DC | HEALTH
Health Regulation & Licensing Administration

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

899 NORTH CAPITOL ST. NE – 2ND FLR.
WASHINGTON, DC 20002

October 7, 2021

9:30 am

OPEN SESSION AGENDA
(VIA ZOOM MEETING DUE TO THE COVID-19 PUBLIC HEALTH EMERGENCY)

Board of Pharmacy Mission Statement:
"To protect and improve the public health through the efficient and effective regulation of the practice of Pharmacy and Pharmaceutical Detailing; through the licensure of Pharmacists, Pharmaceutical Detailers, Pharmacy Interns, and Pharmacy Technicians."

CALL TO ORDER:

PRESIDING:

BOARD MEMBERSHIP/ATTENDANCE:

BOARD MEMBERS:		
	DR. TAMARA MCCANTS, PHARM.D. R.PH CHAIRPERSON	
	MR. ALAN FRIEDMAN, R.PH, VICE CHAIRPERSON	
	DR. BENJAMIN MILES, PHARM.D. R.PH	
	DR. ASHLEE BOW, PHARM.D. R.PH	
	DR. ALLISON HILL, PHARM.D. R.PH	
	MR. GREGORY CENDANA, CONSUMER MEMBER	
STAFF:	DR. JUSTIN ORTIQUE, INTERIM EXECUTIVE DIRECTOR	
	KARIN BARRON, HEALTH LICENSING SPECIALIST	
	LUANNE GREENAWAY, PROGRAM SPECIALIST	
	COUNTEE GILLIAM, BOARD INVESTIGATOR	
LEGAL STAFF:	CARLA WILLIAMS, SENIOR ASSISTANT GENERAL COUNSEL	
VISITORS:		

Open Session Agenda

Quorum:

Introduction:		
1007-O-01	**Approval of the Open Session Meeting Minutes for** August 5, 2021 September 2, 2021	
Consent Agenda	**None**	
Chairperson Report	**Interprofessional Workgroup**	Dr. Tamara McCants
Executive Director Report	▪ **Statistical Report on Pharmacy professionals in the District of Columbia** ▪ **Prescription Drug Monitoring Program Updates** ▪ **DCRx (DC Center for Rational Prescribing)**	Dr. Justin Ortique
Senior Assistant General Counsel Report		
1007-O-02	**Notice of Emergency And Proposed Rulemaking** (a) Continuing Education For Sars-Cov-2 Vaccine Counseling	Ms. Carla Williams
Subcommittee Reports		
1007-O-03	**Legislative and Regulatory Subcommittee Report**	Mr. Alan Friedman
1007-O-04	**Communications Subcommittee Report**	Dr. Ashlee Bow
Matters for Consideration		
1007-O-05	**Administration of Monoclonal Antibodies by Pharmacy Students Inquiry** **Bonnie Levin, PharmD, MBA, FASHP** **AVP, Pharmacy Services, MedStar Health** (a) Email Communication (b) Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (c) Expanding Access to COVID-19 Therapeutics HHS PREP Act Declaration: 9th Amendment	

NABP E-Newsletter	**<u>September 22, 2021</u>** Help Educate Patients on the Importance of Buying Medication From Verified Sites Final Guidance Released on Biosimilar Development and BPCI Act DEA to Hold Next Drug Take Back Day on October 23rd Toolkit Available to Help Educate Older Adults on Safe Acetaminophen Use Pharmacists in Two New York Counties Required to Include Safe Disposal Kits With Every Opioid Prescription FDA Continues Collaboration With Drug Compounders Through Compounding Quality Center of Excellence SAMHSA Awards More Than $123 Million to Combat Opioid Epidemic **<u>September 29, 2021</u>** COVID-19 Booster Authorized for Certain Groups NABP Joins Other Regulatory Associations In Launching Opioid Regulatory Collaborative Montana Board of Pharmacy Reinstates Emergency Rule to Help Pharmacists Oversee, Administer Vaccinations DEA Warns of Increase in Counterfeit Pills Containing Fentanyl Recall Issued for Cefazolin Injection Products Due to a Lack of Sterility Assurance DEA Announces Virtual Red Ribbon Rally October 5 to Help Promote Drug-Free Lifestyles Celebrate World Heart Day by Raising Awareness on How Substandard, Falsified Medicines Can Endanger Cardiac Patients Note to the Public: To receive weekly updates from NABP, please sign up by using the following link: https://nabp.pharmacy/newsroom/news/.	Dr. Tamara McCants
<u>Comments from the Public</u>		

Motion to Adjourn the Open Session		

This concludes the Public Open Session of the meeting. The Board will now move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the reasons set forth in the motion.

Open Session Meeting Adjourned at _:_ AM.

This meeting is governed by the Open Meetings Act. Please address any questions or complaints arising under this meeting to the Office of Open Government at opengovoffice@dc.gov.

DC | HEALTH
Health Regulation & Licensing Administration

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

899 NORTH CAPITOL ST. NE – 2ND FLOOR.
WASHINGTON, DC 20002

August 5, 2021

9:32 AM – 10:25 AM

OPEN SESSION MINUTES
(VIA ZOOM MEETING DUE TO THE COVID-19 PUBLIC HEALTH EMERGENCY)

Board of Pharmacy Mission Statement:
"To protect and improve the public health through the efficient and effective regulation of the practice of Pharmacy and Pharmaceutical Detailing; through the licensure of Pharmacists, Pharmaceutical Detailers, Pharmacy Interns, and Pharmacy Technicians."

