



U.S. Department of Health & Human Services
Office of the Assistant Secretary for Health
September 3, 2020

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

On January 31, 2020, the Secretary of Health and Human Services [declared](#) that, effective January 27, 2020, the 2019 novel coronavirus (COVID-19) is a public-health emergency for the United States. The United States Department of Health and Human Services (HHS) is the lead agency for the federal government's response to the COVID-19 pandemic.

A key component of that response will be access to a COVID-19 vaccine across the United States. Pharmacists, in partnership with other healthcare providers, are well-positioned to increase access to vaccinations—particularly in certain areas that have too few pediatricians and other primary-care providers, or that are otherwise medically underserved.¹ As of 2018, nearly 90 percent of Americans lived within five miles of a community pharmacy.² Pharmacies often offer extended hours and added convenience. What is more, pharmacists are trusted healthcare professionals with established relationships with their patients. Pharmacists also have strong relationships with local medical providers and hospitals to refer patients as appropriate. For example, pharmacists already play a significant role in annual influenza vaccination. In the early 2018-19 season, they administered the influenza vaccine to nearly a third of all adults who received the vaccine.³ Nearly every State permits pharmacists to order and administer vaccines to both adults and children under certain circumstances. Therefore, as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), the Office of the Assistant Secretary for Health (OASH) issues this guidance. Subject to satisfaction of the requirements listed

¹ See, e.g., *Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies during the COVID-19 Response*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html> (last updated June 28, 2020) (“As a vital part of the healthcare system, pharmacies play an important role in providing medicines, therapeutics, vaccines, and critical health services to the public.”); Kimberly McKeirnan & Gregory Sarchet, *Implementing Immunizing Pharmacy Technicians in a Federal Healthcare Facility*, 7 PHARMACY 1, 7 (2019), <https://www.mdpi.com/2226-4787/7/4/152/htm> (last visited Aug. 5, 2020) (HHS Indian Health Service study demonstrating “the effective implementation of immunization-trained pharmacy technicians and the positive impact utilization of pharmacy support personnel can create” on childhood vaccination rates in medically underserved populations).

² *Get to Know Your Pharmacist*, CDC, <https://www.cdc.gov/features/pharmacist-month/index.html> (last visited July 14, 2020).

³ *Early-Season Flu Vaccination Coverage — United States, November 2018*, CDC, <https://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2018.htm> (last visited July 14, 2020).

below, this guidance authorizes State-licensed pharmacists to order and administer, and State-licensed or 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).

Such pharmacists and pharmacy interns will qualify as “covered persons” under the PREP Act, subject to other applicable requirements of the Act and the requirements discussed below. They may also receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized or FDA-licensed COVID-19 vaccines. 42 U.S.C. § 247d-6d(a)(1).

To qualify as “covered persons” under 42 U.S.C. § 247d-6d(i)(8)(B) when administering FDA-authorized or licensed COVID-19 vaccines, State-licensed pharmacists and pharmacy interns licensed or registered by their State board of pharmacy must satisfy the following requirements:

- 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 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 or registered 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.
- The licensed pharmacist and licensed or registered 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 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 related 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, 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 licensed pharmacist and the licensed or 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).

This authorization preempts any State and local law that prohibits or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines as set forth above.⁴ But this authorization shall not preempt State and local laws that permit additional individuals to administer COVID-19 vaccines to additional persons.⁵

⁴ *See, e.g.*, Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, available at <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>

⁵ Moreover, nothing herein shall affect federal-law requirements in 42 C.F.R. Part 455, subpart E regarding screening and enrollment of Medicare and Medicaid providers.