

VIRGINIA BOARD OF PHARMACY

HHS Vaccine Allowances for Pharmacists, Pharmacy Interns, and Pharmacy Technicians during COVID-19 Health Emergency

1. United States HHS Declaration under the Public Readiness and Emergency Preparedness (PREP) Act Authorizing Pharmacists to Order and Administer Vaccines to Patients Aged Three through Eighteen Years during the COVID-19 Health Emergency

On August 19, 2020 the U.S. Department of Health and Human Services issued a [declaration](#) authorizing pharmacists "to order and administer," and a "supervised pharmacy intern" "to administer" certain vaccines to patients ages three (3) to eighteen (18) during the federally-declared COVID-19 public health emergency. The purpose of this declaration is to mitigate a potential "decrease in rates of routine childhood vaccinations . . . due to changes in healthcare access, social distancing, and other COVID-19 mitigation strategies."

Counsel to the Board of Pharmacy has advised, based on the PREP Act preemption provision, that pharmacists licensed in Virginia may order and administer vaccinations without authorization of a prescriber and pharmacy interns may administer such vaccinations under pharmacist supervision as long as they meet the requirements set forth in the declaration of the HHS Secretary.

Effective September 22, 2020, emergency regulation [18VAC110-20-271](#) requires pharmacists to report the administration of these vaccines to the Virginia Immunization Information System (VIIS). VIIS is a secured, confidential, reliable computerized registry maintained by Virginia Department of Health (VDH) Division of Immunization Program containing vaccine information from participating providers for individuals of all ages. To register for VIIS, go to the Virginia Electronic Registration for Immunization Programs (VERIP) website at: <https://apps.vdh.virginia.gov/verip/home.aspx>. VDH offers a variety of trainings to include hands-on, group, webinar and online training modules. Once registered, you will be contacted by a VIIS Trainer to schedule training. **Note: Some pharmacies are currently set up to submit vaccine administrations to VIIS under a parent or corporate account. However, in preparation for COVID-19 vaccine, the registration should be updated so every pharmacy location has an account in VIIS and the reporting of administration is specific to that pharmacy location. Check in with the VIIS team today to ensure your pharmacy's reporting is up-to-date: 866-375-9795.**

Additional information:

Comparison of HHS pediatric vaccine provision to current State law:

Below is a description, based on board staff's review, of the conditions under which pharmacists and pharmacy interns may exercise this authority, and how these conditions appear to differ from existing State law. This information is not intended to serve as legal advice.

• **Pharmacists may "order" vaccines for patients ages three (3) to eighteen (18).** This is a new authority. Three provisions exist in State law for pharmacist administration of vaccines.

- 54.1-3408 (I) of the Code of Virginia authorizes pharmacists to administer vaccines to adults pursuant to a Board of Nursing-approved protocol or under the authorization of a prescriber acting on behalf of and in accordance with established protocols of the Department of Health.
- 54.1-3408 (W) of the Code of Virginia authorizes a pharmacist to administer influenza vaccine to minors under the authorization of a prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02. Thirdly,
- Current law authorizes a pharmacist to administer any vaccine to any person pursuant to a patient-specific prescription issued by a prescriber and directing the pharmacist to administer such vaccine.

• ***Pharmacists may order and administer any vaccine found on the CDC’s Advisory Committee on Immunization Practices (ACIP) immunization schedules to patients age (3) to eighteen (18).*** This is partly a new authority. As noted above, current Virginia law limits independent pharmacist ordering of vaccines. However, any vaccine may be administered to a person of any age pursuant to a patient-specific prescription directing the pharmacist to administer such vaccine.

• ***The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.*** This is a new requirement legally, but not operationally. While the State law does not require such training, many employers and liability insurance plans appear to require this training for liability purposes. Contact your professional association for any possible training opportunities.

• ***The pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.*** This is currently required by the schools of pharmacy, under current accreditation standards, prior to the pharmacy intern obtaining required practical experience in a pharmacy setting.

