

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

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HOUSE BILL 766
Committee Substitute Favorable 4/22/15
PROPOSED SENATE COMMITTEE SUBSTITUTE H766-PCS20369-TU-21

Short Title: Amend CBD Oil Statute.

(Public)

Sponsors:

Referred to:

April 15, 2015

1 A BILL TO BE ENTITLED
2 AN ACT AMENDING THE EXEMPTION FOR USE OR POSSESSION OF HEMP
3 EXTRACT AND AUTHORIZING CERTAIN NEUROLOGISTS TO USE HEMP
4 EXTRACT AS AN ALTERNATIVE TREATMENT FOR INTRACTABLE EPILEPSY
5 WITHOUT PARTICIPATING IN A PILOT STUDY.

6 The General Assembly of North Carolina enacts:

7 **SECTION 1.** G.S. 90-94.1(a) reads as rewritten:

8 "(a) As used in this section, "hemp extract" means an extract from a cannabis plant, or a
9 mixture or preparation containing cannabis plant material, that has all of the following
10 characteristics:

- 11 (1) Is composed of less than ~~three-tenths~~ five-tenths of one percent (~~0.3%~~
12 0.5%) tetrahydrocannabinol by weight.
13 (2) Is composed of at least ~~ten-five~~ percent (~~40%~~ 5%) cannabidiol by weight.
14 (3) Contains no other psychoactive substance."

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

16 "**§ 90-113.100. Short title.**

17 (a) This act may be cited as the "North Carolina Epilepsy Alternative Treatment Act."
18 (b) The purpose of this act is to permit medical professionals to ~~conduct limited scope,~~
19 ~~evidence based studies exploring the safety and efficacy of treating~~ treat intractable epilepsy
20 using hemp extract.

21 (c) The General Assembly finds ~~the following:~~

- 22 (1) ~~There~~ that there are children in this State suffering from intractable epilepsy
23 for which currently available treatment options have been ineffective. Hemp
24 extract shows promise in treating children with intractable epilepsy.
25 (2) ~~Additional study of the use of hemp extract for the treatment of intractable~~
26 ~~epilepsy should be undertaken, and the medical research universities of the~~
27 ~~State of North Carolina are well suited for this type of clinical exploration."~~

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

29 "**§ 90-113.101. Definitions.**

30 ...

31 (g) Neurologist. – An individual who is licensed under Article 1 of Chapter 90 of the
32 General Statutes, who is board certified in neurology, and is affiliated with the neurology
33 department at one or more of ~~the following universities:~~ hospitals licensed in this State.

- 34 (1) ~~The University of North Carolina at Chapel Hill.~~
35 (2) ~~East Carolina University.~~



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1 (3) ~~Duke University.~~
 2 (4) ~~Wake Forest University.~~
 3 (h) Patient. – A person who has been diagnosed by a neurologist with intractable
 4 epilepsy.

5 (i) ~~Pilot Study. – An evidence based investigation of the safety and efficacy of treating~~
 6 ~~intractable epilepsy using hemp extract conducted by one or more neurologists registered~~
 7 ~~pursuant to this Article."~~

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

9 "**§ 90-113.102. Intractable Epilepsy Alternative Treatment ~~Pilot Study~~ database;**
 10 **departmental duties.**

11 (a) The Department shall create a secure, electronic, and online Intractable Epilepsy
 12 Alternative Treatment ~~Pilot Study~~ database registry for the registration of ~~pilot studies,~~
 13 neurologists, caregivers, and patients as provided by this Article. The registry must be
 14 accessible to law enforcement agencies in order to verify registration of caregivers. The registry
 15 must prevent an active registration of a patient by multiple neurologists. At a minimum, the
 16 database shall consist of the following:

17 (1) ~~The name and address of each registered caregiver and the name of the pilot~~
 18 ~~study the caregiver is associated with caregiver.~~

19 (2) ~~The name and address of each registered patient and the name of the pilot~~
 20 ~~study the patient is associated with patient.~~

21 (3) ~~The name, address, and qualifying institutional~~ hospital ~~affiliation of~~
 22 ~~neurologists conducting pilot studies~~ approving, recommending, or
 23 providing hemp extract as an alternative treatment for intractable epilepsy
 24 pursuant to this Article.

25 (4) ~~The name, institutional affiliation, affiliated registered neurologists, and~~
 26 ~~parameters of pilot studies.~~

27 (b) The Department shall contact the county department of health where the patient
 28 resides and provide the following information:

29 (1) The name and address of the registered caregiver.

30 (2) Identifying information contained on the caregiver registration card."

31 **SECTION 5.** G.S. 90-113.103 reads as rewritten:

32 "**§ 90-113.103. Registration of ~~pilot studies and neurologists.~~**

33 (a) A neurologist seeking to ~~conduct a pilot study~~ approve, recommend, or provide
 34 hemp extract for one or more patients as an alternative treatment to intractable epilepsy
 35 pursuant to this Article shall submit an application to the Department providing all of the
 36 following information:

37 (1) ~~The name of the pilot study~~ neurologist.

