HOUSE BILL 243: Strengthen Opioid Misuse Prevention (STOP)Act.

2017-2018 General Assembly

Committee:	Senate Rules and Operations of the Senate	**Date:**	June 20, 2017
Introduced by:	Reps. Murphy, Davis, Malone, Horn	**Prepared by:**	Augustus D. Willis
Analysis of:	Fourth Edition		Staff Attorney

OVERVIEW: House Bill 243 would (i) extend the statewide standing order for opioid antagonists to allow practitioners to prescribe an opioid antagonist to any governmental or nongovernmental agency (ii) designate certain Schedule II and III drugs as "targeted controlled substances and make changes to the laws governing the prescribing of those targeted controlled substances, (iii) clarify the allowable funds for syringe exchange programs, (iv) make changes to the statutes governing the Controlled Substance Reporting System (CSRS) database, and (v) amend language in the 2015 budget to facilitate the interstate connectivity of the CSRS database.

BILL ANALYSIS:

Part I. TITLE OF ACT

Section 1 sets forth the title of the act as the Strengthen Opioid Misuse Prevention (STOP) Act of 2017.

Part II. EXTEND STANDING ORDERS FOR OPIOID ANTAGONIST TO COMMUNITY HEALTH GROUPS

G.S. 90-12.7 sets forth statutes governing the prescribing of opioid antagonists for treatment of a drug overdose. These statutes allow a practitioner to, either directly or by standing order, prescribe an opioid antagonist to a person at risk of experiencing an opiate-related overdose, or their family member, friend, or other person in a position to assist such a person. In 2016, the General Assembly expanded this to allow the State Health Director to issue prescriptions to such persons by way of a statewide standing order.

Section 2 would amend the statutes on the treatment of overdoses with opioid antagonist to (1) allow the State Health Director to name a designee to prescribe an opioid antagonist by statewide standing order, and (2) allow practitioners to either directly, or by standing order, prescribe an opioid antagonist to any governmental or nongovernmental organization for the purpose of distribution to persons at risk of experiencing an opiate-related overdose or to a family member, friend, or other person in a position to assist such a person. Any organization distributing the opioid antagonist would be required to include with it basic instruction and information on how to administer it.

PART III. IMPROVE OPIOID PRESCRIBING PRACTICES

Current law authorizes licensed physician assistants and nurse practitioners to write prescriptions so long as a supervising physician has provided written instructions for prescribing drugs and a written policy for periodic review by the physician of drugs prescribed.

Absent an emergency situation, the dispensing of Schedule II controlled substances generally requires a written prescription, made out no more than 6 months prior to the date the substance is dispensed, with an exception that no prescription is needed if the substance is dispensed directly by a practitioner to an

ultimate user. Prescriptions for Schedule II controlled substances may not be refilled. Schedule III and IV controlled substances require a prescription no older than 6 months old and may not be refilled more than five times after the date of the prescription.

Section 3 would define the new term "targeted controlled substance" to include certain controlled substances currently included in Schedule II and Schedule III of the Controlled Substances Act.

Section 4 would amend the statutes authorizing physician assistants to write prescriptions by requiring a physician assistant who is treating a patient in a pain management clinic to consult with the supervising physician prior to prescribing controlled substances included in the newly defined term "targeted controlled substance" if the therapeutic use of the targeted controlled substance will or is expected to exceed a period of 30 days. For as long as a targeted controlled substance is continuously prescribed to the same patient, the physician assistant must consult with the supervising physician at least once every 90 days to verify that the prescription remains medically appropriate for the patient.

Section 5 would amend the statutes authorizing nurse practitioners to write prescriptions by including the same requirements in Section 4.

Section 6 would require electronic prescriptions for all controlled substances included in the newly defined term "targeted controlled substance" unless the prescription is issued by:

- A practitioner who is dispensing directly to an ultimate user.
- A practitioner who orders a controlled substance to be administered in a hospital, nursing home, hospice facility, outpatient dialysis center or residential care facility.
- A practitioner who experiences temporary technological or electrical failure, or other extenuating circumstance that prevents the prescription from being transmitted electronically and the reason for this exception is documented in the patient's medical record.
- A practitioner who writes a prescription to be dispensed by a pharmacy located on federal property and the reason for this exception is documented in the patient's medical record.
- A veterinarian practicing pursuant to Article 11 of Chapter 90 of the General Statutes.

Prescriptions for targeted controlled substances would be limited to no more than a 5 day supply upon the initial consultation and treatment of a patient for acute pain, unless the prescription is for post-operative acute pain relief immediately following a surgical procedure, in which case the practitioner may not prescribe more than a 7-day supply. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription for a targeted controlled substance. The terms "acute pain," "chronic pain," and "surgical procedure" are defined. Dispensers are not required to verify that a practitioner falls within one of the exceptions from the requirement that all targeted controlled substances be e-prescribed and dispensers may continue to dispense targeted controlled substances from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws. Dispensers are further immune from civil or criminal liability or disciplinary action from the Board of Pharmacy for dispensing a prescription written by a prescriber in violation of G.S. 90-106.

Section 7 would require any hospice or palliative care provider who prescribes a targeted controlled substance to be administered to a patient in the patient's home to provide oral and written information to the patient and the patient's family regarding the proper disposal of the controlled substance.

PART IV: CLARIFY ALLOWABLE FUNDS FOR SYRINGE EXCHANGE PROGRAMS

Section 8 would clarify language in the statute authorizing needle and syringe exchange programs to prohibit the use of State funds to purchase needles, hypodermic syringes, or other injection supplies. Non-State public funds could still be used for this purpose.

