

The House Committee on Governmental Affairs offers the following substitute to SB 145:

A BILL TO BE ENTITLED  
AN ACT

1 To amend Title 16, Code Section 31-2A-18, and Chapter 51 of Title 31, relating to crimes  
2 and offenses, the establishment of the Low THC Oil Patient Registry, and the creation of the  
3 low THC oil research program, respectively, so as to change provisions relating to the  
4 regulation of low THC oil; to revise and provide for definitions; to expand conditions for  
5 which low THC oil may be recommended for treatment; to clarify provisions of existing law;  
6 to provide for other lawful activities; to change reporting requirements; to clarify which  
7 entities may conduct low THC oil research; to clarify provisions relating to such research;  
8 to provide for related matters; to repeal conflicting laws; and for other purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 SECTION 1.

11 This Act shall be known and may be cited as "Haleigh's Hope Act - Part II."

12 SECTION 2.

13 Title 16 of the Official Code of Georgia Annotated, relating to crimes and offenses, is  
14 amended by revising Code Section 16-12-190, relating to a definition, as follows:

15 "16-12-190.

16 As used in this article, the term 'low THC oil' means an oil that contains an amount of  
17 cannabidiol and not more than 5 percent by weight of tetrahydrocannabinol,  
18 tetrahydrocannabinolic acid, or a combination of tetrahydrocannabinol and  
19 tetrahydrocannabinolic acid which does not contain plant material exhibiting the external  
20 morphological features of the plant of the genus Cannabis and an amount of cannabidiol  
21 equal to or greater than the amount of tetrahydrocannabinol."

22 **SECTION 3.**

23 Said title is further amended in Code Section 16-12-191, relating to possession, manufacture,  
24 distribution, or sale of low THC oil, by revising paragraph (1) of subsection (a) and  
25 subsection (b) and by revising subsection (e) as follows:

26 "(a)(1) Notwithstanding any provision of Chapter 13 of this title, it shall be lawful for  
27 any person to possess or have under his or her control 20 fluid ounces or less of low THC  
28 oil if:

29 (A) Such person is registered with the Department of Public Health as set forth in Code  
30 Section 31-2A-18;

31 ~~(B) Such person~~ and has in his or her possession a registration card issued by the  
32 Department of Public Health; and

33 ~~(C)(B)~~ Such substance is in a pharmaceutical container labeled by the manufacturer  
34 indicating the percentage of tetrahydrocannabinol or tetrahydrocannabinolic acid  
35 therein."

36 "(b)(1) Notwithstanding any provision of Chapter 13 of this title, it shall be lawful for  
37 any person to possess or have under his or her control 20 fluid ounces or less of low THC  
38 oil if:

39 (A) Such person is involved in or with a ~~clinical~~ research program ~~being conducted by~~  
40 ~~the Board of Regents of the University System of Georgia~~ or any authorized clinical  
41 trial or research study protocol in this state or is an authorized agent pursuant to Chapter  
42 51 of Title 31 as:

43 (i) A ~~program~~ participant;

44 (ii) A parent, guardian, or legal custodian of a ~~program~~ participant;

45 (iii) ~~An~~ A designated employee of the board of regents ~~designated to participate in~~  
46 ~~the research program, a nonprofit corporation research institute, or a nonprofit~~  
47 institution of higher education that conducts research;

48 (iv) ~~A program~~ An agent;

49 (v) A ~~program~~ collaborator and their designated employees;

50 (vi) A ~~program~~ supplier and their designated employees;

51 (vii) A ~~program~~ physician;

52 (viii) A ~~program~~ clinical researcher;

53 (ix) ~~Program pharmacy~~ Pharmacy personnel; or

54 (x) Other ~~program~~ medical personnel;

55 (B) Such person has in his or her possession a permit issued as provided in Code  
56 Section 31-51-7; and

57 (C) Such substance is in a pharmaceutical container labeled by the manufacturer  
 58 indicating the percentage of tetrahydrocannabinol or tetrahydrocannabinolic acid therein.”  
 59 “(e) Subsections (c) and (d) of this Code section shall not apply to a person involved in a  
 60 research program being conducted by the Board of Regents of the University System of  
 61 Georgia or its authorized agent pursuant to Chapter 51 of Title 31 as an employee of the  
 62 board of regents designated to participate in such program, a program agent, a program  
 63 collaborator and their designated employees, a program supplier and their designated  
 64 employees, a physician, clinical researcher, pharmacy personnel, or other medical  
 65 personnel identified in subparagraph (b)(1)(A) of this Code section, provided that such  
 66 person has in his or her possession a permit issued as provided in Code Section ~~31-5-7~~  
 67 31-51-7 and such possession, sale, manufacturing, distribution, or dispensing is solely for  
 68 the purposes set forth in Chapter 51 of Title 31.”

