

Senate Bill 81

By: Senators Unterman of the 45th, Miller of the 49th, Mullis of the 53rd, Burke of the 11th and Hufstetler of the 52nd

AS PASSED SENATE

A BILL TO BE ENTITLED

AN ACT

1 To amend Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated,
2 relating to pharmacies, so as to provide that the state health officer may issue a standing
3 order permitting certain persons and entities to obtain opioid antagonists under the conditions
4 the state health officer may impose; to provide for immunity; to amend Chapter 13 of Title
5 16 of the Official Code of Georgia Annotated, relating to controlled substances, so as to
6 change the definition of a dangerous drug; to add a drug to Schedule V; to change certain
7 provisions of the electronic data base of prescription information; to change the dispenser
8 prescription information transmission frequency; to provide for prescriber requirements; to
9 provide for exemptions; to provide for prescription limitations; to provide for penalties; to
10 amend Code Section 31-12-2 of the Official Code of Georgia Annotated, relating to reporting
11 disease, confidentiality, reporting required by pharmacists, immunity from liability as to
12 information supplied, and notification of potential bioterrorism, so as to add neonatal
13 abstinence syndrome reporting; to amend Chapter 5 of Title 26 of the Official Code of
14 Georgia Annotated, relating to drug abuse treatment and education programs, so as to
15 provide for annual inspection; to provide for annual reporting of certain data; to provide for
16 short titles; to provide for legislative findings; provide for related matters; to repeal
17 conflicting laws; and for other purposes.

18 **BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:**

19 **PART I**
20 **SECTION 1-1.**

21 This part shall be known and may be cited as the "Jeffrey Dallas Gay, Jr., Act."

22 **SECTION 1-2.**

23 WHEREAS, according to the Centers for Disease Control and Prevention's National Center
24 for Health Statistics, the number of overdose deaths involving opioids rose from 28,647 in
25 2014 to 33,091 in 2015; and

26 WHEREAS, according to the Centers for Disease Control and Prevention, two distinct but
27 interconnected trends are driving America's opioid overdose epidemic:

28 (1) A 15 year increase in deaths from prescription opioid overdoses; and

29 (2) A recent surge in illicit opioid overdoses driven mainly by heroin and illegally made
30 fentanyl; and

31 WHEREAS, naloxone is an overdose reversal and life-saving opioid antagonist that the Food
32 and Drug Administration designates as a prescription only drug; and

33 WHEREAS, forty-seven states, including Georgia, have passed laws providing immunity to
34 medical professionals who prescribe or dispense naloxone or persons who administer
35 naloxone, a life-saving opioid antagonist; and

36 WHEREAS, Emergency Rule 480-34-0.31-.11 (naloxone) was signed by the Governor on
37 December 14, 2016, to allow pharmacists to dispense naloxone to individuals pursuant to a
38 state-wide standing order issued by the state health officer; and

39 WHEREAS, other states have passed laws to allow the similar sale of naloxone at
40 pharmacies without a traditional patient-specific prescription, including: Alabama, Alaska,
41 Arkansas, Arizona, California, Colorado, Connecticut, District of Columbia, Florida, Idaho,
42 Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota,
43 Mississippi, Missouri, Montana, Nebraska, New Hampshire, Nevada, New Jersey, New
44 Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania,
45 Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West
46 Virginia, and Wisconsin.

47 **SECTION 1-3.**

48 The General Assembly finds that it is imperative that Emergency Rule 480-34-0.31-.11 be
49 codified to prevent against accidental overdoses and combat the opioid epidemic. The
50 General Assembly further finds that this effort to permanently increase access to naloxone

51 in Georgia shall be dedicated to Jeffrey Dallas Gay, Jr., and his family in Gainesville,
52 Georgia.

53 **SECTION 1-4.**

54 Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
55 pharmacies, is amended by revising Code Section 26-4-116.2, relating to authority of
56 licensed health practitioners to prescribe opioid antagonists and immunity from liability, as
57 follows:

58 "26-4-116.2.

59 (a) As used in this Code section, the term:

60 (1) 'First responder' means any person or agency who provides on-site care until the
61 arrival of a duly licensed ambulance service. This shall include, but not be limited to,
62 persons who routinely respond to calls for assistance through an affiliation with law
63 enforcement agencies, fire departments, and rescue agencies.

64 (2) 'Harm reduction organization' means an organization which provides direct assistance
65 and services, such as syringe exchanges, counseling, homeless services, advocacy, drug
66 treatment, and screening, to individuals at risk of experiencing an opioid related
67 overdose.

