HOUSE BILL 512

Short Title:	Pharmacists Improve Public Health Needs.	(Public)
Sponsors:	Representative Sasser. *For a complete list of sponsors, refer to the North Carolina General Assembly web site.*	
Referred to:	Health, if favorable, Insurance, if favorable, Rules, Calendar, and Operations of the House	

April 12, 2021

A BILL TO BE ENTITLED

AN ACT TO AUTHORIZE CLINICAL PHARMACIST PRACTITIONERS AND IMMUNIZING PHARMACISTS TO PRESCRIBE, DISPENSE, AND ADMINISTER CERTAIN TREATMENT AND MEDICATIONS.

Whereas, it is the intention of the North Carolina General Assembly to improve access to care and health outcomes for its citizens; and

Whereas, North Carolina's public health ranking is in the bottom one-half to one-third of the nation; and

Whereas, one-third of our nation's states have authorized pharmacists to help with access to care related to public health needs beyond immunizations; and

Whereas, North Carolinians need and deserve better accessibility to care; Now, therefore,

The General Assembly of North Carolina enacts:

SECTION 1.(a) G.S. 90-12.7 reads as rewritten:

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

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

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

(1) A ~~practitioner~~ practitioner, an immunizing pharmacist, as defined in G.S. 90-85.3, or a clinical pharmacist practitioner, as defined in G.S. 90-85.3, acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. As an indicator of good faith, the practitioner, prior to prescribing an opioid under this subsection, may require receipt of a written communication that provides a factual basis for a reasonable conclusion as to either of the following:

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

b. The person other than the person who is at risk of experiencing an opiate-related overdose, and who is seeking the opioid antagonist, is

in relation to the person at risk of experiencing an opiate-related overdose:

1. A family member, friend, or other person.
2. In the position to assist a person at risk of experiencing an opiate-related overdose.

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

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

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

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SECTION 1.(b) G.S. 90-85.15B reads as rewritten:

"**§ 90-85.15B. Immunizing pharmacists.**

(a) Except as provided in subsection (b) and (c) of this section, an immunizing pharmacist may administer vaccinations or immunizations only if the vaccinations or immunizations are recommended or required by the Centers for Disease Control and Prevention and administered to persons at least 18 years of age pursuant to a specific prescription order.

(b) An immunizing pharmacist may administer the vaccinations or immunizations listed in subdivisions (1) through (7) of this subsection to persons at least 18 years of age if the vaccinations or immunizations are administered under written protocols as defined in 21 NCAC 46. 2507(b)(12) and 21 NCAC 32U. 0101(b)(12) and in accordance with the supervising physician's responsibilities as defined in 21 NCAC 46. 2507(e) and 21 NCAC 32U. 0101(e), and the physician is licensed in and has a practice physically located in North Carolina:

(1) Pneumococcal polysaccharide or pneumococcal conjugate vaccines.
(2) Herpes zoster vaccine.
(3) Hepatitis B vaccine.
(4) Meningococcal polysaccharide or meningococcal conjugate vaccines and Serogroup B meningococcal vaccines.
(5) Tetanus-diphtheria, tetanus and diphtheria toxoids and pertussis, tetanus and diphtheria toxoids and acellular pertussis, or tetanus toxoid vaccines. However, a pharmacist shall not administer any of these vaccines if the patient discloses that the patient has an open wound, puncture, or tissue tear.
(6) Human Papillomavirus vaccine.
(7) Hepatitis A vaccine.

(c) An immunizing pharmacist may administer the influenza vaccine to persons at least 10 years of age pursuant to 21 NCAC 46. 2507 and 21 NCAC 32U. 0101. An immunizing pharmacist may administer an influenza vaccine <u>and any other vaccinations approved by the United States Food and Drug Administration in accordance with the protocols established by the Advisory Committee on Immunization Practices</u> to persons at least six years of age pursuant to a specific prescription order initiated by a prescriber following a physical examination of the patient by the prescriber.

(c1) An immunizing pharmacist may administer a long-acting injectable medication to persons at least 18 years of age pursuant to a specific prescription order initiated by a prescriber following a physical examination of the patient by the prescriber. An immunizing pharmacist who administers a long-acting injectable medication pursuant to this section shall do all of the following:

(1) Maintain a record of any administration of a long-acting injectable performed by the immunizing pharmacist to the patient in a patient profile or record.

