GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013

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SENATE BILL 749*
PROPOSED COMMITTEE SUBSTITUTE S749-PCS15449-RF-41

Short Title: Strengthen Controlled Substances Monitoring. (Public)

Sponsors:

Referred to:

May 15, 2014

A BILL TO BE ENTITLED

AN ACT TO STRENGTHEN THE MONITORING OF CONTROLLED SUBSTANCES.

The General Assembly of North Carolina enacts:

SECTION 1. Statewide Opioid Prescribing Guidelines.

(a) The following State health officials and health care provider licensing boards shall develop statewide opioid prescribing guidelines that the health care provider occupational licensing boards shall then adopt:

(1) The Director of the Division of Public Health of the Department of Health and Human Services (DHHS).
(2) The Director of the Division of Medical Assistance, DHHS.
(3) The Director of the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, DHHS.
(4) The directors of medical, dental, and mental health services within the Department of Public Safety.
(5) North Carolina State Board of Dental Examiners.
(6) North Carolina Board of Nursing.
(7) North Carolina Board of Podiatry Examiners.
(8) North Carolina Medical Board.

(b) In developing statewide opioid prescribing guidelines, other state and federal prescribing guidelines shall serve as models to develop and refine North Carolina's prescribing guidelines. Developers of the guidelines also shall consider establishing opioid dosage thresholds for physician consultation. The guidelines shall be developed based on the criteria for clinical practice guidelines set forth by the Institute of Medicine of the National Academies and shall do all of the following:

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

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

SECTION 2. Continuing Education Requirements.

(a) The following health care provider occupational licensing boards shall require continuing education on the abuse of controlled substances as a condition of license renewal for health care providers who prescribe controlled substances:

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

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

SECTION 3. Improve Controlled Substances Reporting System Access and Utilization.

(a) G.S. 90-113.74 reads as rewritten:

"**§ 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 and~~ law, (ii) for regulatory ~~activities.~~ activities, or (iii) to inform medical records and 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.

…

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

…

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

…."

(b) The Department of Health and Human Services shall adopt appropriate policies and procedures documenting and supporting the additional functionality and expanded access added by subsection (a) of this section for the Controlled Substances Reporting System (CSRS) for the entities added to G.S. 90-113.74(c) by subsection (a) of this section and shall amend its contract with the vendor that operates the CSRS to support the additional functionality and expanded access to the CSRS.

SECTION 4. Improve Controlled Substances Reporting System Contract.

(a) The Department of Health and Human Services (DHHS) shall modify the contract for the Controlled Substances Reporting System (CSRS) to improve performance, establish user access controls, establish data security protocols, and ensure availability of data for advanced analytics. Specifically, the contract shall be modified to include the following:

(1) A connection to the North Carolina Health Information Exchange (NC HIE).
(2) The establishment of interstate connectivity. DHHS shall execute a memorandum of understanding with the National Association of Boards of Pharmacy to participate in PMP InterConnect.
(3) A system feature requiring users to update account information annually.

(4) Confirmation of prescriber number validity by cross-referencing CSRS users with DEA numbers to ensure access is limited to users with valid, up-to-date information.

(5) Data security protocols that meet or exceed the Federal Information Processing Standards (FIPS) established by the National Institute of Standards and Technology (NIST).

(6) The quarterly transfer of a copy of the complete CSRS database to DHHS. Transferred data must be encrypted, include identified and deidentified cases, and be conducted through standard file transfer protocol.

(7) Up to five ad hoc reports per month from the contractor that DHHS staff cannot produce through the online system.

(b) DHHS shall complete the contract modifications required by subsection (a) of this section by December 31, 2014. DHHS shall report by November 15, 2014, to the Joint Legislative Program Evaluation Oversight Committee and the Joint Legislative Oversight Committee on Health and Human Services regarding the progress to modify the contract.

(c) DHHS shall apply for grant funding from the National Association of Boards of Pharmacy to establish the connection to PMP InterConnect. The Department shall request forty-thousand thirty-five dollars ($40,035) to establish the initial interface for PMP InterConnect and thirty thousand dollars ($30,000) for two years of ongoing service, maintenance and support for PMP InterConnect in order to create interstate connectivity for the drug monitoring program as required by subdivision (2) of subsection (a) of this section.