68 (3) 'Opioid antagonist' means any drug that binds to opioid receptors and blocks or
69 inhibits the effects of opioids acting on those receptors and that is approved by the federal
70 Food and Drug Administration for the treatment of an opioid related overdose.

71 (4) 'Opioid related overdose' means an acute condition, including, but not limited to,
72 extreme physical illness, decreased level of consciousness, respiratory depression, coma,
73 mania, or death, resulting from the consumption or use of an opioid or another substance
74 with which an opioid was combined or that a layperson would reasonably believe to be
75 resulting from the consumption or use of an opioid or another substance with which an
76 opioid was combined for which medical assistance is required.

77 (5) 'Pain management clinic' means a clinic licensed pursuant to Article 10 of Chapter 34
78 of Title 43.

79 (6) 'Practitioner' means a physician licensed to practice medicine in this state.

80 (b) The following persons may prescribe an opioid antagonist:

81 (1) A practitioner acting in good faith and in compliance with the standard of care
82 applicable to that practitioner may prescribe an opioid antagonist for use in accordance
83 with a protocol specified by such practitioner to a person at risk of experiencing an opioid
84 related overdose or to a pain management clinic, first responder, harm reduction

85 organization, family member, friend, or other person in a position to assist a person at risk
 86 of experiencing an opioid related overdose; or

87 (2) The state health officer may issue a standing order permitting certain persons and
 88 entities, or categories of persons or entities, to obtain opioid antagonists under such
 89 conditions as the state health officer may impose. Such an order shall have state-wide
 90 effect.

91 (c) A pharmacist acting in good faith and in compliance with the standard of care
 92 applicable to pharmacists may dispense opioid antagonists pursuant to a prescription issued
 93 in accordance with subsection (b) of this Code section.

94 (d) A person acting in good faith and with reasonable care to another person whom he or
 95 she believes to be experiencing an opioid related overdose may administer an opioid
 96 antagonist that was prescribed pursuant to subsection (b) of this Code section in accordance
 97 with the protocol specified by the practitioner or state health officer.

98 (e) The following individuals are immune from any civil or criminal liability or
 99 professional licensing sanctions for the following actions authorized by this Code section:

100 (1) Any practitioner acting in good faith and in compliance with the standard of care
 101 applicable to that practitioner who prescribes an opioid antagonist pursuant to subsection
 102 (b) of this Code section;

103 (2) Any practitioner or pharmacist acting in good faith and in compliance with the
 104 standard of care applicable to that practitioner or pharmacist who dispenses an opioid
 105 antagonist pursuant to a prescription issued in accordance with paragraph (1) of
 106 subsection (b) of this Code section; and

107 (3) The state health officer acting pursuant to paragraph (2) of subsection (b) of this Code
 108 section; and

109 ~~(3)~~(4) Any person acting in good faith, other than a practitioner, who administers an
 110 opioid antagonist pursuant to subsection (d) of this Code section.

111 (f) Pursuant to any standing order issued under paragraph (2) of subsection (b) of this
 112 Code section, every pharmacy operating in this state shall keep a copy of the standing order
 113 issued by the state health officer and shall keep a record of every opioid antagonist
 114 dispensed pursuant to such standing order. Each record shall include the name of the
 115 purchaser, and the personal information of such purchaser shall include such purchaser's
 116 name and address, including the city, state, and ZIP Code. Such record shall be maintained
 117 by the pharmacy for two years. Nothing in this subsection shall prevent such record from
 118 being maintained electronically. Pharmacists shall not be required to submit this
 119 information to the Prescription Drug Monitoring Program. Such standing order shall not
 120 require pharmacies in this state to maintain opioid antagonists in their biennial inventories."

SECTION 1-5.

121
122 Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled
123 substances, is amended by revising Code Section 16-13-29, relating to Schedule V, as
124 follows:

125 "16-13-29.

126 The controlled substances listed in this Code section are included in Schedule V:

127 (1) Any compound, mixture, or preparation containing limited quantities of any of the
128 following narcotic drugs, or salts thereof, which also contains one or more nonnarcotic,
129 active, medicinal ingredients in sufficient proportion to confer upon the compound,
130 mixture, or preparation valuable medicinal qualities other than those possessed by the
131 narcotic drug alone:

132 (A) Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or
133 per 100 grams;

134 (B) Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100
135 milliliters or per 100 grams;

136 (C) Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100
137 milliliters or per 100 grams;

138 (D) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms
139 of atropine sulfate per dosage unit;

140 (E) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

141 (2) Lacosamide;

142 (3) Pregabalin;

143 (4) Pyrovalerone;

144 (5) Pseudoephedrine as an exempt over-the-counter Schedule V controlled substance
145 distributed in the same manner as set forth in Code Section 16-13-29.2; provided,
146 however, that such exemption shall take effect immediately and shall not require
147 ~~rulemaking~~ rule making by the State Board of Pharmacy; provided, further, that
148 wholesale drug distributors located within this state and licensed by the State Board of
149 Pharmacy and which are registered and regulated by the DEA shall not be subject to any
150 board requirements for controlled substances for the storage, reporting, record keeping,
151 or physical security of drug products containing pseudoephedrine which are more
152 stringent than those included in DEA regulations; ~~or~~

153 (6) Ezogabine; or

154 (7) Naloxone as an exempt Schedule V controlled substance, which shall require rule
155 making by the State Board of Pharmacy and such rule shall require such substance to be
156 sold only in a pharmacy. Such rule shall further authorize pharmacists and pharmacy

157 interns and externs under the supervision of a licensed pharmacist to dispense naloxone
 158 only with a prescription by a licensed practitioner or under a standing order issued
 159 pursuant to Code Section 26-4-116.2."

160 **SECTION 1-6.**

161 Said chapter is further amended by revising paragraph (635) of subsection (b) of Code
 162 Section 16-13-71, relating to the definition of a dangerous drug, as follows:

163 "(635) ~~Naloxone~~ Reserved;"

164 **PART II**

165 **SECTION 2-1.**

166 This part shall be known and may be cited as the "Substance Abuse Treatment and Overdose
 167 Prevention Act" or the "STOP Act."

168 **SECTION 2-2.**

169 The General Assembly finds that it is important to understand the needs of its residents with
 170 serious substance abuse disorders and the state's ability to provide appropriate and necessary
 171 programs and services to Georgia's citizens. Overdose deaths result from a variety of
 172 substances, including prescription painkillers, heroin, and synthetic designer drugs. Further,
 173 addressing the opioid epidemic will require a state-wide approach that is coordinated and
 174 focused on improving addiction and recovery services, overdose prevention resources,
 175 disease reporting, and prescription drug policies and monitoring programs. Therefore, the
 176 General Assembly has determined it is in the best interests of the state and its citizenry to
 177 address these issues through the STOP Act.

178 **SECTION 2-2.1.**

179 Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled
 180 substances, is amended by adding a new Code section to read as follows:

181 "16-13-57.1.

182 Beginning on July 1, 2018, the electronic data base established pursuant to this part shall
 183 meet or exceed industry standards and shall be accessible and operating 99.5 percent of the
 184 time or such other operational standard as is deemed to meet the industry standard."

185 **SECTION 2-3.**

186 Said chapter is further amended in Code Section 16-13-59, relating to information to include
 187 for each Schedule II, III, IV, or V controlled substance prescription and compliance, by
 188 revising subsection (b) as follows:

189 "(b) Each dispenser shall submit the prescription information required in subsection (a) of
 190 this Code section in accordance with transmission methods ~~and frequency requirements~~
 191 established by the agency ~~on at least a weekly basis~~ every 24 hours and shall report, at a
 192 minimum, such prescription information no later than ~~ten days~~ 24 hours after the
 193 prescription is dispensed. If a dispenser is temporarily unable to comply with this
 194 subsection due to an equipment failure or other circumstances, such dispenser shall notify
 195 the board and agency."

196 **SECTION 2-4.**

197 Said chapter is further amended in Code Section 16-13-60, relating to privacy and
 198 confidentiality, use of data, and security program, by revising subsections (a), (c), and (c.1)
 199 as follows:

200 "(a) Except as otherwise provided in subsections (c), (c.1), and (d) of this Code section,
 201 prescription information submitted pursuant to Code Section 16-13-59 shall be confidential
 202 and shall not be subject to open records requirements, as contained in Article 4 of
 203 Chapter 18 of Title 50."

204 "(c) The agency shall be authorized to provide requested prescription information collected
 205 pursuant to this part only as follows:

206 (1) To persons authorized to prescribe or dispense controlled substances for the sole
 207 purpose of providing medical or pharmaceutical care to a specific patient or to delegates
 208 of such persons authorized to prescribe or dispense controlled substances in accordance
 209 with the following:

210 (A) Such delegates are members of the prescriber or dispenser's staff and retrieve and
 211 review information and reports strictly for purposes of determining usage, misuse,
 212 abuse, or underutilization of prescribed medication;

213 (B) Such dispenser's delegates are licensed, ~~registered, or certified by the state~~
 214 ~~regulatory board governing the delegating prescriber or dispenser, and or registered~~
 215 under Title 26, provided that the delegating prescriber or dispenser shall be held
 216 responsible for the use of the information and data by their his or her delegates. Such
 217 delegates shall be limited to no more than two delegates per shift or rotation per
 218 dispenser; and

219 (C) Such prescriber's delegates may include any member of the prescriber's staff or
 220 health care facility staff in which the prescriber is practicing, provided that the

221 delegating prescriber shall be held responsible for the use of the information and data
 222 by his or her delegates. Such delegates shall be limited to no more than two delegates
 223 per shift or rotation per prescriber; and

224 ~~(C)~~(D) All information and reports retrieved and reviewed by delegates shall be
 225 maintained in a secure and confidential manner in accordance with the requirements of
 226 subsection (f) of this Code section;

227 (2) Upon the request of a patient, prescriber, or dispenser about whom the prescription
 228 information requested concerns or upon the request on his or her behalf of his or her
 229 attorney;

230 (3) To local or state law enforcement or prosecutorial officials pursuant to the issuance
 231 of a search warrant from an appropriate court or official in the county in which the office
 232 of such law enforcement or prosecutorial officials are located pursuant to Article 2 of
 233 Chapter 5 of Title 17 or to federal law enforcement or prosecutorial officials pursuant to
 234 the issuance of a search warrant pursuant to 21 U.S.C. or a grand jury subpoena pursuant
 235 to 18 U.S.C.; and

236 (4) To the agency, the Georgia Composite Medical Board or any other state regulatory
 237 board governing prescribers or dispensers in this state, or the Department of Community
 238 Health for purposes of the state Medicaid program upon the issuance of a subpoena by
 239 such agency, board, or department pursuant to their existing subpoena power or to the
 240 federal Centers for Medicare and Medicaid Services upon the issuance of a subpoena by
 241 the federal government pursuant to its existing subpoena powers.

242 (c.1) An individual authorized to access electronic data base prescription information
 243 pursuant to this part may:

244 (1) Communicate concerns about a patient's potential usage, misuse, abuse, or
 245 underutilization of a controlled substance with ~~other~~ prescribers and dispensers that are
 246 involved in the patient's health care; or

247 (2) Report potential violations of this article to the agency for review or investigation.
 248 Following such review or investigation, the agency may:

249 (A) Refer instances of a patient's possible personal misuse or abuse of controlled
 250 substances to the patient's primary prescriber to allow for potential intervention and
 251 impairment treatment;

252 (B) Refer probable violations of controlled substances being acquired for illegal
 253 distribution, and not solely for a patient's personal use, to the appropriate authorities for
 254 further investigation and potential prosecution; or

255 (C) Refer probable regulatory violations by prescribers or dispensers to the regulatory
 256 board governing such person."

257 **SECTION 2-5.**

258 Said chapter is further amended by revising Code Section 16-13-63, relating to liability, as
 259 follows:

260 "16-13-63.

261 (a)(1) Nothing in this part shall require a dispenser ~~or prescriber~~ to obtain information
 262 about a patient from the program established pursuant to this part. A dispenser ~~or~~
 263 ~~prescriber~~ shall not have a duty and shall not be held civilly liable for damages to any
 264 person in any civil or administrative action or criminally responsible for injury, death, or
 265 loss to person or property on the basis that the dispenser ~~or prescriber~~ did or did not seek
 266 or obtain information from the electronic data base established pursuant to Code
 267 Section 16-13-57. ~~Nothing in this part shall create a private cause of action against a~~
 268 ~~prescriber or dispenser.~~

269 (1.1) Nothing in this part shall create a private cause of action against a prescriber or
 270 dispenser.

271 (2) Every prescriber prescribing Schedule II, III, IV, or V controlled substances in this
 272 state shall register with the electronic data base established pursuant to Code Section
 273 16-13-57 beginning January 1, 2018, and no later than July 1, 2018.

