

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2019

S

1

SENATE BILL 546

Short Title: Opioid Epidemic Response Act. (Public)

Sponsors: Senator J. Davis (Primary Sponsor).

Referred to: Rules and Operations of the Senate

April 3, 2019

A BILL TO BE ENTITLED

AN ACT REMOVING THE REQUIREMENT THAT BUPRENORPHINE PRESCRIBERS REGISTER WITH THE STATE, IN ADDITION TO REGISTERING WITH THE FEDERAL GOVERNMENT; DECRIMINALIZING THE USE OF DRUG TESTING EQUIPMENT TO DETECT CONTAMINANTS; BROADENING THE OBJECTIVES OF SYRINGE EXCHANGE PROGRAMS TO ENCOMPASS REDUCING THE NUMBER OF DRUG OVERDOSES IN THE STATE AND REMOVING THE BAN ON THE USE OF STATE FUNDS TO PURCHASE CERTAIN SUPPLIES; ADDING REPORTING REQUIREMENTS FOR GABAPENTIN AND NALOXONE HYDROCHLORIDE TO THE CONTROLLED SUBSTANCES REPORTING SYSTEM; REQUIRING PRESCRIBERS TO CHECK THE CONTROLLED SUBSTANCES REPORTING SYSTEM WHEN PRESCRIBING BENZODIAZEPINES; CLARIFYING THE ROLE OF THE STATE OPIOID TREATMENT AUTHORITY; ESTABLISHING A STATE OPIOID TREATMENT AUTHORITY FUND; AND ESTABLISHING AN OPIOID TREATMENT PROGRAM CENTRAL REGISTRY FEE.

The General Assembly of North Carolina enacts:

PART I. ELIMINATION OF STATE REGISTRATION REQUIREMENT FOR BUPRENORPHINE PRESCRIBERS

SECTION 1.1. G.S. 90-101(a1) is repealed.

PART II. DECRIMINALIZATION OF DRUG TESTING EQUIPMENT USED TO DETECT CONTAMINANTS IN CONTROLLED SUBSTANCES

SECTION 2.1. G.S. 90-113.22 is amended by adding a new subsection to read:

"(d) Notwithstanding the provisions of subsection (a) of this section, it is not unlawful for (i) a person who introduces a controlled substance into his or her body, or intends to introduce a controlled substance into his or her body, to knowingly use, or to possess with intent to use, testing equipment for identifying or analyzing the strength, effectiveness, or purity of that controlled substance; or (ii) a governmental or nongovernmental organization that promotes scientifically proven ways of mitigating health risks associated with drug use and other high-risk behaviors to possess such testing equipment or distribute such testing equipment to a person who intends to introduce a controlled substance into his or her body."

SECTION 2.2. G.S. 90-113.22A is amended by adding a new subsection to read:

"(c) Notwithstanding the provisions of subsection (a) of this section, it is not unlawful for (i) a person who introduces a controlled substance into his or her body, or intends to introduce a controlled substance into his or her body, to knowingly use, or to possess with intent to use,



1 testing equipment for identifying or analyzing the strength, effectiveness, or purity of that
 2 controlled substance; or (ii) a governmental or nongovernmental organization that promotes
 3 scientifically proven ways of mitigating health risks associated with drug use and other high-risk
 4 behaviors to possess such testing equipment or distribute such testing equipment to a person who
 5 intends to introduce a controlled substance into his or her body."
 6

7 **PART III. BROADENING THE OBJECTIVES OF SYRINGE EXCHANGE**
 8 **PROGRAMS TO ENCOMPASS REDUCING THE NUMBER OF DRUG OVERDOSES**
 9 **IN THE STATE AND REMOVING THE BAN ON THE USE OF STATE FUNDS TO**
 10 **PURCHASE CERTAIN SUPPLIES.**

11 **SECTION 3.1.** G.S. 90-113.27 reads as rewritten:

12 **"§ 90-113.27. Needle and hypodermic syringe exchange programs authorized; limited**
 13 **immunity.**

14 (a) Any governmental or nongovernmental organization, including a local or district
 15 health department or an organization that promotes scientifically proven ways of mitigating
 16 health risks associated with drug use and other high-risk behaviors, may establish and operate a
 17 needle and hypodermic syringe exchange program. The objectives of the program shall be to do
 18 all of the following:

- 19 (1) Reduce the spread of HIV, AIDS, viral hepatitis, and other bloodborne
 20 diseases in this State.
 21 (2) Reduce needle stick injuries to law enforcement officers and other emergency
 22 personnel.
 23 (3) Encourage individuals who ~~inject~~ use drugs illicitly to enroll in
 24 evidence-based treatment.
 25 (4) Reduce the number of drug overdoses in this State.

