GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2015

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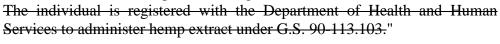
HOUSE BILL 766

Committee Substitute Favorable 4/22/15 Senate Health Care Committee Substitute Adopted 6/11/15 Fourth Edition Engrossed 7/1/15

Fourth Edition Engrossed 7/1/15
Short Title: Amend CBD Oil Statute. (Public
Sponsors:
Referred to:
April 15, 2015
A BILL TO BE ENTITLED AN ACT AMENDING THE EXEMPTION FOR USE OR POSSESSION OF HEME EXTRACT AND PERMITTING THE USE OF HEMP EXTRACT AS AN ALTERNATIVE TREATMENT FOR INTRACTABLE EPILEPSY WITHOUT PARTICIPATING IN A PILOT STUDY AND REPEALING THE EPILEPSY ALTERNATIVE TREATMENT ACT IN 2021. The General Assembly of North Carolina enacts: SECTION 1. G.S. 90-94.1 reads as rewritten: "§ 90-94.1. Exemption for use or possession of hemp extract. (a) As used in this section, "hemp extract" means an extract from a cannabis plant, or a mixture or preparation containing cannabis plant material, that has all of the following
characteristics:
(1) Is composed of less than three-tenths nine-tenths of one percent (0.3%)
(0.9%) tetrahydrocannabinol by weight. (2) Is composed of at least ten five percent (10%) (5%) cannabidiol by weight. (3) Contains no other psychoactive substance.
(b) Notwithstanding any other provision of this Chapter, an individual may possess of
use hemp extract, and is not subject to the penalties described in this Chapter, if the individual satisfies all of the following criteria:
(1) Possesses or uses the hemp extract only to treat intractable epilepsy, as defined in G.S. 90-113.101.
(2) Possesses, in close proximity to the hemp extract, a certificate of analysis that indicates the hemp extract's ingredients, including its percentages of tetrahydrocannabinol and cannabidiol by weight.
(3) Has a current hemp extract registration card issued by the Department of Health and Human Services under Article 5G of Chapter 90 of the General Statutes. Is a caregiver, as defined in G.S. 90-113.101.
(c) Notwithstanding any other provision of this Chapter, an individual who possesses
hemp extract lawfully under this section may administer hemp extract to another person under the individual's care and is not subject to the penalties described in this Chapter for administering the hemp extract to the person if both of the following conditions are satisfied:

(1)

(2)



The the individual is the person's caregiver, as defined in G.S. 90-113.101.



SECTION 2. G.S. 90-113.100 reads as rewritten:

"§ 90-113.100. Short title.

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- (a) This act may be cited as the "North Carolina Epilepsy Alternative Treatment Act."
- (b) The purpose of this act is to permit medical professionals to conduct limited scope, evidence based studies exploring the safety and efficacy of treating intractable epilepsy using hemp extract. the use of hemp extract as an alternative treatment for intractable epilepsy.
 - (c) The General Assembly finds the following:
 - (1) There that there are children in this State suffering from intractable epilepsy for which currently available treatment options have been ineffective. Hemp extract shows promise in treating children with intractable epilepsy.
 - (2) Additional study of the use of hemp extract for the treatment of intractable epilepsy should be undertaken, and the medical research universities of the State of North Carolina are well-suited for this type of clinical exploration."

SECTION 3. G.S. 90-113.101 reads as rewritten:

"§ 90-113.101. Definitions.

- (a) Caregiver. An individual that is at least 18 years of age and a resident of North Carolina who is a parent, legal guardian, or custodian of a person diagnosed with intractable epilepsy-patient and is registered with the Department of Health and Human and Services under G.S. 90-113.102 who possesses a written statement dated and signed by a neurologist that states all of the following:
 - (1) The patient has been examined and is under the care of the neurologist.
 - (2) The patient suffers from intractable epilepsy.
 - (3) The patient may benefit from treatment with hemp extract.
- (b) Caregiver Registration Card. A registration card issued by the Department of Health and Human Services under this Article to a caregiver.
- (c) Database. The Intractable Epilepsy Alternative Treatment Pilot Study database, established by the Department of Health and Human Services pursuant to this Article, to register caregivers, patients, and recommending neurologists. Article.

. . .

