

**GUIDANCE TO S.L. 2021-110: AN ACT TO AUTHORIZE IMMUNIZING
PHARMACISTS TO DISPENSE, DELIVER, AND ADMINISTER CERTAIN
TREATMENT AND MEDICATIONS**

On August 19, 2021 Governor Cooper signed S.L. 2021-110, which expands practice authority for certain pharmacists and pharmacy technicians. This guidance document reviews the granted authorities, timelines and conditions for implementation, and how existing US DHHS PREP Act declarations intersect with (and in some cases supersede) this authority.

As this guidance details, full implementation of S.L. 2021-110 requires a number of actions over a number of different timelines. Board staff will update this guidance document regularly as those processes go forward.

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Q. Which pharmacists obtain additional authority under this statute?

A. Each of the expanded practice authorities is granted to “immunizing pharmacists.” An “immunizing pharmacist” is one who:

- (1) Holds a current provider level cardiopulmonary resuscitation certification issued by the American Heart Association or the American Red Cross, or an equivalent certification.
- (2) Has successfully completed a certificate program in vaccine administration accredited by the Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education, or a similar health authority or professional body approved by the Board.
- (3) Maintains documentation of three hours of continuing education every two years, designed to maintain competency in the disease states, drugs, and vaccine administration.
- (4) Has successfully completed training approved by the Division of Public Health's Immunization Branch for participation in the North Carolina Immunization Registry.
- (5) Has notified the North Carolina Board of Pharmacy and the North Carolina Medical Board of immunizing pharmacist status.
- (6) Administers vaccines or immunizations in accordance with G.S. 90-18.15B.

NOTE These are not new requirements for immunizing pharmacist status.

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Q. What are the changes to immunizing pharmacists' vaccine administration authority?

A. Influenza vaccine. There are no changes to immunizing pharmacists' ability to administer influenza vaccines. Immunizing pharmacists may administer influenza vaccine to any patient age 10 or older pursuant to protocol, and to any patient age 6 or older pursuant to a prescription order. ***NOTE*** Under US DHHS PREP Act declarations, pharmacists have authority to order and administer any ACIP-recommended vaccine (including flu) to patients age 3 to 18 and flu vaccine to any patient age 19 or older. When PREP Act declarations are rescinded, pharmacist authority will be governed by state law as described above.

COVID vaccine. Immunizing pharmacists may administer a COVID vaccine (that has received FDA approval or emergency use authorization) to any patient age 10 or older pursuant to protocol, and any patient age 6 or older pursuant to a prescription order. This revised authority is effective September 1, 2021. ***NOTE*** Under US DHHS PREP Act declarations, pharmacists have authority to order and administer COVID vaccine to patients age 3 or older (should one be approved for the patient's age group). When PREP Act declarations are rescinded, pharmacist authority will be governed by state law as described above.

Existing protocol-based vaccination authority unchanged. The list of vaccines that a pharmacist may administer to a patient age 18 or older pursuant to protocol – pneumococcal, herpes zoster, hepatitis B, meningococcal, tetanus-diphtheria, tetanus, diphtheria, HPV, and hepatitis A, in addition to the influenza vaccine – has not changed.

Vaccines pursuant to prescription. Effective February 1, 2022, the age for patients to receive any FDA-approved vaccine in accordance with ACIP recommendations from any immunizing pharmacist pursuant to a specific prescription order has been lowered to patients age 6 or older. Until February 1, 2022, state law will continue to allow any immunizing pharmacist to administer any CDC-recommended vaccines to patients age 18 or older pursuant to prescription. ***NOTE*** Under US DHHS PREP Act declarations, pharmacists have authority to order and administer any ACIP-recommended vaccine to patients age 3 to 18. When PREP Act declarations are rescinded, pharmacist authority will be governed by state law.

Minor's consent to emergency use authorization vaccines. North Carolina law allows minors to consent to their own medical health services in certain circumstances – and those include services for the prevention, diagnosis, and treatment of COVID-19. S.L. 2021-110, however, changes that statute to require a health care provider to “obtain written consent from a parent or legal guardian prior to administering any vaccine that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration to an individual under 18 years of age.” A minor would be able to consent to their own vaccination for COVID with a fully FDA-approved vaccine. This provision is effective immediately.

