



U.S. Department of Health & Human Services
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Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing

On January 31, 2020, the Secretary of Health and Human Services declared that the 2019 novel coronavirus disease (COVID-19) is a public health emergency for the United States.¹ 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.

Key components of that response are rapidly expanding COVID-19 testing across America, expanding access to childhood vaccinations to help address a decrease in childhood vaccination rates due to the COVID-19 pandemic, and expanding access to COVID-19 vaccines when they become available. Within HHS, the Office of the Assistant Secretary for Health (OASH) leads federal efforts to support such expansions.

Childhood and COVID-19 Vaccine Guidance for Qualified Pharmacy Technicians And State-Authorized Pharmacy Interns

Pharmacies, 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.² For example, pharmacists already play a significant role in annual influenza vaccination. In the early 2018-19 season, pharmacists administered the influenza vaccine to nearly a third of all adults who received the vaccine.³ Some states permit pharmacy technicians to administer vaccines to both adults and children under certain circumstances.⁴

¹ The Secretary’s declaration of a public health emergency was retroactively effective on January 27, 2020.

² 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) (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).

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

⁴ Deeb Eid, et al., *Moving the Needle: A 50-State and District of Columbia Landscape Review of Laws Regarding Pharmacy Technician Vaccine Administration*, Pharmacy 7, 168 (2019) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6958442/>.

On March 10, 2020, the Secretary of Health and Human Services (Secretary) issued a Declaration under the Public Readiness and Emergency Preparedness (PREP) Act.⁵ On August 19, 2020, the Secretary amended the March 10, 2020 declaration to identify an additional category of persons who are qualified persons for liability protection under 42 U.S.C. § 247d-6d(i)(8)(B) of the PREP Act.⁶ The definition of qualified persons in this Third Amendment included pharmacy interns authorized to administer to persons ages three through 18 childhood vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends according to ACIP’s standard immunization schedule, provided that certain conditions are met.⁷ For PREP Act liability protection to attach, the Third Amendment also required the pharmacy intern to act under the supervision of a pharmacist and to be licensed or registered by his or her State board of pharmacy.⁸ On September 3, 2020, OASH issued guidance authorizing 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), provided that certain conditions are met—thereby making them “covered persons” under the PREP Act with respect to this activity.⁹

Some states do not require pharmacy interns to be licensed or registered by the State board of pharmacy.¹⁰ This guidance clarifies that the pharmacy intern must be authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs, but this authorization need not take the form of a license from, or registration with, the State board of pharmacy.

Similarly, states vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. For purposes of this guidance, to be a “qualified pharmacy technician,” pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or National Healthcareer Association.

Therefore, as an Authority Having Jurisdiction under the Secretary’s March 10, 2020 declaration under the PREP Act, OASH issues this guidance. Subject to satisfaction of the requirements listed below, this guidance authorizes both qualified pharmacy technicians and State-authorized

⁵ See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020); 85 Fed. Reg. 21,012 (Apr. 15, 2020); 85 Fed. Reg. 35,100 (June 8, 2020); 85 Fed. Reg. 52,136 (Aug. 24, 2020); see also Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.

⁶ See Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 52,136, 52,140 (Aug. 24, 2020) (Third Amendment).

⁷ *Id.*

⁸ *Id.* Pharmacists, pharmacy interns, and pharmacy technicians might have already been subject to PREP Act immunity for certain activities prior to this amendment.

⁹ See <https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Sept. 28, 2020).

¹⁰ See e.g., 21 N.C.A.C. 46.1317 (West 2020) (requiring an intern to be registered with the State board of pharmacy or be enrolled in approved academic internship program); Tenn. Code Ann. § 63-10-204 (West 2020) (requiring enrollment in or graduation from recognized school or college of pharmacy under rules established by board); Wis. Stat. § 450.03 (West 2020) (requiring completion of second year of and current enrollment at accredited school of pharmacy).

pharmacy interns acting under the supervision of a qualified pharmacist¹¹ 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.

Such qualified pharmacy technicians and State-authorized 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 such vaccines. 42 U.S.C. § 247d-6d(a)(1).¹²

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.
- 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).

¹¹ For purposes of this guidance, "qualified pharmacist" means those pharmacists who satisfy the requirements listed in Section V(d) of the Third Amendment. *See* 85 Fed. Reg. at 52140 (Aug. 24, 2020).

¹² Regarding vaccines subject to the National Vaccine Injury Compensation Program, the Third Amendment to the COVID-19 PREP Act Declaration states: "Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa-10 et seq. are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program." 85 Fed. Reg. at 52140 (Aug. 24, 2020).

- 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).

This authorization preempts any state and local law that prohibits or effectively prohibits those who satisfy these requirements from administering COVID-19 or routine childhood vaccines as set forth above. It does not preempt state and local laws that permit additional individuals to administer COVID-19 or routine childhood vaccines to additional persons.¹³

COVID-19 Testing Guidance for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns

For the reasons stated herein, pharmacies, in partnership with other healthcare providers, are also well positioned to aid COVID-19 testing expansion. Pharmacists are trusted healthcare providers with established relationships with their patients. As of 2018, nearly 90 percent of Americans lived within five miles of a community pharmacy.¹⁴ That proximity reduces travel to testing locations, which is an important mitigation measure. Pharmacies often offer extended hours and added convenience. Pharmacists supervising qualified pharmacy technicians and State-authorized pharmacy interns also have strong relationships with medical providers and hospitals to appropriately refer patients when necessary.

Therefore, as an Authority Having Jurisdiction under the Secretary’s PREP Act Declaration, OASH issues this guidance authorizing qualified pharmacy technicians and State-authorized pharmacy interns to administer COVID-19 tests, including serology tests, that the FDA has approved, cleared, or authorized.¹⁵ By doing so, such qualified pharmacy technicians and State-authorized pharmacy interns will qualify as “covered persons” under the PREP Act. And they may 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 COVID-19 tests. 42 U.S.C. § 247d-6d(a)(1).

¹³ Nothing herein shall affect federal-law requirements in 42 C.F.R. Part 455, subpart E regarding screening and enrollment of Medicaid and Children's Health Insurance Program (CHIP) providers. This guidance does not speak to or change reimbursement policy with respect to whether a qualified pharmacy technician or State-authorized pharmacy intern may obtain reimbursement from a government or private payer for ordering or administering an FDA-authorized test, administering a COVID-19 vaccine, or administering routine childhood immunizations.

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

¹⁵ FDA’s Emergency Use Authorizations for diagnostic and therapeutic medical devices to diagnose and respond to particular public health emergencies are available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

This authorization preempts any state and local law that prohibits or effectively prohibits those who satisfy these requirements from administering COVID-19 tests as set forth above. It does not preempt state and local laws that permit additional individuals to administer COVID-19 tests to additional persons.¹⁶

¹⁶ Nothing herein shall affect federal-law requirements in 42 C.F.R. Part 455, subpart E regarding screening and enrollment of Medicaid and CHIP providers. This guidance does not speak to or change reimbursement policy with respect to whether a qualified pharmacy technician or State-authorized pharmacy intern may obtain reimbursement from a government or private payer for ordering or administering an FDA-authorized test, administering a COVID-19 vaccine, or administering routine childhood immunizations.