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

(Public)

Sponsors:

Referred to:

March 6, 2017

A BILL TO BE ENTITLED

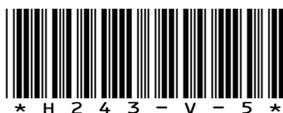
1 AN ACT STRENGTHENING OPIOID MISUSE PREVENTION BY EXTENDING
2 STANDING ORDERS FOR OPIOID ANTAGONIST TO COMMUNITY HEALTH
3 GROUPS; REQUIRING SUPERVISING PHYSICIANS TO PERSONALLY CONSULT
4 WITH PHYSICIAN ASSISTANTS AND NURSE PRACTITIONERS WHO PRESCRIBE
5 CERTAIN SCHEDULE II OR III CONTROLLED SUBSTANCES FOR LONG-TERM
6 USE; REQUIRING ELECTRONIC PRESCRIBING OF CERTAIN SCHEDULE II AND
7 III CONTROLLED SUBSTANCES; ESTABLISHING MAXIMUM LIMITS FOR
8 INITIAL PRESCRIPTIONS OF CERTAIN SCHEDULE II AND III CONTROLLED
9 SUBSTANCES; REQUIRING HOSPICE AND PALLIATIVE CARE PROVIDERS TO
10 PROVIDE EDUCATION REGARDING PROPER DISPOSAL OF CERTAIN UNUSED
11 CONTROLLED SUBSTANCES; CLARIFYING ALLOWABLE FUNDS FOR SYRINGE
12 EXCHANGE PROGRAMS; REQUIRING VETERINARIAN PARTICIPATION IN THE
13 CONTROLLED SUBSTANCES REPORTING SYSTEM; ESTABLISHING CIVIL
14 PENALTIES FOR PHARMACIES THAT EMPLOY DISPENSERS WHO IMPROPERLY
15 REPORT INFORMATION TO THE CONTROLLED SUBSTANCES REPORTING
16 SYSTEM (CSRS); EXPANDING THE ROLE OF THE DEPARTMENT OF HEALTH
17 AND HUMAN SERVICES (DHHS) IN USING CSRS DATA TO DETECT AND
18 PREVENT FRAUD AND MISUSE; MANDATING DISPENSER REGISTRATION FOR
19 ACCESS TO THE CSRS; MANDATING DISPENSER AND PRACTITIONER USE OF
20 THE CSRS; REQUIRING DHHS TO REPORT PRACTITIONERS WHO FAIL TO
21 PROPERLY USE THE CSRS; CREATING A SPECIAL REVENUE FUND TO
22 SUPPORT THE CSRS; AND REQUIRING AN ANNUAL REPORT FROM DHHS ON
23 THE CSRS.
24

25 Whereas, the General Assembly recognizes the substantial impact the nationwide
26 opioid epidemic continues to have on the State of North Carolina; and

27 Whereas, North Carolina has seen a 442% increase in overdose deaths caused by
28 commonly prescribed opioids between 1999 and 2015; and

29 Whereas, the General Assembly fully recognizes the appropriate use of opioids in
30 the treatment of acute and chronic pain; Now, therefore,
31 The General Assembly of North Carolina enacts:
32

33 PART I. TITLE OF ACT



1 **SECTION 1.** This act shall be known and may be cited as the "Strengthen Opioid
2 Misuse Prevention Act of 2017" or the "STOP Act."

3
4 **PART II. EXTEND STANDING ORDERS FOR OPIOID ANTAGONIST TO**
5 **COMMUNITY HEALTH GROUPS**

6 **SECTION 2.** G.S. 90-12.7 reads as rewritten:

7 **"§ 90-12.7. Treatment of overdose with opioid antagonist; immunity.**

8 (a) As used in this section, "opioid antagonist" means naloxone hydrochloride that is
9 approved by the federal Food and Drug Administration for the treatment of a drug overdose.

