

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. – 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. – A controlled substance as defined in G.S. 90-87(5).
- (3) Department. – The Department of Health and Human Services.
- (4) Dispenser. – 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. Repealed by Session Laws 2013-152, s. 1, effective January 1, 2014, and applicable to prescriptions delivered on or after that date.
  - 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.
- (4a) Pharmacy. – A person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A.
- (5) Ultimate user. – 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); 2013-152, s. 1; 2017-74, s. 9.)

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

(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 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 no later than the close of the next business day after the prescription is delivered; 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. In the event the dispenser is unable to report the information within the time frame required by this section because the system is not operational or there is some other temporary electrical or technological failure, this inability shall be documented in the dispenser's records. Once the electrical or technological failure has been resolved, the dispenser shall promptly report the information.

(b) **(Effective until March 1, 2024)** 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.
    - 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.
  - (10a) Prescriber's national provider identification number, for any prescriber that has a national provider identification number. A pharmacy shall not be subject to a civil penalty under subsection (e) of this section for failure to report the prescriber's national provider identification number when it is not received by the pharmacy.
  - (11) Method of payment for the prescription.
- (b) **(Effective March 1, 2024)** 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 for prescriptions of controlled substances, and for prescriptions of gabapentin, whether the dispenser has a 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.
    - 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) The metric quantity of the dispensed drug.
  - (8) The estimated days of supply of dispensed drug, if provided to the dispenser.
  - (9) The National Drug Code of dispensed drug.
  - (10) The prescriber's DEA number for prescriptions of controlled substances, and for prescriptions of gabapentin, if the prescriber has a DEA number and the number is known by the dispenser.
  - (10a) The prescriber's national provider identification number, for any prescriber that has a national provider identification number. A pharmacy shall not be subject to a civil penalty under subsection (e) of this section for failure to report the prescriber's national provider identification number when it is not received by the pharmacy.
  - (11) The method of payment for the prescription.

(c) **(Effective until March 1, 2024)** 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.

(c) **(Effective March 1, 2024)** A dispenser shall not be required to report instances in which a controlled substance, or gabapentin, is provided directly to the ultimate user and the quantity provided does not exceed a 48-hour supply.

(c1) **(Effective March 1, 2024)** A dispenser shall not be required to report gabapentin to the controlled substances reporting system when gabapentin is a component of a compounded prescription that is dispensed in dosages of 100 milligrams or less.

(d) A dispenser shall not be required to report instances in which a Schedule V non-narcotic, non-anorectic Schedule V controlled substance is provided directly to the ultimate user for the purpose of assessing a therapeutic response when prescribed according to indications approved by the United States Food and Drug Administration.

(e) The Department shall assess, against any pharmacy that employs dispensers found to have failed to report information in the manner required by this section within a reasonable period of time after being informed by the Department that the required information is missing or incomplete, a civil penalty of not more than one hundred dollars (\$100.00) for a first violation, two hundred fifty dollars (\$250.00) for a second violation, and five hundred dollars (\$500.00) for each subsequent violation if the pharmacy fails to report as required under this section, up to a maximum of five thousand dollars (\$5,000) per pharmacy per calendar year. Each day of a continuing violation shall constitute a separate violation. A pharmacy acting in good faith that attempts to report the information required by this section shall not be assessed any civil penalty. 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 to implement this subsection that include factors to be considered in determining the amount of the penalty to be assessed.

(f) **(Effective until March 1, 2025)** For purposes of this section, a "dispenser" includes a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes when that person dispenses any Schedule II through V controlled substances. Notwithstanding subsection (b) of this section, the Commission shall adopt rules requiring the information to be reported by a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.

(f) **(Effective March 1, 2025)** For purposes of this section, a "dispenser" includes a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes when that person dispenses any Schedule II through V controlled substance or gabapentin. Notwithstanding subsection (b) of this section, the Commission shall adopt rules requiring the information to be reported by a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes.

(g) Expired pursuant to Session Laws 2018-76, s. 10, effective October 1, 2019. (2005-276, s. 10.36(a); 2005-345, s. 17; 2009-438, s. 1; 2013-152, s. 2; 2014-115, s. 41.5; 2017-74, s. 10; 2018-44, s. 10; 2018-76, ss. 6, 10; 2023-65, ss. 11.1, 11.2, 11.2A, 11.3.)

