

GUIDANCE TO NORTH CAROLINA PHARMACIES ON THE SALE OF PRODUCTS DERIVED FROM HEMP

Recent statutory and regulatory changes have authorized a state pilot program on the sale and marketing of industrial hemp products, which includes certain hemp seeds and hemp seed oils. These legal changes certainly do not authorize the sale of marijuana or other cannabidiol products that do not fit within the definitions (discussed below) in the laws governing the pilot program. It is therefore important for retailers, including pharmacies, to understand the law governing industrial hemp production and sale. This Board staff guidance clarifies for pharmacists and pharmacies the state law governing industrial hemp, in the view of Board staff. This guidance replaces the FAQ document entitled, “North Carolina Law Does Not Authorize Pharmacies to Possess or Sell Cannabidiol Products,” which did not reflect the recent legal changes. This guidance reflects the views of Board of Pharmacy staff only, may not reflect the views of other enforcement agencies (including the DEA) and does not bind the actions of those enforcement agencies.

1. I heard that there is recent legislation governing industrial hemp. Is that true?

Yes. Effective February 24, 2017, the state adopted regulations to operate a pilot program for the production of industrial hemp. The institution of that program also triggered certain exceptions in state and federal law for industrial hemp produced pursuant to pilot programs.

2. What are “industrial hemp” and “hemp products”?

North Carolina law defines “industrial hemp” to include all parts of the plant *Cannabis sativa* (L.), cultivated by a grower licensed by the North Carolina Industrial Hemp Commission, whether growing or not, that “contain a delta-9 tetrahydrocannabinol (‘THC’) concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis.” N.C. Gen. Stat. § 106-568.51(7). The law further defines hemp products to be all products made from “industrial hemp,” “including, but not limited to, cloth, cordage, fiber, food, fuel, paint, paper, particleboard, plastics, seed, seed meal and seed oil for consumption.” N.C. Gen. Stat. § 106-568.51(6).

Federal law contains an identical definition of “industrial hemp” as being cannabis plants and plant parts that contain a THC concentration of not more than .3% on a dry weight basis. 7 U.S.C. § 5940(b)(2)

3. Why is it important that a product be made from “industrial hemp,” as defined in North Carolina and federal law?

North Carolina law excludes from the definition of “marijuana,” any “industrial hemp as defined in G.S. 106-568.51, when the industrial hemp is produced and used in compliance with rules issued by the North Carolina Industrial Hemp Commission.” N.C. Gen. Stat. § 90-87(16). Because “industrial hemp” and “hemp products” subject to this

definition are not “marijuana” under state law, they are not subject to the North Carolina Controlled Substances Act.

Federal law similarly says that “industrial hemp” that is produced pursuant to an authorized state pilot program can be grown, cultivated and marketed by the pilot program “[n]otwithstanding the Controlled Substances Act.” 7 U.S.C. § 5940(a).

4. So does this allow me to sell hemp seeds, hemp seed oils or other hemp products?

The laws do allow the sale of hemp products for consumption, such as hemp seeds and hemp seed oils, as well as other products containing hemp oils. However, they permit only the sale of those hemp products that are specifically authorized by the applicable laws. Therefore, these hemp products must be: (a) made of “industrial hemp” containing not more than .3% THC on a dry weight basis; and (b) produced pursuant to a state pilot program. See 7 U.S.C. § 5940; N.C. Gen. Stat. §§ 90-87(16) and 106-568.51.

Indeed, the North Carolina statute – by its terms – permits the sale of only those products “produced by a grower licensed by the [North Carolina Industrial Hemp] Commission,” N.C. Gen. Stat. § 106-568.51(7), meaning that the hemp in the product must have been grown under the North Carolina pilot program.

5. How do I know if hemp products are made of “industrial hemp” with a THC concentration less than 0.3% and are produced pursuant to a state pilot program?

The Board can’t assist you in making those determinations. Obviously, the Board is not in a position to test the THC concentration of the components in your products or to certify that they meet the standards. Moreover, the North Carolina Industrial Hemp Commission is the entity with the authority for operating the pilot program, and you should contact the Commission with any questions about whether your product is lawful and was produced pursuant to an authorized state program.

But all pharmacists must exercise due diligence in ensuring that any industrial hemp product they sell is, in fact, what it purports to be, for reasons discussed below.

Contact information for the North Carolina Industrial Hemp Commission is found here: <http://www.ncagr.gov/hemp/>

6. What could happen to me if my hemp product is not made of “industrial hemp” as authorized by the statute?

Any product that is not made of “industrial hemp” as defined in the statute falls within the definition of “marijuana” in the state and federal controlled substances act and cannot be sold, as a Schedule I controlled substance. All penalties associated with possession and sale of marijuana would come into play.