NOTE ON IMPLEMENTATION TIMELINES Note that the General Assembly decided to make the COVID vaccine changes effective on September 1, 2021, while delaying the expanded age groups for vaccinations pursuant to prescription until February 1, 2022. However, as noted, pharmacists have existing authority under the PREP Act declarations that is broader than the revised state law authority. Board of Pharmacy staff will update pharmacists when PREP Act authority changes to bring these revised state law authorities into practical effect.

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Q. What is the new authority for pharmacy technicians to administer certain vaccines?

A. A pharmacy technician who is supervised by an immunizing pharmacist and has completed immunization-related continuing pharmacy education approved by ACPE may administer flu vaccine and COVID vaccine (that has received FDA approval or emergency use authorization) to patients age 10 or older pursuant to protocol. This new authority is effective September 1, 2021.

NOTES

(1) Implementation Timeline. Although this technician authority is effective September 1, 2021, the statute requires the Pharmacy and Medical Boards to “adopt rules to govern the administration of vaccines by pharmacy technicians as authorized in this act” that will be effective October 1, 2021 or later. While this gap would otherwise be undesirable, the existing PREP Act authority fills that gap, as described below.

(2) Existing PREP Act authority. Notwithstanding the state law implementation timeline, qualified pharmacy technicians already have authority under US DHHS PREP Act declarations to administer COVID and flu vaccinations to patients age 3 or older under the supervision of a pharmacist. When PREP Act declarations are rescinded, technician authority will revert to state law.

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Q. What are the changes to immunizing pharmacists’ ability to administer long-acting injectable medications?

A. In March 2021, S.L. 2021-3 gave immunizing pharmacists an authority to administer long-acting injectable (“LAI”) medications to patients 18 or older pursuant to prescription. That authority is effective October 1, 2021, and the Board is engaged in a temporary rulemaking to implement it. The proposed temporary rule defines long-acting injectable”, sets training requirements, and sets recordkeeping requirements. It is found here:

<http://www.ncbop.org/LawsRules/ProposedTemporaryRule2514AdminLongActingInjectables.pdf>

S.L. 2021-110 makes the following adjustments to the LAI administration authority:

- (1) specifically includes “testosterone injections” and “vitamin B12” within the class of “long-acting injectable”;
- (2) modifies the time period in which a pharmacist must notify the prescriber that a psychotropic long-acting injectable was administered to 48 hours (from 72 hours for other LAIs); and
- (3) requires the pharmacist to notify the prescriber within 72 hours of receiving an LAI prescription if the medication was not administered; or within 48 hours if a psychotropic medication was not administered.

The additional provisions become effective on October 1, 2021, at the same time as the original LAI authority passed in March 2021. Board staff does not view these refinements as requiring any change to the already-proposed rule. And Board staff will issue a long-acting injectable FAQ document when the rule is approved.

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Q. What new drug therapy authority does the statute grant to immunizing pharmacists?

A. Immunizing pharmacists are authorized to dispense, deliver or administer the following without a prescription from a prescriber:

- (1) Nicotine replacement therapy;
- (2) Self-administered oral or transdermal contraceptives after the patient completes an assessment consistent with the CDC’s U.S. Medical Eligibility Criteria for Contraceptive Use. Ulipristal acetate may not be provided for emergency contraception without a prescription.;
- (3) Prenatal Vitamins;
- (4) Post-exposure prophylaxis for the prevention of HIV infection consistent with CDC guidelines; and
- (5) Glucagon to treat severe hypoglycemia.

This authority is effective February 1, 2022.

Q: How will this authority be implemented?

A. The statute creates a two-stage implementation:

The first stage – issuance of standing orders by the State Health Director authorizing immunizing pharmacists to dispense, deliver, and administer these medications – is largely complete.

