

**GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013**

**SENATE BILL 222
RATIFIED BILL**

AN ACT TO REVISE THE NORTH CAROLINA CONTROLLED SUBSTANCES REPORTING SYSTEM ACT, AS RECOMMENDED BY THE CHILD FATALITY TASK FORCE.

The General Assembly of North Carolina enacts:

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

"§ 90-113.72. Definitions.

The following definitions apply in this Article:

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

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

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

(a) The Department shall establish and maintain a reporting system of prescriptions for all Schedule II through V controlled substances. Each dispenser shall submit the information in accordance with transmission methods and frequency established by rule by the Commission. The Department may issue a waiver to a dispenser ~~that who~~ is unable to submit prescription information by electronic means. The waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required of electronically submitted data is submitted. The dispenser shall report the information required under this section ~~on a monthly basis for the first 12 months of the Controlled Substances Reporting System's operation, and twice monthly thereafter, until January 2, 2010, at which time dispensers shall report no later than seven days~~ no later than the close of business three business days after the day when the prescription is dispensed was delivered, beginning the next day after the delivery date; however, dispensers are encouraged to report the information no later than 24 hours after the prescription was delivered. The information shall be submitted in a format as determined annually by the Department based on the format used in the majority of the states operating a controlled substances reporting system.



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

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

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

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

"§ 90-113.74. Confidentiality.

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

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

(b1) The Department may review the prescription information data in the controlled substances reporting system and upon review may:

- (1) Notify practitioners that a patient may have obtained prescriptions for controlled substances in a manner that may represent abuse, diversion of controlled substances, or an increased risk of harm to the patient.
- (2) Report information regarding the prescribing practices of a practitioner to the agency responsible for licensing, registering, or certifying the practitioner pursuant to rules adopted by the agency as set forth below in subsection (b2) of this section.

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

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

- (1) Persons authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients. A person authorized to receive data pursuant to this paragraph may delegate the authority to receive the data to other persons working under his or her direction and supervision, provided the Department approves the delegation.
- (2) An individual who requests the individual's own controlled substances reporting system information.

- (3) Special agents of the North Carolina State Bureau of Investigation who are assigned to the Diversion & Environmental Crimes Unit and whose primary duties involve the investigation of diversion and illegal use of prescription ~~medication and medication.~~ SBI agents assigned to the Diversion & Environmental Crimes Unit may then provide this information to other SBI agents who are engaged in a bona fide specific investigation related to enforcement of laws governing licit drugs. The SBI shall notify the Office of the Attorney General of North Carolina of each request for inspection of records maintained by the Department.
- (4) Primary monitoring authorities for other states pursuant to a specific ongoing investigation involving a designated person, if information concerns the dispensing of a Schedule II through V controlled substance to an ultimate user who resides in the other state or the dispensing of a Schedule II through V controlled substance prescribed by a licensed health care practitioner whose principal place of business is located in the other state.
- (5) To a ~~court~~sheriff or designated deputy sheriff or a police chief or a designated police investigator who is assigned to investigate the diversion and illegal use of prescription medication or pharmaceutical products identified in Article 5 of this Chapter of the General Statutes as Schedule II through V controlled substances and who is engaged in a bona fide specific investigation related to the enforcement of laws governing licit drugs pursuant to a lawful court order ~~in a criminal action~~ specifically issued for that purpose.
- (6) The Division of Medical Assistance for purposes of administering the State Medical Assistance Plan.
- (7) Licensing boards with jurisdiction over health care disciplines pursuant to an ongoing investigation by the licensing board of a specific individual licensed by the board.
- (8) Any county medical examiner appointed by the Chief Medical Examiner pursuant to G.S. 130A-382 and the Chief Medical Examiner, for the purpose of investigating the death of an individual.

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

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

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

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

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

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

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

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

Commission shall adopt rules establishing the factors to be considered in determining the amount of the penalty to be assessed.

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

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

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

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

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

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

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

In the General Assembly read three times and ratified this the 13th day of June, 2013.

s/ Daniel J. Forest
President of the Senate

s/ Thom Tillis
Speaker of the House of Representatives

Pat McCrory
Governor

Approved _____, m. this _____ day of _____, 2013