7. Does the DEA agree with your interpretation?

Board staff cannot speak for the DEA. The DEA, the U.S. Department of Agriculture, and the FDA have interpreted the laws in a document called the Statement of Principles on Industrial Hemp, 81 Fed. Reg. 53395 (Aug. 12, 2016). The Statement of Principles expresses those agencies' interpretation of those statutes, in which the DEA continues to assert authority to regulate and restrict certain transactions in industrial hemp. The Statement of Principles expresses the DEA's position that hemp products may be sold only for "marketing research" by the state pilot programs, and not "for the purpose of general commercial activity." The Statement of Principles further expresses the DEA's position that industrial hemp seeds may not be transported across State lines. Board staff has no opinion what the DEA means by these restrictions. Because the appropriate scope of "marketing research" (as opposed to "general commercial activity") under a state pilot program is beyond the scope of the Board's authority, you should contact the DEA and the North Carolina Industrial Hemp Commission with any questions.

Contact information for the North Carolina Industrial Hemp Commission is found here: <http://www.ncagr.gov/hemp/>

The Greensboro DEA Office can be reached at (336) 547-4219

8. I've heard about the claimed health benefits of hemp products. Can I advertise those?

The advertising of health benefits of foods, supplements, cosmetics and other products is heavily regulated by both state and federal law, including, but not limited to, the Federal Food, Drug and Cosmetic Act, and the North Carolina Food, Drug and Cosmetic Act. The laws governing industrial hemp do not except hemp products from the restrictions in those food, drug and cosmetics laws. Therefore, health claims about hemp products are regulated in a similar fashion to claims about other products, and pharmacies should be careful and consult their attorneys before advertising any such claims.

More specifically, Board staff understands that some "industrial hemp" products are marketed as dietary supplements. The federal Dietary Supplement Health and Education Act limits the kinds of claims that can be made about a dietary supplement. More information may be found here:

<https://www.fda.gov/food/ingredientpackaginglabeling/labelingnutrition/ucm2006881.htm> In particular, claims that a dietary supplement is to be used "in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" would mean the pharmacy is, in fact, marketing an unapproved drug.

9. How about "hemp extract"? Is that something different?

Yes. "Hemp extract" has a special definition under North Carolina law as an "extract from a cannabis plant . . . that . . . [i]s composed of less than nine-tenths of one percent (0.9%) tetrahydrocannabinol by weight," "[i]s composed of at least five percent (5%)

cannabidiol by weight,” and “contains no other psychoactive substance.” N.C. Gen. Stat. § 90-94.1(a). Therefore, hemp extract may have a higher percentage of THC than the “industrial hemp” that comprises lawful “hemp products.”

10. I’ve heard “hemp extract” is being prescribed for certain conditions. May I dispense that or sell it over the counter?

No. While you may be able to sell “hemp products” made from hemp with a THC concentration no more than .3%, you may not sell higher THC-content “hemp extract.” North Carolina permits hemp extract to be prescribed and dispensed under limited circumstances for the treatment of intractable epilepsy. That hemp extract may only be possessed by a “caregiver,” defined as “a parent, legal guardian, or custodian of a patient and is registered with the Department of Health and Human Services . . . who possesses a written statement dated and signed by a neurologist that states all of the following: the patient . . . has been examined and is under the care of the neurologist . . . suffers from intractable epilepsy . . . [and] may benefit from treatment with hemp extract.” N.C. Gen. Stat. § 90-113.101 (emphasis added). Pharmacies and pharmacists are not “caregivers” of their patients and are not authorized to possess hemp extract. Moreover, the statute prohibits North Carolina pharmacies and pharmacists from dispensing hemp extract to caregivers, instead requiring those caregivers to acquire their hemp extract “from another jurisdiction.” N.C. Gen. Stat. § 90-113.105(a).

Moreover, hemp extract is not excluded from the federal definition of “marijuana,” and the DEA takes the position that marijuana extract is still a Schedule I controlled substance. See Establishment of a New Drug Code for Marihuana Extract, 81 Fed. Reg. 90194 (Dec. 14, 2016).

11. I’ve heard that there is a CBD product undergoing clinical trials for FDA approval. Is that true?

Yes. At least one pharmaceutical company, GW Pharmaceuticals, is developing a CBD product called Epidiolex. Epidiolex is currently undergoing Phase 3 clinical trials for use in the treatment of Dravet syndrome and Lennox-Gastaut syndrome. The company announced promising Phase 3 study results in December 2016 and reported “good progress” toward an NDA submission.

12. If a pharmaceutical company gets FDA approval of a CBD product, would I be able to dispense it from my pharmacy?

Yes. If GW Pharma (or any other pharmaceutical company) obtains FDA approval for a CBD product, a pharmacy would be authorized to dispense it on a valid prescription just like any other FDA-approved prescription drug. Board staff does not view the North Carolina statutes as placing any limitation on the dispensing of any such FDA-approved

product that may become available in the future. The prescription and dispensing requirements would be set by existing federal and North Carolina law.