NOVEMBER 2021

# ALABAMA STATE BOARD OF PHARMACY

*newsletter to promote pharmacy and drug law compliance*

## Updates to Board of Pharmacy Communications

The Alabama State Board of Pharmacy continues to work toward better communication with all regulated entities. Last month, the Board unveiled its updated website *www.albop.com.* The new website is compliant with the Americans with Disabilities Act and has received very positive feedback from users. In addition, the Board now has the capability to send email blasts to regulated entities. The Board hopes that this will allow for better communication and feedback to and from regulated entities.

## Alabama Administrative Code Rule Changes

The Board has adopted or amended the following new rules:

### *680-X-2-.12 Supervising Pharmacist*

This rule was amended to provide a specific process by which pharmacists who will no longer be acting as supervising pharmacists shall notify the Board. The process is as follows:

> (j) Whenever a registered Pharmacist terminates his/her duties as supervising pharmacist, he/she shall, within (10) days, so advise the Board by completing the 'Notice of Change of Supervising Pharmacist' form provided by the Board.

The form is electronic and available on the Board's website. This rule went into effect on October 15, 2021.

### *680-X-2-.14 The Role of Technicians in Pharmacies in Alabama*

This rule was amended to allow for more disciplinary options for noncompliance of required technician training. Specifically, the rule will now read:

> (10)(a) . . . The Board may impose allowable sanctions for violation of this Rule against the employing pharmacy permit holder, the Supervising Pharmacist of the employing pharmacy and/or the pharmacy technician.

This change went into effect on October 15, 2021.

### *680-X-2-.46 Immunization Training*

This new rule sets standards to ensure greater access to immunizations for the public and improve patient care. The rule reads as follows:

(1) Purpose: The Alabama State Board of Pharmacy (Board) is charged with the duty and responsibility to maintain standards of professional conduct and to regulate professional practice and is further charged to protect the health, safety, and welfare of the citizens of the State of Alabama. In conformity with this purpose, this rule shall provide guidelines for administering vaccinations by Alabama licensed pharmacists and/or registered interns, externs, and technicians.

(2) In order to administer immunizations, a pharmacist, intern, or extern must be licensed and/or registered by the Alabama Board of Pharmacy and comply with the following requirements:

a. The pharmacist, intern, and/or extern must have and maintain a current certificate in basic cardiopulmonary resuscitation.

b. The intern and/or extern must be under the direct supervision of an Alabama licensed pharmacist.

(3) Technicians must be registered by the Alabama Board of Pharmacy, in good standing, acting under the direct supervision of an Alabama licensed pharmacist and in order to administer vaccines, shall comply with the following requirements:

a. The registered pharmacy technician must complete a minimum two (2) hours of Accreditation Council for Pharmacy Education (ACPE) approved practical training program to include hands-on injection technique training, the recognition and treatment of emergency reactions to vaccines and successful examination to assure sufficient knowledge of vaccines;

b. The registered technician must have a current certificate in basic cardiopulmonary resuscitation;

c. The vaccine must be ordered by an Alabama licensed pharmacist or pursuant to a valid prescription;

d. The Alabama licensed pharmacist must be readily and immediately available to the immunizing registered pharmacy technician;

e. The registered technician shall submit to the Board of Pharmacy documentation of the satisfactory completion of the requirements of (3)(a) within 10 days of completion.

f. For each submission of the documentation referenced in paragraph e. above, the Secretary of the Board shall issue to the registered technician a certificate for immunization authority, which shall be displayed in a conspicuous place.

(4) The pharmacist, in his or her capacity and as part of their supervision of intern, extern, and/or technician shall report any adverse event required by the Vaccine Adverse Event Reporting System (VAERS), including but not limited to:
   a. Any adverse event listed in the VAERS table of Reporting Events Following Vaccination within the listed specified time period.
   b. Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

(5) The pharmacist is further responsible to ensure, the following:
   a. The vaccine must be FDA-authorized or FDA-licensed;
   b. In the case of a designated emergency vaccine, the vaccine must be ordered and administered according to the Advisory Committee on Immunization Practices (ACIP) vaccine recommendation(s);
   c. A childhood vaccine must be ordered and administered according to ACIP's standard immunization schedule;
   d. Storage, use and administration of any sterile product used in the administration of immunizations meets the United States Pharmacopeia (USP) requirements, as well as those of the Centers for Disease Control and any applicable provision of the Alabama Pharmacy Practice Act and/or any rules of the Board now in effect or which may become effective in the future;
   e. The pharmacy must have available an epinephrine kit (epinephrine in 1mg/ml aqueous solution) or an epinephrine autoinjector;
   f. Compliance with blood borne pathogen requirements, including, but not limited to medical waste disposal, and FDA-cleared sharps disposal containers;
   g. Compliance with all record keeping and reporting requirements, which are now in effect or may become required in the future.