#### **§ 90-113.73A. Expand monitoring capacity; report.**

(a) The North Carolina Controlled Substances Reporting System shall expand its monitoring capacity by establishing data use agreements with the Prescription Behavior

Surveillance System. In order to participate, the CSRS shall establish a data use agreement with the Center of Excellence at Brandeis University no later than January 1, 2016.

(b) Repealed by Session Laws 2020-78, s. 4B.1(a), effective July 1, 2020. (2015-241, s. 12F.16(j), (k); 2020-78, s. 4B.1(a).)

#### **§ 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 (i) for investigative or evidentiary purposes related to violations of State or federal law, (ii) for regulatory activities, or (iii) to inform medical records or clinical care. 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.
- (1a) Notify practitioners and their respective licensing boards of prescribing behavior that (i) increases risk of diversion of controlled substances, (ii) increases risk of harm to the patient, or (iii) is an outlier among other practitioner behavior.
- (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 this delegation.

The administrator of a hospital emergency department or hospital acute care facility shall provide the Department with a list of prescribers who are authorized to prescribe controlled substances for the purpose of providing medical care for patients of the hospital emergency department or hospital acute care facility and a list of delegates who are authorized to receive data on behalf

of the providers listed. The administrator acting under this paragraph shall submit the lists to the Department no later than December 1 of the calendar year preceding the year during which the delegates are to receive data and may provide updated lists at any time during the course of the year. Within one week of receiving the initial or updated lists described in this paragraph, the Department shall establish all of the delegate accounts necessary to enable each delegate listed by the administrator of the hospital emergency department or hospital acute care facility to receive data on behalf of the listed prescribers. Delegations made pursuant to this paragraph are valid during the calendar year for which submitted by the administrator.

- (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. 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 Attorney General of North Carolina, or a designee who is a full-time employee in the North Carolina Department of Justice, shall have access to the system to monitor requests for inspection of records.
- (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 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 specifically issued for that purpose.
- (5a) Local law enforcement officers pursuant to subsection (i) of this section.
- (6) The Division of Health Benefits 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.
- (9) The federal Drug Enforcement Administration's Office of Diversion Control or Tactical Diversion Squad in North Carolina.

(10) The North Carolina Health Information Exchange Authority (NC HIE Authority), established under Article 29B of this Chapter, through Web-service calls.

(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, on a quarterly basis, purge from the controlled substances reporting system database all information more than six years old. The Department shall maintain in a separate database all information purged from the controlled substances reporting system database pursuant to this subsection and may release data from that separate database only as provided in subsection (d) of this section.

(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.

(i) Data released by the Department from the controlled substances reporting system to local law enforcement officers is subject to all of the following conditions and requirements:

(1) The Department shall release data in the controlled substances reporting system to a local law enforcement officer only if all of the following conditions are satisfied:

- a. The local law enforcement officer is a certified diversion investigator.
- b. The agency that supervises the investigator is a qualified law enforcement agency.
- c. The request is reasonably related to a bona fide active investigation involving a specific violation of any State or federal law involving a controlled substance.
- d. The request has been reviewed and approved by the State Bureau of Investigation, Diversion & Environmental Crimes Unit.

(2) In the event a special agent of the State Bureau of Investigation, Diversion & Environmental Crimes Unit, takes action upon a request by a certified diversion investigator for access to data in the controlled substances reporting system, the special agent shall not incur criminal or civil liability for such action or for actions taken by the certified diversion investigator making the request.

(3) The conditions outlined in this subsection shall create an audit trail that may be used to investigate or prosecute violations of this section. The Department shall

grant access to the system to the Attorney General of North Carolina or a designee and Special Agents of the State Bureau of Investigation who are assigned to the Diversion & Environmental Crimes Unit for the purpose of reviewing the audit trail. The State Bureau of Investigation shall conduct periodic audits of a random sample of requests from certified diversion investigators for access to data in the controlled substances reporting system.

- (4) Data obtained by certified diversion investigators from the controlled substances reporting system in the manner prescribed by this subsection may be shared with other law enforcement personnel or prosecutorial officials (i) only upon the direction of the certified diversion investigator who originally requested the information and (ii) in the case of law enforcement personnel from other law enforcement agencies, only with law enforcement personnel who are directly participating in an official joint investigation or as provided in subdivision (5) of this subsection.
- (5) In the event the data provided to the local law enforcement officer indicates transactions solely outside of that local law enforcement officer's jurisdiction, the matter shall be referred to the State Bureau of Investigation, Diversion & Environmental Crimes Unit, or to a certified diversion investigator employed by a qualified law enforcement agency with jurisdiction over the transactions at issue.
- (6) Certified diversion investigators may not request or receive prescription data from other states through PMP Interconnect or any other mechanism established by the Department to facilitate interstate connectivity of the controlled substances reporting system.
- (7) As used in this subsection, the following terms have the following meanings:
  - a. Bona fide active investigation. – An investigation of one or more specific persons conducted with a reasonable, good-faith belief based on specific facts and circumstances equivalent to those normally necessary for the issuance of a court order, as described in G.S. 90-113.74(c)(5).
  - a1. Certified diversion investigator. – An officer affiliated with a qualified law enforcement agency who is certified as a diversion investigator by either the North Carolina Sheriffs' Education and Training Standards Commission or the North Carolina Criminal Justice Education and Training Standards Commission. If for any reason a certified diversion investigator leaves a position involving diversion investigation, the qualified law enforcement agency shall notify the North Carolina Department of Health and Human Services Controlled Substance Reporting System and the State Bureau of Investigation, Diversion & Environmental Crimes Unit, within 72 hours after the effective date of the change.
  - b. Certified diversion supervisor. – The head of a municipal police department, a county police department, a sheriff's office, or the designee of the agency head with supervisory authority over that agency's diversion investigators who is certified as a diversion supervisor by either the North Carolina Sheriffs' Education and Training

Standards Commission or the North Carolina Criminal Justice Education and Training Standards Commission.

- c. Qualified law enforcement agency. – Any of the following entities whose head is a certified diversion investigator or that employs at least one certified diversion investigator and at least one certified diversion supervisor:
  - 1. A municipal police department.
  - 2. A county police department.
  - 3. A sheriff's office.

(j) The Department shall do all of the following:

- (1) Enable each certified diversion investigator associated with a qualified law enforcement agency to register with the controlled substances reporting system by providing, at a minimum, all of the following information:
  - a. The investigator's name and certification number.
  - b. The name of the qualified law enforcement agency for whom the investigator works.
  - c. The name and certification number of each certified diversion supervisor with whom the investigator works.
- (2) Enable each certified diversion investigator associated with a qualified law enforcement agency to request and receive data in connection with a bona fide active investigation involving a specific violation of any state or federal law involving a controlled substance by providing, at a minimum, all of the following:
  - a. The case number associated with the request.
  - b. A description of the nature and purpose of the request.
  - c. The first name, last name, and date of birth of each individual whose prescription data the investigator seeks, including, when appropriate, any alternative name, spelling, or date of birth associated with each such individual.
  - d. An acknowledgement that the certified diversion investigator is aware of the penalties associated with improperly obtaining, disclosing, or disseminating data from the controlled substances reporting system.
- (3) Enable the State Bureau of Investigation, Diversion & Environmental Crimes Unit, to review each request for data from a certified diversion investigator associated with a qualified law enforcement agency and, upon such review, to determine if the request is approved, denied, or delayed pending further review or investigation.
- (4) Create an audit trail that may be used to investigate or prosecute violations of this Part and ensure that the Attorney General of North Carolina or a designee and Special Agents of the North Carolina State Bureau of Investigation who are assigned to the Diversion & Environmental Crimes Unit have access to the system to review the audit trail.

(k) In addition to the civil penalties provided in G.S. 90-113.75(a) and any other applicable civil or criminal penalties, the following criminal penalties apply to any individual authorized to access data in the controlled substances reporting system when that access is authorized by subdivisions (3) through (10) of subsection (c) of this section:

- (1) An individual who knowingly and intentionally accesses prescription information in the controlled substances reporting system for a purpose not authorized by this section shall be guilty of a Class I felony.
- (2) An individual who knowingly and intentionally discloses or disseminates prescription information from the system for a purpose not authorized by this section shall be guilty of a Class I felony.
- (3) An individual who willfully and maliciously obtains, discloses, or disseminates prescription information for a purpose not authorized by this section and with the intent to use such information for commercial advantage or personal gain, or to maliciously harm any person, shall be guilty of a Class H felony.

Any person who is convicted of a criminal offense under this subsection is permanently barred from accessing the controlled substances reporting system.

(l) The State Bureau of Investigation, Diversion & Environmental Crimes Unit, may investigate suspected violations of this section and shall notify the Department of any charges or convictions pursuant to this section. (2005-276, s. 10.36(a); 2009-438, s. 2; 2013-152, s. 3; 2015-241, s. 12F.16(d); 2016-94, s. 12F.6; 2017-74, s. 11; 2018-44, s. 11(a), (b); 2019-81, s. 15(a).)

**§ 90-113.74A. Mandatory prescriber registration for access to controlled substances reporting system.**

Within 30 days after obtaining an initial or renewal license that confers the authority to prescribe a controlled substance for the purpose of providing medical care for a patient, the licensee shall demonstrate to the satisfaction of the licensing board that he or she is registered for access to the controlled substances reporting system. A violation of this section may constitute cause for the licensing board having jurisdiction over the licensee to suspend or revoke the license. (2016-94, s. 12F.7(c).)

**§ 90-113.74B. Mandatory dispenser registration for access to controlled substances reporting system; exception.**

(a) Within 30 days after obtaining an initial or renewal license to practice pharmacy, the licensee shall demonstrate to the satisfaction of the North Carolina Board of Pharmacy that he or she is registered for access to the controlled substances reporting system. A violation of this section may constitute cause for the Board of Pharmacy to suspend or revoke the license.

(b) This section does not apply to a licensee employed in a pharmacy practice setting where a Schedule II, III, or IV controlled substance will not be dispensed. (2017-74, s. 12.)

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

(a) Prior to initially prescribing a targeted controlled substance to a patient, a practitioner shall review the information in the controlled substances reporting system pertaining to the patient for the 12-month period preceding the initial prescription. For every subsequent three-month period that the targeted controlled substance remains a part of the patient's medical care, the practitioner shall review the information in the controlled substances reporting system pertaining to the patient for the 12-month period preceding the determination that the targeted controlled substance should remain a part of the patient's medical care. Each instance in which the practitioner reviews the information in the controlled substances reporting system pertaining to the patient shall be documented in the patient's medical record. In the event the practitioner is unable to review the

information in the controlled substances reporting system pertaining to the patient because the system is not operational or there is some other temporary electrical or technological failure, this inability shall be documented in the patient's medical record. Once the electrical or technological failure has been resolved, the practitioner shall review the information in the controlled substances reporting system pertaining to the patient and the review shall be documented in the patient's medical record.

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

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

(c) The Department shall conduct periodic audits of the review of the controlled substances reporting system by prescribers. The Department shall determine a system for selecting a subset of prescriptions to examine during each auditing period. The Department shall report to the appropriate licensing board any prescriber found to be in violation of this section. A violation of this section may constitute cause for the licensing board to suspend or revoke a prescriber's license.

(d) For purposes of this section, a "practitioner" does not include a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes. (2017-74, s. 12; 2018-76, s. 4.)

#### **§ 90-113.74D. Dispenser use of controlled substances reporting system.**

(a) Prior to dispensing a targeted controlled substance, a dispenser shall review the information in the controlled substances reporting system pertaining to the patient for the preceding 12-month period and document this review under any of the following circumstances:

- (1) The dispenser has a reasonable belief that the ultimate user may be seeking a targeted controlled substance for any reason other than the treatment of the ultimate user's existing medical condition.
- (2) The prescriber is located outside of the usual geographic area served by the dispenser.
- (3) The ultimate user resides outside of the usual geographic area served by the dispenser.
- (4) The ultimate user pays for the prescription with cash when the patient has prescription insurance on file with the dispenser.
- (5) The ultimate user demonstrates potential misuse of a controlled substance by any one or more of the following:
  - a. Over-utilization of the controlled substance.
  - b. Requests for early refills.
  - c. Utilization of multiple prescribers.
  - d. An appearance of being overly sedated or intoxicated upon presenting a prescription.

e. A request by an unfamiliar ultimate user for an opioid drug by a specific name, street name, color, or identifying marks.

(b) If a dispenser has reason to believe a prescription for a targeted controlled substance is fraudulent or duplicative, the dispenser shall withhold delivery of the prescription until the dispenser is able to contact the prescriber and verify that the prescription is medically appropriate.