CALL TO ORDER: 9:32 AM

PRESIDING: MR. ALAN FRIEDMAN, R.PH, VICE CHAIRPERSON

BOARD MEMBERSHIP/ATTENDANCE:

BOARD MEMBERS:		
	DR. TAMARA MCCANTS, PHARM.D. R.PH CHAIRPERSON	ABSENT
	MR. ALAN FRIEDMAN, R.PH, VICE CHAIRPERSON	PRESENT
	DR. BENJAMIN MILES, PHARM.D. R.PH	PRESENT
	DR. ASHLEE BOW, PHARM.D. R.PH	ABSENT
	DR. ALLISON HILL, PHARM.D. R.PH	PRESENT
	GREGORY CENDANA, CONSUMER MEMBER	PRESENT
STAFF:	SHAUNA WHITE, EXECUTIVE DIRECTOR	PRESENT
	KARIN BARRON, HEALTH LICENSING SPECIALIST	PRESENT
	LUANNE GREENAWAY, PROGRAM SPECIALIST	PRESENT
	COUNTEE GILLIAM, BOARD INVESTIGATOR	PRESENT
LEGAL STAFF:	CARLA WILLIAMS, SENIOR ASSISTANT GENERAL COUNSEL	PRESENT
VISITORS:	ANGELA BRYANT, CVS SPECIALTY PHARMACY	
	CHARLENE FAIRFAX, DEPARTMENT OF HEALTH CARE FINANCE	
	GAIL ELLIOTT, KAISER PERMANENTE	
	KRISTN FINK, KAISER PERMENENTE	
	CASSANDRA LATNEY, HOWARD UNIVERSITY COLLEGE OF PHARMACY	
	TOYIN TOFADE, HOWARD UNIVERSITY COLLEGE OF PHARMACY	
	DON ZOWADER, PUBLIC	
	SADA PHATTHANAPHUTI, PHARMACY INTERN	
	TEGESTY TEREFE, PHARMACY INTERN	

Open Session Agenda

Quorum: Yes

Introduction:		
0805-O-01	**Approval of the Open Session Meeting Minutes for** June 3, 2021 **Motion**: Board Member, Dr. Benjamin Miles moves the Board to approve the June 3, 2021 Board of Pharmacy Open Session Minutes. **Seconded by**: Mr. Gregory Cendana. **Roll Call Vote:** Dr. Benjamin Miles: Votes in favor of the motion. Mr. Gregory Cendana: Votes in favor of the motion. Dr. Allison Hill: Abstained from the motion. **Abstentions: Dr. Allison Hill.** **Motion carried.**	
Consent Agenda	**None**	
Chairperson Report	**Interprofessional Workgroup** The Interprofessional Workgroup has nothing to report.	Mr. Alan Friedman
Executive Director Report	**Statistical Report on pharmacy professionals in the District of Columbia** ➢ Pharmacists: 2,004 ➢ Pharmacists with Vaccination and Immunization Authority: 686 ➢ Pharmacy Interns: 788 ➢ Pharmacy Technicians:851 ➢ Pharmacy Technician Trainees:137 ➢ Pharmacy Technician Training Programs:14 ➢ Pharmaceutical Detailers:717 **Prescription Drug Monitoring Program (PDMP) Updates** ➢ Pharmacists who recently became licensed in the District of Columbia are advised to register for the Prescription Drug Monitoring Program. Information regarding registration is on https://dchealth.dc.gov/service/prescription-drug-monitoring-program.	Dr. Shauna White

DC RX (DC Center for Rational Prescribing)

- DCRX is continuing to publish continuing education credit courses, all of which can be reviewed at https://dchealth.dc.gov/dcrx.
- A special Implicit Bias training for all licensed health care providers and anyone who is employed in the medical field is forthcoming. The course, which is a collaborative effort between the DC Board of Pharmacy and DC Health, will be available in mid-September, 2021.

DC Health Licensing System

- The Health Regulation and Licensing Administration recently migrated to a new health licensing system on an online platform. Should anyone experience delays in licensing, please be patient with the DC Board of Pharmacy staff as it continues to work towards a full transition.
- Applications for licensure that are mailed to DC Health will not be considered and will be returned to the individual seeking licensure.
- Official documents (i.e. notarized documents and transcripts) are to be mailed to DC Health in support of online applications. Please note that e-transcripts are accepted by the DC Board of Pharmacy at dcbop@dc.gov.
- Please note also that while mailed documents are received by the office of the Board of Pharmacy, the documents are not received by the team under 2-3 weeks after arriving in the office.

Continuing Education

- DC Health has issued emergency regulations on COVID-19 requirements for specific and licensed health care professionals.
- In addition to the regulated continuing education credit requirements, pharmacists are required to complete two (2.0) credit hours in SARS, COVID Vaccines, where the subject matter pertains to vaccine safety, best practices for counseling patients, vaccine efficacy, vaccine ineffectiveness,
- The continuing education credits must be completed before September 30, 2021.
- These two (2.0) credit hours may be used as public health priorities training. For professionals who will comply with this requirement, these two hours will not increase the total number of continuing education credits required; nor does it increase the total number of public health priorities training continuing education credits required.
- The emergency rulemaking concerning 2.0 credit hours was adopted on and effective as of July 22, 2021. The requirement must be satisfied by September 30, 2021.

	➢ The individual practitioner may go to www.coronavirus.dc.gov for further information on resources concerning available continuing education credits. ➢ These continuing education credits will be included in the upcoming continuing education audits. There will be a coordinated effort between the Health Regulation and Licensing Administration and the Boards to disseminate this information concerning this new requirement.	
Senior Assistant General Counsel Report		
	None	
Subcommittee Reports		
0805-O-02	**Legislative and Regulatory Subcommittee Report** ➢ The Legislative and Regulatory Subcommittee has met every month to review and suggest changes to Chapter 65, particularly the Practice Act. ➢ The team has also reviewed the definition of pharmaceutical care; as well as immunization, and how the laws and regulations inform each other. ➢ The subcommittee has reviewed other subject matter that is not commonly under the Board of Pharmacy's oversight, but is overseen by the Pharmaceutical Control Division. The intent is to share its recommendations with the Pharmaceutical Control Division on changes to regulations that the division may consider. ➢ The subcommittee will also share these recommendations with the Board of Pharmacy during the open session of the October, 2021 monthly meeting. **Opioid Amendment Act of 2019** ➢ The proposal was introduced by the DC Council on November 5, 2019, and was published in the DC Register and in effect as of March 16, 2021. ➢ The fundamental change is in 47-2885.14, clause (b): *"If the drug derives from opium, a label shall be affixed to the container, in which such opioid medication is sold or dispensed, stating that the drug is an opioid and that with opioids there is a risk of overdose and addictions."* ➢ No action is required by the DC Board of Pharmacy, relative to this law.	Mr. Friedman
0805-O-03	**Communications Subcommittee Report** ➢ The DC Board of Pharmacy anticipates a forthcoming Newsletter in September, 2021, which will be published on the Board's website, as well as at www.nabp.pharmacy.	Dr. Shauna White

