

Title: COVID-19 Public Health Emergency: Policy No. I.D.28
Guidance for Licensees re PREP Act Declaration by HHS

Approved: 02-24-2021



1. The Public Readiness and Emergency Preparedness Act (PREP Act) was enacted on December 30, 2005 as Division C, Section 2 of Public Law 109-148. The act authorizes the Secretary of the United States Department of Health and Human Services (HHS) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. The Declaration is subject to amendment as circumstances warrant.
2. Pursuant to the federal declaration of the COVID-19 public health emergency on January 31, 2020, the HHS Secretary issued a [Declaration Under PREP Act for Medical Countermeasures Against COVID-19 \(85 FR 15198\)](#) on March 10, 2020 with a retroactive effective date of February 4, 2020. The Declaration describes the Covered Persons and Covered Countermeasures eligible for liability immunity under the PREP Act. The Declaration also provides for a termination date of October 1, 2024, and further, provides an additional one year period for the disposition of Covered Countermeasures.
3. On April 8, 2020, the Assistant Secretary for Health (ASOH) in HHS issued [guidance](#) relative to the PREP Act Declaration authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, which have been authorized by FDA. The guidance indicated such pharmacists qualify as Covered Persons under the PREP Act and may receive the immunity protections available under the PREP Act.
4. The HHS Secretary issued the [First Amendment to the Declaration Under PREP Act for Medical Countermeasures Against COVID-19 \(85 FR 21012\)](#) on April 15, 2020. The amendment added respiratory protective devices approved by the National Institute for Occupational Safety and Health (NIOSH) to the list of Covered Countermeasures eligible for liability immunity under the PREP Act.
5. The General Counsel of HHS issued [Advisory Opinion 20-02](#) relative to the PREP Act Declaration on May 19, 2020. This opinion concludes the PREP Act and the Secretary’s March 10, 2020 Declaration preempts any local or state requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the FDA has authorized
6. The HHS Secretary issued the [Second Amendment to the Declaration Under PREP Act for Medical Countermeasures Against COVID-19 \(85 FR 35100\)](#) on June 8, 2020. The amendment clarified the Secretary’s intent with respect to the

original Declaration that the Covered Countermeasures should have also included “products that limit the harm such a pandemic or epidemic might otherwise cause”, citing as an example the pandemic-related shortages of FDA-approved drugs and devices.

7. The HHS Secretary issued the *Third Amendment to the Declaration Under PREP Act for Medical Countermeasures Against COVID-19* ([85 FR 52136](#)) on August 24, 2020.

- A. The Secretary amended Section V of the Declaration to identify as Covered Persons (1) certain state-licensed pharmacists to order and administer, and (2) pharmacy interns [who are licensed or registered by their state board of pharmacy and acting under the supervision of a state-licensed pharmacist] to administer, any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to [ACIP’s standard immunization schedule](#) (ACIP-recommended vaccines). The Secretary conditioned the inclusion of pharmacists and pharmacy interns as Covered Persons on their compliance with the following eight requirements:
- (1) The vaccine must be FDA-authorized or FDA-approved.
 - (2) The vaccination must be ordered and administered according to ACIP’s standard immunization schedule.
 - (3) 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.
 - (4) The licensed or registered pharmacy intern must complete a practical training program that 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.
 - (5) The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
 - (6) The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.
 - (7) 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.
 - (8) The licensed pharmacist must inform his or her childhood

vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

- B. The Secretary amended Section VIII of the Declaration to identify conditions warranting the use of Covered Countermeasures to include not only the COVID-19 disease caused by SARS-CoV-2 or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating therefrom, including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.
8. On September 3, 2020, the ASOH in HHS issued additional [guidance](#) relative to the PREP Act Declaration. This guidance authorizes (1) state-licensed pharmacists to order and administer, and (2) 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 FDA. In addition to the eight requirements cited in the Secretary's Third Amendment issued on August 24, 2020, this guidance added an additional requirement:
- (9) 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).
9. On October 20, 2020, the ASOH in HHS issued additional [guidance](#) relative to the PREP Act Declaration. This guidance extended the applicability of the Secretary's Third Amendment to include "authorized pharmacy interns" and "qualified pharmacy technicians."
- A. The Third Amendment authorizes licensed or registered pharmacy interns to administer vaccines under the supervision of a pharmacist; however, some states do not license or register pharmacy interns. This guidance clarifies the pharmacy intern must be authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs, but the authorization need not take the form of a license or registration with the state board of pharmacy.
- B. The guidance describes "qualified pharmacy technicians." Pharmacy technicians working in states with licensure or registration requirements must be licensed or registered in accordance with state requirements; pharmacy technicians working in states without licensure registration requirements must have a Certified Pharmacy Technician (CPhT) designation from either the Pharmacy Technician Certification Board or National Healthcareer Association.
- C. Subject to the requirements cited below, this guidance authorizes both qualified pharmacy technicians and state-authorized pharmacy interns acting under the supervision of a qualified pharmacist (*meaning those pharmacists who satisfy the requirements of the Third Amendment*) 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. Qualified pharmacy technicians and state-authorized pharmacy interns are considered Covered Persons and are eligible for PREP Act immunity provided they meet the following requirements:

- (1) The vaccination must be ordered by the supervising qualified pharmacist.
- (2) The supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician.
- (3) The vaccine must be FDA-authorized or FDA-licensed.
- (4) In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to [ACIP's COVID-19 vaccine recommendation\(s\)](#).
- (5) In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- (6) 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.
- (7) The qualified pharmacy technician or state-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- (8) 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).
- (9) 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 immunizations information system (vaccine registry).
- (10) The supervising qualified pharmacist is responsible for complying with requirements related to reporting adverse events.
- (11) 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.
- (12) 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.
- (13) The supervising qualified pharmacist must comply with any applicable requirements (or conditions of use) as set forth in CDC's COVID-19 vaccination provider agreement and any other federal

requirements that apply to the administration of COVID-19 vaccine(s).

- D. The guidance document authorizes qualified pharmacy technicians and state-authorized pharmacy interns to administer COVID-19 tests, including serology tests, that the FDA has [approved, cleared, or authorized](#). By doing so, qualified pharmacy technicians and state-authorized pharmacy interns will qualify as Covered Persons under the PREP Act and may receive immunity under that same law.
10. The General Counsel of HHS issued [Advisory Opinion 20-03](#) on October 23, 2020 to address three vaccination-related issues under the PREP Act:
- (1) Does the PREP Act preempt state licensing laws that are less stringent than the federal standards under the Third Amendment to the Secretary's March 10, 2020 Declaration? [*short answer: no*]
 - (2) May a state require a pharmacist to enter into a collaborative practice agreement with a licensed physician as a condition of administering ACIP-recommended vaccines to children between ages 3 and 18? [*short answer: no*]
 - (3) Is epinephrine, when used to treat a severe acute vaccine reaction, a Covered Countermeasure within the meaning of the PREP Act? [*short answer: yes*]
11. The General Counsel of HHS issued [Advisory Opinion 20-04](#) on October 23, 2020 to address the scope and meaning of a "program planner" under the PREP Act as well as the breadth of PREP Act immunity. One of the examples cited in the opinion is that of a pharmacy administering COVID-19 vaccines according to CDC-recommended population priorities in the face of limited vaccine availability. Pharmacies participating in vaccine administration may wish to review this opinion.
12. On October 29, 2020, the ASOH in HHS issued additional [guidance](#) relative to the PREP Act Declaration. This guidance extended the applicability of the Secretary's Third Amendment to include pharmacies as Covered Persons when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer, Covered Countermeasures consistent with the terms and conditions of the Secretary's Declaration and guidance, as of the date that these staff pharmacists, pharmacy interns and pharmacy technicians were authorized to order and administer these Covered Countermeasures. The guidance indicates this recognition authorizes pharmacies to submit claims for reimbursement for testing or vaccine administration carried out by its staff pharmacists, pharmacy interns and pharmacy technicians.
13. The HHS Secretary issued the Fourth Amendment to the Declaration Under PREP Act for Medical Countermeasures Against COVID-19 (85 FR 79190) on December 3, 2020. This amendment recognizes that multiple advisory opinions and guidance documents have been issued since the Declaration was issued on March 10, 2020. The Secretary republishes the Declaration as amended, in full, to incorporate all prior amendments, advisory opinions and guidance.
- A. *Section V. Covered Persons* was amended to add a new category:

healthcare personnel who are permitted to order and administer a Covered Countermeasure through telehealth in a state may do so for patients in another state as long as the healthcare personnel comply with the legal requirements of the state in which the healthcare personnel are permitted to order and administer Covered Countermeasures by means of telehealth.