(c) A dispenser shall be immune from any civil or criminal liability for actions authorized by this section. Failure to review the system in accordance with subsection (a) of this section shall not constitute medical negligence. (2017-74, s. 12.)

#### **§ 90-113.74E. Certification of diversion investigators and diversion supervisors.**

Pursuant to its authority under G.S. 17C-6 and G.S. 17E-4, the North Carolina Criminal Justice Education and Training Standards Commission and the North Carolina Sheriffs' Education and Training Standards Commission, in consultation with the Department of Justice, North Carolina Justice Academy, and State Bureau of Investigation, shall ensure that educational materials are created and that training programs are conducted for the certification of diversion investigators and diversion supervisors, as defined in G.S. 90-113.74(i). (2018-44, s. 13.)

#### **§ 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 Article or a rule adopted pursuant to this Article shall be assessed a civil penalty by the Department not to exceed ten thousand dollars (\$10,000) per violation and shall be temporarily barred from accessing the system until further findings by the Department. 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 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) Notwithstanding the foregoing, G.S. 8-53, G.S. 75-65, or any other provision of international, federal, State, or local law, a practitioner as defined in G.S. 90-87, a dispenser, or other person or entity permitted access to or required or permitted to submit or transmit reports or other records, data, or information, including, without limitation, any protected health information or any other individually identifying or personal information, under this Article that, in good faith, submits or transmits such reports or other records, data, or information as required or allowed by this Article is immune from civil or criminal liability that might otherwise be incurred or imposed as a result of submitting or transmitting such reports or other records, data, or information, or as a result of any subsequent actual or attempted access to or use or disclosure of such reports or other records, data, or information, whether by the Department, any law enforcement officer or agency,

or any other person or entity. (2005-276, s. 10.36(a); 2013-152, s. 4; 2013-410, s. 18.5; 2018-44, s. 12.)

**§ 90-113.75A. Creation of Controlled Substances Reporting System Fund.**

(a) The Controlled Substances Reporting System Fund is created within the Department as a special revenue fund. The Department shall administer the Fund. The Department shall use the Fund only for operation of the controlled substances reporting system and to carry out the provisions of this Article.

(b) The Fund shall consist of the following:

- (1) Any moneys appropriated to the Fund by the General Assembly.
- (2) Any moneys received from State, federal, private, or other sources for deposit into the Fund.

(c) All interest that accrues to the Fund shall be credited to the Fund. Any balance remaining in the Fund at the end of any fiscal year shall remain in the Fund and shall not revert to the General Fund. (2017-74, s. 12.)

**§ 90-113.75B. Annual report to General Assembly and licensing boards.**

Annually on February 1, beginning February 1, 2019, the Department shall report to the Joint Legislative Oversight Committee on Health and Human Services, the North Carolina Medical Board, the North Carolina Board of Podiatry Examiners, the North Carolina Board of Nursing, the North Carolina Dental Board, the North Carolina Veterinary Medical Board, and the North Carolina Board of Pharmacy on data reported to the controlled substances reporting system. The report shall include at least all of the following information about targeted controlled substances reported to the system during the preceding calendar year:

- (1) The total number of prescriptions dispensed, broken down by Schedule.
- (2) Demographics about the ultimate users to whom prescriptions were dispensed.
- (3) Statistics regarding the number of pills dispensed per prescription.
- (4) The number of ultimate users who were prescribed a controlled substance by two or more practitioners.
- (5) The number of ultimate users to whom a prescription was dispensed in more than one county.
- (6) The categories of practitioners prescribing controlled substances and the number of prescriptions authorized by each category of practitioner. For the purpose of this subdivision, medical doctors, surgeons, palliative care practitioners, oncologists and other practitioners specializing in oncology, pain management practitioners, practitioners who specialize in hematology, including the treatment of sickle cell disease, and practitioners who specialize in treating substance use disorder shall be treated as distinct categories of practitioners.
- (7) Any other data deemed appropriate and requested by the Joint Legislative Oversight Committee on Health and Human Services, the North Carolina Medical Board, the North Carolina Board of Podiatry Examiners, the North Carolina Board of Nursing, the North Carolina Dental Board, the North Carolina Veterinary Medical Board, or the North Carolina Board of Pharmacy. (2017-74, s. 12.)