Matters for Consideration		
0805-O-04	**DC Immunization Consent Question** **Kristen Fink, PharmD, BCPS, BCACP, CDCES** **Kaiser Permanente** **Mr. Alan Friedman, Chairperson, is recused from this matter** ➢ Dr. Kristen Fink explains that patients are able to sign their consent via an electronic pad, and a copy is maintained in the electronic medical record within the pharmacy where anyone with access to the file is able to print a copy of the written consent. Does the Board agree that an electronic written consent is consistent with the regulations and does not constitute a waiver? ➢ By general consensus, the Board agrees that the electronic written consent is consistent with the [District's] regulations as currently written.	Ms. Carla Williams
NABP E-Newsletter	**July 28, 2021** Reminder – Register for NABP's Upcoming Live Webinar on Biosimilar and Interchangeable Products Former NECC Supervisory Pharmacist Who Sparked Deadly 2012 Meningitis Outbreak Resentenced to Prison New CDC Data Show Record Numbers of Overdose Deaths in 2020 New FIP Vaccination Handbook for Pharmacists Pharmacy Has Played a Vital Role in COVID-19 Vaccinations, New Data Highlights South Carolina's Opioid Emergency Response Team Issues Warning of Counterfeit 'Blue Pills' Circulating in the State **July 21, 2021** New NABP Patient Education Kit Allows Boards of Pharmacy, Health Care Providers to Share Important Online Medication Safety Information New Web Page Promotes NABP President Juran's Drug Importation Initiative New Survey Results Show Americans Are Prioritizing Cost Over Safety When Buying Medications Online	Mr. Alan Friedman

	FDA Alerts Health Care Professionals About Chantix Recall Due to Nitrosamine Impurities Note to the Public: To receive weekly updates from NABP, please sign up by using the following link: https://nabp.pharmacy/newsroom/news/.	
Comments from the Public	Don Zowader, DC Public asks the following: ➢ With regard to the survey of Americans prioritizing cost over safety by purchasing prescriptions online because these drugs are less expensive, can the Board notify the general public about the risk(s) taken in such practice? ➢ Board Chair, Mr. Alan Friedman informs Mr. Zowader that such information can be shared in the Board's newsletter. ➢ Dr. White informs Mr. Zowader that concerning this subject matter: the current or future plans of the [DC Health] are unknown at this time.	
Motion to Adjourn the Open Session	**Board member, Dr. Benjamin Miles moves as follows:** "Madam Chair, I move that the Board close the Open Public session portion of the meeting and move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the following purposes: to discuss disciplinary matters pursuant to § 2-575(b)(9); to seek the advice of counsel to the board, to preserve the attorney-client privilege, or to approve settlement agreements pursuant to § 2-575(b)(4); and to plan, discuss, or hear reports concerning ongoing or planned investigations pursuant to § 2-575(b)(14)." **Seconded by**: Mr. Gregory Cendana. **Roll Call Vote:** Dr. Benjamin Miles: Votes in favor of the motion. Mr. Gregory Cendana: Votes in favor of the motion. Dr. Allison Hill: Votes in favor of the motion. **Abstentions: None.** **Motion Carried.**	

This concludes the Public Open Session of the meeting. The Board will now move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the reasons set forth in the motion.

Open Session Meeting Adjourned at 10:25 AM.

This meeting is governed by the Open Meetings Act. Please address any questions or complaints arising under this meeting to the Office of Open Government at opengovoffice@dc.gov.

DC | HEALTH
Health Regulation & Licensing Administration

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

899 NORTH CAPITOL ST. NE – 2ND FLOOR.
WASHINGTON, DC 20002

September 2, 2021

9:30 am

OPEN SESSION AGENDA
(VIA ZOOM MEETING DUE TO THE COVID-19 PUBLIC HEALTH EMERGENCY)

Board of Pharmacy Mission Statement:
"To protect and improve the public health through the efficient and effective regulation of the practice of Pharmacy and Pharmaceutical Detailing; through the licensure of Pharmacists, Pharmaceutical Detailers, Pharmacy Interns, and Pharmacy Technicians."

CALL TO ORDER:

PRESIDING:

BOARD MEMBERSHIP/ATTENDANCE:

BOARD MEMBERS:		
	DR .TAMARA MCCANTS, PHARM.D. R.PH CHAIRPERSON	
	DR. BENJAMIN MILES, PHARM.D. R.PH	
	MR. ALAN FRIEDMAN, R.PH	
	DR. ASHLEE BOW, PHARM.D. R.PH	
	DR. ALLISON HILL, PHARM.D.R.PH.	
	GREGORY CENDANA, CONSUMER MEMBER	
STAFF:	SHAUNA WHITE, EXECUTIVE DIRECTOR	
	KARIN BARRON, HEALTH LICENSING SPECIALIST	
	LUANNE GREENAWAY, HEALTH LICENSING SPECIALIST	
	COUNTEE GILLIAM, BOARD INVESTIGATOR	
LEGAL STAFF:	CARLA WILLIAMS, ASSISTANT GENERAL COUNSEL	
VISITORS:	N/A	

Open Session Agenda

Quorum:

Introduction:		
Motion to Adjourn the Open Session	"Madam Chair, I move that the Board close the Open Public session portion of the meeting and move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the following purposes: to discuss disciplinary matters pursuant to § 2-575(b)(9); to seek the advice of counsel to the board, to preserve the attorney-client privilege, or to approve settlement agreements pursuant to § 2-575(b)(4); and to plan, discuss, or hear reports concerning ongoing or planned investigations pursuant to § 2-575(b)(14)." (Roll Call Vote).	

