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SENATE DRS75125-LHz-80C* (02/14)

Short Title: Revise Controlled Substances Reporting. (Public)

Sponsors: Senators Allran and Bingham (Primary Sponsors).

Referred to:

1 A BILL TO BE ENTITLED
2 AN ACT TO REVISE THE NORTH CAROLINA CONTROLLED SUBSTANCES
3 REPORTING SYSTEM ACT, AS RECOMMENDED BY THE CHILD FATALITY
4 TASK FORCE.

5 The General Assembly of North Carolina enacts:

6 SECTION 1. G.S. 90-113.72 reads as rewritten:

7 "§ 90-113.72. Definitions.

8 The following definitions apply in this Article:

- 9 (1) "Commission" means the Commission for Mental Health, Developmental
10 Disabilities, and Substance Abuse Services established under Part 4 of
11 Article 3 of Chapter 143B of the General Statutes.
12 (2) "Controlled substance" means a controlled substance as defined in
13 G.S. 90-87(5).
14 (3) "Department" means the Department of Health and Human Services.
15 (4) "Dispenser" means a person who delivers a Schedule II through V controlled
16 substance to an ultimate user in North Carolina, but does not include any of
17 the following:
18 a. A licensed hospital or long-term care pharmacy that dispenses such
19 substances for the purpose of inpatient administration.
20 b. ~~A person authorized to administer such a substance pursuant to~~
21 ~~Chapter 90 of the General Statutes.~~
22 c. A wholesale distributor of a Schedule II through V controlled
23 substance.
24 d. A person licensed to practice veterinary medicine pursuant to Article
25 11 of Chapter 90 of the General Statutes.
26 (5) "Ultimate user" means a person who has lawfully obtained, and who
27 possesses, a Schedule II through V controlled substance for the person's own
28 use, for the use of a member of the person's household, or for the use of an
29 animal owned or controlled by the person or by a member of the person's
30 household."

31 SECTION 2. G.S. 90-113.73 reads as rewritten:

32 "§ 90-113.73. Requirements for controlled substances reporting system.

33 (a) The Department shall establish and maintain a reporting system of prescriptions for
34 all Schedule II through V controlled substances. Each dispenser shall submit the information in
35 accordance with transmission methods and frequency established by rule by the Commission.
36 The Department may issue a waiver to a dispenser that is unable to submit prescription



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1 information by electronic means. The waiver may permit the dispenser to submit prescription
2 information by paper form or other means, provided all information required of electronically
3 submitted data is submitted. The dispenser shall report the information required under this
4 section ~~on a monthly basis for the first 12 months of the Controlled Substances Reporting~~
5 ~~System's operation, and twice monthly thereafter, until January 2, 2010, at which time~~
6 ~~dispensers shall report no later than seven days~~ no later than 24 hours after the prescription is
7 dispensed in a format as determined annually by the Department based on the format used in
8 the majority of the states operating a controlled substances reporting system.

9 (b) The Commission shall adopt rules requiring dispensers to report the following
10 information. The Commission may modify these requirements as necessary to carry out the
11 purposes of this Article. The dispenser shall report:

- 12 (1) The dispenser's DEA number.
- 13 (2) The name of the patient for whom the controlled substance is being
14 dispensed, and the patient's:
 - 15 a. Full address, including city, state, and zip code,
 - 16 b. Telephone number, and
 - 17 c. Date of birth.
- 18 (3) The date the prescription was written.
- 19 (4) The date the prescription was filled.
- 20 (5) The prescription number.
- 21 (6) Whether the prescription is new or a refill.
- 22 (7) Metric quantity of the dispensed drug.
- 23 (8) Estimated days of supply of dispensed drug, if provided to the dispenser.
- 24 (9) National Drug Code of dispensed drug.
- 25 (10) Prescriber's DEA number.
- 26 (11) Method of payment for the prescription.
- 27 (12) Specialty of practitioner, if known.
- 28 (13) Documentation of photographic identification presented by the person
29 seeking dispensation of the prescription, when such documentation is
30 required by G.S. 90-106.1.

31 (c) A dispenser shall not be required to report instances in which a controlled substance
32 is provided directly to the ultimate user and the quantity provided does not exceed a 48-hour
33 supply."

34 **SECTION 3.** G.S. 90-113.74 reads as rewritten:

35 "**§ 90-113.74. Confidentiality.**

36 (a) Prescription information submitted to the Department is privileged and confidential,
37 is not a public record pursuant to G.S. 132-1, is not subject to subpoena or discovery or any
38 other use in civil proceedings, and except as otherwise provided below may only be used for
39 investigative or evidentiary purposes related to violations of State or federal law and regulatory
40 activities. Except as otherwise provided by this section, prescription information shall not be
41 disclosed or disseminated to any person or entity by any person or entity authorized to review
42 prescription information.

43 (b) The Department may use prescription information data in the controlled substances
44 reporting system only for purposes of implementing this Article in accordance with its
45 provisions.

46 (b1) The Department may review the prescription information data in the controlled
47 substances reporting system in order to:

- 48 (1) Identify information that may indicate a person is obtaining prescriptions for
49 controlled substances in a manner that may represent abuse, diversion of
50 controlled substances, or an increased risk of harm to the patient. When such

1 information is identified, the Department may notify the practitioners who
2 prescribed or dispensed the controlled substances.

3 (2) Identify information that may indicate a breach of professional standards by
4 a practitioner who prescribes or dispenses controlled substances. When such
5 information is identified, the Department may notify the agency responsible
6 for licensing, registering, or certifying the practitioner.