10 (b) The following individuals may prescribe an opioid antagonist in the manner
11 prescribed by this subsection:

12 (1) A practitioner acting in good faith and exercising reasonable care may
13 directly or by standing order prescribe an opioid antagonist to (i) a person at
14 risk of experiencing an opiate-related overdose or (ii) a family member,
15 friend, or other person in a position to assist a person at risk of experiencing
16 an opiate-related overdose. As an indicator of good faith, the practitioner,
17 prior to prescribing an opioid under this subsection, may require receipt of a
18 written communication that provides a factual basis for a reasonable
19 conclusion as to either of the following:

20 a. The person seeking the opioid antagonist is at risk of experiencing an
21 opiate-related overdose.

22 b. The person other than the person who is at risk of experiencing an
23 opiate-related overdose, and who is seeking the opioid antagonist, is
24 in relation to the person at risk of experiencing an opiate-related
25 overdose:

26 1. A family member, friend, or other person.

27 2. In the position to assist a person at risk of experiencing an
28 opiate-related overdose.

29 (2) The State Health Director or a designee may prescribe an opioid antagonist
30 pursuant to subdivision (1) of this subsection by means of a statewide
31 standing order.

32 (3) A practitioner acting in good faith and exercising reasonable care may
33 directly or by standing order prescribe an opioid antagonist to any
34 governmental or nongovernmental organization, including a local health
35 department, a law enforcement agency, or an organization that promotes
36 scientifically proven ways of mitigating health risks associated with
37 substance use disorders and other high-risk behaviors, for the purpose of
38 distributing, through its agents, the opioid antagonist to (i) a person at risk of
39 experiencing an opiate-related overdose or (ii) a family member, friend, or
40 other person in a position to assist a person at risk of experiencing an
41 opiate-related overdose.

42 (c) A pharmacist may dispense an opioid antagonist to a person ~~described in~~
43 ~~subdivision (b)(1) of this section~~ or organization pursuant to a prescription issued ~~pursuant to in~~
44 accordance with subsection (b) of this section. For purposes of this section, the term
45 "pharmacist" is as defined in G.S. 90-85.3.

46 (c1) A governmental or nongovernmental organization, including a local health
47 department, a law enforcement agency, or an organization that promotes scientifically proven
48 ways of mitigating health risks associated with substance use disorders and other high-risk
49 behaviors may, through its agents, distribute an opioid antagonist obtained pursuant to a
50 prescription issued in accordance with subdivision (3) of subsection (b) of this section to (i) a
51 person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or

1 other person in a position to assist a person at risk of experiencing an opiate-related overdose.
2 An organization, through its agents, shall include with any distribution of an opioid antagonist
3 pursuant to this subsection basic instruction and information on how to administer the opioid
4 antagonist.

5 (d) A person who receives an opioid antagonist that was prescribed pursuant to
6 subsection (b) of this section or distributed pursuant to subsection (c1) of this section may
7 administer an opioid antagonist to another person if (i) the person has a good faith belief that
8 the other person is experiencing a drug-related overdose and (ii) the person exercises
9 reasonable care in administering the drug to the other person. Evidence of the use of reasonable
10 care in administering the drug shall include the receipt of basic instruction and information on
11 how to administer the opioid antagonist.

12 (e) All of the following individuals are immune from any civil or criminal liability for
13 actions authorized by this section:

- 14 (1) Any practitioner who prescribes an opioid antagonist pursuant to subsection
15 (b) of this section.
- 16 (2) Any pharmacist who dispenses an opioid antagonist pursuant to subsection
17 (c) of this section.
- 18 (3) Any person who administers an opioid antagonist pursuant to subsection (d)
19 of this section.
- 20 (4) The State Health Director acting pursuant to subsection (b) of this section.
- 21 (5) Any organization, or agent of the organization, that distributes an opioid
22 antagonist pursuant to subsection (c1) of this section."

23 24 **PART III. IMPROVE OPIOID PRESCRIBING PRACTICES**

25 **SECTION 3.** G.S. 90-87 reads as rewritten:

26 **"§ 90-87. Definitions.**

27 As used in this Article:

28 ...

29 (26a) "Targeted controlled substance" means any controlled substance included in
30 G.S. 90-90(1) or (2) or G.S. 90-91(d).