**§ 90-113.75C: Reserved for future codification purposes.**

**§ 90-113.75D: Reserved for future codification purposes.**

**§ 90-113.75E. Opioid and Prescription Drug Abuse Advisory Committee; statewide strategic plan.**

(a) There is hereby created the Opioid and Prescription Drug Abuse Advisory Committee, to be housed in and staffed by the Department. The Committee shall develop and, through its members, implement a statewide strategic plan to combat the problem of opioid and prescription drug abuse. The Committee shall include representatives from the following, as well as any other persons designated by the Secretary of Health and Human Services:

- (1) The Department's Division of Health Benefits.
- (2) The Department's Division of Mental Health, Developmental Disabilities, and Substance Use Services.
- (3) The Department's Division of Public Health.
- (4) The Office of Rural Health. Department's
- (5) The Division of Juvenile Justice of the Department of Public Safety.
- (5a) The Division of Community Supervision and Reentry of the Department of Adult Correction.
- (5b) The Division of Prisons of the Department of Adult Correction.
- (6) The State Bureau of Investigation.
- (7) The Attorney General's Office.
- (8) The following health care regulatory boards with oversight of prescribers and dispensers of opioids and other prescription drugs:
  - a. North Carolina Board of Dental Examiners.
  - b. North Carolina Board of Nursing.
  - c. North Carolina Board of Podiatry Examiners.
  - d. North Carolina Medical Board.
  - e. North Carolina Board of Pharmacy.
  - f. North Carolina Veterinary Medical Board
- (9) The UNC Injury Prevention Research Center.
- (10) The substance abuse treatment community.
- (11) Governor's Institute on Substance Abuse, Inc.
- (12) The Department of Insurance's drug take-back program.

After developing the strategic plan, the Committee shall be the State's steering committee to monitor achievement of strategic objectives and receive regular reports on progress made toward reducing opioid and prescription drug abuse in North Carolina.

(b) In developing the statewide strategic plan to combat the problem of opioid and prescription drug abuse, the Opioid and Prescription Drug Abuse Advisory Committee shall, at a minimum, complete the following steps:

- (1) Identify a mission and vision for North Carolina's system to reduce and prevent opioid and prescription drug abuse.
- (2) Scan the internal and external environment for the system's strengths, weaknesses, opportunities, and challenges (a SWOC analysis).
- (3) Compare threats and opportunities to the system's ability to meet challenges and seize opportunities (a GAP analysis).

- (4) Identify strategic issues based on SWOC and GAP analyses.
  - (5) Formulate strategies and resources for addressing these issues.
- (c) The strategic plan for reducing opioid and prescription drug abuse shall include three to five strategic goals that are outcome-oriented and measurable. Each goal must be connected with objectives supported by the following five mechanisms of the system:
- (1) Oversight and regulation of prescribers and dispensers by State health care regulatory boards.
  - (2) Operation of the Controlled Substances Reporting System.
  - (3) Operation of the Medicaid lock-in program to review behavior of patients with high use of prescribed controlled substances.
  - (4) Enforcement of State laws for the misuse and diversion of controlled substances.
  - (5) Any other appropriate mechanism identified by the Committee.
- (d) The Department, in consultation with the Opioid and Prescription Drug Abuse Advisory Committee, shall develop and implement a formalized performance management system that connects the goals and objectives identified in the statewide strategic plan to operations of the Controlled Substances Reporting System and Medicaid lock-in program, law enforcement activities, and oversight of prescribers and dispensers. The performance management system must be designed to monitor progress toward achieving goals and objectives and must recommend actions to be taken when performance falls short.
- (e) Beginning on December 1, 2016, and annually thereafter, the Department shall submit an annual report on the performance of North Carolina's system for monitoring opioid and prescription drug abuse to the Joint Legislative Oversight Committee on Health and Human Services, the Joint Legislative Oversight Committee on Justice and Public Safety, and the Fiscal Research Division. (2015-241, s. 12F.16(m)-(q); 2015-268, s. 4.5; 2017-57, s. 11F.10; 2018-76, s. 9; 2019-81, s. 15(a); 2021-180, s. 19C.9(iii); 2023-65, s. 5.2(b).)

**§ 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.**

**§ 90-113.78. Reserved for future codification purposes.**

**§ 90-113.79. Reserved for future codification purposes.**