GENERAL ASSEMBLY OF NORTH CAROLINA **SESSION 2015**

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HOUSE DRH40315-MG-70 (03/05)

| Short Title: | Amend CBD Oil Statute. | (Public) |
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| Sponsors: | Representative McElraft. | |
| Referred to: | | |

| 1 | | | A BILL TO BE ENTITLED |
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| 2 | AN ACT | AM | ENDING THE EXEMPTION FOR USE OR POSSESSION OF HEMP |
| 3 | EXTRA | ACT | AND AUTHORIZING CERTAIN NEUROLOGISTS TO USE HEMP |
| 4 | EXTRA | ACT | AS AN ALTERNATIVE TREATMENT FOR INTRACTABLE EPILEPSY |
| 5 | WITH | OUT | PARTICIPATING IN A PILOT STUDY. |
| 6 | The Gener | al As | sembly of North Carolina enacts: |
| 7 | | SEC | TION 1. G.S. 90-94.1(a) reads as rewritten: |
| 8 | "(a) | As u | sed in this section, "hemp extract" means an extract from a cannabis plant, or a |
| 9 | mixture of | r pre | paration containing cannabis plant material, that has all of the following |
| 10 | characteris | tics: | |
| 11 | | (1) | Is composed of less than three-tenths five-tenths of one percent $(0.3\%)(0.5\%)$ |
| 12 | | | tetrahydrocannabinol by weight. |
| 13 | | (2) | Is composed of at least ten five percent (10%)(5%) cannabidiol by weight. |
| 14 | | (3) | Contains no other psychoactive substance." |
| 15 | | | TION 2. G.S. 90-113.100 reads as rewritten: |
| 16 | "§ 90-113. | | Short title. |
| 17 | (a) | | act may be cited as the "North Carolina Epilepsy Alternative Treatment Act." |
| 18 | (b) | | purpose of this act is to permit medical professionals to conduct limited scope, |
| 19 | | | studies exploring the safety and efficacy of treatingtreat intractable epilepsy |
| 20 | using hemp | | |
| 21 | (c) | | General Assembly finds the following: |
| 22 | | (1) | Therethat 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 | | a a a | State of North Carolina are well-suited for this type of clinical exploration." |
| 28 | | | TION 3. G.S. 90-113.101 reads as rewritten: |
| 29 | "§ 90-113. | 101. | Definitions. |
| 30 | ••• | | |
| 31 | (g) | | rologist. – An individual who is licensed under Article 1 of Chapter 90 of the |
| 32 | | | s, who is board certified in neurology, and is affiliated with the neurology |
| 33 | department | | ne or more of the following universities: hospitals licensed in this State. |
| 34 | | (1) | The University of North Carolina at Chapel Hill. |
| 35 | | $\frac{(2)}{(2)}$ | East Carolina University. |
| 36 | | (3) | Duke University. |
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| | (4) Wake Forest University. |
| (h) | Patient. – A person who has been diagnosed by a neurologist with intractab |
| 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 register |
| | this Article." |
| 1 | SECTION 4. G.S. 90-113.102 reads as rewritten: |
| "§ 90-11. | .102. Intractable Epilepsy Alternative Treatment Pilot Study databas |
| | departmental duties. |
| (a) | The Department shall create a secure, electronic, and online Intractable Epilep |
| Alternativ | Treatment Pilot Study database registry for the registration of pilot studie |
| neurologis | s, caregivers, and patients as provided by this Article. The registry must |
| accessible | to law enforcement agencies in order to verify registration of caregivers. The regist |
| | nt an active registration of a patient by multiple neurologists. At a minimum, the |
| database s | all consist of the following: |
| | (1) The name and address of each registered caregiver and the name of the pil |
| | study the caregiver is associated with.caregiver. |
| | (2) The name and address of each registered patient and the name of the pil |
| | study the patient is associated with.patient. |
| | (3) The name, address, and qualifying institutional hospital affiliation |
| | neurologists conducting pilot studiesapproving, recommending, or providing |
| | hemp extract as an alternative treatment for intractable epilepsy pursuant |
| | 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 patie |
| resides an | provide the following information: |
| | (1) The name and address of the registered caregiver. |
| | (2) Identifying information contained on the caregiver registration card." |
| | SECTION 5. G.S. 90-113.103 reads as rewritten: |
| "§ 90-113 | 103. Registration of pilot studies and neurologists . |
| (a) | A neurologist seeking to conduct a pilot study approve, recommend, or provide |
| hemp ext | act for one or more patients as an alternative treatment to intractable epilep |
| - | this Article shall submit an application to the Department providing all of the |
| - | nformation: |
| U | (1) The name of the pilot study.neurologist. |
| | (2) The affiliated research institution.name of the hospital with which the |
| | neurologist is affiliated. |
| | (3) The scientific and clinical parameters of the study. |
| | (4) The An explanation of the treatment protocols established for approvin |
| | recommending, or providing hemp extract as an alternative treatment f |
| | intractable epilepsy 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 protect patient safety |
| (b) | The Department shall examine applications received pursuant to subsection (a) |
| · · · | n and register in the database the proposed pilot studies that <u>neurologists</u> the |
| | t certifies follow minimal scientific methods and protect patient safety.certifies |
| - | ecommend, or provide hemp extract for one or more patients as an alternativ |
| approve, | toliment, of provide hemp extract for one of more patients as an alternation |

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| | (c) The Department may monitor registered pilot studies to ensure continued adherence |
| | to patient safety protocols and the scientific parameters of the study." |
| | SECTION 6. G.S. 90-113.104 reads as rewritten: |
| - | "§ 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.epilepsy. |
| | 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." |
| | SECTION 7. G.S. 90-113.105 reads as rewritten: |
| | "§ 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 or providing a written statement or health records to the Department for the use of hemp extract pursuant to this Article. |
| - - - | 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 |
| | extract pursuant to this Article. |
| | extract pursuant to this Article. (c) A neurologist conducting a registered pilot study who signs a statement as described |

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| 1 | (2) Transmit the record described in subdivision (1) of this subsection to the |
| 2 | Department upon request. |
| 3 | (d) All medical records received or maintained by the Department pursuant to this |
| 4 | Article are confidential and may not be disclosed to the public. Nothing in this Article is |
| 5 | intended to alter the provisions of G.S. 8-53 or G.S. 8-53.1." |
| 6 | SECTION 8. This act becomes effective December 1, 2015. |