31"

32 **SECTION 4.** G.S. 90-18.1(b) is amended by adding a new subdivision to read:

33 "(5) A physician assistant shall personally consult with the supervising physician
34 prior to prescribing a targeted controlled substance as defined in Article 5 of
35 this Chapter when all of the following conditions apply:

- 36 a. The patient is being treated by a facility that primarily engages in the
37 treatment of pain by prescribing narcotic medications or advertises in
38 any medium for any type of pain management services.
- 39 b. The therapeutic use of the targeted controlled substance will or is
40 expected to exceed a period of 30 days.

41 When a targeted controlled substance prescribed in accordance with this
42 subdivision is continuously prescribed to the same patient, the physician
43 assistant shall consult with the supervising physician at least once every 90
44 days to verify that the prescription remains medically appropriate for the
45 patient."

46 **SECTION 5.** G.S. 90-18.2(b) is amended by adding a new subdivision to read:

47 "(5) A nurse practitioner shall personally consult with the supervising physician
48 prior to prescribing a targeted controlled substance as defined in Article 5 of
49 this Chapter when all of the following conditions apply:

- 1 a. The patient is being treated by a facility that primarily engages in the
2 treatment of pain by prescribing narcotic medications or advertises in
3 any medium for any type of pain management services.
4 b. The therapeutic use of the targeted controlled substance will or is
5 expected to exceed a period of 30 days.

6 When a targeted controlled substance prescribed in accordance with this
7 subdivision is continuously prescribed to the same patient, the nurse
8 practitioner shall consult with the supervising physician at least once every
9 90 days to verify that the prescription remains medically appropriate for the
10 patient."

11 **SECTION 6.** G.S. 90-106 reads as rewritten:

12 **"§ 90-106. Prescriptions and labeling.**

13 ~~(a) Except when dispensed directly by a practitioner, other than a pharmacist, to an~~
14 ~~ultimate user, no controlled substance included in Schedule II of this Article may be dispensed~~
15 ~~without the written prescription of a practitioner. No Schedule II substance shall be dispensed~~
16 ~~pursuant to a written or electronic prescription more than six months after the date it was~~
17 ~~prescribed.~~

18 (a1) Electronic Prescription Required; Exceptions. – Unless otherwise exempted by this
19 subsection, a practitioner shall electronically prescribe all targeted controlled substances. This
20 subsection does not apply to prescriptions for targeted controlled substances issued by any of
21 the following:

- 22 (1) A practitioner, other than a pharmacist, who dispenses directly to an ultimate
23 user.
24 (2) A practitioner who orders a controlled substance to be administered in a
25 hospital, nursing home, hospice facility, outpatient dialysis facility, or
26 residential care facility, as defined in G.S. 14-32.2.
27 (3) A practitioner who experiences temporary technological or electrical failure
28 or other extenuating circumstance that prevents the prescription from being
29 transmitted electronically; provided, however, that the practitioner
30 documents the reason for this exception in the patient's medical record.
31 (4) A practitioner who writes a prescription to be dispensed by a pharmacy
32 located on federal property; provided, however, that the practitioner
33 documents the reason for this exception in the patient's medical record.
34 (5) A person licensed to practice veterinary medicine pursuant to Article 11 of
35 Chapter 90 of the General Statutes.

36 (a2) Verification by Dispenser Not Required. – A dispenser is not required to verify that
37 a practitioner properly falls under one of the exceptions specified in subsection (a1) of this
38 section prior to dispensing a targeted controlled substance. A dispenser may continue to
39 dispense targeted controlled substances from valid written, oral, or facsimile prescriptions that
40 are otherwise consistent with applicable laws.

41 (a3) Limitation on Prescriptions Upon Initial Consultation for Acute Pain. – A
42 practitioner may not prescribe more than a five-day supply of any targeted controlled substance
43 upon the initial consultation and treatment of a patient for acute pain, unless the prescription is
44 for post-operative acute pain relief for use immediately following a surgical procedure. A
45 practitioner shall not prescribe more than a seven-day supply of any targeted controlled
46 substance for post-operative acute pain relief immediately following a surgical procedure.
47 Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate
48 renewal, refill, or new prescription for a targeted controlled substance. This subsection does not
49 apply to prescriptions for controlled substances issued by a practitioner who orders a controlled
50 substance to be wholly administered in a hospital, nursing home licensed under Chapter 131E
51 of the General Statutes, hospice facility, or residential care facility, as defined in

1 G.S. 14-32.2(c1). A practitioner who acts in accordance with the limitation on prescriptions as
2 set forth in this subsection shall be immune from any civil liability or disciplinary action from
3 the practitioner's occupational licensing agency for acting in accordance with this subsection.