This concludes the Public Open Session of the meeting. The Board will now move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the reasons set forth in the motion.

Open Session Meeting Adjourned at __:__

This meeting is governed by the Open Meetings Act. Please address any questions or complaints arising under this meeting to the Office of Open Government at opengovoffice@dc.gov.

DEPARTMENT OF HEALTH

NOTICE OF EMERGENCY AND PROPOSED RULEMAKING

The Director of the District of Columbia Department of Health, pursuant to section 1 of An Act To Authorize the Commissioners of the District of Columbia to make regulations to prevent and control the spread of communicable and preventable diseases, approved August 11, 1939 (53 Stat. 1408, D.C. Official Code §§ 7-131 *et seq*.) (2018 Repl.)) and section 2 of Mayor's Order 98-141, dated August 20, 1998, hereby gives notice of the adoption, on an emergency basis, of the following amendments to Chapter 2 (Communicable and Reportable Diseases) of Subtitle B (Public Health and Medicine) of Title 22 (Health) of the District of Columbia Municipal Regulations (DCMR).

The purpose of this rulemaking is to: (1) continue or modify provisions of Administrative Orders issued by the Department of Health during the public health emergency for COVID-19, which is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), previously known as "2019 novel coronavirus", that will be needed after the public health emergency ends; and (2) add other provisions described in the next paragraph that are needed to provide the Department of Health with information after the public health emergency ends.

Emergency action is necessary because the spread of a contagious disease such as COVID-19, caused by SAR-CoV-2, is an imminent threat to the health, safety, and welfare of District residents. Therefore, it is necessary that the Department of Health and the Health Information Exchange receive prompt reports of new positive test results for SARS-CoV-2, that genomic sequencing be performed for residents who test positive for SARS-CoV-2, that certain persons who are not fully vaccinated who must work or learn in person have access to SARS-CoV-2 testing, that unlicensed persons continue to be authorized to administer SARS-CoV-2 vaccines after being trained and while supervised, and that certain health professionals receive continuing education on SARS-CoV-2 vaccines to improve vaccine counseling to residents.

This emergency rule was adopted on July 22, 2021 and became effective immediately on that date. The emergency rule will expire one hundred twenty (120) days from the date of adoption, on November 18, 2021, or upon publication of a final rulemaking in the *D.C. Register*, whichever occurs first.

The Director also give notice of her intent to take final rulemaking action to adopt these proposed rules in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

Chapter 2, COMMUNICABLE AND REPORTABLE DISEASES, of Subtitle B, PUBLIC HEALTH AND MEDICINE, of Title 22, HEALTH, of the District of Columbia Municipal Regulations is amended as follows:

Subsection 201, COMMUNICABLE DISEASE SURVEILLANCE, is amended by adding a new subsection 201.4 to read as follows:

201.4 The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), previously known as "2019 novel coronavirus" and more commonly known as COVID-19, shall be considered a communicable disease for the purpose of communicable disease surveillance and shall be electronically reported to the Department of Health immediately upon the provisional diagnosis of or the appearance of suspicious symptoms of SARS-CoV-2 and shall be electronically reported to the Department of Health immediately upon a laboratory confirmed diagnosis.

Section 202, REPORTING OCCURRENCES, is amended by adding new subsections 202.13 and 202.14, to read as follows:

202.13 In addition to the reporting required by subsections 202.1 through 202.12, the Public Health Laboratory shall report within twenty-four (24) hours after completion of each test result each positive or negative SARS-CoV-2 test result to the District of Columbia Health Information Exchange established by Chapter 87 of Title 29 of the District of Columbia Municipal Regulations.

202.14 In addition to the reporting required by subsections 202.1 through 202.12, each clinical laboratory operating in the District of Columbia, a clinical laboratory providing services to a health care facility located in the District of Columbia, or a clinical laboratory providing services to a health care provider located in the District of Columbia shall report each positive or negative SARS-CoV-2 test result to the District of Columbia Health Information Exchange established by Chapter 87 of Title 29 of the District of Columbia Municipal Regulations.

A new Section 221, CLINICAL LABORATORY WITH CAPACITY TO PERFORM GENOMIC SEQUENCING, is added to read as follows:

221 CLINICAL LABORATORY GENOMIC SEQUENCING OF SARS-CoV-2

221.1 A clinical laboratory operating in the District of Columbia, a clinical laboratory providing services to a health care facility located in the District of Columbia, or a clinical laboratory providing services to a health care provider located in the District of Columbia must conduct genomic sequencing using a widely accepted methodology for SARS-CoV-2 and in compliance with subsection 221.2 when a resident of the District of Columbia tests positive for SARS-CoV-2 based on a polymerase chain reaction (PCR) testing if the clinical laboratory has the capacity to conduct genomic sequencing.

221.2 Each clinical laboratory operating in the District of Columbia, a clinical laboratory providing services to a health care facility located in the District of Columbia, or a clinical laboratory providing services to a health care provider located in the District of Columbia conducting genomic sequencing for SARS-CoV-2 shall:

(a) Conduct genomic sequencing on a minimum of ten percent (10%) of specimens from residents of the District of Columbia that are positive for SARS-CoV-2 for each period of time starting at 12:00 midnight on Sunday through 11:59 p.m. on the next Saturday;

(b) Submit all genomic sequencing results for residents of the District of Columbia to the Department of Health and the Public Health Laboratory; and,

(c). Store all specimens from residents of the District of Columbia that are positive for SARS-CoV-2 for a minimum of thirty (30) calendar days; provided, that if the clinical laboratory lacks the capacity or capability to store positive SARS-CoV-2 specimens for thirty (30) days, the clinical laboratory may request a hardship waiver from the Department of Health.