7 (b2) The Commission, in consultation with a panel of medical experts, shall develop
8 criteria that shall be used to evaluate whether there is a breach of professional standards under
9 subdivision (2) of subsection (b1) of this section by a practitioner who prescribes or dispenses
10 controlled substances.

11 (c) The Department shall release data in the controlled substances reporting system to
12 the following persons only:

13 (1) Persons authorized to prescribe or dispense controlled substances for the
14 purpose of providing medical or pharmaceutical care for their patients. A
15 person authorized to receive data pursuant to this paragraph may delegate
16 the authority to receive the data to other persons working under his or her
17 direction and supervision, provided the Department approves the delegation.

18 (2) An individual who requests the individual's own controlled substances
19 reporting system information.

20 (3) Special agents of the North Carolina State Bureau of Investigation who are
21 assigned to the Diversion & Environmental Crimes Unit and whose primary
22 duties involve the investigation of diversion and illegal use of prescription
23 medication and who are engaged in a bona fide specific investigation related
24 to enforcement of laws governing licit drugs. The SBI shall notify the Office
25 of the Attorney General of North Carolina of each request for inspection of
26 records maintained by the Department.

27 (4) Primary monitoring authorities for other states pursuant to a specific ongoing
28 investigation involving a designated person, if information concerns the
29 dispensing of a Schedule II through V controlled substance to an ultimate
30 user who resides in the other state or the dispensing of a Schedule II through
31 V controlled substance prescribed by a licensed health care practitioner
32 whose principal place of business is located in the other state.

33 (5) To a court pursuant to a lawful court order in a criminal action.

34 (6) The Division of Medical Assistance for purposes of administering the State
35 Medical Assistance Plan.

36 (7) Licensing boards with jurisdiction over health care disciplines pursuant to an
37 ongoing investigation by the licensing board of a specific individual licensed
38 by the board.

39 (8) Any county medical examiner appointed by the Chief Medical Examiner
40 pursuant to G.S. 130A-382 and the Chief Medical Examiner, for the purpose
41 of investigating the death of an individual.

42 (d) The Department may provide data to public or private entities for statistical,
43 research, or educational purposes only after removing information that could be used to identify
44 individual patients who received prescription medications from dispensers.

45 (e) In the event that the Department finds patterns of prescribing medications that are
46 unusual, the Department shall inform the Attorney General's Office of its findings. The Office
47 of the Attorney General shall review the Department's findings to determine if the findings
48 should be reported to the SBI for investigation of possible violations of State or federal law
49 relating to controlled substances.

50 (f) The Department shall purge from the controlled substances reporting system
51 database all information more than six years old.

1 (g) Nothing in this Article shall prohibit a person authorized to prescribe or dispense
2 controlled substances pursuant to Article 1 of Chapter 90 of the General Statutes from
3 disclosing or disseminating data regarding a particular patient obtained under subsection (c) of
4 this section to another person (i) authorized to prescribe or dispense controlled substances
5 pursuant to Article 1 of Chapter 90 of the General Statutes and (ii) authorized to receive the
6 same data from the Department under subsection (c) of this section.

7 (h) Nothing in this Article shall prevent persons licensed or approved to practice
8 medicine or perform medical acts, tasks, and functions pursuant to Article 1 of Chapter 90 of
9 the General Statutes from retaining data received pursuant to subsection (c) of this section in a
10 patient's confidential health care record."

11 **SECTION 4.** G.S. 90-113.75 reads as rewritten:

12 "**§ 90-113.75. Civil penalties; other remedies; immunity from liability.**

13 (a) A person who intentionally, knowingly, or negligently releases, obtains, or attempts
14 to obtain information from the system in violation of a provision of this ~~section~~ Article or a rule
15 adopted pursuant to this ~~section~~ Article shall be assessed a civil penalty by the Department not
16 to exceed ~~five thousand dollars (\$5,000)~~ ten thousand dollars (\$10,000) per violation. The clear
17 proceeds of penalties assessed under this section shall be deposited to the Civil Penalty and
18 Forfeiture Fund in accordance with Article 31A of Chapter 115C of the General Statutes. The
19 Commission shall adopt rules establishing the factors to be considered in determining the
20 amount of the penalty to be assessed.

21 (b) In addition to any other remedies available at law, an individual whose prescription
22 information has been disclosed in violation of this ~~section~~ Article or a rule adopted pursuant to
23 this Article may bring an action against any person or entity who has intentionally, knowingly,
24 or negligently released confidential information or records concerning the individual for either
25 or both of the following:

26 (1) Nominal damages of one thousand dollars (\$1,000). In order to recover
27 damages under this subdivision, it shall not be necessary that the plaintiff
28 suffered or was threatened with actual damages.

29 (2) The amount of actual damages, if any, sustained by the individual.

30 (c) A health care provider licensed, or an entity permitted under this Chapter that, in
31 good faith, makes a report or transmits data required or allowed by this Article is immune from
32 civil or criminal liability that might otherwise be incurred or imposed as a result of making the
33 report or transmitting the data."

34 **SECTION 5.** G.S. 90-5.2 is amended by adding a new subsection to read:

35 "(a1) The Board shall make e-mail addresses and facsimile numbers reported pursuant to
36 G.S. 90-5.2(a)(7) available to the Department of Health and Human Services for use in the
37 North Carolina Controlled Substance Reporting System established by Article 5E of this
38 Chapter."

39 **SECTION 6.** This act is effective when it becomes law.