- (g) Neurologist. An individual who is licensed under Article 1 of Chapter 90 of the General Statutes, who is board certified in neurology, and is affiliated with the neurology department at one or more of the following universities: hospitals licensed in this State.
 - (1) The University of North Carolina at Chapel Hill.
 - (2) East Carolina University.
 - (3) Duke University.
 - (4) Wake Forest University.
- (h) Patient. A person who has been diagnosed by a neurologist with intractable epilepsy.
- (i) Pilot Study. An evidence-based investigation of the safety and efficacy of treating intractable epilepsy using hemp extract conducted by one or more neurologists registered pursuant to this Article."

SECTION 4. G.S. 90-113.102 reads as rewritten:

"§ 90-113.102. Intractable Epilepsy Alternative Treatment Pilot Study database; departmental duties.

(a) The Department shall create a secure, electronic, and online secure and electronic Intractable Epilepsy Alternative Treatment Pilot Study database registry for the registration of pilot studies, neurologists, caregivers, and patients as provided by this Article. All caregivers shall be required to register with the Department. Law enforcement agencies are authorized to contact the Department to confirm a caregiver's registration. The registry must be accessible to law enforcement agencies in order to verify registration of caregivers. The registry must prevent an active registration of a patient by multiple neurologists. At a minimum, the The

database shall consist of the <u>following:following information to be provided by the caregivers</u> <u>at the time of registration:</u>

- (1) The name and address of each registered caregiver and the name of the pilot study the caregiver is associated with the caregiver.
- (2) The name and address of each registered patient and the name of the pilot study the patient is associated with the caregiver's patient.
- (3) The name, address, and qualifying institutional affiliation of neurologists conducting pilot studies pursuant to this Article.
- (4) The name, institutional affiliation, affiliated registered neurologists, and parameters of pilot studies.address, and hospital affiliation of the neurologist recommending hemp extract as an alternative treatment for intractable epilepsy for the patient.
- (b) The Department shall contact the county department of health where the patient resides and provide the following information:
 - (1) The name and address of the registered caregiver.
 - (2) Identifying information contained on the caregiver registration card.
- (c) If at any time following registration, the name, address, or hospital affiliation of the patient's neurologist changes, the caregiver shall notify the Department and provide the Department with the patient's new neurologist's name, address, and hospital affiliation."

SECTION 5. G.S. 90-113.103 is repealed.

SECTION 6. G.S. 90-113.104 is repealed.

SECTION 7. G.S. 90-113.105 reads as rewritten:

"§ 90-113.105. Immunity for neurologists; medical records.confidentiality.

- (a) On a case-by-case basis, neurologists conducting a registered pilot study may approve of dispensation to a registered caregiver, as approved by this Article, hemp extract acquired from another jurisdiction.
- (b) A neurologist shall not be subject to arrest or prosecution, penalized or disciplined in any manner, or denied any right or privilege for approving or recommending the use of hemp extract or providing a written statement or health records to the Department for the use of hemp extract pursuant to this Article.
- (c) A neurologist conducting a registered pilot study who signs a statement as described in G.S. 90-113.104(b)(3) shall do the following:
 - (1) Keep a record of the evaluation and observation of a patient under the neurologist's care, including the patient's response to hemp extract treatment.
 - (2) Transmit the record described in subdivision (1) of this subsection to the Department upon request.
- (d) All medical records received or maintained by the Department pursuant to this Article are—The identities of the caregivers, patients, and neurologists reported to the Department pursuant to this Article are confidential and may not be disclosed to the public are not matters of public record. However, this information may be provided to law enforcement agencies pursuant to G.S. 9-113.102. Nothing in this Article is intended to alter the provisions of G.S. 8-53 or G.S. 8-53.1."
- **SECTION 7.2.** The University of North Carolina at Chapel Hill and East Carolina University may and are encouraged to, and Duke University and Wake Forest University are encouraged to, conduct research on hemp extract development, production, and use for the treatment of seizure disorders and to participate in any ongoing or future clinical studies or trials, including those exploring the safety and efficacy of treating intractable epilepsy with hemp extract.

SECTION 8. Section 5 of S.L. 2014-53 reads as rewritten:

"SECTION 5. Section 3 of this act becomes effective upon adoption of rules pursuant to Section 4 of this act. The remainder of this This act is effective when it becomes law."

SECTION 8.5.(a) Article 5G of Chapter 90 of the General Statutes is repealed.

SECTION 8.5.(b) This section becomes effective July 1, 2021.

SECTION 9. Section 1 becomes effective August 1, 2015, and applies to offenses committed on or after that date. Except as otherwise provided in this act, the remainder of the act is effective when it becomes law.