• ***The licensed pharmacist and pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.*** This is currently required for influenza immunizations of minors pursuant to guidelines developed by VDH, pursuant to 54.1-3408(W) of the Code of Virginia. Many employers and liability insurance plans appear to broadly require such certification for liability purposes.

• ***The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.*** This is a new requirement as this is not currently required under State law.

• ***The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient’s primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.*** This is a partly new requirement. Recordkeeping of administration is currently required, however, notification to the primary care provider is a new requirement. Additionally, reporting the administration of these vaccines to the Virginia Immunization Information System is a new requirement under emergency regulation [18VAC110-20-271](#), effective 9/22/2020.

- *The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.* This is a new requirement.
- *The HHS declaration does not condition a pharmacist’s ability to order or administer a qualifying vaccine to a patient age three (3) to eighteen (18) on the existence of a supervising physician written protocol.* This is a new requirement.

2. HHS Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act

On September 3, 2020, HHS issued [guidance](#) for licensed pharmacists and pharmacy interns regarding COVID-19 vaccines and immunity under the PREP Act. In accordance with the guidance, it authorizes licensed pharmacists to order and administer, and registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, to persons ages three or older COVID-19 vaccinations that have been authorized or licensed by the Food and Drug Administration (FDA).

Additional information:

Comparison of HHS COVID-19 vaccine provision to current State law:

In addition to the requirements noted in item #1 for a pharmacist to order and administer a vaccine for a patient between the ages of three and eighteen, the following requirements also apply when ordering and administering COVID-19 vaccinations for persons ages three or older:

- *The vaccine must be FDA-authorized or FDA-licensed.*
- *The vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices’ (ACIP’s) COVID-19 vaccine recommendation.*
- *The licensed pharmacist and the registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).*

Reporting to VIIS:

- Refer to page 1 for information on how to report COVID-19 vaccine administrations to the Virginia Immunization Information System.

3. HHS Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines and COVID-19 Vaccines

On October 20, 2020, U.S. Department of Health and Human Services issued additional [guidance](#) under the PREP Act authorizing both “qualified pharmacy technicians” and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer FDA-authorized or FDA-licensed

COVID-19 vaccines to persons ages three or older and to administer FDA-authorized or FDA-licensed ACIP-recommended vaccines to persons ages three through 18 according to ACIP's standard immunization schedule.

As with the previous two HHS declarations referenced in this document, counsel to the Board of Pharmacy has advised based on the PREP Act preemption provision that the allowances identified in the HHS guidance issued on October 20, 2020 are legally permissible as long as they meet the requirements set forth in the declaration of the HHS Secretary.

Additional information:

As indicated in the HHS guidance, to qualify as "qualified persons" under 42 U.S.C. § 247d-6d(i)(8)(B) when administering FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older or ACIP-recommended childhood vaccinations to persons ages three through 18, qualified pharmacy technicians and State-authorized pharmacy interns must satisfy the following requirements:

- The vaccination must be ordered by the supervising qualified pharmacist. (Refer also to items #1 and #2 within this document for qualifying requirements of a pharmacist).
- The supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technicians.
- The vaccine must be FDA-authorized or FDA-licensed.
- In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s).
- In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The qualified pharmacy technician or State-authorized pharmacy intern must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.
- The qualified pharmacy technician or State-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The qualified pharmacy technician must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during the relevant State licensing period(s).
- The supervising qualified pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary care provider when available and submitting the required immunization information to the state or local immunization information system (vaccine registry).
- The supervising qualified pharmacist is responsible for complying with requirements related to reporting adverse events.

- The supervising qualified pharmacist must review the vaccine registry or other vaccination records prior to ordering the vaccination to be administered by the qualified pharmacy technician or State-authorized pharmacy intern.
- The qualified pharmacy technician and State-authorized pharmacy intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.
- The supervising qualified pharmacist must comply with any applicable requirements (or conditions of use) as set forth in the CDC's COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).