- B. *Section V. Covered Persons* was also amended to make explicit that the requirement for qualified persons to have a current certificate in basic cardiopulmonary resuscitation is satisfied, by among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center (ANCC), the Accreditation Council for Pharmacy Education (ACPE), or the Accreditation Council for Continuing Medical Education (ACCME).
 - C. *Section V. Covered Persons* was further amended to specify the licensed pharmacist desiring to order or administer vaccines must have completed the immunization training that the licensing state requires in order for pharmacists to administer vaccines. If the state does not specify training requirements for licensed pharmacists to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order administer vaccines. 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.
 - D. *Section XII. Effective Time Period* was amended to clarify that liability protections under the PREP Act began with the declaration of the public health emergency on January 31, 2020 and will terminate upon the earliest of (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024. An exception exists with respect to qualified persons who order or administer a routine childhood vaccination that ACIP recommends to persons ages three through 18 according to ACIP standard immunization schedule; for these persons and countermeasures, PREP Act coverage began on August 24, 2020. The termination date shall be the same for all other Covered Persons and Covered Countermeasures.
14. The General Counsel of HHS issued [Advisory Opinion 21-01](#) on January 8, 2021 to address the scope of the preemption of the PREP Act. That office had received numerous questions whether the PREP Act applies where a Covered Person declined to use a Covered Countermeasure when it arguably ought to have been use. The inquiries were stimulated by multiple lawsuits where patients or their estates allege that patients contracted COVID-19 because the healthcare facility failed to provide its staff with personal protective equipment (PPE), failed to teach the staff how to properly use that equipment, or failed to ensure that its staff used the PPE that it had been given. The Advisory Opinion addresses those and other questions relative to the scope of the preemption of the PREP Act.

15. The General Counsel of HHS issued [Advisory Opinion 21-02](#) on January 12, 2021 in response to requests to clarify the meaning of the requirement that a COVID-19 vaccination “must be ordered and administered according to ACIP’s COVID-19 vaccine recommendations.” Some have raised concerns that satisfying the Advisory Committee on Immunization Practices (ACIP) allocation recommendations is a precondition of PREP Act coverage. It is not.
16. The HHS Secretary issued the *[Fifth Amendment to the Declaration Under PREP Act for Medical Countermeasures Against COVID-19 \(86 FR 7872\)](#)* on January 28, 2021. The amendment adds two additional categories of personnel to *Section V. Covered Persons*:
 - A. Any healthcare professional who holds a license to prescribe, dispense or administer COVID-19 vaccines under the law of any state as of the effective date of the amendment who prescribes, dispenses or administers COVID-19 vaccines in any jurisdiction where the PREP Act applies, other than the state in which the license is held, in association with a COVID-19 vaccination effort by a federal, state, local, tribal or territorial authority or by an institution in the state, provided however that the license has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest and that the individual is not on the List of Excluded Individuals maintained by the HHS Office of Inspector General, subject to:
 - (1) Documentation of completion of the Centers for Disease Control & Prevention [\(CDC\) Vaccine Training Modules](#), and
 - (2) For those healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID-19 vaccine(s) to be administered.
 - B. Any physician, advanced practice registered nurse, registered nurse or practical nurse who has held an active license or certification to prescribe, dispense or administer vaccines under the law of any state within the past five years, which is inactive, expired or lapsed who prescribes, dispenses or administers COVID-19 vaccines in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a federal, state, local, tribal or territorial authority or by an institution, provided however that the license was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest and that the individual is not on the List of Excluded Individuals maintained by the HHS Office of Inspector General, subject to:
 - (1) Documentation of completion of the [CDC Vaccine Training Modules](#), and
 - (2) Documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and

administration of the particular COVID-19 vaccine(s) to be administered.

Note: HHS published a technical correction notice on 02-22-2021 indicating the effective date for liability protections for qualified persons identified in the Fifth Amendment began on February 2, 2021 and will terminate on October 1, 2024.

17. The HHS Acting Secretary issued the *Sixth Amendment to the Declaration Under PREP Act for Medical Countermeasures Against COVID-19* ([86 FR 9516](#)) effective February 16, 2021. This amendment adds one additional category of personnel to *Section V. Covered Persons* – any federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such federal government employees, contractors, or volunteers are qualified persons if the following requirement is met: the executive department or agency by or for which the federal employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that employee, contractor, or volunteer to prescribe, administer, deliver, distribute or dispense the Covered Countermeasure as any part of the duties or responsibilities of that employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such employees, contractors, or volunteers are authorized to carry out under this declaration.

One practical application of this expansion will be pharmacy personnel recruited by the Federal Emergency Management Agency (FEMA) to staff federally supported vaccination sites.

Note: HHS published a technical correction notice on 02-22-2021 indicating the effective date for liability protections for qualified persons identified in the Sixth Amendment began on February 16, 2021 and will terminate on October 1, 2024.