274 (3) Beginning on July 1, 2018, a prescriber or his or her delegate shall seek and review
 275 information from the electronic data base established pursuant to Code Section 16-13-57
 276 whenever he or she is prescribing benzodiazepines, opiates, opioids, opioid analgesics,
 277 or opioid derivatives to a patient for the first time and at least once every 90 days
 278 thereafter if such prescriber continues to prescribe a controlled substance to such patient.
 279 A prescriber or delegate shall be exempt from the duty to seek and review information
 280 from the electronic data base pursuant to this paragraph if:

281 (A) The patient is terminally ill or under the supervised care of a hospice program;

282 (B) The patient is in a long-term care facility that has dedicated or institutional
 283 long-term care pharmacies or the controlled substances under this paragraph are
 284 dispensed by a hospital pharmacy;

285 (C) The patient is undergoing addiction treatment in a program that is administering
 286 methadone or buprenorphine;

287 (D) The prescription is for a supply of three days or less with no refills permitted; or

288 (E) The electronic data base is not operational due to a systematic technological
 289 interruption or widespread electrical failure as a result of a natural disaster, provided
 290 that the prescriber notifies the board and agency of such incident.

291 (4)(A) When prescribing benzodiazepines, opiates, opioids, opioid analgesics, or
 292 opioid derivatives to an adult patient for the first time, a prescriber shall not issue a
 293 prescription for more than a five-day supply of such controlled substance.

294 (B) Nothing in this paragraph shall limit a prescriber who, in his or her professional
 295 medical judgment, determines that more than a five-day supply of benzodiazepines,
 296 opiates, opioids, opioid analgesics, or opioid derivatives is medically necessary for
 297 palliative care or to treat a patient's acute medical condition, chronic pain, or pain
 298 associated with a cancer diagnosis. Such condition shall be documented in the patient's
 299 medical record and the prescriber shall indicate that an alternative to such controlled
 300 substance was not appropriate to treat such medical condition.

301 (C) Nothing in this paragraph shall apply to controlled substances specifically
 302 designated for treatment of abuse of or dependence on a Schedule II, III, IV, or V
 303 controlled substance.

304 (b) A dispenser or prescriber acting in good faith shall not be held civilly liable for
 305 damages to any person in any civil or administrative action or criminally responsible for
 306 injury, death, or loss to person or property for receiving or using information from the
 307 electronic data base established pursuant to Code Section 16-13-57."

308

309

PART III

310

SECTION 3-1.

311 Code Section 31-12-2 of the Official Code of Georgia Annotated, relating to reporting
 312 disease, confidentiality, reporting required by pharmacists, immunity from liability as to
 313 information supplied, and notification of potential bioterrorism, is amended by adding a new
 314 subsection to read as follows:

315 "(a.1)(1) As used in this subsection, the term 'neonatal abstinence syndrome' means a
 316 group of physical problems that occur in a newborn infant who was exposed to addictive
 317 illegal or prescription drugs while in the mother's womb.

318 (2) The department shall require notice and reporting of incidents of neonatal abstinence
 319 syndrome. The department shall require the reporting thereof to the department from a
 320 health care provider, coroner, or medical examiner, or any other person or entity the
 321 department determines has knowledge of diagnosis or health outcomes related, directly
 322 or indirectly, to neonatal abstinence syndrome. The department shall provide an annual
 323 report to the President of the Senate, the Speaker of the House of Representatives, the
 324 chairperson of the House Committee on Health and Human Services, and the chairperson
 325 of the Senate Health and Human Services Committee. Such annual report shall include

326 any department findings and recommendations on how to reduce the number of infants
327 born with neonatal abstinence syndrome."

328 **PART IV.**
329 **SECTION 4-1.**

330 Chapter 5 of Title 26 of the Official Code of Georgia Annotated, relating to drug abuse
331 treatment and education programs, is amended by adding new Code sections to read as
332 follows:

333 "26-5-22.

334 The authorized department shall conduct an annual onsite inspection of each narcotic
335 treatment program licensed in this state. Such inspection shall include, but not be limited
336 to, the premises, staff, persons in care, and documents pertinent to the continued licensing
337 of such narcotic treatment program so that the department may determine whether a
338 provider is operating in compliance with licensing requirements.

339 26-5-23.

340 The Department of Community Health and the Department of Behavioral Health and
341 Developmental Disabilities shall publish an annual report using data from the department's
342 central registry data base on the number of patients in enrolled treatment, the number of
343 patients discharged from treatment, patients' state of residence, and other information
344 determined by the departments. Such published report shall exclude patient identifying
345 information and be compliant with state and federal laws."

346 **PART V.**
347 **SECTION 5-1.**

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