

**GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013**

**SESSION LAW 2014-53
HOUSE BILL 1220**

AN ACT TO CREATE AN INTRACTABLE EPILEPSY ALTERNATIVE TREATMENT PILOT STUDY PROGRAM AND REGISTRY FOR THE SCIENTIFIC INVESTIGATION OF THE SAFETY AND EFFICACY OF HEMP EXTRACT TREATMENT FOR INTRACTABLE EPILEPSY.

The General Assembly of North Carolina enacts:

SECTION 1. The University of North Carolina at Chapel Hill and East Carolina University may, 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.

SECTION 2. Chapter 90 of the General Statutes is amended by adding a new Article to read:

"Article 5G.

"Epilepsy Alternative Treatment Act.

"§ 90-113.100. Short title.

- (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.
- (c) The General Assembly finds the following:
 - (1) 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.

"§ 90-113.101. Definitions.

- (a) Caregiver. – An individual who is a parent, legal guardian, or custodian of a person diagnosed with intractable epilepsy.
- (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.
- (d) Department. – The Department of Health and Human Services.
- (e) Hemp Extract. – An extract from a cannabis plant, as defined in G.S. 90-94.1(a).
- (f) Intractable Epilepsy. – A seizure disorder that, as determined by a neurologist, does not respond to three or more treatment options overseen by the neurologist.
- (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:
 - (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.

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

(a) The Department shall create a secure, electronic, and online Intractable Epilepsy Alternative Treatment Pilot Study database registry for the registration of pilot studies, neurologists, caregivers, and patients as provided by this Article. 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 database shall consist of the following:

- (1) The name and address of each registered caregiver and the name of the pilot study the caregiver is associated with.
- (2) The name and address of each registered patient and the name of the pilot study the patient is associated with.
- (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.

(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.

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

(a) A neurologist seeking to conduct a pilot study pursuant to this Article shall submit an application to the Department providing all of the following information:

- (1) The name of the pilot study.
- (2) The affiliated research institution.
- (3) The scientific and clinical parameters of the study.
- (4) The protocols established to ensure patient safety.
- (5) The name and address of the one or more neurologists associated with the pilot study.
- (6) Any other information deemed necessary by the Department to determine the safety and evidence-based nature of the pilot study.

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

(c) The Department may monitor registered pilot studies to ensure continued adherence to patient safety protocols and the scientific parameters of the study.

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

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

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

- (1) Is at least 18 years of age.
- (2) Is a resident of North Carolina.
- (3) Provides the Department with a statement signed by a neurologist conducting a pilot study that satisfies all of the following:
 - a. Demonstrates that a patient in the caregiver's care satisfies all of the following criteria:
 1. Has been examined and is under the care of the neurologist.
 2. Suffers from intractable epilepsy.
 3. May benefit from treatment with hemp extract.
 4. Is eligible for inclusion in the registered pilot study.
 - b. Contains a recommendation for the use of hemp extract for treatment of intractable epilepsy as part of a registered pilot study.
 - c. Is consistent with records received from the neurologist, concerning the patient, contained in the database described in G.S. 90-113.102.

- (4) Pays the Department a fee, not to exceed fifty dollars (\$50.00), established by the Department under G.S. 90-113.106.
- (5) Submits an application to the Department that contains all of the following:
 - a. The caregiver's name and address.
 - b. The patient's name and address.
 - c. A copy of the caregiver's valid government-issued photo identification.
 - d. Any additional information the Department finds necessary to implement this Article.

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

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

(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 confidential and may not be disclosed to the public. Nothing in this Article is intended to alter the provisions of G.S. 8-53 or G.S. 8-53.1.

"§ 90-113.106. Rule making.

The Department shall adopt rules in accordance with Article 2A of Chapter 150B of the General Statutes to implement the provisions of this Article."

SECTION 3. Article 5 of Chapter 90 of the General Statutes is amended by adding a new section to read:

"§ 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 of one percent (0.3%) tetrahydrocannabinol by weight.
- (2) Is composed of at least ten percent (10%) cannabidiol by weight.
- (3) Contains no other psychoactive substance.

(b) Notwithstanding any other provision of this Chapter, an individual may possess or 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.

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

(2) The individual is registered with the Department of Health and Human Services to administer hemp extract under G.S. 90-113.103."

SECTION 4. No later than October 1, 2014, the Department of Health and Human Services shall establish and adopt temporary rules to implement the provisions of this act.

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

In the General Assembly read three times and ratified this the 26th day of June, 2014.

s/ Philip E. Berger
President Pro Tempore of the Senate

s/ Justin P. Burr
Presiding Officer of the House of Representatives

s/ Pat McCrory
Governor

Approved 9:08 a.m. this 3rd day of July, 2014