

the introduction of influenza infection to households that have school-age

children, as well as within-household influenza transmission.
CDC requests approval for 434 annual burden hours. There is no cost to

respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Parents of children/adolescents or adult students (≥18 yo) attending schools.	Screening Form	345	1	5/60
	Acute Respiratory Infection and Influenza Surveillance Form.	300	1	15/60
	Household Study Form A	300	1	5/60
Student	Biospecimen collection (Day 0)	300	1	5/60
Parents of children/adolescents or adult students (≥18 yo) attending schools.	Household Study Form B (Day 7 and 14)	240	1	5/60
	Biospecimen collection (Day 7 and 14)	240	1	5/60
Household members	Household Study Form B (Day 0, 7 and 14)	720	2	5/60
Household members	Biospecimen collection (Day 0, 7 and 14)	720	2	5/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB or the Board) is authorized under Section 319M of the Public Health Service (PHS) Act, as added by Section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by Section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act. The Board is governed by the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The NBSB provides expert advice and guidance on scientific, technical, and other matters of special interest to the Department regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

DATES: The NBSB will meet in public (virtually) on September 28, 2021, to discuss high priority issues related to national public health emergency preparedness and response. A more detailed agenda will be available on the

NBSB meeting website <https://www.phe.gov/nbsb>.

ADDRESSES: Members of the public may attend the meeting via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting link to pre-register will be posted on <https://www.phe.gov/nbsb>. Members of the public may provide written comments or submit questions for consideration by the NBSB at any time via email to NBSB@hhs.gov. Members of the public are also encouraged to provide comments after the meeting.

FOR FURTHER INFORMATION CONTACT: CAPT Christopher L. Perdue, MD, MPH, NBSB Designated Federal Officer, Washington, DC, Office, 202-401-5837, NBSB@hhs.gov.

SUPPLEMENTARY INFORMATION: The NBSB invites those who are involved in or represent a relevant industry, academia, health profession, health care consumer organization, or state, Tribal, territorial or local government to request up to seven minutes to address the board in person via Zoom. Requests to provide remarks to the NBSB during the public meeting must be sent to NBSB@hhs.gov at least 15 days prior to the meeting along with a brief description of the topic. We would specifically like to request inputs from the public on challenges, opportunities, and strategic priorities for national health security and biodefense. Presenters who are selected for the public meeting will have audio only during the meeting. Slides, documents, and other presentation material sent along with the request to speak will be provided to the board members separately. Please indicate additionally whether the presenter will be willing to take questions from the board members (at

their discretion) immediately following their presentation (for up to seven additional minutes).

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

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BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to expand the authority for certain Qualified Persons authorized to prescribe, dispense, and administer COVID-19 therapeutics that are covered countermeasures under section VI of this Declaration.

DATE: This amendment is effective as of September 14, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202-260-0365, paige.ezernack@hhs.gov.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes

the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused 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. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the former Secretary, Alex M. Azar II, declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation’s health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, January 21, 2021, April 21, 2021 and July 20, 2021.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the

administration or use of the Covered Countermeasures. (85 FR 52136, Aug. 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary’s Declaration and authorizations issued by the Department’s Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration’s liability protections; made explicit that there are substantive federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190, Dec. 9, 2020). On February 2, 2021, the Acting Secretary Norris Cochran amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 7872, Feb. 2, 2021). On February 16, 2021, the Acting Secretary amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 9516, Feb. 16, 2021) and on February 22, 2021, the Department filed a notice of correction to the February 2 and February 16 notices correcting effective dates stated in the Declaration, and correcting the description of qualified persons added by the February 16, 2021 amendment. (86 FR 10588, Feb. 22, 2021). On March 11, 2021, the Acting Secretary amended the Declaration to add additional Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under the Declaration. (86 FR 14462, Mar. 16, 2021). On August 4, 2021, Secretary Xavier Becerra amended the Declaration to clarify categories of Qualified Persons and to expand the scope of authority for

certain Qualified Persons to administer seasonal influenza vaccines to adults. (86 FR 41977, Aug. 4, 2021).

Secretary Xavier Becerra now amends section V of the Declaration to add subsection (i) to expand the scope of authority for licensed pharmacists to order and administer and qualified pharmacy technicians and pharmacy interns to administer COVID–19 therapeutics subcutaneously, intramuscularly, or orally as authorized, approved, or licensed by the U.S. Food and Drug Administration (FDA).