(6) The licensed pharmacist must complete a minimum of two hours of Board approved, immunization-related continuing pharmacy education each renewal cycle.

(7) The supervising pharmacist shall ensure any pharmacists, interns, externs, and registered technicians prior to providing immunizations completion of the immunization training set out above and is acting in compliance with all requirements of the rule.

(8) Any pharmacist, intern, extern, or technician performing immunizations without complying with this rule shall be subject to discipline by the Board.

This rule went into effect on October 15, 2021.

### *680-X-2-.47 Off Site Vaccine Order Entry Processing*

The new rule is to provide standards for off-site order entry processing for immunizations by any pharmacy in the state of Alabama. Please see specifics below.

(1) The purpose of this Rule is to provide standards for off-site vaccine order entry processing for immunizations by any pharmacy in the state of Alabama to which a permit has been issued by the Alabama State Board of Pharmacy.

(2) 'Off-site vaccine order entry processing' is a means by which a licensed pharmacist, registered technician and/or intern under the direct supervision of a licensed pharmacist, may remotely access their own pharmacy's electronic database from outside the pharmacy in order to process vaccinations provided that the pharmacy establishes controls to protect the privacy and security of patient records or any other confidential records. This processing shall be limited to: 1. Interpreting or clarifying vaccine orders; 2. Data entry of the vaccine order information; 3. Performing drug regimen review; and 4. Providing clinical vaccine information concerning a patient's immunizations. 'Off-site vaccine processing' does not include the order entry or dispensing of any legend or controlled substance prescriptions.

(3) Off-site vaccine order entry processing of vaccinations shall be completed in real time at the remote site where the vaccine is being administered, after which the technology used to complete the vaccine processing is returned to the pharmacy for secure storage within the permitted pharmacy.

(4) Any records generated in this process whether in a hard copy or electronic format shall be maintained at the pharmacy for a minimum period of two years from the date of entry.

At the time of this writing, the rule underwent a public comment period and a public hearing was conducted on October 13, 2021. This rule will go into effect on December 13, 2021.

## *DEA's Response to Sale of Delta-8-Tetrahydrocannabinol*

The Board has received multiple inquiries related to the sale of delta-8-tetrahydrocannabinol ($\Delta^8$-THC).

In response to these inquiries, the Board requested an opinion from Drug Enforcement Administration (DEA). DEA's opinion, dated September 15, 2021, sets forth as follows:

> $\Delta^8$-THC is a tetrahydrocannabinol substance contained in the plant *Cannabis sativa L.* and also can be produced synthetically from non-cannabis materials. The CSA classifies tetrahydrocannabinols as controlled in schedule I. 21 U.S.C. 812, Schedule I(c)(17); 21 CFR §1308.11(d)(31). Subject to limited exceptions, for the purposes of the CSA, the term 'tetrahydrocannabinols' means those 'naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant and/or synthetic substances, derivatives, and their isomers with similar

chemical structure and pharmacological activity to those substances contained in the plant.' 21 CFR §1308.11(d)(31). Thus, $\Delta^8$-THC synthetically produced from non-cannabis materials is controlled under the CSA as a 'tetrahydrocannabinol.'

The CSA, however, excludes from control 'tetrahydrocannabinols in hemp (as defined under section 1639o of Title 7).' Hemp, in turn, is defined as 'the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol [($\Delta^9$-THC)] concentration of not more than 0.3 percent on a dry weight basis.' 7 U.S.C. 1639o(1).

Accordingly, cannabinoids extracted from the cannabis plant that have a $\Delta^9$-THC concentration of not more than 0.3 percent on a dry weight basis meet the definition of 'hemp' and thus are not controlled under the CSA. Conversely, naturally derived cannabinoids having a Δ9-THC concentration more than 0.3 percent on a dry weight basis is controlled in schedule I under the CSA as tetrahydrocannabinols.

## *Reminder – Technician Manual*

As a reminder, pharmacies are required to have on hand, either via hard copy or electronically, a copy of a technician manual, as referenced in rule 680-X-2-.14 below:

(5) Written control procedures and guidelines for supervision of technicians by a licensed pharmacist and for performance of tasks by technicians shall be established and made available for review by the Board of Pharmacy.



All rules, adopted and proposed, are available for review on the Board's website under Resources – Statutes and Rules.

*The Alabama State Board of Pharmacy News is published by the Alabama 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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