



November 23, 2020

To: All Pharmacies, Pharmacists, Pharmacy Interns and Pharmacy Technicians Licensed in the State of Maine

Re: Guidance Concerning Vaccination Under the Public Health Emergency from the Commissioners of the Maine Departments of Health and Human Services & Professional and Financial Regulation

This document provides guidance regarding the Federal policy concerning vaccination under the public health emergency. In addition, it provides guidance concerning implementation of that policy in Maine.

On August 19, 2020, and updated on August 24, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) issued the [Third Amendment to the Declaration under the Public Readiness and Emergency Preparedness Act \(PREP Act\)](#) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks. Per the [HHS press release](#): "Today's action means easier access to lifesaving vaccines for our children, as we seek to ensure immunization rates remain high during the COVID-19 pandemic," said HHS Secretary Alex Azar. "The amendment authorizes State-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her State board of pharmacy) to order and administer vaccines to individuals ages three through 18 years, subject to several requirements outlined in the amendment." Additional [guidance](#), dated September 3, 2020, under the PREP Act from HHS was announced on [September 9, 2020](#), in regards to administration of the COVID-19 vaccine by pharmacists. On October 20, 2020, HHS issued additional [guidance](#) that expanded the authorization to administer vaccines to include "qualified pharmacy technicians" acting under supervision of a qualified pharmacist and in compliance with the Federal requirements.

The Federal policy provides, as a matter of Federal law, that qualified pharmacists as well as pharmacy interns and pharmacy technicians (acting under the supervision of a qualified pharmacist) may provide influenza and other vaccines to patients ages 3 years and up to 19 years of age, as detailed in the Third Amendment and subsequent HHS guidance.

The Commissioners of the Maine Departments of Health and Human Services (DHHS) and Professional and Financial Regulation (DPFR) are providing guidance to pharmacists, pharmacy interns, pharmacy technicians, and pharmacies who intend to provide vaccines to children under this temporary Federal policy. This guidance aims to ensure that (1) vaccines are delivered safely and consistent with the requirements in the PREP Act, (2) there is sufficient access to vaccines at pharmacy locations, (3) pharmacies communicate with patients' primary care providers, and (4) children and youth, 3 years and up to 19 years of age, receive vaccines at no cost within the current immunization system overseen by the Maine Center for Disease Control and Prevention (CDC). This approach is consistent with [22 MRS §1066](#), which authorizes the universal purchase of vaccines for the children of Maine through the established Maine Vaccine Board covering all privately insured Maine children.

**Federal Requirements per the Third Amendment and Subsequent HHS Guidance: The key elements of the Federal policy include the following:**

- The vaccine must be authorized, or approved, by the Food and Drug Administration (FDA).
- The vaccination must be administered according to the U.S. Centers for Disease Control and Prevention (CDC's) Advisory Committee on Immunization Practices (ACIP) standard immunization schedules.
- 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.
- The licensed pharmacist and licensed pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with State-specific record keeping and reporting requirements, including informing the patient's primary care provider when available, submitting the required immunization information to the State's 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.
- 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.
- The licensed pharmacist and the licensed pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the U.S. CDC COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

**Under the Federal policy, the following [additional requirements](#) apply where pharmacy interns and pharmacy technicians act under the supervision of a qualified pharmacist:**

- The vaccination must be ordered by the supervising qualified pharmacist.
- The supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technicians.
- The qualified pharmacy technician or State-authorized pharmacy intern must complete a practical training program that is approved by the 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, known as ImmPact).
- 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 U.S. CDC's COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

**Maine DHHS and DPHR Commissioners' Guidance on Implementation of Federal Policy.**

- Pharmacies providing childhood immunization to children who are 3 years until 19 years of age must enroll as providers in the Maine Immunization Program, which administers Maine's [Vaccines for Children \(VFC\) Program](#). As part of the provider agreement, the pharmacy will list who is authorized to prescribe and administer vaccines. The pharmacy will also designate a vaccine coordinator who will ensure that vaccine storage and handling protocols are followed. Pharmacists, pharmacy interns, pharmacy technicians and pharmacies ("providers") enrolled in the Maine Immunization Program must adhere to policies and procedures outlined in the [Maine Immunization Program Provider Policy and Procedures Manual](#). Once a pharmacy enrolls in the Immunization Program, the provider will be trained on how to use Maine's immunization registry (ImmPact) and how to order the vaccines. Pharmacies interested in enrolling into the Maine Immunization Program or who would like more information should email Valerie MacKenzie at [valerie.mackenzie@maine.gov](mailto:valerie.mackenzie@maine.gov).
- The Maine CDC requires that any new vaccine coordinators and their back up complete the Vaccines for Children Training. Additional training will be required for COVID-19 vaccine administration.
- Providers administering vaccines need to be enrolled in the state immunization registry, ImmPact, and pharmacists must obtain a PIN number to enter information. If the pharmacy location would like

interns and technicians to access ImmPact, they must authorize them as users. Pharmacists must have the ability to enter per patient dose information within 5 days for childhood immunizations. This time period may be shortened to 24 hours for an eventual COVID-19 vaccine. Information on the state immunization registry can be found in Chapter 7 of the [Maine Immunization Program Provider Policy and Procedures Manual](#).

- Pharmacies should not bill consumers or insurers for the cost of vaccines that are available to them at no cost through the Maine Immunization Program for children 3 years until 19 years of age. Insurers pay an annual assessment per child to ensure universal access to vaccines for all children in Maine. Similarly, pharmacies should not bill MaineCare or the Children’s Health Insurance Program (CHIP) for vaccine costs provided under the VFC Program. More information about billing and administration requirements can be found in chapter 4 of the [Maine Immunization Program Provider Policy and Procedures Manual](#).
- Pharmacists ordering or administering vaccines must comply with [statutorily required certification and training requirements](#) approved by the Maine Board of Pharmacy.
- A pharmacy technician or pharmacy intern administering vaccines must register with the Maine Board of Pharmacy. The pharmacy technician and pharmacy intern registrant must submit evidence of the following:
  - a. Valid unrestricted license in Maine.
  - b. Completion of a practical training program of at least 20 hours 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, treatment of emergency reactions to vaccines, and life support training.
  - c. Evidence of a current cardiovascular life support certification accepted by the American Heart Association, the American Red Cross or other similar training organizations.
- The DPFR will maintain a list of pharmacists, pharmacy interns, and pharmacy technicians who have completed the above educational requirements to be able to offer childhood and other vaccines.

**Contact information:**

Maine Immunization Program at:

Main Line: (207) 287-3746

ImmPact Helpdesk: (207) 287-3006; Support/Education: (207) 287-9972

[www.ImmunizeME.org](http://www.ImmunizeME.org)

For COVID vaccine related questions, contact the Maine Immunization Program at [C19Vaccine.MECDC@maine.gov](mailto:C19Vaccine.MECDC@maine.gov)

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