222.3 A clinical laboratory operating in the District of Columbia, a clinical laboratory providing services to a health care facility located in the District of Columbia, or a clinical laboratory providing services to a health care provider located in the District of Columbia that lacks the capacity to conduct genomic sequencing shall submit all specimens positive for SARS-CoV-2 for residents of the District of Columbia to the Public Health Laboratory.

A new Section 222, SARS-CoV-2 TESTING FOR IN-PERSON WORK AND LEARNING, is added to read as follows:

222 SARS-CoV-2 TESTING FOR IN-PERSON WORK AND LEARNING

222.1 A person who is not fully vaccinated and who must report, in person, to work in the District of Columbia is not required to have an order from a physician or other authorized health professional in order to be receive SARS-CoV-2 testing. Such person may be tested for SARS-CoV-2 without an order from a physician or other authorized health professional once in every seven (7) day period.

222.2 A person who is not fully vaccinated and who must report, in person, to learn in the District of Columbia is not required to have an order from a

physician or other authorized health professional in order to be receive SARS-CoV-2 testing. Such person may be tested for SARS-CoV-2 without an order from a physician or other authorized health professional once in every seven (7) day period if there is not a testing of a proportion of students each week for screening testing.

222.3 Each person tested pursuant to this section may be responsible for payment for some or all of the costs of SARS-CoV-2 testing when any third-party is not required to pay for the testing.

A new Section 223, SARS-CoV-2 VACCINE ADMINISTRATION, is added to read as follows:

223 SARS-CoV-2 VACCINE ADMINISTRATION

223.1 An individual, including a medical assistant or a health technician, who is not licensed, registered, or certified to practice a health occupation pursuant to Chapter 12 of Subtitle I of Chapter 3 of the District of Columbia Official Code, is authorized to administer a SARS-CoV-2 vaccine provided that:

(a) The individual has successfully completed training, provided by a licensed health professional authorized by an existing scope of practice of a health profession to administer a vaccination in the District of Columbia, on the administration of the SARS-CoV-2 vaccine;

(b) A licensed health professional authorized by an existing scope of practice of a health profession to administer a vaccination in the District of Columbia must supervise the individual at the vaccination site;

(c) The licensed health professional reasonably determines that the individual is able to administer the SARS-CoV-2 vaccine under appropriate supervision;

(d) The individual administers the SARS-CoV-2 vaccine at the vaccination site under the general supervision of a licensed health professional supervising the unlicensed person at the vaccination site; and

(e) The training, authorization, and supervision are appropriately documented in the records maintained by the vaccination site.

A new Section 224, CONTINUING EDUCATION FOR SARS-CoV-2 VACCINE COUNSELING, is added to read as follows:

224 CONTINUING EDUCATION FOR SARS-CoV-2 VACCINE COUNSELING

224.1 In addition to any other continuing education requirements and subject to subsection 224.2, a person licensed to practice one of the following professions must complete two (2) hours of continuing education on SARS-CoV-2 vaccines, including, but not limited to, SARS-CoV-2 vaccine safety, best practices for counseling patients about SARS-CoV-2 vaccines, and SARS-CoV-2 vaccine efficacy and effectiveness, on or before September 30, 2021:

(a) Advanced Practice Registered Nurse;

(b) Audiologist;

(c) Chiropractor;

(d) Dentist;

(e) Dietician;

(f) Doctor of Osteopath;

(g) Licensed Clinical Social Worker;

(h) Licensed Graduate Professional Counselor;

(i) Licensed Graduate Social Worker;

(j) Licensed Independent Clinical Social Worker;

(k) Licensed Practical Nurse;

(l) Licensed Professional Counselor;

(m) Long Term Care Administrator;

(n) Marriage and Family Therapist;

(o) Medical Doctor;

(p) Nutritionist;

(q) Occupational Therapist;

(r) Optometrist;

(s) Pharmacist;

(t) Physical Therapist;

(u) Physician Assistant;

(v) Podiatrist;

(w) Psychologist;

(x) Registered Nurse;

(y) Respiratory Care Therapist; or

(z) Speech Language Pathologist.

224.2 The hours of continuing education required by subsection 224.1 may be counted as hours required for public health priorities training hours or optional training hours where applicable.

All persons desiring to comment on the subject of this proposed rulemaking should file comments in writing not later than thirty (30) days after the date of the publication of this notice in the *D.C. Register*. Comments should be sent to the Department of Health, Office of the General Counsel, 899 North Capitol Street, N.E., 6th Floor, Washington, D.C. 20002, or by email to Angli.Black@dc.gov. Copies of the proposed rules may be obtained during the hours of 9:00 AM to 5:00 PM, Monday through Friday, excluding holidays by contacting Angli Black, Paralegal Specialist, at (202) 442-5977 or Angli.Black@dc.gov.

Good Morning

The Board of Pharmacy would need to opine on if this is appropriate.

This can be presented at the next board meeting for a Board opinion

Thanks
Shauna

Shauna White, PharmD, RPh, MS
Executive Director – District of Columbia Board of Pharmacy
Program Manager - Pharmaceutical Control Division
Health Regulation and Licensing Administration
DC | HEALTH GOVERNMENT OF THE DISTRICT OF COLUMBIA MURIEL BOWSER, MAYOR
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Washington, DC 20002
202.997.4947(cell)
202.442.4767 (fax)*NEW
shauna.white@dc.gov
Pharmaceutical Control
http://dchealth.gov/pcd
Board of Pharmacy
www.dcboard.pharmacy
http://dchealth.dc.gov/bop

From: Levin, Bonnie [mailto:Bonnie.Levin@medstar.net]
Sent: Friday, August 27, 2021 4:38 PM
To: White, Shauna (DOH) <shauna.white@dc.gov>
Subject: SQ administration of monoclonal antibodies by pharmacy students

Hi, there. Apparently there are pharmacists and pharmacy students in other parts of the country administering the Covid monoclonal antibodies (Regen-Cov for now) to patients SQ since there is a new route of adm approved under EUA for patients for whom an IV can't be started.