Accordingly, subsection V(i) authorizes:

(i) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy)¹ FDA authorized, approved, or licensed COVID–19 therapeutics. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

i. The COVID–19 therapeutic must be authorized, approved, or licensed by the FDA;

ii. In the case of a licensed pharmacist ordering a COVID–19 therapeutic, the therapeutic must be ordered for subcutaneous, intramuscular, or oral administration and in accordance with the FDA approval, authorization, or licensing;

¹ Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, “State-licensed or registered intern” (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but 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. As used herein, 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. See Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

iii. In the case of licensed pharmacists, qualified pharmacy technicians, and licensed or registered pharmacy interns administering the COVID-19 therapeutic, the therapeutic must be administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, or licensing;

iv. In the case of qualified pharmacy technicians, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician;

v. In the case of COVID-19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician 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, clinical evaluation of indications and contraindications of COVID-19 therapeutics, the recognition and treatment of emergency reactions to COVID-19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing;

vi. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation;²

vii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events;

viii. The licensed pharmacist, the licensed or registered pharmacy intern

and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID-19 therapeutics.

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a "qualified person" is a "covered person." Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure.

"Qualified person" includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) "a person within a category of persons so identified in a declaration by the Secretary" under subsection (b) of the PREP Act. 42 U.S.C. 247d-6d(i)(8).

By this amendment to the Declaration, the Secretary clarifies and expands the authorization for a category of persons who are qualified persons under section 247d-6d(i)(8)(B). First, the amendment clarifies that licensed pharmacists are authorized to order and administer and licensed or registered pharmacy interns and qualified pharmacy technicians are authorized to administer COVID-19 therapeutics that are Covered Countermeasures under section VI of this Declaration. The Secretary anticipates that there will be a need to increase the available pool of providers able to order and administer COVID-19 therapeutics to address rising COVID-19 cases, to expand patient access to these critical therapies, and to keep as many patients out of the hospital as possible. Rising COVID-19 cases, largely attributable to the Delta variant, is a public health threat caused by COVID-19, placing additional strains on our healthcare system. Pharmacists, pharmacy technicians, and pharmacy interns are well positioned to increase access to therapeutics and have played a critical role in this pandemic in overseeing COVID-19 testing and vaccine administration. Given their skill set and training, as well as looming provider shortages, pharmacists, pharmacy technicians, and pharmacy interns will quickly expand access to COVID-19 therapeutics.

COVID-19 therapeutics may be administered as intramuscular injections, subcutaneous injections, or orally and would require minimal, if any, additional training to administer beyond training pharmacists, pharmacy technicians, and pharmacy interns have already received for vaccine administration, and would not place any undue training burden on providers.

As qualified persons, these licensed pharmacists, qualified pharmacy technicians and interns will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. Second, to the extent that any State law that would otherwise prohibit these healthcare professionals who are a "qualified person" from prescribing, dispensing, or administering COVID-19 therapeutics or other Covered Countermeasures, such law is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are "qualified persons" under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID-19 diagnostic tests.³ The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as "qualified persons" would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of "qualified persons" specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F-3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer

² This requirement 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, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

³ Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Jan. 24, 2021). See also, Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2021, available at: <https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf> (last visited Jan. 24, 2021).

covered countermeasures within its jurisdiction under State law.

The plain language of the PREP Act makes clear that there is preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID-19 as it will enable States to quickly expand the vaccination, treatment and prevention workforces with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID-19 countermeasure program.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19.

Section V of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID-19, as amended April 10, 2020, June 4, 2020, August 19, 2020, as amended and republished on December 3, 2020, as amended on February 2, 2021, as amended March 11, 2021, and as amended on August 4, 2021, is further amended pursuant to section 319F-3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as republished at 85 FR 79190 (Dec. 9, 2020).

1. Covered Persons, section V, delete in full and replace with:
- V. Covered Persons
- 42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are “manufacturers,” “distributors,” “program planners,” “qualified persons,” and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. “Order” as used herein and in guidance issued by the Office of the Assistant Secretary for Health⁴ means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes

prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration;⁵

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by

his or her State board of pharmacy),⁶ (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP’s standard immunization schedule or (2) seasonal influenza vaccine administered by qualified pharmacy technicians and interns that the ACIP recommends to persons aged 19 and older according to ACIP’s standard immunization schedule; or (3) FDA authorized or FDA licensed COVID-19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP’s COVID-19 vaccine recommendation(s);
- iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP’s standard immunization schedule;
- iv. In the case of seasonal influenza vaccine administered by qualified pharmacy technicians and interns, the vaccination must be ordered and administered according to ACIP’s standard immunization schedule;
- v. In the case of pharmacy technicians, the supervising pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician;
- vi. The licensed pharmacist must have completed the immunization

⁶ Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, “State-licensed or registered intern” (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but 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. As used herein, 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 CPhT certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. See Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020 at 2, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

⁴ See Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021).