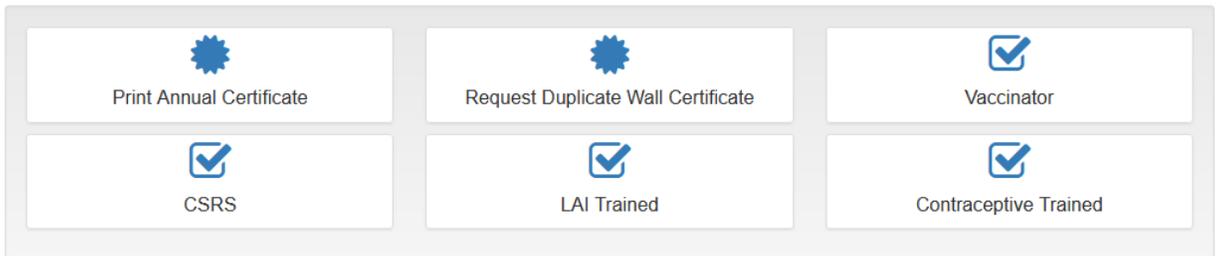
The State Health Director has issued standing orders to implement all these authorities: nicotine replacement therapy, self-administered oral or transdermal contraceptive, prenatal vitamins, and post-exposure prophylaxis, and glucagon. Each of these standing orders, as well as accompanying patient documentation and communication forms, is found here: <https://ncpublichealth.info/HDSO-pharmacists.htm>

REQUIRED TRAINING FOR THE HORMONAL CONTRACEPTIVE STANDING ORDER Pharmacists who wish to exercise authority under the hormonal contraceptive standing order are reminded that, in addition to meeting immunizing pharmacist qualifications, complete the North Carolina Hormonal Contraception Training Program. That Program is administered by the North Carolina Association of Pharmacists pursuant to a grant that makes the program available without cost for up to 6,000 North Carolina pharmacists. More information here:

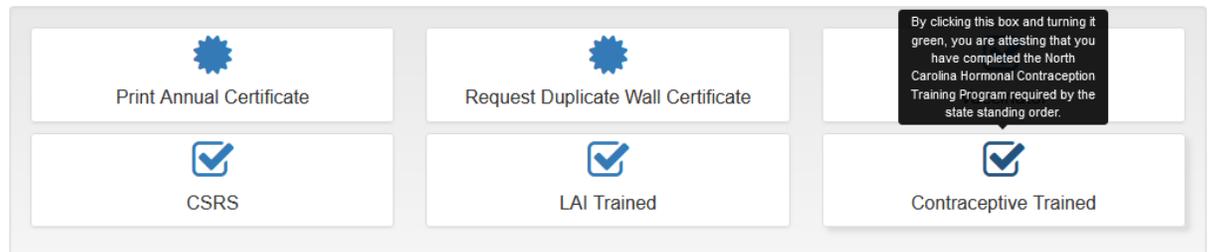
<https://ncap.memberclicks.net/2022-hormonal-contraception-training-and-toolkit>

Once an immunizing pharmacist has completed the North Carolina Hormonal Contraception Training Program, the pharmacist must report that to the Board by logging on to their profile at the Board’s Licensure Gateway, selecting the “Pharmacist” tile under “Licenses & Registrations”, and clicking on the “Contraceptive Trained” option:

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These standing orders will remain in effect until the Pharmacy and Medical Boards develop permanent protocols or January 1, 2023, whichever is later.

The second stage involves the Pharmacy and Medical Boards developing permanent statewide protocols to implement the new authority. Again, the State Health Director's standing orders will remain in effect until this happens or January 1, 2023, whichever is later.

Q. Will all immunizing pharmacists have this authority?

A. The statute directs the Pharmacy and Medical Boards to create rules governing the approval of an immunizing pharmacist to exercise this authority. These rules will more specifically define the process for authorizing exercise of this authority. Between February 1, 2022 and the adoption of these rules, the State Health Director's standing orders will govern the authorization of immunizing pharmacists.

Q: What process must an immunizing pharmacist follow when exercising this authority?

A. By statute, when the authority becomes effective on February 1, 2022, the immunizing pharmacist must:

- (1) Maintain a patient profile that includes any medications provided under this authority.
- (2) Notify a patient's identified primary care provider with 72 hours of doing so. If the patient does not identify a primary care provider, direct the patient to information about the benefits of having one. (Similar to the requirement for vaccinations)
- (3) Provide records to the patient or the patient's primary care provider on request.
- (4) If a hormonal contraceptive is dispensed, counsel the patient about preventative care, including well-woman visits, sexually transmitted infection testing information, and Pap smear testing.
- (5) Provide the name, address, phone, and fax of the pharmacy on any communication with a prescriber/primary care provider.
- (6) Provide the name of the immunizing pharmacist who dispenses, delivers, or administers medication under this authority on any communication with the provider. (Only this sixth obligation has a delayed effective date of March 1, 2022)

The process and procedures are further by the State Health Director's standing orders.