4 (a4) Definitions. – As used in this subsection, the following terms have the following
5 meanings:

6 (1) Acute pain. – Pain, whether resulting from disease, accident, intentional
7 trauma, or other cause, that the practitioner reasonably expects to last for
8 three months or less. The term does not include chronic pain or pain being
9 treated as part of cancer care, hospice care, palliative care, or
10 medication-assisted treatment for substance use disorder.

11 (2) Chronic pain. – Pain that typically lasts for longer than three months or that
12 lasts beyond the time of normal tissue healing.

13 (3) Surgical procedure. – A procedure that is performed for the purpose of
14 structurally altering the human body by incision or destruction of tissues as
15 part of the practice of medicine. This term includes the diagnostic or
16 therapeutic treatment of conditions or disease processes by use of
17 instruments such as lasers, ultrasound, ionizing, radiation, scalpels, probes,
18 or needles that cause localized alteration or transportation of live human
19 tissue by cutting, burning, vaporizing, freezing, suturing, probing, or
20 manipulating by closed reduction for major dislocations and fractures, or
21 otherwise altering by any mechanical, thermal, light-based, electromagnetic,
22 or chemical means.

23 (a5) Dispenser Immunity. – A dispenser shall be immune from any civil or criminal
24 liability or disciplinary action from the Board of Pharmacy for dispensing a prescription written
25 by a prescriber in violation of this section.

26 (b) In emergency situations, as defined by rule of the Commission, Schedule II drugs
27 may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed
28 by the dispensing agent. Prescriptions shall be retained in conformity with the requirements of
29 G.S. 90-104. No prescription for a Schedule II substance may be refilled.

30 (c) Except when dispensed directly by a practitioner, other than a pharmacist, to an
31 ultimate user, no controlled substance included in Schedules III or IV, except paregoric, U.S.P.,
32 as provided in G.S. 90-91(e)1, may be dispensed without a prescription, and oral prescriptions
33 shall be promptly reduced to writing and filed with the dispensing agent. Such prescription may
34 not be filled or refilled more than six months after the date thereof or be refilled more than five
35 times after the date of the prescription.

36 (d) No controlled substance included in Schedule V of this Article or paregoric, U.S.P.,
37 may be distributed or dispensed other than for a medical purpose.

38 (e) No controlled substance included in Schedule VI of this Article may be distributed
39 or dispensed other than for scientific or research purposes by persons registered under, or
40 permitted by, this Article to engage in scientific or research projects.

41 (f) No controlled substance shall be dispensed or distributed in this State unless such
42 substance shall be in a container clearly labeled in accord with regulations lawfully adopted and
43 published by the federal government or the Commission.

44 (g) When a copy of a prescription for a controlled substance under this Article is given
45 as required by G.S. 90-70, such copy shall be plainly marked: "Copy – for information only."
46 Copies of prescriptions for controlled substances shall not be filled or refilled.

47 (h) A pharmacist dispensing a controlled substance under this Article shall enter the
48 date of dispensing on the prescription order pursuant to which such controlled substance was
49 dispensed.

50 (i) A manufacturer's sales representative may distribute a controlled substance as a
51 complimentary sample only upon the written request of a practitioner. Such request must be

1 made on each distribution and must contain the names and addresses of the supplier and the
2 requester and the name and quantity of the specific controlled substance requested. The
3 manufacturer shall maintain a record of each such request for a period of two years."