⁵ See, e.g., Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf> (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf> (last visited Jan. 24, 2021) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the ACPE to order and administer vaccines. Such a 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;

vii. The licensed or registered pharmacy intern and qualified pharmacy technician 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;

viii. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation;⁷

ix. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

x. 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;

xi. 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; and

xii. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician 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).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.⁸ Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services;

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or a pharmacist or pharmacy intern as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction

where the PREP Act applies, other than the State in which the license or certification 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 in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional 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 the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to: (i) Documentation of completion of the Centers for Disease Control and Prevention COVID-19 (CDC) Vaccine Training Modules⁹ and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the COVID-19 vaccine(s) to be administered;

(g) Any member of a uniformed service (including members of the National Guard in a Title 32 duty status) (hereafter in this paragraph "service member") or Federal government, employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government service members, employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal service member, employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that service member, employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that service member, 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 service member, employees, contractors,

⁷ This requirement 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, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

⁸ See, e.g., Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf> (last visited Jan. 24, 2021).

⁹ See COVID-19 Vaccine Training Modules, available at <https://www.cdc.gov/vaccines/covid-19/training.html>.

or volunteers are authorized to carry out under this declaration; and

(h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered;

2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification 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 the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections

who administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered;

Subject to the following requirements:

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. Vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s);
- iii. The healthcare professionals and students must have documentation of completion of the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;
- iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering vaccinations is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID-19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;
- v. The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation;¹⁰

¹⁰ This requirement 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, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See *Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act*, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); *Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing*, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

vi. The healthcare professionals and students 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; and

vii. The healthcare professionals and students 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).

(i) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy)¹¹ FDA authorized, approved, or licensed COVID-19 therapeutics. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are

¹¹ Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, "State-licensed or registered intern" (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but 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. As used herein, 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 CPhT certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. See *Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing*, OASH, Oct. 20, 2020 at 2, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

qualified persons only if the following requirements are met:

ix. The COVID-19 therapeutic must be authorized, approved, or licensed by the FDA;

x. In the case of a licensed pharmacist ordering a COVID-19 therapeutic, the therapeutic must be ordered for subcutaneous, intramuscular, or oral administration and in accordance with the FDA approval, authorization, or licensing;

xi. In the case of licensed pharmacists, qualified pharmacy technicians, and licensed or registered pharmacy interns administering the COVID-19 therapeutic, the therapeutic must be administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, or licensing;

xii. In the case of qualified pharmacy technicians, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician;

xiii. In the case of COVID-19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician 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 COVID-19 therapeutics, the recognition and treatment of emergency reactions to COVID-19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing;

xiv. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation;¹²

xv. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events;

xvi. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID-19 therapeutics.

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. All other terms and conditions of the Declaration apply to such covered countermeasures.

2. Effective Time Period, section XII, delete in full and replace with:

Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in Section VII(a) of this Declaration, begin on March 27, 2020 and extend through October 1, 2024.

Liability protections for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution identified in Section VII(a) of this Declaration, begin on February 4, 2020 and extend through October 1, 2024.

Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in Section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in Section VII (except that, 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's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of

guidance-documents//prep-act-guidance.pdf (last visited Jan. 24, 2021).

Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begin on December 9, 2020 and last through (a) the final day the Declaration of Emergency is in effect or (b) October 1, 2024 whichever occurs first.

Liability protections for Qualified Persons under section V(d) of the Declaration who are qualified pharmacy technicians and interns to seasonal influenza vaccine to persons aged 19 and older begin on August 4, 2021.

Liability protections for Qualified Persons under section V(f) of the Declaration begin on February 2, 2021, and last through October 1, 2024.

Liability protections for Qualified Persons under section V(g) of the Declaration begin on February 16, 2021, and last through October 1, 2024.

Liability protections for Qualified Persons who are physicians, advanced practice registered nurses, registered nurses, or practical nurses under section V(h) of the Declaration begins on February 2, 2021 and last through October 1, 2024, with additional conditions effective as of March 11, 2021 and liability protections for all other Qualified persons under section V(h) begins on March 11, 2021 and last through October 1, 2024.

Liability protections for Qualified Persons under section V(i) of the Declaration who are licensed pharmacists to order and administer and qualified pharmacy technicians and licensed or registered pharmacy interns to administer COVID-19 therapeutics begin on September 9, 2021.

Authority: 42 U.S.C. 247d-6d.

Dated: September 9, 2021.

Xavier Becerra,

Secretary, U.S. Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

¹² This requirement 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, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs->