DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Unaccompanied Children Office of the Ombuds (UCOO) Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, Department of Health and Human Services (HHS).

ACTION: Notice of reorganization; Establishment of the Unaccompanied Children Office of the Ombuds (UCOO).

SUMMARY: The Administration for Children and Families (ACF) has reorganized to establish the Unaccompanied Children Office of the Ombuds (UCOO) within the Immediate Office of the Assistant Secretary, to be headed by a Director (''Ombuds''), who reports directly to the HHS Assistant Secretary for Children and Families.

FOR FURTHER INFORMATION CONTACT: Leah Chavla, Senior Advisor, Administration for Children and Families, 330 C Street SW, Washington, DC 20201, (202) 838–3307.

SUPPLEMENTARY INFORMATION: This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KA, Immediate Office of the Assistant Secretary as last amended by 88 FR 17229–17233 dated March 22, 2023.

I. Amend Chapter K, Administration for Children and Families, Chapter KA, Office of the Assistant Secretary for Children and Families, Subchapter KA.10 Organization, by Adding

Unaccompanied Children Office of the Ombuds (KAO)

II. Amend Chapter KA, Office of the Assistant Secretary for Children and Families, by Establishing Chapter KAO, Unaccompanied Children Office of the Ombuds

KAO.00 Mission. The Mission of the Unaccompanied Children Office of the Ombuds (UCOO) is to be an independent, impartial office with authority to receive reports, including confidential and informal reports, of concerns regarding the care and custody of unaccompanied children; to investigate such reports; to work collaboratively with the Office of Refugee Resettlement (ORR) to potentially resolve such reports; issue its own reports concerning UCOO's efforts; and make recommendations to ORR regarding UC program policies and procedures related to protecting unaccompanied children in the care and custody of ORR.

KAO.10 Organization. The UCOO is headed by a Director (''Ombuds''), who reports directly to the ACF Assistant Secretary, and consists of:

Immediate Office of the Ombuds for Unaccompanied Children (KAO1)
Division of Case Management (KAO2)
Division of Operations (KAO3)

KAO.20 Functions. The UCOO may engage in activities including, but not limited to: (1) Receiving reports from unaccompanied children, potential sponsors, other stakeholders in a child's case, and the public regarding ORR's adherence to its regulations and standards; (2) Investigating implementation of or adherence to Federal law and ORR regulations, in response to reports it receives, and meeting with interested parties to receive input on ORR's compliance with Federal law and ORR policy; (3) Requesting and receiving information or documents, such as the Ombuds deems relevant, from ORR and ORR care provider facilities, to determine implementation of and adherence to Federal law and ORR policy; (4) Preparing formal reports and recommendations on findings to publish or present, including an annual report describing activities conducted in the prior year; (5) Conducting investigations, interviews, and site visits at care provider facilities as necessary to aid in the preparation of reports and recommendations; (6) Visiting ORR care providers in which unaccompanied children are or will be housed; (7) Reviewing individual circumstances, including, but not limited to, concerns about unaccompanied children's access to services, ability to communicate with service providers, parents/legal guardians of children in ORR custody, sponsors, and matters related to transfers within or discharge from ORR care; (8) Making efforts to resolve complaints or concerns raised by interested parties as it relates to ORR's implementation or adherence to Federal law or ORR policy; (9) Hiring and retaining others, including, but not limited to, independent experts, specialists, assistants, interpreters, and translators to assist the Ombuds in the performance of their duties; (10) Making non-binding recommendations to ORR regarding its policies and procedures, specific to protecting unaccompanied children in the care of ORR; (11) Providing general educational information about pertinent laws, regulations, and policies, ORR child advocates, and legal services as appropriate; and (12) Advising and updating the Director of ORR, Assistant Secretary, and the Secretary, as appropriate, on the status of ORR's implementation and adherence with Federal law or ORR policy.

The Ombuds shall manage the files, records, and other information of the program, regardless of format, and such files must be maintained in a manner that preserves the confidentiality of the records except in instances of imminent harm or judicial action and is prohibited from using or sharing information for any immigration enforcement related purpose.

III. Continuation of Policy

Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

IV. Delegation of Authority

All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them, or their successors, pending further re-delegations, provided they are consistent with this reorganization.

V. Funds, Personnel, and Equipment

Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Xavier Becerra,

Secretary, Health and Human Services.