(d) In order to support certain requirements of subsection (a) of this section, the following appropriations are made from the General Fund to DHHS:

(1) Five thousand one hundred dollars ($5,100) for fiscal year 2014-2015 for the purpose of connecting the CSRS and the NC HIE, as required by subdivision (1) of subsection (a) of this section.

(2) The sum of fifteen thousand dollars ($15,000) for fiscal year 2014-2015, recurring, for the cost of maintaining a connection between the CSRS and the NC HIE, as required by subdivision (1) of subsection (a) of this section.

(3) The sum of forty thousand thirty five dollars ($40,035) for fiscal year 2014-2015 to establish the initial interface for PMP InterConnect as required by subdivision (2) of subsection (a) of this section. This amount shall be adjusted or eliminated if DHHS is successful in obtaining grant awards or identifying other allowable receipts for this purpose. If receipts are used for this purpose, this nonrecurring appropriation shall revert to the General Fund.

(4) The sum of fifteen thousand dollars ($15,000) for fiscal year 2014-2015, nonrecurring, for the cost of annual service fees for the interstate connection for the drug monitoring program, as required by subdivision (2) of subsection (a) of this section. This amount shall be adjusted or eliminated if DHHS is successful in obtaining grant awards or identifying other allowable receipts for this purpose. If receipts are used for this purpose, this nonrecurring appropriation shall revert to the General Fund.

SECTION 5. Expand Monitoring Capacity.

(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, 2015.

(b) Beginning September 1, 2015, and every two years thereafter, the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services of the Department of Health and Human Services shall report on its participation with the Prescription Behavior

Surveillance System to the Joint Legislative Oversight Committee on Health and Human Services and the Joint Legislative Oversight Committee on Justice and Public Safety.

SECTION 6. Medicaid Lock-In Program.

The Division of Medical Assistance of the Department of Health and Human Services (DMA) shall take the following steps to improve the effectiveness and efficiency of the Medicaid lock-in program:

(1) Establish written procedures for the operation of the lock-in program, including specifying the responsibilities of DMA and the program contractor.

(2) Establish procedures for the sharing of bulk data with the Controlled Substances Regulatory Branch.

(3) In consultation with the Physicians Advisory Group, extend lock-in duration to two years and revise program eligibility criteria to align the program with the statewide strategic goals for preventing prescription drug abuse. DMA shall report an estimate of the cost-savings from the revisions to the eligibility criteria to the Joint Legislative Program Evaluation Oversight Committee and the Joint Legislative Oversight Committee on Health and Human Services within one year of the lock-in program again becoming operational.

(4) Develop a Web site and communication materials to inform lock-in enrollees, prescribers, pharmacists, and emergency room health care providers about the program.

(5) Increase program capacity to ensure that all individuals who meet program criteria are locked in.

(6) Conduct an audit of the lock-in program within six months of the lock-in program again becoming operational in order to evaluate the effectiveness of program restrictions in preventing overutilization of controlled substances, identify any program vulnerabilities, and address whether there is evidence of any fraud or abuse within the program.

DMA shall report to the Joint Legislative Program Evaluation Oversight Committee by September 30, 2014, on its progress towards implementing all items included in this section.

SECTION 7. Statewide Strategic Plan.

(a) There is hereby created the Prescription Drug Abuse Advisory Committee, to be housed in and staffed by the Department of Health and Human Services (DHHS). The Committee shall develop and, through its members, implement a statewide strategic plan to combat the problem of 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 Division of Medical Assistance, DHHS.

(2) The Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, DHHS.

(3) The Division of Public Health, DHHS.

(4) The Office of Rural Health and Community Care, DHHS.

(5) The State Bureau of Investigation.

(6) The Attorney General's Office.

(7) The following health care regulatory boards with oversight of prescribers and dispensers of 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.

(8) The UNC Injury Prevention Research Center.

(9) The substance abuse treatment community.

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

(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 prescription drug abuse in North Carolina.

(b) In developing the statewide strategic plan to combat the problem of prescription drug abuse, the 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 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 prescription drug abuse shall include three to five strategic goals that are outcome-oriented and measureable. Each goal must be connected with objectives supported by the following four 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) DHHS, in consultation with the 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, 2015, and annually thereafter, DHHS shall submit an annual report on the performance of North Carolina's system for monitoring prescription drug abuse to the Joint Legislative Oversight Committee on Health and Human Services and the Joint Legislative Oversight Committee on Justice and Public Safety.

SECTION 8. This act is effective when it becomes law.