(2) Within 72 hours after the administration of the long-acting injectable performed by the immunizing pharmacist to the patient, notify the prescriber regarding which medication and dosage was administered to the patient.

(c2) An immunizing pharmacist may prescribe and dispense the following medications:

(1) Naloxone or other opioid antagonist and any drug delivery paraphernalia necessary to administer the opioid antagonist in accordance with G.S. 90-12.7.

(2) Tobacco cessation medications that are approved by the United States Food and Drug Administration.

(3) Epinephrine or other anaphylaxis management medication, including self-administered formulations for the management of severe allergic reaction.

(4) Glucagon or other self-administered formulations for the management of hypoglycemia.

(5) Short-acting bronchodilators, for patients with an established diagnosis of asthma.

(6) Hormonal contraceptives, injectable or self-administered, after the patient completes an assessment consistent with the Centers for Disease Control and Prevention's United States Medical Eligibility Criteria (USMEC) for Contraceptive Use.

(7) Prenatal vitamins.

(8) Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

(9) Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services.

(10) Prescription medications, not requiring a diagnosis, that are recommended by the Centers for Disease Control and Prevention for individuals traveling outside the United States.

(d) An immunizing pharmacist who administers a vaccine or immunization to any patient pursuant to this section or prescribes and dispenses a medication listed in subsection (c2) of this section to a patient shall do all of the following:

(1) Maintain a record of any vaccine or immunization administered to the patient in a patient ~~profile.~~profile for a period of five years from the patient's most recent provision of service.

(2) Within 72 hours after administration of the vaccine or immunization, or medication listed in subsection (c2) of this section, notify any primary care provider identified by the patient. If the patient does not identify a primary care provider, the immunizing pharmacist shall direct the patient to information describing the benefits to a patient of having a primary care physician, including information about federally qualified health centers, free clinics, and local health departments, prepared by any of the following: North

Carolina Medical Board, North Carolina Academy of Family Physicians, North Carolina Medical Society, or Community Care of North Carolina.

(3) Except for influenza vaccines administered under G.S. 90-85.15B(c), access the North Carolina Immunization Registry prior to administering the vaccine or immunization and record any vaccine or immunization administered to the patient in the registry within 72 hours after the administration. In the event the registry is not operable, an immunizing pharmacist shall report as soon as reasonably possible.

(4) Furnish patient records to the patient upon the patient's request.

(5) Furnish patient records to the primary care provider identified by the patient upon the primary care provider's request.

(6) If the immunizing pharmacist has administered or dispensed a hormonal contraceptive to the patient, the immunizing pharmacist shall counsel the patient about preventative care, including well-woman visits, sexually transmitted infection testing information, and Pap smear testing.

(e) An immunizing pharmacist may test or screen for and treat minor, nonchronic health conditions. An immunizing pharmacist may use tests waived under the federal Clinical Laboratory Improvement Amendments of 1988, or applicable federal rules and regulations that are approved for performance by pharmacists. For the purposes of this subsection, a "minor, nonchronic health condition" is a short-term condition that is generally managed with minimal treatment or self-care. An immunizing pharmacist that tests or screens for and treats a minor, nonchronic health condition must do all of the following:

(1) Maintain a record of any vaccine or immunization administered to the patient in a patient profile for a period of five years from the patient's most recent provision of service.

(2) Furnish patient records to the patient upon the patient's request.

(3) Furnish patient records to the primary care provider identified by the patient upon the primary care provider's request.

(f) An immunizing pharmacist that prescribes and dispenses the medications listed in subsection (c2) of this section shall comply with the following conditions:

(1) The North Carolina Medical Board and the North Carolina Board of Pharmacy have adopted rules developed by a joint subcommittee governing the approval of the individual immunizing pharmacist to administer, prescribe, and dispense the medications with limitations that the Boards determine to be in the best interest of patient health and safety.

(2) The immunizing pharmacist has current approval from both Boards.

(3) The North Carolina Medical Board has assigned an identification number to the immunizing pharmacist which is shown on written prescriptions written by the immunizing pharmacist."