Any objections to using the vaccine certification for this? We'd train the students and they'd have clinical oversight (RN or NP).

Thanks.

And don't you love my off the wall questions? It's Friday!

Bonnie Levin, PharmD, MBA, FASHP
AVP, Pharmacy Services, MedStar Health
10980 Grantchester Way, 7th floor
Columbia, MD 21044
C: 240-472-7947

Admin/Project Manager: Leslie Su
Leslie.Y.Su@Medstar.net
C: 202-365-4851

We serve our communities by driving excellence in patient-centered pharmacy practice.

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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
Student	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.

[FR Doc. 2021–19754 Filed 9–13–21; 8:45 am]

BILLING CODE 4163–18–P

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.

[FR Doc. 2021–19789 Filed 9–13–21; 8:45 am]

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 Health [4] 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

[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.

[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).

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 Modules [9] 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]

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

[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).

[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 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, 2021and 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.

[FR Doc. 2021–19790 Filed 9–9–21; 4:15 pm]

BILLING CODE 4150–28–P

[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 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).

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

Expanding Access to COVID-19 Therapeutics
HHS PREP Act Declaration: 9th Amendment

September 2021

Agenda

1. Public Readiness and Emergency Preparedness (PREP) Act
2. March 2020 PREP Act Declaration
3. Ninth Amendment to the PREP Act Declaration
4. Communication Resources

The Public Readiness and Emergency Preparedness (PREP) Act

The PREP Act

- The **Public Readiness and Emergency Preparedness Act** (PREP Act) authorizes the Secretary of the Department of Health and Human Services (HHS) to issue a PREP Act declaration.
- A declaration provides immunity from liability (except for willful misconduct) for claims:
  - of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions
  - determined by the Secretary to constitute a present, or credible risk of a future public health emergency
  - to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures
- A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

The March 2020 PREP Act Declaration

Public Readiness and Emergency Preparedness (PREP) Act Declaration

In March 2020, the Secretary of HHS issued a PREP Act declaration **providing liability protections to manufacturers, distributors, states, localities, territories, tribes, licensed healthcare professionals, and others identified by the Secretary (qualified persons) who administer covered countermeasures, including COVID-19 therapeutics** authorized under an EUA by the U.S. Food and Drug Administration (FDA).

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19
(https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures)

COVID-19 PREP Act Declaration

What is the PREP Act Declaration?

- Covers COVID-19 tests, drugs and vaccines, providing liability protections to manufacturers, distributors, SLTTs, licensed healthcare professionals, and others identified by the Secretary (qualified persons) who administer COVID-19 countermeasures
- The Declaration has been amended several times to expand liability protections, including prior amendments to cover licensed healthcare professionals who cross state borders and federal response teams

Who is Covered?

- Licensed or certified health professionals or other individuals authorized by the state to administer COVID-19 countermeasures
- Health professionals and other individuals identified as qualified persons under the PREP Act Declaration amendments are also covered

What is the Impact on SLTTs?

- The PREP Act and Declaration preempt state requirements, such as more limited licensing or scope of practice requirements, that effectively prohibit a qualified person from prescribing, dispensing or administering vaccines.
- Requirements that do not effectively prohibit qualified persons, such as additional training, are not preempted. Ultimately, states and territories may choose which qualified persons to use for administering COVID 19 therapeutics in their jurisdiction.

PHE.gov | Public Readiness and Emergency Preparedness Act (https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx)

Ninth Amendment to the March 2020 PREP Act Declaration

Ninth Amendment: Adding Covered Qualified Persons

WHY:

Provide a pathway for increased access to COVID-19 therapeutics, particularly in surge states with rising numbers of COVID-19 cases and in rural areas where access to inpatient and outpatient services may be more limited

WHAT:

Expanded pool of providers to **administer covered COVID-19 therapeutics** authorized under an EUA by the U.S. Food and Drug Administration (FDA)

The PREP Act Declaration should be used by SLTTs to ***complement other efforts*** *to increase access to COVID-19 therapeutics, such as health education.* ***States are encouraged to further expand the categories of persons authorized*** *to administer COVID-19 therapeutics in their states and territories, as authorized under the PREP Act, to respond to the local needs and availability.*

Expanded Coverage of Qualified Persons

The 9th amendment to the COVID-19 PREP Act Declaration provides liability immunity and authorizes **licensed pharmacists** to order and administer select COVID-19 therapeutics authorized by the FDA and for **pharmacy technicians**, and **pharmacy interns** to **administer COVID-19 therapeutics** authorized by the FDA when the following criteria are met:

- The COVID-19 therapeutic must be authorized, approved, licensed, or cleared by the FDA.
- 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, clearance, or licensing.

- 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, clearance, or licensing.
- In the case of qualified pharmacy technicians, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician.

(continued on next slide)

Expanded Coverage of Qualified Persons

The 9th amendment to the COVID-19 PREP Act Declaration provides liability immunity and authorizes **licensed pharmacists** to order and administer select COVID-19 therapeutics authorized by the FDA and for **pharmacy technicians**, and **pharmacy interns** to **administer COVID-19 therapeutics** authorized by the FDA when the following criteria are met (*continued*):

- 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, clearance, or licensing.

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

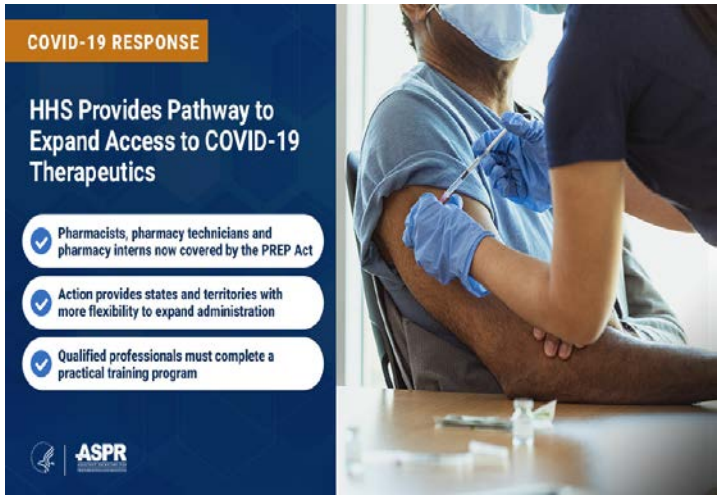
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events.