26 (b) Programs established pursuant to this section shall offer all of the following:

- 27 ...
 28 (2) Needles, hypodermic syringes, and other injection supplies at no cost and in
 29 quantities sufficient to ensure that needles, hypodermic syringes, and other
 30 injection supplies are not shared or reused. ~~No State funds may be used to~~
 31 ~~purchase needles, hypodermic syringes, or other injection supplies.~~

32"

33
 34 **PART IV. REVISIONS TO THE CONTROLLED SUBSTANCES REPORTING**
 35 **SYSTEM**

36 **SECTION 4.1.** G.S. 90-113.72 reads as rewritten:

37 **"§ 90-113.72. Definitions.**

38 The following definitions apply in this Article:

- 39 (1) Benzodiazepine. – A psychoactive drug whose core chemical structure is the
 40 fusion of a benzene ring and a diazepine ring and works on the central nervous
 41 system, acting selectively on gamma-aminobutyric acid type A receptors in
 42 the brain.

- 43 ~~(4)~~(1a) Commission. – The Commission for Mental Health, Developmental
 44 Disabilities, and Substance Abuse Services established under Part 4 of Article
 45 3 of Chapter 143B of the General Statutes.

46"

47 **SECTION 4.2.** G.S. 90-113.73(a) reads as rewritten:

48 **"§ 90-113.73. Requirements for controlled substances reporting system; civil penalties for**
 49 **failure to properly report.**

50 (a) The Department shall establish and maintain a reporting system of prescriptions for
 51 all Schedule II through V controlled ~~substanees.~~ substances, and for gabapentin and naloxone

1 hydrochloride. Each dispenser shall submit the information in accordance with transmission
2 methods and frequency established by rule by the Commission. The Department may issue a
3 waiver to a dispenser who is unable to submit prescription information by electronic means. The
4 waiver may permit the dispenser to submit prescription information by paper form or other
5 means, provided all information required of electronically submitted data is submitted. The
6 dispenser shall report the information required under this section no later than the close of the
7 next business day after the prescription is delivered; however, dispensers are encouraged to report
8 the information no later than 24 hours after the prescription was delivered. The information shall
9 be submitted in a format as determined annually by the Department based on the format used in
10 the majority of the states operating a controlled substances reporting system. In the event the
11 dispenser is unable to report the information within the time frame required by this section
12 because the system is not operational or there is some other temporary electrical or technological
13 failure, this inability shall be documented in the dispenser's records. Once the electrical or
14 technological failure has been resolved, the dispenser shall promptly report the information."

15 **SECTION 4.3.** G.S. 90-113.74C reads as rewritten:

16 "**§ 90-113.74C. Practitioner use of controlled substances reporting system; mandatory**
17 **reporting of violations.**

18 (a) Prior to initially prescribing a targeted controlled substance or a benzodiazepine to a
19 patient, a practitioner shall review the information in the controlled substances reporting system
20 pertaining to the patient for the 12-month period preceding the initial prescription. For every
21 subsequent three-month period that the targeted controlled substance or a benzodiazepine
22 remains a part of the patient's medical care, the practitioner shall review the information in the
23 controlled substances reporting system pertaining to the patient for the 12-month period
24 preceding the determination that the targeted controlled substance or a benzodiazepine should
25 remain a part of the patient's medical care. Each instance in which the practitioner reviews the
26 information in the controlled substances reporting system pertaining to the patient shall be
27 documented in the patient's medical record. In the event the practitioner is unable to review the
28 information in the controlled substances reporting system pertaining to the patient because the
29 system is not operational or there is some other temporary electrical or technological failure, this
30 inability shall be documented in the patient's medical record. Once the electrical or technological
31 failure has been resolved, the practitioner shall review the information in the controlled
32 substances reporting system pertaining to the patient and the review shall be documented in the
33 patient's medical record.

34 (b) A practitioner may, but is not required to, review the information in the controlled
35 substances reporting system pertaining to a patient prior to prescribing a targeted controlled
36 substance or a benzodiazepine to the patient in any of the following circumstances:

- 37 (1) The controlled substance is to be administered to a patient in a health care
38 setting, hospital, nursing home, outpatient dialysis facility, or residential care
39 facility, as defined in G.S. 14-32.2.
- 40 (2) The controlled substance is prescribed for the treatment of cancer or another
41 condition associated with cancer.
- 42 (3) The controlled substance is prescribed to a patient in hospice care or palliative
43 care.