SECTION 1.(c) G.S. 90-18.4 reads as rewritten:

"**§ 90-18.4. Limitations on clinical pharmacist practitioners.**

(a) Any pharmacist who is approved under the provisions of G.S. 90-18(c)(3a) to perform medical acts, tasks, and functions may use the title "clinical pharmacist practitioner". Any other person who uses the title in any form or holds himself or herself out to be a clinical pharmacist practitioner or to be so licensed shall be deemed to be in violation of this Article.

(b) Clinical pharmacist practitioners are authorized to implement predetermined drug therapy, which includes diagnosis and product selection by the patient's physician, modify prescribed drug dosages, dosage forms, and dosage schedules, and to order laboratory tests pursuant to a drug therapy management agreement that is physician, pharmacist, patient, and disease specific under the following conditions:

(1) The North Carolina Medical Board and the North Carolina Board of Pharmacy have adopted rules developed by a joint subcommittee governing the approval of individual clinical pharmacist practitioners to practice drug therapy management with such limitations that the Boards determine to be in the best interest of patient health and safety.
(2) The clinical pharmacist practitioner has current approval from both Boards.
(3) The North Carolina Medical Board has assigned an identification number to the clinical pharmacist practitioner which is shown on written prescriptions written by the clinical pharmacist practitioner.
(4) The drug therapy management agreement prohibits the substitution of a chemically dissimilar drug product by the pharmacist for the product prescribed by the physician without the explicit consent of the physician and includes a policy for periodic review by the physician of the drugs modified pursuant to the agreement or changed with the consent of the physician.

(b1) Clinical pharmacist practitioners may prescribe and dispense the following medications:

(1) Naloxone or other opioid antagonist and any drug delivery paraphernalia necessary to administer the opioid antagonist in accordance with G.S. 90-12.7.
(2) Tobacco cessation medications that are approved by the United States Food and Drug Administration.
(3) Epinephrine or other anaphylaxis management medication, including self-administered formulations for the management of severe allergic reaction.
(4) Glucagon or other self-administered formulations for the management of hypoglycemia.
(5) Short-acting bronchodilators, for patients with an established diagnosis of asthma.
(6) Hormonal contraceptives, injectable or self-administered, after the patient completes an assessment consistent with the Centers for Disease Control and Prevention's United States Medical Eligibility Criteria (USMEC) for Contraceptive Use.
(7) Prenatal vitamins.
(8) Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.
(9) Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services.
(10) Prescription medications, not requiring a diagnosis, that are recommended by the Centers for Disease Control and Prevention for individuals traveling outside the United States.

(b2) Clinical pharmacist practitioners that prescribe and dispense the medications listed in subsection (b1) of this section shall comply with the following conditions:

(1) The North Carolina Medical Board and the North Carolina Board of Pharmacy have adopted rules developed by a joint subcommittee governing the approval of individual clinical pharmacist practitioners to administer, prescribe, and dispense the medications with limitations that the Boards determine to be in the best interest of patient health and safety.
(2) The clinical pharmacist practitioner has current approval from both Boards.

(3) The North Carolina Medical Board has assigned an identification number to the clinical pharmacist practitioner which is shown on written prescriptions written by the clinical pharmacist practitioner.

…."

SECTION 2.(a) The North Carolina Medical Board and the North Carolina Board of Pharmacy joint subcommittee shall develop statewide written protocols and amend existing rules and protocols to implement all of the following:

(1) Provide and develop certification for clinical pharmacist practitioners and immunizing pharmacists that encompass the new authorized treatments and practices as authorized in this act.

(2) Develop training for screening, testing, and treating minor, nonchronic health conditions, including patient assessments, triage and referral, point-of-care testing procedures, safe and effective treatment, identification of contraindications, patient education, and documentation requirements.

(3) Create a list of minor, nonchronic health conditions eligible for testing, screening, and treatment by clinical pharmacist practitioners and immunizing pharmacists.

(4) Create a formulary of medications approved by the United States Food and Drug Administration to treat the specific minor, nonchronic health conditions. The medications must not be Schedule I–IV Controlled Substances as defined by the North Carolina Controlled Substances Act.

SECTION 2.(b) This section becomes effective October 1, 2021.

SECTION 3. Except as otherwise provided, this act becomes effective October 1, 2022, and applies to immunizing pharmacists and clinical pharmacist practitioners on or after that date.