69 **SECTION 4.**

70 Said title is further amended by adding a new Code section to read as follows:

71 “16-12-192.

72 Notwithstanding any provision of Chapter 13 of this title, it shall be lawful for a  
 73 manufacturer of low THC oil to ship low THC oil to a person registered with the  
 74 Department of Public Health under Code Section 31-2A-18.”

75 **SECTION 5.**

76 Said title is further amended by revising paragraph (16) of Code Section 16-13-21, relating  
 77 to the definitions for the regulation of controlled substances, as follows:

78 “(16) 'Marijuana' means all parts of the plant of the genus Cannabis, whether growing or  
 79 not, the seeds thereof, the resin extracted from any part of such plant, and every compound,  
 80 manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin; but  
 81 shall not include ~~samples~~ tetrahydrocannabinol as described in subparagraph (P) of  
 82 paragraph (3) of Code Section 16-13-25 and shall not include the completely defoliated  
 83 mature stalks of such plant, fiber produced from such stalks, oil, or cake, or the completely  
 84 sterilized samples of seeds of the plant which are incapable of germination.”

85 **SECTION 6.**

86 Said title is further amended by revising subparagraph (P) of paragraph (3) of Code Section  
 87 16-13-25, relating to Schedule I controlled substances, as follows:

88 “(P) ~~Tetrahydrocannabinols which shall include, but are not limited to:~~

89 ~~(i) All synthetic or naturally produced samples containing more than 15 percent by~~  
 90 ~~weight of tetrahydrocannabinols; and~~

91 ~~(ii) All synthetic or naturally produced tetrahydrocannabinol samples which do~~  
 92 ~~Tetrahydrocannabinol, tetrahydrocannabinolic acid, or a combination of~~  
 93 ~~tetrahydrocannabinol and tetrahydrocannabinolic acid which does not contain plant~~  
 94 ~~material exhibiting the external morphological features of the plant cannabis of the~~  
 95 ~~genus Cannabis;~~"

## 96 SECTION 7.

97 Code Section 31-2A-18, relating to the establishment of the Low THC Oil Patient Registry,  
 98 definitions, purpose, registration cards, quarterly reports, and waiver forms, is amended by  
 99 revising paragraph (3) of subsection (a) and subsections (c) and (e) as follows:

100 "(3) 'Condition' means:

101 (A) Cancer, when such ~~diagnosis is end stage or the treatment~~ disease produces related  
 102 wasting illness, recalcitrant nausea, and vomiting;

103 (B) Amyotrophic lateral sclerosis, ~~when such diagnosis is severe or end stage;~~

104 (C) Seizure disorders related to diagnosis of epilepsy or trauma related head injuries;

105 (D) Multiple sclerosis, ~~when such diagnosis is severe or end stage;~~

106 (E) Crohn's disease, ulcerative colitis, or irritable bowel syndrome;

107 (F) Mitochondrial disease;

108 (G) Parkinson's disease, ~~when such diagnosis is severe or end stage; or~~

109 (H) Sickle cell disease, ~~when such diagnosis is severe or end stage;~~

110 (I) Autism spectrum disorder;

111 (J) Epidermolysis bullosa;

112 (K) Human immunodeficiency virus or acquired immune deficiency syndrome;

113 (L) Peripheral neuropathy;

114 (M) Tourette's syndrome;

115 (N) Terminal illness, with a probable life expectancy of less than two years, if the  
 116 illness or its treatment produces one or more of the following:

117 (i) Severe pain;

118 (ii) Nausea or severe vomiting; or

119 (iii) Cachexia or severe wasting; or

120 (O) Post-traumatic stress disorder."

121 "(c) The purpose of the registry is to provide a registration of individuals and caregivers  
 122 who have been issued registration cards. The department shall establish procedures and  
 123 promulgate rules and regulations for the establishment and operation of the registration  
 124 process and dispensing of registry cards to individuals and caregivers. ~~Only individuals~~  
 125 ~~residing in this state for at least one year or a child born in this state less than one year old~~  
 126 ~~shall be eligible for registration under this Code section. Nothing in this Code section shall~~

127 ~~apply to any Georgia residents living temporarily in another state for the purpose of~~  
 128 ~~securing THC oil for treatment of any condition under this Code section."~~

129 "(e) The board shall require physicians to issue ~~quarterly reports~~ an annual report to the  
 130 board. Such ~~reports~~ report shall require physicians to provide information, including, but  
 131 not limited to, dosages recommended for a particular condition, clinical responses,  
 132 compliance, responses to treatment, side effects, and drug interactions."

