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HOUSE BILL 173
Committee Substitute Favorable 4/11/13
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Short Title: Revise Controlled Substances Reporting.

(Public)

Sponsors:

Referred to:

February 28, 2013

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.



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1 The Department may issue a waiver to a dispenser ~~that~~ who is unable to submit prescription
2 information by electronic means. The waiver may permit the dispenser to submit prescription
3 information by paper form or other means, provided all information required of electronically
4 submitted data is submitted. The dispenser shall report the information required under this
5 section ~~on a monthly basis for the first 12 months of the Controlled Substances Reporting~~
6 ~~System's operation, and twice monthly thereafter, until January 2, 2010, at which time~~
7 ~~dispensers shall report no later than seven days~~ no later than the close of business three
8 business days after the day when the prescription is dispensed ~~was delivered~~, beginning the next
9 day after the delivery date; however, dispensers are encouraged to report the information no
10 later than 24 hours after the prescription was delivered. The information shall be submitted in a
11 format as determined annually by the Department based on the format used in the majority of
12 the states operating a controlled substances reporting system.

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

- 16 (1) The dispenser's DEA number.
- 17 (2) The name of the patient for whom the controlled substance is being
18 dispensed, and the patient's:
 - 19 a. Full address, including city, state, and zip code,
 - 20 b. Telephone number, and
 - 21 c. Date of birth.
- 22 (3) The date the prescription was written.
- 23 (4) The date the prescription was filled.
- 24 (5) The prescription number.
- 25 (6) Whether the prescription is new or a refill.
- 26 (7) Metric quantity of the dispensed drug.
- 27 (8) Estimated days of supply of dispensed drug, if provided to the dispenser.
- 28 (9) National Drug Code of dispensed drug.
- 29 (10) Prescriber's DEA number.
- 30 (11) Method of payment for the prescription.

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 and upon review may:

- 48 (1) Notify practitioners that a patient may have obtained 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.

1 (2) Report information regarding the prescribing practices of a practitioner to
2 the agency responsible for licensing, registering, or certifying the
3 practitioner, pursuant to rules adopted by the agency as set forth below in
4 subsection (b2) of this section.

5 (b2) In order to receive a report pursuant to subdivision (2) of subsection (b1) of this
6 section, an agency responsible for licensing, registering, or certifying a practitioner with
7 prescriptive or dispensing authority shall adopt rules setting the criteria by which the
8 Department may report the information to the agency. The criteria for reporting established by
9 rule shall not establish the standard of care for prescribing or dispensing, and it shall not be a
10 basis for disciplinary action by an agency that the Department reported a practitioner to an
11 agency based on the criteria.

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

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

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

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

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

34 (5) To a court sheriff or designated deputy sheriff or a police chief or a
35 designated police investigator who is assigned to investigate the diversion
36 and illegal use of prescription medication or pharmaceutical products
37 identified in Article 5 of this Chapter of the General Statutes as Schedule II
38 through V controlled substances and who is engaged in a bona fide specific
39 investigation related to the enforcement of laws governing licit drugs
40 pursuant to a lawful court order in a criminal action specifically issued for
41 that purpose.

42 (6) The Division of Medical Assistance for purposes of administering the State
43 Medical Assistance Plan.

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

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

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

4 (e) In the event that the Department finds patterns of prescribing medications that are
5 unusual, the Department shall inform the Attorney General's Office of its findings. The Office
6 of the Attorney General shall review the Department's findings to determine if the findings
7 should be reported to the SBI and the appropriate sheriff for investigation of possible violations
8 of State or federal law relating to controlled substances.

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

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

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

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

22 "**§ 90-113.75. Civil penalties; other remedies; immunity from liability.**

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

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

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

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

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

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

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

49 **SECTION 6.** Sections 1 and 2 of this act become effective January 1, 2014, and
50 apply to prescriptions delivered on or after that date. The remainder of this act is effective when
51 it becomes law.