

Article 5E.

North Carolina Controlled Substances Reporting System Act.

§ 90-113.70. Short title.

This Article shall be known and may be cited as the "North Carolina Controlled Substances Reporting System Act." (2005-276, s. 10.36(a).)

§ 90-113.71. Legislative findings and purpose.

- (a) The General Assembly makes the following findings:
- (1) North Carolina is experiencing an epidemic of poisoning deaths from unintentional drug overdoses.
 - (2) Since 1997, the number of deaths from unintentional drug overdoses has increased threefold, from 228 deaths in 1997 to 690 deaths in 2003.
 - (3) The number of unintentional deaths from illicit drugs in North Carolina has decreased since 1992 while unintentional deaths from licit drugs, primarily prescriptions, have increased.
 - (4) Licit drugs are now responsible for over half of the fatal unintentional poisonings in North Carolina.
 - (5) Over half of the prescription drugs associated with unintentional deaths are narcotics (opioids).
 - (6) Of these licit drugs, deaths from methadone, usually prescribed as an analgesic for severe pain, have increased sevenfold since 1997.
 - (7) Methadone from opioid treatment program clinics is a negligible source of the methadone that has contributed to the dramatic increase in unintentional methadone-related deaths in North Carolina.
 - (8) Review of the experience of the 19 states that have active controlled substances reporting systems clearly documents that implementation of these reporting systems do not create a "chilling" effect on prescribing.
 - (9) Review of data from controlled substances reporting systems help:
 - a. Support the legitimate medical use of controlled substances.
 - b. Identify and prevent diversion of prescribed controlled substances.
 - c. Reduce morbidity and mortality from unintentional drug overdoses.
 - d. Reduce the costs associated with the misuse and abuse of controlled substances.
 - e. Assist clinicians in identifying and referring for treatment patients misusing controlled substances.
 - f. Reduce the cost for law enforcement of investigating cases of diversion and misuse.
 - g. Inform the public, including health care professionals, of the use and abuse trends related to prescription drugs.

(b) This Article is intended to improve the State's ability to identify controlled substance abusers or misusers and refer them for treatment, and to identify and stop diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate medical utilization of licit controlled substances. (2005-276, s. 10.36(a).)

§ 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.
- (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. (2005-276, s. 10.36(a).)

§ 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 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 after the prescription is dispensed 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. (2005-276, s. 10.36(a); 2005-345, s. 17; 2009-438, s. 1.)

§ 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.

(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.
- (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 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 pursuant to a lawful court order in a criminal action.
- (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 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. (2005-276, s. 10.36(a); 2009-438, s. 2.)

§ 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 or a rule adopted pursuant to this section shall be assessed a civil penalty not to exceed five thousand dollars (\$5,000) 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.

(b) In addition to any other remedies available at law, an individual whose prescription information has been disclosed in violation of this section 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 entity permitted under this Chapter that, in good faith, makes a report or transmits data required 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. (2005-276, s. 10.36(a).)

§ 90-113.76. Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services to adopt rules.

The Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services shall adopt rules necessary to implement this Article. (2005-276, s. 10.36(a).)

§ 90-113.77. Reserved for future codification purposes.

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