133 **SECTION 8.**

134 Chapter 51 of Title 31 of the Official Code of Georgia Annotated, relating to the creation of  
 135 the low THC oil research program, is amended by revising subsection (b) of Code Section  
 136 31-51-1, relating to the creation of the program, as follows:

137 "(b) The Board of Regents of the University System of Georgia, a nonprofit corporation  
 138 research institute, a nonprofit institution of higher education that conducts research, or any  
 139 combination thereof may cause to be designed, developed, implemented, and administered  
 140 a low THC oil research program to develop rigorous data that will inform and expand the  
 141 scientific community's understanding of potential treatments for individuals under 18 years  
 142 of age with medication-resistant epilepsies."

143 **SECTION 9.**

144 Said chapter is further amended by revising subsections (b) and (c) of Code Section 31-51-3,  
 145 relating to authorized agents, as follows:

146 "(b) Any nonprofit corporation research institute or nonprofit institution of higher  
 147 education that conducts research which is approved by the board of regents to participate  
 148 in ~~the~~ its research program established under this chapter and any nonprofit corporation  
 149 research institute, nonprofit institution of higher education that conducts research, or any  
 150 combination thereof that is authorized under this chapter to conduct low THC oil research  
 151 shall be required to have the necessary experience, expertise, industry standards and  
 152 security procedures, and infrastructure to implement such research in accordance with  
 153 accepted scientific and regulatory standards.

154 (c) The board of regents and its authorized agent and any nonprofit corporation research  
 155 institute, nonprofit institution of higher education that conducts research, or any  
 156 combination thereof may enter into such agreements, among themselves and with other  
 157 parties, as are reasonable and necessary to implement the provisions of this chapter."

158 **SECTION 10.**

159 Said chapter is further amended by revising Code Section 31-51-4, relating to suppliers of  
 160 low THC oil, as follows:

161 "31-51-4.

162 (a) The board of regents, ~~or its authorized agent, a nonprofit corporation research institute,~~  
 163 a nonprofit institution of higher education that conducts research, or any combination  
 164 thereof may designate an FDA approved supplier of low THC oil and collaborate with a  
 165 designated supplier to develop a clinical trial or research study protocol to study the use of  
 166 low THC oil in the treatment of individuals under 18 years of age with medication-resistant  
 167 epilepsies, which trial or research study shall be conducted at one or more locations in this  
 168 state. Such supplier shall be required to supply a source of low THC oil that has been  
 169 standardized and tested in keeping with such standards.

170 (b) The board of regents, ~~or its authorized agent, a nonprofit corporation research institute,~~  
 171 a nonprofit institution of higher education that conducts research, or any combination  
 172 thereof shall work with any supplier of low THC oil to commit personnel and other  
 173 resources to such collaboration and to supply low THC oil for a collaborative study under  
 174 reasonable terms and conditions to be agreed upon mutually."

175 **SECTION 11.**

176 Said chapter is further amended by revising Code Section 31-51-6, relating to funds, as  
 177 follows:

178 "31-51-6.

179 ~~All activities~~ Activities undertaken by the board of regents pursuant to this chapter shall  
 180 be subject to the availability of funds appropriated to the board of regents ~~or to any other~~  
 181 ~~academic or research institution or otherwise made available~~ for the purposes of this  
 182 chapter."

183 **SECTION 12.**

184 Said chapter is further amended by revising Code Section 31-51-7, relating to immunity, as  
 185 follows:

186 "31-51-7.

187 ~~(a)(1) Research program participants and their parents, guardian, or legal custodian,~~  
 188 ~~employees of the board of regents designated to participate in the research program,~~  
 189 ~~program agents and collaborators and their designated employees, and program suppliers~~  
 190 ~~of low THC oil and their designated employees shall be immune from state prosecution~~  
 191 ~~as provided in Code Section 16-12-191.~~

192 ~~(2) Physicians, clinical researchers, pharmacy personnel, and all medical personnel in~~  
 193 ~~the research program authorized by this chapter shall be immune from state prosecution~~  
 194 ~~as provided in Code Section 16-12-191~~ shall provide for immunity from state prosecution

195 for individuals participating in or with a research program, clinical trial, or research study  
196 protocol authorized under this chapter.

197 (b) For purposes of providing proof of research program, clinical trial, or research study  
198 protocol participation, the board of regents, or its authorized agent, a nonprofit corporation  
199 research institute, a nonprofit institution of higher education that conducts research, or any  
200 combination thereof which administers ~~the research~~ such program, trial, or protocol  
201 authorized by this chapter shall provide appropriate permits, suitable for carrying on their  
202 persons or display, as applicable, to individuals participating in or with such research  
203 program, ~~participants and their parents, guardian, or legal custodian, employees of the~~  
204 ~~board of regents designated to participate in the research program, program agents and~~  
205 ~~collaborators and their designated employees, program suppliers of low THC oil and their~~  
206 ~~designated employees, physicians, clinical researchers, pharmacy personnel, and all~~  
207 ~~medical personnel in the program~~ clinical trial, or research study protocol."

208

### SECTION 13.

209 All laws and parts of laws in conflict with this Act are repealed.