[FR Doc. 2024–29188 Filed 12–9–24; 11:15 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

12th 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

extend the duration of the Declaration to December 31, 2029, and to republish the Declaration in full.

DATES: This amendment is effective as of January 1, 2025.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services, 400 7th St. SW, Washington, DC 20024; 202–260–0365, *paige.ezernack@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness (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, section 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 (PHE) 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 declaration was renewed effective April 26, 2020, July 25, 2020, October 23, 2020, January 21, 2021, April 21, 2021, July 20, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 11, 2023. The PHE declared under section 319 of the PHS Act ended on May 11, 2023. Nonetheless, as stated in section I of this amended PREP Act Declaration, I have determined there is a credible risk that COVID–19 may in the future constitute such an emergency and am thus amending this Declaration to prepare for and mitigate that risk.

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, 2020, 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, 2020, 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, 2020, 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, *i.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 permitted to practice; 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, I 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). On September 14, 2021, I amended the Declaration to expand the scope of authority for certain Qualified Persons to administer COVID–19 therapeutics subcutaneously, intramuscularly, or orally (86 FR 51160, Sept. 14, 2021), and on September 30, 2021, the Department filed a notice of correction to the September 14 notice clarifying the terms ''ACIP recommendations'' and ''ACIP's standard immunization schedules'' (86 FR 54696, Oct. 4, 2021). On January 7, 2022, I amended the Declaration to expand the scope of authority for licensed pharmacists to order and administer and qualified pharmacy interns to administer seasonal influenza vaccines (87 FR 982, January 7, 2022).

On May 9, 2023, I amended the Declaration to update the determination of a PHE to state that COVID–19 continues to present a credible risk of a future PHE after the end of the PHE declared pursuant to section 319 of the PHS Act; to add a new limitation on distribution to provide coverage under the PREP Act Declaration through December 31, 2024, for manufacturing, distribution, administration and use of Covered Countermeasures while they are authorized for emergency use (EUA) by the U.S. Food and Drug

Administration (FDA) pursuant to section 564 of the Federal Food, Drug & Cosmetic (FD&C) Act, regardless of any Federal agreement related to manufacturing, distribution, administration or use of the countermeasures, and regardless of any Federal, regional, state, or local emergency Declaration; to add a new limitation on distribution to provide coverage under this PREP Act Declaration through December 31, 2024, for manufacturing, distribution, administration and use of Covered Countermeasures that are COVID–19 vaccines licensed by FDA, and any FDA-approved or cleared in vitro diagnostic product or other device used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom regardless of any Federal agreement related to manufacturing, distribution, administration or use of the vaccines, and regardless of any Federal, regional, state, or local emergency Declaration; to clarify that the category of disease, health condition or health threat includes the burden on healthcare providers caused by coterminous seasonal influenza infections and COVID–19 infections; to extend the time period of PREP Act coverage through December 31, 2024, to Qualified Persons who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, Covered Countermeasures that are COVID–19 vaccines, seasonal influenza vaccines, and COVID–19 tests regardless of any Federal agreement related to manufacturing, distribution, administration or use of these Covered Countermeasures and regardless of any Federal, regional, state, or local emergency Declaration or other limitations on distribution stated in section VII of the Declaration; to clarify the time period of coverage for other qualified persons authorized under section V of the Declaration; and to extend the duration of the Declaration to December 2024 (88 FR 30769, May 12, 2023).

I am now amending section XII of the Declaration to extend the time period of PREP Act coverage through December 31, 2029. COVID–19 continues to present a credible risk of a future public health emergency. COVID–19 continues to cause significant serious illness, morbidity, and mortality during outbreaks. The risk of domestic cases is high due to ongoing outbreaks that continue domestically and internationally in the year since the PHE for COVID–19 ended. Development of and stockpiling vaccines, therapeutics, devices, and diagnostics for COVID–19 continues to be needed for U.S. preparedness against the credible threat of a public health emergency due to outbreaks of COVID–19. Continued coverage under the PREP Act, as provided in this Declaration, is intended to prepare for and mitigate the credible risk presented by COVID–19. This includes extending the time period for PREP Act coverage for licensed pharmacists, pharmacy interns, and qualified technicians, which allows for continued access by the recipient Population to Covered Countermeasures that are COVID–19 vaccines, seasonal influenza vaccines and COVID–19 tests. As stated in prior amendments to this Declaration, licensed pharmacists, pharmacy interns and qualified pharmacy technicians are well positioned to provide continued access to Covered Countermeasures, particularly in certain areas or for certain populations that have too few primary-care providers or that are otherwise medically underserved. As of 2022, nearly 90 percent of Americans lived within five miles of a community pharmacy. During the COVID–19 pandemic, the majority of Americans have received their COVID–19 vaccines and tests from a pharmacy. In addition, continued access by the Population to seasonal influenza vaccines mitigates risks that seasonal influenza infections, in conjunction with COVID–19 infections, could overwhelm healthcare providers.

As qualified persons, these licensed pharmacists, pharmacy interns, and qualified pharmacy technicians will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. To the extent that any State law would otherwise prohibit these healthcare professionals who are a ''qualified person'' from prescribing, dispensing, or administering Covered Countermeasures that are COVID–19 vaccines, seasonal influenza vaccines or COVID–19 tests, such law is preempted.

Other conforming changes and technical corrections are made throughout the Declaration for consistency and clarity.

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Medical Countermeasures Against COVID–19

To the extent any term previously in the Declaration, including its amendments, is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling. This Declaration must be construed in accordance with the Advisory Opinions of the Office of the General Counsel (Advisory Opinions). I incorporate those Advisory Opinions as part of this Declaration. Declaration is a ''requirement'' under the PREP Act.

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that the spread of SARS–CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a credible risk of a future public health emergency. I have also determined that use of any respiratory protective device approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, was a priority for use during the public health emergency that former Secretary Azar declared on January 31, 2020, under section 319 of the PHS Act for the entire United States to aid in the response of the nation's healthcare community to the COVID–19 outbreak, and that ended on May 11, 2023.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Protections

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability protections as prescribed in the PREP Act and conditions stated in this Declaration are in effect for the Recommended Activities described in Section III.

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 means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required.

''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)

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;

(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), (1) vaccines that the Centers for Disease Control and Prevention (CDC)/Advisory Committee on Immunization Practices (ACIP) recommend to persons ages three through 18 according to CDC's/ACIP's standard immunization schedule; or (2) seasonal influenza vaccine administered by qualified pharmacy technicians and interns that the CDC/ACIP recommends to persons aged 19 and older according to CDC's/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 CDC's/ACIP's COVID–19 vaccine recommendation(s);

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to CDC's/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 CDC's/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 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 Accreditation Council for Pharmacy Education (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;

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 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. 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 Documentation of completion of the COVID–19 (CDC) Vaccine Training Modules 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, or volunteers are authorized to carry out under this Declaration.

(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 CDC's/ACIP's COVID–19 vaccine recommendation(s);

iii. The healthcare professionals and students must have documentation of completion of the CDC 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;

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 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) 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;

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 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;

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; and

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.

(j) Any pharmacist who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State or who is authorized under section V(d) of this Declaration who prescribes, dispenses, or administers seasonal influenza vaccines, or a pharmacy intern as authorized under the section V(d) of this Declaration who administers seasonal influenza vaccines, in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, so long as the license or certification of the pharmacist or pharmacy intern 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.

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.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are:

(a) Any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured:

i. To diagnose, mitigate, prevent, treat, or cure COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause;

(b) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in paragraph (a) above;

(c) a product or technology intended to enhance the use or effect of a product described in paragraph (a) or (b) above; or

(d) any device used in the administration of any such product, and all components and constituent materials of any such product.

To be a Covered Countermeasure under the Declaration, a product must also meet 42 U.S.C. 247d–6d(i)(1)'s definition of ''Covered Countermeasure.''

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability protections are afforded to Covered Persons only for Recommended Activities involving:

(a) Covered Countermeasures that are related to present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements;

(b) Covered Countermeasures that are related to activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of Emergency;

(c) Covered Countermeasures other than licensed COVID–19 vaccines that are:

i. Licensed, approved, or cleared by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. A respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom.

To qualify for this third distribution channel, a Covered Person must

manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA licensure, approval, or clearance (or pursuant to an Investigational New Drug Application or Investigational Device Exemption), or the NIOSH approval;

(d) Covered Countermeasures that are authorized by the FDA under section 564 of the FD&C Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom. To qualify for this fourth distribution channel, a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA authorization; or

(e) Covered Countermeasures that are COVID–19 vaccines licensed by the FDA to prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom and any approved or cleared in vitro diagnostic product or other device used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom. To qualify for this fifth distribution channel, a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA license, clearance, or approval.