PART V: STRENGTHEN CONTROLLED SUBSTANCES REPORTING SYSTEM

The Controlled Substances Reporting System (CSRS) is a database maintained by the Department of Health and Human Services that tracks prescriptions for Schedule II through V controlled substances. Dispensers are required to report certain information on prescriptions they fill within 3 days after the prescription is delivered, but are encouraged to report such information within 24 hours. Such information is confidential and may only be accessed by certain persons for specific purposes set forth by statute. Under current law, veterinarians are not considered to be a "dispenser" for purposes of CSRS reporting requirements.

Section 9 would define the term "pharmacy" as a person or entity who holds a valid pharmacy permit, and make other technical changes to the definitions used in the CSRS laws.

Section 10 would require dispensers to report required information by the close of the next business day after filling a prescription unless the system is temporarily not operational and the inability to report is documented in the dispenser's records. The Department of Health and Human Services would be required to assess civil penalties of up to $100 for a first violation, up to $250 for a second violation, and up to $500 for each subsequent violation, not to exceed $5,000 per pharmacy in a calendar year to pharmacies found to have failed to report required information within a reasonable period of time after being informed that such information is missing or incomplete; however pharmacies who, in good faith, attempt to report, will not be assessed a civil penalty.

Section 11 would amend the laws governing the confidentiality of CSRS data to allow the Department to notify practitioners and their respective licensing boards of prescribing behavior that increases risk of diversion of controlled substances, increases risk of harm to the patient, or is an outlier among other practitioner behavior. The PCS adds to Section 11 a requirement that the administrator of a hospital emergency department or hospital acute care facility provide the Department with lists of delegates who are authorized to receive data on behalf of providers within the facility. The lists must be submitted to the Department by December 1 of the calendar year preceding the year in which the delegation is to occur, however the lists may be updated at any time throughout the year. The Department has one week from the time it receives a list to establish the necessary delegate accounts within the CSRS.

Section 12 would add the following new sections to Article 5E of Chapter 90 of the General Statutes governing the CSRS:

- 90-113.74B: would require recipients of new or renewed pharmacist licenses to demonstrate to the NC Board of Pharmacy registration for access to the CSRS within 30 days of licensure.
- 90-113.74C: would require practitioners to review a patient's 12-month history in the CSRS prior to prescribing "targeted controlled substance" and review the patient's 12-month history in the CSRS every three months while the targeted controlled substance remains part of the patient's medical care plan. These reviews would have to be documented in the patient's medical records, along with the occasion of any CSRS outage that prevents such a review; the practitioner would be required to review the 12-month history upon restoration of the CSRS after an outage. In addition, a practitioner would be able to, but not required to, review a patient's CSRS history if: (1) the controlled substance is to be administered to the patient in a health care setting, hospital, nursing home, outpatient dialysis facility, or residential care facility; (2) the controlled substance is for the treatment of cancer or a cancer-associated condition; or (3) the controlled substance is prescribed to a patient in hospice or palliative care. The Department would be required to

conduct periodic audits of the review of the CSRS by prescribers and report to the appropriate licensing board any prescriber found to be in violation.

- 90-113.74D: would require a dispenser to review an individual's 12-month history in the CSRS prior to dispensing a targeted controlled substance whenever: 1) the dispenser believes the individual is seeking controlled substances for reasons other than treatment of a medical condition; 2) the prescriber is located outside of the usual area the dispenser serves; 3) the individual lives outside the usual area the dispenser serves; 4) the individual pays with cash when there is an insurance plan on file with the dispenser; or 5) the individual demonstrates potential misuse of a controlled substance. A dispenser would be required to withhold delivery of a prescription until verified if the dispenser believes it to be duplicative or fraudulent. Dispensers would be immune from civil or criminal liability for actions authorized by this section and failure to review the system prior to dispensing a controlled substance would not constitute medical negligence.
- 90-113.75A: would create a special revenue fund in DHHS for use in administering the CSRS.
- 90-113.75B: would require DHHS to make annual reports starting February 1, 2019, 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 Medicine Board, and the North Carolina Board of Pharmacy. The reports would be required to include specified data on targeted controlled substances reported to the CSRS database during the preceding calendar year.

Section 13 would amend language from the 2015 budget to direct the Department of Health and Human Services, Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, to continue working toward establishing interstate connectivity for the CSRS system.

Section 14 would direct the Department of Health and Human Services to conduct a study, in consultation with the Office of the Attorney General and the North Carolina Veterinary Medical Board on how to implement the provisions of the act pertaining to electronic prescriptions and the submission of data to the CSRS as they relate to the practice of veterinary medicine. The Department would be required to submit a report to the Joint Legislative Oversight Committee on Health and Human Services by February 1, 2018.

EFFECTIVE DATE: Sections 1, 2, 3, 4, 5, 7, 8, 11, and 13 would become effective July 1, 2017. The new subsections of G.S. 90-106 dealing with e-prescribing in Section 6 would become effective January 1, 2020. The new subsections of G.S. 90-106 establishing limits on initial prescriptions for acute pain in Section 6 would become effective January 1, 2018. The portion of Section 12 creating the new statutes G.S. 90-113.75A through G.S. 90-113.75C would become effective September 1, 2017. The portion of Section 10 updating the information required to be reported to the CSRS database by dispensers becomes effective 30 days after the date the Chief Information Officer notifies the Revisor of Statutes that the CSRS database has the capability to record the information required. The remainder of the act would become effective when it becomes law and would apply to acts committed on or after the date the State Chief Information Officer notifies the Revisor of Statutes that (i) the upgrades to the CSRS database described in subdivisions (1) and (2) of subsection (a) of Section 12F.7 of S.L. 2016-94 have been completed and (ii) the upgraded CSRS database is fully operational within the Department of Information Technology and connected to the statewide health information exchange.