4 **SECTION 7.** Article 5 of Chapter 90 of the General Statutes is amended by adding
5 a new section to read:

6 **"§ 90-106.3. Disposal of residual pain prescriptions following death of hospice or**
7 **palliative care patient.**

8 Any hospice or palliative care provider who prescribes a targeted controlled substance to be
9 administered to a patient in his or her home for the treatment of pain as part of in-home hospice
10 or palliative care shall, at the commencement of treatment, provide oral and written information
11 to the patient and his or her family regarding the proper disposal of such targeted controlled
12 substances. This information shall include the availability of permanent drop boxes or periodic
13 "drug take-back" events that allow for the safe disposal of controlled substances such as those
14 permanent drop boxes and events that may be identified through North Carolina Operation
15 Medicine Drop."

16
17 **PART IV. CLARIFY ALLOWABLE FUNDS FOR SYRINGE EXCHANGE**
18 **PROGRAMS**

19 **SECTION 8.** G.S. 90-113.27(b)(2) reads as rewritten:

20 "(2) Needles, hypodermic syringes, and other injection supplies at no cost and in
21 quantities sufficient to ensure that needles, hypodermic syringes, and other
22 injection supplies are not shared or reused. No ~~public~~-State funds may be
23 used to purchase needles, hypodermic syringes, or other injection supplies."
24

25 **PART V. STRENGTHEN CONTROLLED SUBSTANCES REPORTING SYSTEM**

26 **SECTION 9.** G.S. 90-113.72 reads as rewritten:

27 **"§ 90-113.72. Definitions.**

28 The following definitions apply in this Article:

- 29 (1) ~~"Commission" means the Commission.~~ – The Commission for Mental
30 Health, Developmental Disabilities, and Substance Abuse Services
31 established under Part 4 of Article 3 of Chapter 143B of the General
32 Statutes.
- 33 (2) ~~"Controlled substance" means a Controlled substance.~~ – A controlled
34 substance as defined in G.S. 90-87(5).
- 35 (3) ~~"Department" means the Department.~~ – The Department of Health and
36 Human Services.
- 37 (4) ~~"Dispenser" means a Dispenser.~~ – A person who delivers a Schedule II
38 through V controlled substance to an ultimate user in North Carolina, but
39 does not include any of the following:
- 40 a. A licensed hospital or long-term care pharmacy that dispenses such
41 substances for the purpose of inpatient administration.
- 42 b. Repealed by Session Laws 2013-152, s. 1, effective January 1, 2014,
43 and applicable to prescriptions delivered on or after that date.
- 44 c. A wholesale distributor of a Schedule II through V controlled
45 substance.
- 46 d. A person licensed to practice veterinary medicine pursuant to Article
47 11 of Chapter 90 of the General Statutes.
- 48 (4a) Pharmacy. – A person or entity holding a valid pharmacy permit pursuant to
49 G.S. 90-85.21 or G.S. 90-85.21A.
- 50 (5) ~~"Ultimate user" means a Ultimate user.~~ – A person who has lawfully
51 obtained, and who possesses, a Schedule II through V controlled substance

1 for the person's own use, for the use of a member of the person's household,
2 or for the use of an animal owned or controlled by the person or by a
3 member of the person's household."

4 **SECTION 10.** G.S. 90-113.73 reads as rewritten:

5 "**§ 90-113.73. Requirements for controlled substances reporting ~~system~~system; ~~civil~~
6 penalties for failure to properly report.**

7 (a) The Department shall establish and maintain a reporting system of prescriptions for
8 all Schedule II through V controlled substances. Each dispenser shall submit the information in
9 accordance with transmission methods and frequency established by rule by the Commission.
10 The Department may issue a waiver to a dispenser who is unable to submit prescription
11 information by electronic means. The waiver may permit the dispenser to submit prescription
12 information by paper form or other means, provided all information required of electronically
13 submitted data is submitted. The dispenser shall report the information required under this
14 section no later than ~~the close of business three business days after the day when the~~
15 ~~prescription was delivered, beginning the next day after the delivery date; however, dispensers~~
16 ~~are encouraged to report the information no later than 24 hours~~the close of the next business
17 day after the prescription is delivered; however, dispensers are encouraged to report the
18 information no later than 24 hours after the prescription was delivered. The information shall
19 be submitted in a format as determined annually by the Department based on the format used in
20 the majority of the states operating a controlled substances reporting system. In the event the
21 dispenser is unable to report the information within the time frame required by this section
22 because the system is not operational or there is some other temporary electrical or
23 technological failure, this inability shall be documented in the dispenser's records. Once the
24 electrical or technological failure has been resolved, the dispenser shall promptly report the
25 information.

26 (b) The Commission shall adopt rules requiring dispensers to report the following
27 information. The Commission may modify these requirements as necessary to carry out the
28 purposes of this Article. The dispenser shall report:

- 29 (1) The dispenser's DEA number.
30 (2) The name of the patient for whom the controlled substance is being
31 dispensed, and the patient's:
32 a. Full address, including city, state, and zip code,
33 b. Telephone number, and
34 c. Date of birth.
35 (3) The date the prescription was written.
36 (4) The date the prescription was filled.
37 (5) The prescription number.
38 (6) Whether the prescription is new or a refill.
39 (7) Metric quantity of the dispensed drug.
40 (8) Estimated days of supply of dispensed drug, if provided to the dispenser.
41 (9) National Drug Code of dispensed drug.
42 (10) Prescriber's DEA number.
43 (11) Method of payment for the prescription.

44 (c) A dispenser shall not be required to report instances in which a controlled substance
45 is provided directly to the ultimate user and the quantity provided does not exceed a 48-hour
46 supply.

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

1 (e) The Department shall assess, against any pharmacy that employs dispensers found
2 to have failed to report information in the manner required by this section within a reasonable
3 period of time after being informed by the Department that the required information is missing
4 or incomplete, a civil penalty of not more than one hundred dollars (\$100.00) for a first
5 violation, two hundred fifty dollars (\$250.00) for a second violation, and five hundred dollars
6 (\$500.00) for each subsequent violation if the pharmacy fails to report as required under this
7 section, up to a maximum of five thousand dollars (\$5,000) per pharmacy per calendar year.
8 Each day of a continuing violation shall constitute a separate violation. A pharmacy acting in
9 good faith that attempts to report the information required by this section shall not be assessed
10 any civil penalty. The clear proceeds of penalties assessed under this section shall be deposited
11 to the Civil Penalty and Forfeiture Fund in accordance with Article 31A of Chapter 115C of the
12 General Statutes. The Commission shall adopt rules to implement this subsection that include
13 factors to be considered in determining the amount of the penalty to be assessed."

14 **SECTION 11.** G.S. 90-113.74 reads as rewritten:

15 "**§ 90-113.74. Confidentiality.**

16 ...
17 (b1) The Department may review the prescription information data in the controlled
18 substances reporting system and upon review may:

19 ...
20 (1a) Notify practitioners and their respective licensing boards of prescribing
21 behavior that (i) increases risk of diversion of controlled substances, (ii)
22 increases risk of harm to the patient, or (iii) is an outlier among other
23 practitioner behavior.

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

27 (1) Persons authorized to prescribe or dispense controlled substances for the
28 purpose of providing medical or pharmaceutical care for their patients. A
29 person authorized to receive data pursuant to this paragraph may delegate
30 the authority to receive the data to other persons working under his or her
31 direction and supervision, provided the Department approves this delegation.
32 a. The administrator of a hospital emergency department or hospital
33 acute care facility shall provide the Department with a list of
34 prescribers who are authorized to prescribe controlled substances for
35 the purpose of providing medical care for patients of the hospital
36 emergency department or hospital acute care facility and a list of
37 delegates who are authorized to receive data on behalf of the
38 providers listed. The administrator acting under this paragraph shall
39 submit the lists to the Department no later than December 1 of the
40 calendar year preceding the year during which the delegates are to
41 receive data and may provide updated lists at any time during the
42 course of the year. Within one week of receiving the initial or
43 updated lists described in this paragraph, the Department shall
44 establish all of the delegate accounts necessary to enable each
45 delegate listed by the administrator of the hospital emergency
46 department or hospital acute care facility to receive data on behalf of
47 the listed prescribers. Delegations made pursuant to this paragraph
48 are valid during the calendar year for which submitted by the
49 administrator.

50 "

1 SECTION 12. Article 5E of Chapter 90 of the General Statutes is amended by
2 adding new sections to read:

3 **"§ 90-113.74B. Mandatory dispenser registration for access to controlled substances**
4 **reporting system; exception.**

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

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

11 **"§ 90-113.74C. Practitioner use of controlled substances reporting system; mandatory**
12 **reporting of violations.**

13 (a) Prior to initially prescribing a targeted controlled substance to a patient, a
14 practitioner shall review the information in the controlled substances reporting system
15 pertaining to the patient for the 12-month period preceding the initial prescription. For every
16 subsequent three-month period that the targeted controlled substance remains a part of the
17 patient's medical care, the practitioner shall review the information in the controlled substances
18 reporting system pertaining to the patient for the 12-month period preceding the determination
19 that the targeted controlled substance should remain a part of the patient's medical care. Each
20 instance in which the practitioner reviews the information in the controlled substances reporting
21 system pertaining to the patient shall be documented in the patient's medical record. In the
22 event the practitioner is unable to review the information in the controlled substances reporting
23 system pertaining to the patient because the system is not operational or there is some other
24 temporary electrical or technological failure, this inability shall be documented in the patient's
25 medical record. Once the electrical or technological failure has been resolved, the practitioner
26 shall review the information in the controlled substances reporting system pertaining to the
27 patient and the review shall be documented in the patient's medical record.

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

31 (1) The controlled substance is to be administered to a patient in a health care
32 setting, hospital, nursing home, outpatient dialysis facility, or residential care
33 facility, as defined in G.S. 14-32.2.

34 (2) The controlled substance is prescribed for the treatment of cancer or another
35 condition associated with cancer.

36 (3) The controlled substance is prescribed to a patient in hospice care or
37 palliative care.

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

44 **"§ 90-113.74D. Dispenser use of controlled substances reporting system.**

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

49 (1) The dispenser has a reasonable belief that the ultimate user may be seeking a
50 targeted controlled substance for any reason other than the treatment of the
51 ultimate user's existing medical condition.

- 1 (2) The prescriber is located outside of the usual geographic area served by the
2 dispenser.
- 3 (3) The ultimate user resides outside of the usual geographic area served by the
4 dispenser.
- 5 (4) The ultimate user pays for the prescription with cash when the patient has
6 prescription insurance on file with the dispenser.
- 7 (5) The ultimate user demonstrates potential misuse of a controlled substance by
8 any one or more of the following:
- 9 a. Over-utilization of the controlled substance.
- 10 b. Requests for early refills.
- 11 c. Utilization of multiple prescribers.
- 12 d. An appearance of being overly sedated or intoxicated upon
13 presenting a prescription.
- 14 e. A request by an unfamiliar ultimate user for an opioid drug by a
15 specific name, street name, color, or identifying marks.

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

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

23 **"§ 90-113.75A. Creation of Controlled Substances Reporting System Fund.**

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

28 (b) The Fund shall consist of the following:

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

32 (c) All interest that accrues to the Fund shall be credited to the Fund. Any balance
33 remaining in the Fund at the end of any fiscal year shall remain in the Fund and shall not revert
34 to the General Fund.

35 **"§ 90-113.75B. Annual report to General Assembly and licensing boards.**

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

- 43 (1) The total number of prescriptions dispensed, broken down by Schedule.
- 44 (2) Demographics about the ultimate users to whom prescriptions were
45 dispensed.
- 46 (3) Statistics regarding the number of pills dispensed per prescription.
- 47 (4) The number of ultimate users who were prescribed a controlled substance by
48 two or more practitioners.
- 49 (5) The number of ultimate users to whom a prescription was dispensed in more
50 than one county.

1 (6) The categories of practitioners prescribing controlled substances and the
2 number of prescriptions authorized by each category of practitioner. For the
3 purpose of this subdivision, medical doctors, surgeons, palliative care
4 practitioners, oncologists and other practitioners specializing in oncology,
5 pain management practitioners, practitioners who specialize in hematology,
6 including the treatment of sickle cell disease, and practitioners who
7 specialize in treating substance use disorder shall be treated as distinct
8 categories of practitioners.

9 (7) Any other data deemed appropriate and requested by the Joint Legislative
10 Oversight Committee on Health and Human Services, the North Carolina
11 Medical Board, the North Carolina Board of Podiatry Examiners, the North
12 Carolina Board of Nursing, the North Carolina Dental Board, the North
13 Carolina Veterinary Medical Board, or the North Carolina Board of
14 Pharmacy."

15 **SECTION 13.(a)** Section 12F.16(h) of S.L. 2015-241 reads as rewritten:

16 "**SECTION 12F.16.(h)** ~~DHHS shall apply for grant funding from the National Association~~
17 ~~of Boards of Pharmacy to establish the connection to PMP InterConnect. The Department shall~~
18 ~~request forty thousand thirty five dollars (\$40,035) to establish the initial interface for PMP~~
19 ~~InterConnect and thirty thousand dollars (\$30,000) for two years of ongoing service,~~
20 ~~maintenance, and support for PMP InterConnect in order to create interstate connectivity for~~
21 ~~the drug monitoring program as required by subdivision (2) of subsection (f) of this section.~~The
22 Department of Health and Human Services, Division of Mental Health, Developmental
23 Disabilities, and Substance Abuse Services, shall continue to work toward establishing
24 interstate connectivity for the Controlled Substances Reporting System established under
25 G.S. 90-113.73."

26 **SECTION 13.(b)** Section 12F.16(i)(3) of S.L. 2015-241 reads as rewritten:

27 "(3) ~~For the 2015-2016 fiscal year, the sum of forty thousand thirty five dollars~~
28 ~~(\$40,035) shall be used to establish the initial interface for PMP~~
29 ~~InterConnect, as required by subdivision (2) of subsection (f) of this section.~~
30 ~~This amount shall be adjusted or eliminated if DHHS is successful in~~
31 ~~obtaining grant awards or identifying other allowable receipts for this~~
32 ~~purpose. If receipts are used for this purpose, this nonrecurring appropriation~~
33 ~~shall revert to the General Fund.~~The Department of Health and Human
34 Services, Division of Mental Health, Developmental Disabilities, and
35 Substance Abuse Services, shall continue to work toward establishing
36 interstate connectivity for the Controlled Substances Reporting System
37 established under G.S. 90-113.73."

38 **SECTION 14.** The Department of Health and Human Services shall conduct a
39 study, in consultation with the Office of the Attorney General and the North Carolina
40 Veterinary Medical Board, on how to implement the provisions of this act pertaining to
41 electronic prescriptions and the submission of data to the Controlled Substances Reporting
42 System as they relate to the practice of veterinary medicine. The Department shall submit a
43 report to the Joint Legislative Oversight Committee on Health and Human Services no later
44 than February 1, 2018.

45 **PART VI. EFFECTIVE DATE**

46 **SECTION 15.(a)** Sections 1, 2, 3, 4, 5, 7, 8, 11, and 13 of this act become effective
47 July 1, 2017.

48 **SECTION 15.(b)** Subsections (a), (a1), and (a2) of G.S. 90-106, as amended by
49 Section 6 of this act, become effective January 1, 2020.
50

1 **SECTION 15.(c)** Subsections (a3) and (a4) of G.S. 90-106, as amended by Section
2 6 of this act, become effective January 1, 2018.

3 **SECTION 15.(d)** Section 10 of this act and G.S. 90-113.75A and
4 G.S. 90-113.75B, as enacted by Section 12 of this act, become effective September 1, 2017.

5 **SECTION 15.(e)** The remainder of this act is effective when it becomes law and
6 applies to acts committed 30 days after the date the State Chief Information Officer notifies the
7 Revisor of Statutes that (i) the upgrades to the Controlled Substances Reporting System
8 (CSRS) database described in subdivisions (1) and (2) of subsection (a) of Section 12F.7 of
9 S.L. 2016-94 have been completed and (ii) the upgraded CSRS database is fully operational
10 within the Department of Information Technology and connected to the statewide health
11 information exchange.