- 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.

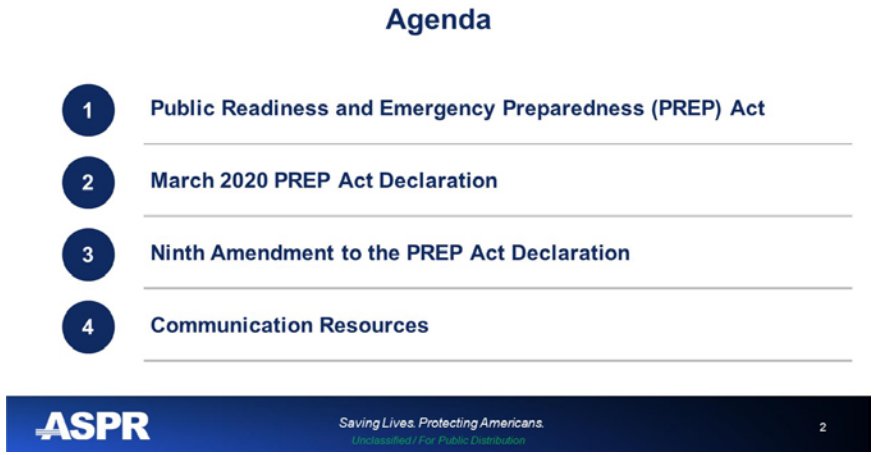
Communication: Amplification of Update

Share information about the March 2020 PREP Act Declaration Ninth Amendment with your stakeholders

Social Media



Slide Presentation



Fact Sheet

More Information

For more information on the March 2020 PREP Act and its amendments, visit:
https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx
and
www.PHE.gov/COVIDvaccinators

If you have any questions, please email ASPRStakeholder@hhs.gov

View this email in your browser

Help Educate Patients on the Importance of Buying Medication From Verified Sites

As part of its 2021 consumer awareness campaign, NABP has created a patient education kit for boards of pharmacy and other health care organizations and providers to share important online medication safety information with patients in their state. The education kit includes:

- social media posts and images,
- a public service announcement video,
- a newsletter article, and
- a PowerPoint presentation outlining the risks of buying medications online.

View the Patient Education Kit

In May 2021, NABP launched its 2021 consumer awareness campaign to inform consumers about the dangers of buying medicine from unlicensed pharmacies online and through social media accounts. You can learn more about the

safe.pharmacy/buy-safely.

Final Guidance Released on Biosimilar Development and BPCI Act

Food and Drug Administration (FDA) issued a guidance document on biosimilar development and the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The document provides answers to common questions from applicants and other interested parties regarding the BPCI Act, and is intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as describe FDA's interpretation of certain statutory requirements added by the BPCI Act. FDA will regularly update the guidance document with new questions and answers.

Read More

DEA to Hold Next Drug Take Back Day on October 23

The next National Prescription Drug Take Back Day will be held on Saturday, October 23, 2021, from 10 AM to 2 PM. During the event, thousands of collection sites will be available across the country to accept unneeded prescription drugs, including controlled substances, for safe and legal disposal. This marks the 21st National Take Back Day event that Drug Enforcement Administration (DEA) has held.

spring and once in the fall. Take Back Days give Americans the opportunity to prevent substance use disorders and overdose deaths by disposing of prescription drugs. In addition to opportunities provided by DEA Take Back Days, many locations offer medication disposal kiosks year-round. More than 9,600 locations can be found by using NABP's Drug Disposal Locator Tool, available on the consumer website, *www.safe.pharmacy*. By entering a zip code or city and state, consumers can find the nearest drug disposal sites on a map.

Learn More

Toolkit Available to Help Educate Older Adults on Safe Acetaminophen Use

September is both Healthy Aging Month and Pain Awareness Month, as well as the start of flu shot season. With older adults being at greater risk of unintentional misuse of acetaminophen, it is important to make sure older patients understand safe use of acetaminophen during this time.

Health care providers are the primary sources of relaying this information to patients when it comes to the medicine they are taking. Health care providers are encouraged to use the Know Your Dose Campaign's *Older Adults Outreach Communications Toolkit* to help educate patients on how to safely use medicines that contain acetaminophen. Share messages from the toolkit throughout the month to support acetaminophen safe use among older adults.

Help Educate Patients

Pharmacists in Two New York Counties Required to Include Safe Disposal Kits With Every Opioid Prescription

Two local counties in New York have mandated an at-home disposal option for opioid prescriptions in an effort to prevent opioid misuse and overdoses. Rensselaer County and Albany County in New York are now requiring that pharmacies include a safe disposal kit with each opioid prescription. The kits are for at-home use and can be disposed in the trash. The kit also includes materials that will deactivate the opioids when they are mixed with water.

Read More

FDA Continues Collaboration With Drug Compounders Through Compounding Quality Center of Excellence

FDA continues its collaboration with drug compounders as the second anniversary of its Compounding Quality Center of Excellence (COE) approaches. FDA established the COE in December 2019 with outsourcing facilities, compounders, and other stakeholders to improve the quality of prescription drugs for patients. FDA's goal is to keep patients safe by careful review of drug safety and quality before they are marketed for patient use. The COE supports the overall quality of compounded drugs through training, market research, and outreach, as well as an annual conference, which took place on September 14-15, 2021.

SAMHSA Awards More Than $123 Million to Combat Opioid Epidemic

To provide multifaceted support to communities and health care providers in combating the nation's opioid epidemic, the Substance Abuse and Mental Health Services Administration (SAMHSA) is awarding more than $123 million in funding through six grant programs. According to the Centers for Disease Control and Prevention, more than 94,000 fatal overdoses occurred in 12 months ending January 2021, which is about 31% more than the overdoses recorded ending in January 2020. SAMHSA will be awarding funding throughout the nation to six different grant programs.

Learn More About the Grant Programs

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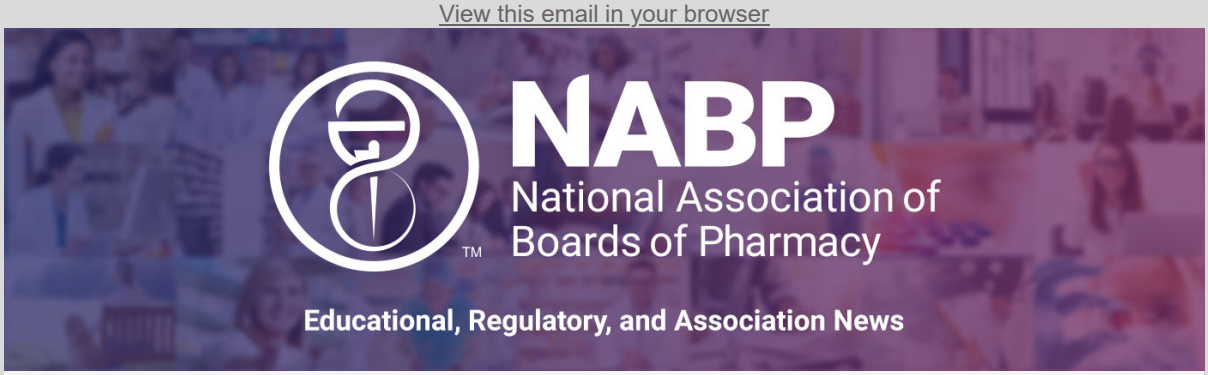

COVID-19 Booster Authorized for Certain Groups

Food and Drug Administration (FDA) has authorized a booster dose of the coronavirus disease 2019 (COVID-19) Pfizer-BioNTech vaccine for certain individuals. The amended emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine makes the booster available to the following groups:

- Individuals 65 and older,
- Individuals with high risk of severe COVID-19 who are ages 18 through 64, and
- Individuals whose occupational exposure puts them at high risk of serious complications of COVID-19 who are ages 18 through 64.

FDA notes that the single booster dose is to be administered at least six months after the individual's first series of the COVID-19 vaccine.

Learn More about the EUA

NABP Joins Other Regulatory Associations In Launching Opioid Regulatory Collaborative

NABP and three other state board associations have launched the Opioid Regulatory Collaborative (ORC). The ORC will bring together senior leaders from NABP, the American Association of Dental Boards, the Federation of State Medical Boards, and the National Council of State Boards of Nursing to share resources and strategies to slow opioid substance use disorder by uniting key health professionals. Like NABP, these organizations each support state boards

States.

Read the Press Release

Montana Board of Pharmacy Reinstates Emergency Rule to Help Pharmacists Oversee, Administer Vaccinations

The Montana Board of Pharmacy has issued an emergency order to help pharmacists oversee other health care professionals and administer more vaccines. With the high demand for COVID-19 vaccines and as the fall flu season gets underway, pharmacies will be faced with more vaccine workload.

Learn More

DEA Warns of Increase in Counterfeit Pills Containing Fentanyl

Drug Enforcement Administration (DEA) has posted a public safety alert about an increase in counterfeit prescription pills that contain fentanyl and methamphetamine. International and domestic criminal drug networks are producing counterfeit pills. In some cases, Americans are purchasing these pills thinking they are legitimate prescription opioids without realizing the danger that even small doses of fentanyl can create. DEA noted that these deadly counterfeit pills are widely available and easy for individuals to purchase.

According to the Centers for Disease Control and Prevention, last year marked the largest number of overdose deaths in the US with more than 93,000 deaths from drug overdoses.

Read the Alert

Recall Issued for Cefazolin Injection Products Due to a Lack of Sterility Assurance

IntegraDose Compounding Services, LLC is voluntarily recalling nine lots of

mL 0.9% sodium chloride bag for injection.The recall is due to lack of sterility assurance resulting from compounding in a newly installed biologic safety cabinet without completing dynamic smoke study testing.

IntegraDose Compounding Services is notifying its customers with a recall letter and requesting that impacted products be returned.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

Learn More

DEA Announces Virtual Red Ribbon Rally October 5 to Help Promote Drug-Free Lifestyles

DEA's National Red Ribbon Rally will be held virtually this year on October 5, 2021, and will be available to share as a video throughout all of October. Red Ribbon raises awareness about illicit drug use and related problems facing communities. The event also encourages parents, educators, business owners, and community organizations to promote drug-free lifestyles. The Red Ribbon Rally will feature special guests and voices from multiple communities to share diverse experiences and perspectives on drug prevention. Tickets are not required.

Red Ribbon Week began after DEA Special Agent Enrique S. "Kiki" Camarena was killed by drug traffickers. Shortly after his death, citizens from his hometown of Calexico, CA, began wearing red ribbons to remember and commemorate his sacrifice. The first official National Red Ribbon Week celebration was created by the National Family Partnership in 1988.

View the Invitation

Celebrate World Heart Day by Raising Awareness on How Substandard, Falsified Medicines Can Endanger Cardiac Patients

World Heart Day is September 29, 2021. Fight the Fakes has partnered with the

to Connect."

Health care providers can help raise awareness this World Heart Day by sharing with patients how substandard and falsified medicines can endanger cardiac patients' safety. Social media posts and other visuals are available for download on the Fight the Fake's and World Heart Federation's websites.

Spread the Word ♥

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NABP e-News *is a weekly publication prepared by NABP. Please send any comments, questions, or suggestions about the electronic newsletter to commdept@nabp.pharmacy. We look forward to receiving your feedback.*