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SENATE DRS25119-MEza-108B* (05/01)

Short Title: Strengthen Controlled Substances Monitoring. (Public)

Sponsors: Senators Hartsell and Clark (Primary Sponsors).

Referred to:

1 A BILL TO BE ENTITLED
2 AN ACT TO STRENGTHEN THE MONITORING OF CONTROLLED SUBSTANCES, AS
3 RECOMMENDED BY THE JOINT LEGISLATIVE PROGRAM EVALUATION
4 OVERSIGHT COMMITTEE.

5 The General Assembly of North Carolina enacts:

6 **SECTION 1.** Statewide Opioid Prescribing Guidelines. – (a) The following State
7 health officials and health care provider licensing boards shall develop statewide opioid
8 prescribing guidelines that the health care provider licensing boards shall then adopt:

- 9 (1) The State Health Director.
- 10 (2) The Director of Medical Assistance.
- 11 (3) The Director of the Division of Mental Health, Developmental Disabilities,
12 and Substance Abuse Services.
- 13 (4) The directors of medical, dental, and mental health services within the
14 Department of Public Safety.
- 15 (5) North Carolina Board of Dental Examiners.
- 16 (6) North Carolina Board of Nursing.
- 17 (7) North Carolina Board of Podiatry Examiners.
- 18 (8) North Carolina Medical Board.

19 **SECTION 1.(b)** Other state and federal prescribing guidelines should serve as
20 models to develop and refine North Carolina's prescribing guidelines. The development of the
21 guidelines should consider use of opioid dosage thresholds for physician consultation. The
22 guidelines must be developed based on the criteria for clinical practice guidelines set forth by
23 the Institute of Medicine of the National Academies and must do all of the following:

- 24 (1) Make recommendations for clinical actions based on review of empirical
25 evidence.
- 26 (2) Rate the strength of each clinical recommendation.
- 27 (3) Rate the quality of evidence used to support recommendations for clinical
28 action.
- 29 (4) Explain and assess the benefits and harms associated with options for
30 alternative treatments.

31 **SECTION 1.(c)** The statewide prescribing guidelines shall be completed by
32 December 31, 2014. The health care provider occupational licensing boards listed in subsection
33 (a) of this section shall adopt the opioid prescribing guidelines by no later than July 1, 2015.

34 **SECTION 2.** Continuing Education Requirements. – (a) The following health care
35 provider occupational licensing boards shall require continuing education on the abuse of



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1 controlled substances as a condition of license renewal for health care providers who prescribe
2 controlled substances:

- 3 (1) North Carolina Board of Dental Examiners.
- 4 (2) North Carolina Board of Nursing.
- 5 (3) North Carolina Board of Podiatry Examiners.
- 6 (4) North Carolina Medical Board.

7 **SECTION 2.(b)** In establishing the continuing education standards, the boards
8 listed in subsection (a) of this section shall require that at least one hour of the total required
9 continuing education hours consists of a course designed specifically to address prescribing
10 practices. The course must include, but not be limited to, instruction on controlled substance
11 prescribing practices and controlled substance prescribing for chronic pain management.

12 **SECTION 3.** Improve CSRC Access and Utilization. – (a) G.S. 90-113.74 reads
13 as rewritten:

14 **"§ 90-113.74. Confidentiality.**

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

23 ...

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

26 ...

27 (8) Any county medical examiner appointed by the Chief Medical Examiner
28 pursuant to G.S. 130A-382 and the Chief Medical Examiner, for the purpose
29 of investigating the death of an individual.

30 (9) The federal Drug Enforcement Administration's Office of Diversion Control.

31 (10) The North Carolina Health Information Exchange (NC HIE), established
32 under Article 29A of this Chapter, through web-service calls.

33"

34 **SECTION 3.(b)** The Department of Health and Human Services (DHHS) shall
35 adopt appropriate policies and procedures documenting and supporting the additional
36 functionality and expanded access added by subsection (a) of this section for the North
37 Carolina Controlled Substances Reporting System (CSRS) for the entities added to
38 G.S. 90-113.74(c) by subsection (a) of this section, as well as amend its contract with the
39 vendor that operates the CSRS to support the additional functionality and expanded access to
40 the CSRS.

41 **SECTION 4.** Improve CSRS Contract. – (a) The Department of Health and Human
42 Services (DHHS) shall modify the contract for the Controlled Substances Reporting System
43 (CSRS) to improve performance, establish user access controls, establish data security
44 protocols, and ensure availability of data for advanced analytics. Specifically, the contract shall
45 be modified to include the following:

- 46 (1) A connection to the North Carolina Health Information Exchange (NC HIE).
- 47 (2) Interstate connectivity with South Carolina, Tennessee, and Virginia. The
48 Department shall establish an interstate data sharing compact with those
49 states.
- 50 (3) A system feature requiring users to update account information annually.

- 1 (4) Validation of prescriber number validation by cross-referencing CSRS users
2 with DEA numbers to ensure access is limited to users with valid, up-to-date
3 information.
- 4 (5) Data security protocols that meet or exceed the Federal Information
5 Processing Standards (FIPS) established by the National Institute of
6 Standards and Technology (NIST).
- 7 (6) The quarterly transfer of a copy of the complete CSRS database to DHHS.
8 Transferred data must be encrypted, include identified and deidentified
9 cases, and be conducted through standard file transfer protocol.
- 10 (7) Up to five ad-hoc reports per month from the contractor that DHHS staff
11 cannot produce through the online system.

12 **SECTION 4.(b)** The Department of Health and Human Services shall complete the
13 contract modifications required by subsection (a) of this section by December 31, 2014. The
14 Department shall report by November 15, 2014, to the Joint Legislative Program Evaluation
15 Oversight Committee and the Joint Legislative Oversight Committee on Health and Human
16 Services regarding the progress to modify the contract.

17 **SECTION 4.(c)** The Department of Health and Human Services shall use forty
18 thousand thirty-five dollars (\$40,035) of existing grant funding from the federal Harold Rogers
19 Prescription Drug Monitoring Program for fiscal year 2014-2015 for the purpose of creating a
20 connection to the RxCheck Hub in order to create interstate connectivity for the drug
21 monitoring program, as required by subdivision (2) of subsection (a) of this section.

22 **SECTION 4.(d)** In order to support certain requirements of subsection (a) of this
23 section, the following appropriations are made from the General Fund to the Department of
24 Health and Human Services:

- 25 (1) Five thousand one hundred dollars (\$5,100) for fiscal year 2014-2015 for the
26 purpose of connecting the Controlled Substances Reporting System (CSRS)
27 and the North Carolina Health Information Exchange (NC HIE), as required
28 by subdivision (1) of subsection (a) of this section.
- 29 (2) The sum of fifteen thousand dollars (\$15,000) for fiscal year 2014-2015,
30 recurring, for the cost of maintaining a connection between the Controlled
31 Substances Reporting System (CSRS) and the North Carolina Health
32 Information Exchange (NC HIE), as required by subdivision (1) of
33 subsection (a) of this section.
- 34 (3) The sum of ten thousand dollars (\$10,000) for fiscal year 2014-2015,
35 recurring, for the cost of annual service fees for the interstate connection for
36 the drug monitoring program, as required by subdivision (2) of subsection
37 (a) of this section.

38 **SECTION 4.(e)** The Department of Health and Human Services shall seek grant
39 funding from the federal Harold Rogers Prescription Drug Monitoring Program or any other
40 available grant funds to offset the cost of providing interstate connectivity for the Controlled
41 Substances Reporting System (CSRS), which is required by subdivision (2) of subsection (a) of
42 this section. If successful in acquiring a grant, the Department shall inform the House
43 Appropriations Subcommittee on Health and Human Services, the Senate Appropriations
44 Committee on Health and Human Services, and the Fiscal Research Division.

45 **SECTION 5. Expand Monitoring Capacity.** – (a) The North Carolina Controlled
46 Substances Reporting System shall expand its monitoring capacity by establishing data use
47 agreements with the Prescription Behavior Surveillance System. In order to participate, the
48 Reporting System shall establish data use agreement with the Center of Excellence at Brandeis
49 University no later than January 1, 2015.

50 **SECTION 5.(b)** Beginning September 1, 2015, and every two years thereafter, the
51 Department of Health and Human Services, Division of Mental Health, Developmental

1 Disabilities, and Substance Abuse Services, shall report on its participation with the
2 Prescription Behavior Surveillance System to the Joint Legislative Oversight Committee on
3 Health and Human Services and the Joint Legislative Oversight Committee on Justice and
4 Public Safety.

5 **SECTION 6.** Medicaid Lock-in Program. – The Department of Health and Human
6 Services, Division of Medical Assistance (DMA), shall take the following steps to improve the
7 effectiveness and efficiency of the Medicaid lock-in program:

- 8 (1) Establish written procedures for the operation of the lock-in program,
9 including specifying the responsibilities of DMA and the program
10 contractor.
- 11 (2) Establish procedures for the sharing of bulk data with the Controlled
12 Substances Regulatory Branch.
- 13 (3) In consultation with the Physicians Advisory Group, extend lock-in duration
14 to two years and revise program eligibility criteria to align the program with
15 the statewide strategic goals for preventing prescription drug abuse. DMA
16 shall report an estimate of the cost-savings from the revisions to the
17 eligibility criteria to the Joint Legislative Program Evaluation Oversight
18 Committee and the Joint Legislative Oversight Committee on Health and
19 Human Services within one year of the lock-in program again becoming
20 operational.
- 21 (4) Develop a Web site and communication materials to inform lock-in
22 enrollees, prescribers, pharmacists, and emergency room health care
23 providers about the program.
- 24 (5) Increase program capacity to ensure that all individuals who meet program
25 criteria are locked-in.
- 26 (6) Conduct an audit of the lock-in program within six months of the lock-in
27 program again becoming operational in order to evaluate the effectiveness of
28 program restrictions in preventing overutilization of controlled substances,
29 identifying any program vulnerabilities, and addressing whether there is
30 evidence of any fraud or abuse within the program.

31 The Department of Health and Human Services, Division of Medical Assistance, shall report to
32 the Joint Legislative Program Evaluation Oversight Committee by September 30, 2014, on its
33 progress towards implementing all items included in this section.

34 **SECTION 7.** Statewide Strategic Plan. – (a) There is hereby created the
35 Prescription Drug Abuse Advisory Committee, to be housed in and staffed by the Department
36 of Health and Human Services. The Committee shall develop and, through its members,
37 implement a statewide strategic plan to combat the problem of prescription drug abuse. The
38 Committee shall include representatives from the following, as well as any other persons
39 designated by the Secretary of Health and Human Services:

- 40 (1) The Division of Medical Assistance.
- 41 (2) The Division of Mental Health, Developmental Disabilities, and Substance
42 Abuse.
- 43 (3) The Division of Public Health.
- 44 (4) The Office of Rural Health and Community Care.
- 45 (5) The State Bureau of Investigation.
- 46 (6) The Attorney General's office.
- 47 (7) The following health care regulatory boards with oversight of prescribers
48 and dispensers of prescription drugs:
 - 49 a. North Carolina Board of Dental Examiners.
 - 50 b. North Carolina Board of Nursing.
 - 51 c. North Carolina Board of Podiatry Examiners.

1 d. North Carolina Medical Board.

2 (8) The UNC Injury Prevention Research Center.

3 (9) The substance abuse treatment community.

4 (10) Community Care of North Carolina's (CCNC's) Project Lazarus.

5 (11) Governor's Institute on Substance Abuse, Inc.

6 (12) The Department of Insurance's drug take-back program.

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

10 **SECTION 7.(b)** In developing the statewide strategic plan to combat the problem
11 of prescription drug abuse, the Prescription Drug Abuse Advisory Committee shall, at a
12 minimum, complete the following steps:

13 (1) Identify a mission and vision for North Carolina's system to reduce and
14 prevent prescription drug abuse.

15 (2) Scan the internal and external environment for the system's strengths,
16 weaknesses, opportunities, and challenges (a SWOC analysis).

17 (3) Compare threats and opportunities to the system's ability to meet challenges
18 and seize opportunities (a GAP analysis).

19 (4) Identify strategic issues based on SWOC and GAP analyses.

20 (5) Formulate strategies and resources for addressing these issues.

21 **SECTION 7.(c)** The strategic plan for reducing prescription drug abuse shall
22 include three to five strategic goals that are outcome-oriented and measureable. Each goal must
23 be connected with objectives supported by the following four mechanisms of the system:

24 (1) Oversight and regulation of prescribers and dispensers by state health care
25 regulatory boards.

26 (2) Operation of the Controlled Substances Reporting System.

27 (3) Operation of the Medicaid lock-in program to review behavior of patients
28 with high use of prescribed controlled substances.

29 (4) Enforcement of state laws for the misuse and diversion of controlled
30 substances.

31 (5) Any other appropriate mechanism identified by the Committee.

32 **SECTION 7.(d)** The Department of Health and Human Services, in consultation
33 with the Prescription Drug Abuse Advisory Committee, shall develop and implement a
34 formalized performance management system that connects the goals and objectives identified
35 in the statewide strategic plan to operations of the Controlled Substances Reporting System and
36 Medicaid lock-in program, law enforcement activities, and oversight of prescribers and
37 dispensers. The performance management system must be designed to monitor progress
38 towards achieving goals and objectives and must recommend actions to be taken when
39 performance falls short.

40 **SECTION 7.(e)** Beginning on December 1, 2015, and annually thereafter, the
41 Department of Health and Human Services shall submit an annual report on the performance of
42 North Carolina's system for monitoring prescription drug abuse to the Joint Legislative
43 Oversight Committee on Health and Human Services and the Joint Legislative Oversight
44 Committee on Justice and Public Safety.

45 **SECTION 8.** Effective Dates. – Except as otherwise provided, this act is effective
46 when it becomes law.