44"

45
46 **PART V. CLARIFICATION OF THE ROLE OF THE STATE OPIOID TREATMENT**
47 **AUTHORITY; ESTABLISHMENT OF A STATE OPIOID TREATMENT AUTHORITY**
48 **FUND; AND ESTABLISHMENT OF AN OPIOID TREATMENT PROGRAM**
49 **CENTRAL REGISTRY FEE**

50 **SECTION 5.1.** G.S. 122C-3, as amended by Section 1 of S.L. 2018-33, reads as
51 rewritten:

1 **"§ 122C-3. Definitions.**

2 ...

3 (25a) "Opioid treatment program" means a program or practitioner with a current
4 and valid registration under 21 U.S.C. § 823(g)(1) that is engaged in
5 dispensing opioid agonist medication for the treatment of individuals with
6 opioid use disorders.

7 (25b) "Opioid Treatment Program Central Registry" or "Central Registry" means
8 the computerized patient database maintained by the State Opioid Treatment
9 Authority to obtain patient identifying information from participating opioid
10 treatment programs for the purposes of (i) allowing opioid treatment programs
11 to avoid an individual's concurrent enrollment in more than one opioid
12 treatment program and (ii) to provide a continuum of care.

13 ...

14 (35c) "State Opioid Treatment Authority" or "SOTA" means the section of the
15 Division of Mental Health, Developmental Disabilities, and Substance Abuse
16 Services that exercises the responsibility and authority within North Carolina
17 for governing the treatment of opioid use disorder with an opioid drug.

18 (35d) "State" or "Local" Consumer Advocate means the individual carrying out the
19 duties of the State or Local Consumer Advocacy Program Office in
20 accordance with Article 1A of this Chapter.

21 ~~(35d)~~(35e) "State Plan" means the State Plan for Mental Health, Developmental
22 Disabilities, and Substance Abuse Services.

23 ~~(35e)~~(35f) "State resources" means State and federal funds and other receipts
24 administered by the Division.

25"

26 **SECTION 5.2.** Chapter 122C of the General Statutes is amended by adding a new
27 Article to read:

28 "Article 2A.

29 "State Opioid Treatment Authority.

30 **"§ 122C-50. Approval of opioid treatment programs.**

31 (a) Prospective opioid treatment programs shall apply for and obtain approval by the
32 State Opioid Treatment Authority prior to seeking licensure by the Division of Health Service
33 Regulation.

34 (b) The State Opioid Treatment Authority shall approve or deny applications by
35 prospective opioid treatment programs based upon consideration of all the following criteria and
36 any rules adopted by the Commission regarding opioid treatment programs:

37 (1) Capacity of the applicant to provide treatment in compliance with applicable
38 federal and State laws, regulations, and accepted clinical standards of practice.

39 (2) Whether the applicant has prior experience operating an opioid treatment
40 program.

41 (3) History of adverse regulatory actions against the applicant while employed
42 by, or as a result of, ownership of an opioid treatment program in North
43 Carolina or another state.

44 (4) Written monitoring reports, compliance reports, or incident reports
45 concerning other opioid treatment programs operated by the applicant or by
46 an owner, principal, or affiliate of the applicant, issued within the five-year
47 period preceding the date of the application, whether in North Carolina or in
48 another state.

49 (5) History of suspension or revocation of, or public action against, professional
50 licenses or narcotic licenses of persons proposed to be employed by the

1 applicant's proposed opioid treatment program or of the proposed sponsor of
2 the opioid treatment program, whether in North Carolina or in another state.

3 (6) The submission of false or misleading information as part of an application
4 for approval.

5 (7) Whether the applicant's proposed opioid treatment program plans to accept
6 health insurance, including health insurance provided by the State or federal
7 government.

8 (8) How the applicant's proposed opioid treatment program would increase access
9 to treatment in underserved regions.

10 (c) A prospective opioid treatment program may contest a denial of its application by the
11 State Opioid Treatment Authority by commencing a contested case under Article 3 of Chapter
12 150B of the General Statutes. In contesting the application denial, the prospective opioid
13 treatment program must file a petition for a contested case within 20 days after the date the State
14 Opioid Treatment Authority mails notice of the denial to the applicant.