38 (2) ~~The affiliated research institution~~ name of the hospital with which the
 39 neurologist is affiliated.

40 (3) ~~The scientific and clinical parameters of the study.~~

41 (4) ~~The~~ An explanation of the treatment protocols established for approving,
 42 recommending, or providing hemp extract as an alternative treatment for
 43 intractable epilepsy to ensure patient safety.

44 (5) ~~The name and address of the one or more neurologists associated with the~~
 45 ~~pilot study.~~

46 (6) Any other information deemed necessary by the Department to ~~determine~~
 47 ~~the safety and evidence based nature of the pilot study~~ protect patient safety.

48 (b) The Department shall examine applications received pursuant to subsection (a) of
 49 this section and register in the database the ~~proposed pilot studies that neurologists~~ the
 50 Department certifies follow minimal scientific methods and protect patient safety certifies to

1 approve, recommend, or provide hemp extract for one or more patients as an alternative
2 treatment for intractable epilepsy pursuant to this Article.

3 ~~(e) The Department may monitor registered pilot studies to ensure continued adherence~~
4 ~~to patient safety protocols and the scientific parameters of the study."~~

5 **SECTION 6.** G.S. 90-113.104 reads as rewritten:

6 **"§ 90-113.104. Caregiver registration card; application; fees.**

7 (a) The Department shall, in coordination with recommendations from the Department
8 of Public Safety, establish the form and content of caregiver registration cards to be issued to
9 individuals who satisfy the requirements set forth in this section.

10 (b) The Department shall issue a caregiver registration card, valid for a period of one
11 year from issuance, to an individual who satisfies all of the following criteria:

12 (1) Is at least 18 years of age.

13 (2) Is a resident of North Carolina.

14 (3) Provides the Department with a statement signed by a neurologist
15 ~~conducting a pilot study~~ that satisfies all of the following:

16 a. Demonstrates that a patient in the caregiver's care satisfies all of the
17 following criteria:

18 1. Has been examined and is under the care of the neurologist.

19 2. Suffers from intractable epilepsy.

20 3. May benefit from treatment with hemp extract.

21 ~~4. Is eligible for inclusion in the registered pilot study.~~

22 b. Contains a recommendation for the use of hemp extract for treatment
23 of intractable ~~epilepsy as part of a registered pilot study.~~ epilepsy.

24 c. Is consistent with records received from the neurologist, concerning
25 the patient, contained in the database described in G.S. 90-113.102.

26 (4) Pays the Department a fee, not to exceed fifty dollars (\$50.00), established
27 by the Department under G.S. 90-113.106.

28 (5) Submits an application to the Department that contains all of the following:

29 a. The caregiver's name and address.

30 b. The patient's name and address.

31 c. A copy of the caregiver's valid government-issued photo
32 identification.

33 d. Any additional information the Department finds necessary to
34 implement this Article.

35 (c) The Department shall renew a caregiver registration card upon certification from the
36 caregiver and the neurologist that all information initially provided to the Department under
37 subsection (b) of this section is current or has been updated to reflect any changes. The
38 Department shall charge a fee for renewal of a caregiver registration card, not to exceed
39 twenty-five dollars (\$25.00), established under G.S. 90-113.106."

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

41 **"§ 90-113.105. Immunity for neurologists; medical records.**

42 (a) On a case-by-case basis, neurologists ~~conducting a registered pilot study~~ may
43 approve of dispensation to a registered caregiver, as approved by this Article, hemp extract
44 acquired from another jurisdiction.

45 (b) A neurologist shall not be subject to arrest or prosecution, penalized or disciplined
46 in any manner, or denied any right or privilege for approving or recommending the use of hemp
47 extract or providing a written statement or health records to the Department for the use of hemp
48 extract pursuant to this Article.

49 (c) A neurologist ~~conducting a registered pilot study~~ who signs a statement as described
50 in G.S. 90-113.104(b)(3) shall do the following:

- 1 (1) Keep a record of the evaluation and observation of a patient under the
- 2 neurologist's care, including the patient's response to hemp extract treatment.
- 3 (2) Transmit the record described in subdivision (1) of this subsection to the
- 4 Department upon request.
- 5 (d) All medical records received or maintained by the Department pursuant to this
- 6 Article are confidential and may not be disclosed to the public. Nothing in this Article is
- 7 intended to alter the provisions of G.S. 8-53 or G.S. 8-53.1."
- 8 **SECTION 8.** Section 5 of S.L. 2014-53 reads as rewritten:
- 9 ~~"SECTION 5. Section 3 of this act becomes effective upon adoption of rules pursuant to~~
- 10 ~~Section 4 of this act. The remainder of this~~ This act is effective when it becomes law."
- 11 **SECTION 9.** The Department of Health and Human Services shall establish and
- 12 adopt rules to implement the provisions of this act.
- 13 **SECTION 10.** This act is effective when it becomes law.