

## CBD, the Farm Bill and Alabama

With the enactment of the Agriculture Improvement Act of 2018 (2018 Farm Bill), many questions have been raised for Alabama pharmacists and the Alabama State Board of Pharmacy. The Farm Bill changes certain federal oversight relating to hemp production, sale, and possession. These changes remove hemp (and therefore, hemp related products) from the federal Controlled Substances Act which means that hemp is no longer an illegal substance under Federal Law. The Farm Bill allows for the sale, production, and possession of cannabidiol (CBD) derived from industrial hemp, with a tetrahydrocannabinol (THC) concentration not more than 0.3% (dry weight). However, the Farm Bill preserves the Food and Drug Administration's authority to regulate products containing cannabis and cannabis-derived products. In particular, the FDA requires any cannabis product that asserts a therapeutic benefit or disease claim, to be approved by the FDA for the purported use prior to the product being introduced into interstate commerce. This is the consistent standard used by the FDA for any product marketed for human or animal use. Deceptive marketing of unproven treatments is a violation of the law.

In addition to the FDA requirements, the Farm Bill requires each State's Department of Agriculture to coordinate with the State's Governor and chief law enforcement officer to develop a plan to license and regulate hemp. This state plan must then be submitted to the Secretary of the United States Department of Agriculture for approval. Only after that plan is approved by the USDA can hemp production commence. This has not yet occurred in Alabama. Many state agencies are working together to develop an understanding of what the USDA expects in this plan, but with the government shutdown, there are more questions than answers at this time.

Given this background, where does all this change put pharmacy?

In exactly the same place as before the Farm Bill passed.

The Alabama Uniform Controlled Substances Act (AUSCA) lists any product containing THC to be a Schedule 1 Controlled Substance.

### Chapter 420-7-2

#### Control Substance List

(d)(31) Tetrahydrocannabinols ----- 7370

Meaning tetrahydrocannabinols naturally contained in a plant of the genus cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

- 1 cis or trans tetrahydrocannabinol, and their optical isomers.
- 6 cis or trans tetrahydrocannabinol, and their optical isomers.
- 3,4 cis or trans tetrahydrocannabinol, and its optical isomers.

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

Until the Alabama Department of Public Health (ADPH) removes hemp, and hemp derived products, from the list of Schedule 1 Controlled Substances, Alabama pharmacies and pharmacists must abide by the

strictest rule. In this situation, the strictest rule is CBD products containing ANY THC are a Schedule 1 controlled substance under Alabama law. If and/or when, the AUCSA is amended by ADPH, then pharmacies would have the ability to sell CBD products if in accordance with current restrictions and any other future regulations that may be implemented by the state.

Current restrictions include:

- Products sold contain less than 0.3% THC by dry weight
- Products sold are manufactured from hemp produced by a licensed grower

To state the situation as clearly as possible, pharmacies and pharmacists CANNOT, at this time, sell or possess hemp or hemp related products containing ANY THC until the AUCSA is changed to remove hemp from Schedule 1. While the Board of Pharmacy understands that there are other entities selling these products, the Board cannot and does not regulate those entities that do not possess a permit with the Board nor does the Board of Pharmacy have any authority to change the status of a controlled substance. However, the Board must enforce current (and the most stringent) law. The Board of Pharmacy is maintaining communication with all pertinent agencies to this situation and will keep the profession updated as to any changes that occur.