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

2017-2018 General Assembly

Committee:	House Health. If favorable, re-refer to Appropriations	**Date:**	March 8, 2017
Introduced by:	Reps. Murphy, Davis, Malone, Horn	**Prepared by:**	Augustus D. Willis Jason Moran-Bates Committee Co-Counsel
Analysis of:	First Edition		

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) make changes to the laws for prescribing Schedule II through IV 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) appropriate $10 million in each of the next two fiscal years to the Department of Health and Human Services, Division of Mental Health, Developmental Disabilities and Substance Abuse for increasing the availability of community-based treatment and recovery services for substance abuse disorders.

[As introduced, this bill was identical to S175, as introduced by Sens. J. Davis, McInnis, Rabon, which is currently in an unknown committee.]

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 amend the statutes authorizing physician assistants to write prescriptions by requiring a physician assistant to consult with the supervising physician prior to prescribing controlled substances included in Schedules II through V if the therapeutic use of the controlled substance will or is expected to exceed a period of 30 days. For as long as a Schedule II through V 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 4 would amend the statutes authorizing nurse practitioners to write prescriptions by including the same requirements in Section 3.

Section 5 would require electronic prescriptions for all controlled substances in Schedules II through V except for prescriptions 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, or residential care facility.
- A practitioner who experiences temporary technological or electrical failure 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.

Prescriptions for controlled substances included in Schedules II through V 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 immediate post-operative pain relief, 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 Schedule II through V controlled substance. Acute pain is defined as pain that the practitioner reasonably expects to last for three months or less and does not include chronic pain or pain being treated as part of cancer care, hospice care, palliative care, or medication-assisted treatment for substance use disorder. Chronic pain is defined as pain that typically lasts for longer than three months or that lasts beyond the time of normal tissue healing.

Section 6 would require any hospice or palliative care provider who prescribes a Schedule II through V controlled substance to be administered to a patient in the patient's home to make diligent efforts to ensure that any residual portion of the controlled substance is safely disposed of following the death of the patient.

Section 7 would add a new section to Article 51 of Chapter 58 of the General Statutes to require any insurance plan that charges a co-payment for prescription drugs to charge a co-payment for any limited, initial prescription of a Schedule II through Schedule V controlled substance. This co-payment would

have to be either proportional to the amount charged for a thirty-day supply and the amount of the substance actually prescribed, or the full rate for a thirty-day supply, so long as no additional co-payment is charged for additional prescriptions of the same substance for the remainder of the thirty-day supply.

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.

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

Section 10 would require dispensers to report required information within 24 hours of filling a prescription and would require the Department of Health and Human Services to assess civil penalties of up to $250 for a first violation and up to $500 for each subsequent violation, not to exceed $10,000 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.

Section 11 would amend the laws governing the confidentiality of CSRS data to allow the Department to notify practitioners 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.

Section 12 would amend the laws governing the confidentiality of CSRS data to add to the list of persons to whom the Department man release CSRS data (i) any third-party payer or pharmacy benefits manager acting as agent of a third-party payer for the purposes of claimant case management, (ii) detection of inappropriate prescribing of a controlled substance to a claimant, or (iii) detection of misuse or diversion of a controlled substance by a claimant.

Section 13 would add the following new sections to Article 5E of Chapter 90 of the General Statutes governing the CSRS:

- 90-113.74A: 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.
- 90-113.74B: would require practitioners to review a patient's 12-month history in the CSRS prior to prescribing a Schedule II through Schedule V drug and review the patient's 12-month history in the CSRS every three months while the 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 hospital or other health care facility; 2) the controlled substance is for the treatment of cancer or a cancer-associated condition; 3) the controlled substance is prescribed to a patient in hospice care; or 4) the prescription is for five days or less and cannot be refilled, or is for seven days or less for relief of post-operative pain.

- 90-113.74C: would require a dispenser to review an individual's 12-month history in the CSRS 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.
- 90-113.75A: would create a special revenue fund in DHHS for use in administering the CSRS.
- 90-113.75B: would require all boards which license individuals who can prescribe controlled substances to charge a $20 CSRS annual fee. The boards would be required to retain 10% of the fees collected and remit 90% to DHHS for the special revenue fund created in G.S. 90-113.75A.
- 90-113.75C: would require DHHS to make annual reports, starting November 1, 2018, to the Joint Legislative Oversight Committee on Health and Human Services, the North Carolina Medical Board, 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 the following information on Schedule II through Schedule V substances reported to the CSRS: 1) total prescriptions dispensed, broken down by Schedule; 2) demographics of ultimate users; 3) number of pills dispensed per prescription; 4) number of ultimate users who were prescribed a controlled substance by two or more practitioners; 5) 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; 7) prescribing behavior of practitioners 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; and 8) 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 Dental Board, the North Carolina Veterinary Medicine Board, and the North Carolina Board of Pharmacy.

PART VI: APPROPRIATION FOR COMMUNITY-BASED SUBSTANCE USE DISORDER TREATMENT AND RECOVERY SERVICES

Section 14 would appropriate 10 million dollars each for the 2017-2018 and the 2018-2019 fiscal year to the Department of Health and Human Services, Division of Mental Health, Developmental Disabilities, and Substance Abuse Services. The funds would only be used for increasing the availability of community-based treatment and recovery services for substance use disorders, including medication-assisted treatment.

EFFECTIVE DATE: Sections 1, 2, 3, 4, 6, 8, and 14 would become effective July 1, 2017. Sections 5 and 7 would become effective July 1, 2018. The portion of Section 13 creating the new statutes G.S. 90-113.75A through G.S. 90-113.75C would become effective September 1, 2017. 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.