15 **"§ 122C-50.1. Rules.**

16 (a) Using updated and nonstigmatizing language and terminology regarding opioid use
17 disorder treatment, the Commission shall adopt or amend rules, as necessary, establishing
18 standards for (i) the State Opioid Treatment Authority's review, approval, and denial of
19 prospective opioid treatment programs and (ii) the licensure and operation of SOTA-approved
20 opioid treatment programs. The rules shall address all of the following in order to improve the
21 quality of, and access to, care in opioid treatment programs:

22 (1) Minimum requirements for staff positions, staffing ratios, and staff training.

23 (2) Minimum operating hours.

24 (3) Counseling requirements.

25 (4) Minimum requirements for admissions processes, procedures to prevent
26 diversion of medication, and use of the Controlled Substances Reporting
27 System and the Central Registry.

28 (5) Requirements for physical plant.

29 (6) Requirements for the provision of take-home medications.

30 (7) Site visits by the State Opioid Treatment Authority.

31 (8) Creation of a system for the approval of medication units and requirements
32 for the operation of medication units.

33 (9) Other changes in the interest of health and safety, as determined by the
34 Commission.

35 (b) The Commission is exempt from the requirements of G.S. 150B-21.4 with respect to
36 the rules adopted under this section.

37 **"§ 122C-50.2. State Opioid Treatment Authority Fund.**

38 (a) The State Opioid Treatment Authority Fund is established within the Department as
39 an interest-bearing special revenue fund. The Department shall administer the SOTA Fund. The
40 Department shall not use moneys in the Fund for any purpose other than to offset the cost of
41 operating the Opioid Treatment Program Central Registry. The SOTA Fund shall be used to
42 supplement and not supplant or replace existing State and local funding available for these
43 purposes.

44 (b) The Fund shall consist of the following:

45 (1) All fees collected by the Department for the Opioid Treatment Program
46 Central Registry pursuant to G.S. 122C-50.3.

47 (2) Any moneys appropriated to the SOTA Fund by the General Assembly.

48 (3) Any money received from State, federal, private, or other sources for deposit
49 into the SOTA Fund.

1 (c) All interest that accrues to the SOTA Fund shall be credited to the Fund. Any balance
2 remaining in the SOTA Fund at the end of any fiscal year shall remain in the Fund and shall not
3 revert to the General Fund.

4 **"§ 122C-50.3. Opioid Treatment Program Central Registry; annual fee.**

5 (a) The State Opioid Treatment Authority shall require the participation of all opioid
6 treatment programs in the Opioid Treatment Program Central Registry. Opioid treatment
7 programs shall submit data to the Central Registry as directed by the State Opioid Treatment
8 Authority.

9 (b) Beginning January 1, 2020, the Department shall charge each opioid treatment
10 program an annual fee in the amount of one thousand six hundred dollars (\$1,600) for
11 participation in the Central Registry. One hundred percent (100%) of each fee collected pursuant
12 to this subsection shall be credited to the State Opioid Treatment Authority Fund established in
13 G.S. 122C-50.2, to be used to offset the cost of operating the Opioid Treatment Program Central
14 Registry. The Commission may by rule, and in consultation with the Secretary, increase this fee
15 by no more than the amount necessary to offset the cost of operating the Central Registry.

16 (c) The fee authorized by this section is due and payable by an opioid treatment program
17 within seven days after the program is granted final certification by the federal Substance Abuse
18 and Mental Health Services Administration to begin operating as an opioid treatment program.
19 The Department shall prorate the amount of this fee on a calendar year basis during the first year
20 an opioid treatment program participates in the Central Registry."

21 **SECTION 5.3.** By May 1, 2020, the Commission for Mental Health, Developmental
22 Disabilities, and Substance Abuse Services shall amend or adopt rules to address the areas
23 prescribed by G.S. 122C-50.1, as enacted by this act.
24

25 **PART VI. EFFECTIVE DATE**

26 **SECTION 6.1.(a)** Sections 4.1 and 4.3 of this act are effective 30 days after the date
27 the State Chief Information Officer notifies the Revisor of Statutes that (i) the upgrades to the
28 Controlled Substances Reporting System (CSRS) database described in subdivisions (1) and (2)
29 of subsection (a) of Section 12F.7 of S.L. 2016-94 have been completed and (ii) the upgraded
30 CSRS database is fully operational within the Department of Information Technology and
31 connected to the statewide health information exchange.

32 **SECTION 6.1.(b)** Section 4.2 of this act becomes effective January 1, 2020.

33 **SECTION 6.1.(c)** G.S. 122C-50.2, as enacted by Section 5.2 of this act, becomes
34 effective July 1, 2019.

35 **SECTION 6.1.(d)** The remainder of this act is effective when it becomes law.