which he/she shall act as such. The permit holder must notify the Board of the assignment of the temporary supervising pharmacist prior to the time the temporary supervising pharmacist begins to act as such. The permit holder will inform the board of the date of the original supervising pharmacist's return from his/her absence.

In an effort to facilitate the reporting requirement of these changes, the Board has added online forms for change of supervising pharmacist and temporary change of supervising pharmacist. These forms can be accessed on the Board's website.

1. Access *www.albop.com*
2. Choose Applications and Forms on the right side of the web page.
3. Scroll to Pharmacists, In-State Pharmacies, or Non-Resident Pharmacies, and then choose "Change of Supervising Pharmacist."

A Reminder for Pharmacy Technicians

Due to the coronavirus disease 2019 pandemic, any technician registered on or after January 1, 2020, has until December 31, 2020, or six months after the initial registration date, whichever is later, to complete the required technician training program as stated in 680-X-2-.14(10):

(a) All technicians receiving their initial registration on or after January 1, 2020, shall complete a Board-approved training program within the first six months after their registration and submit evidence of completion to the board within 10 days of completion. The technician and the employing pharmacy shall keep documentation of this training for a period of two years from the completion of the training. The passage of a Board-recognized pharmacy technician certification examination shall be accepted as a training program. The training program shall be the responsibility of the technician and the pharmacy employing the technician. The Board of Pharmacy may issue a fine of up to one thousand ($1,000) to the pharmacy and revocation of the registration of a technician for violation of this rule.

Approved technician training programs are listed on the Board's website.

1. Access *www.albop.com*
2. Choose the dropdown "Quick Links"
3. Select "Board Approved Technician Training Programs"
4. Website addresses are provided for any program not associated with employment

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