As used in this Declaration, the terms ''Authority Having Jurisdiction'' and ''Declaration of Emergency'' have the following meanings:

(i) The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

(ii) A Declaration of Emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise.

I have also determined that, for governmental program planners only, liability protections are afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (a) donation; (b) commercial sale; (c) deployment of Covered Countermeasures from federal stockpiles; or (d) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is not only COVID–19 caused by SARS–CoV–2, or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID–19, SARS–CoV–2, or a virus mutating therefrom, including the threat of increased burden on the healthcare system due to seasonal influenza infections occurring at the same time as COVID–19 infections, which will lead to an increase in the rate of infectious diseases.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures. Where there are limited Covered Countermeasures, *not* administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute ''relating to . . . the administration to . . . an individual'' under 42 U.S.C. 247d-6d. For example, consider a situation where there is only one dose of a COVID–19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID–19. In that circumstance, the failure to administer the COVID–19 vaccine to the person in a less-vulnerable population ''relat[es] to . . . the administration to'' the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals to whom the liability protections of this Declaration extend include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability protections are afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability protections are afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability protections are afforded to manufacturers and distributors without regard to whether the Covered Countermeasure is used by or administered in any designated geographic area; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

COVID–19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc.* v. *Darue Eng'g. & Mf'g.,* 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities. The world faced an unprecedented pandemic. To effectively respond, there needed to be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy

interests within the meaning of *Grable & Sons Metal Products, Inc.* v. *Darue Eng'g. & Mf'g.,* 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act. Under the PREP Act, the sole exception to the immunity from suit and liability of covered persons under the PREP Act is an exclusive federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct by such covered person. In all other cases, an injured party's exclusive remedy is an administrative remedy under section 319F–4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate federal-state balance with respect to Covered Countermeasures through PREP Act Declarations.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

The effective time period for Covered Countermeasures and Covered Persons depends on the means of distribution identified in Section VII of this Declaration as applied to categories of Countermeasures and Qualified Persons:

(a) 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 December 31, 2029.

(b) 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 December 31, 2029.

(c) 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 CDC/ACIP recommends to persons ages three through 18 according to CDC's/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) December 31, 2029, whichever occurs first.

(d) Liability protections for all Covered Countermeasures identified in section VII(c)(i) of this Declaration begin on December 9, 2020, and last through the final day the Declaration of Emergency is in effect or December 31, 2029, whichever occurs first. Liability protections for all Covered Countermeasures identified in section VII(c)(ii) of this Declaration last for the time period stated in section (a) of this section XII if applicable, or otherwise December 31, 2024.

(e) Liability protections for all Covered Countermeasures identified in section VII(d) of this Declaration begin on December 9, 2020, and last until December 31, 2029, regardless of any Declaration of Emergency that might otherwise terminate the time period of coverage under paragraphs (c) or (d) of this section XII.

(f) Liability protections for all Covered Countermeasures identified in section VII(e) of this Declaration begin on December 9, 2020, and last until December 31, 2029, regardless of any Declaration of Emergency that might otherwise terminate the time period of coverage under paragraphs (c) or (d) of this section XII.

(g) Liability protections for Manufacturers, Distributors, and Program Planners, as defined at 42 U.S.C. 247d–6d(i), begin on February 4, 2020, and last through the time periods stated in paragraphs (a)–(f) of this section XII.

(h) Liability protections for Qualified Persons who are 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 begin on February 4, 2020, and last through the time periods stated in paragraphs (a)–(f) of this section XII.

(i) Liability protections for Additional Qualified Persons identified under section V of the Declaration and in Guidance implementing section V of the Declaration begin on the dates listed below, and last through the time periods stated in paragraphs (a)–(d) of this section XII of the Declaration, unless otherwise stated in this paragraph (i).

i. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and licensed or registered pharmacy interns and qualified pharmacy technicians to administer CDC/ACIP recommended vaccines for persons aged three through 18 (other than seasonal influenza vaccines and COVID–19 vaccines) begins on August 24, 2020.

ii. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and licensed or registered pharmacy interns and qualified pharmacy technicians to administer CDC/ACIP recommended seasonal influenza vaccines for persons aged three through 18 begins on August 24, 2020, and lasts through December 31, 2029, regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

iii. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, COVID–19 vaccines to individuals aged three and above begins on February 4, 2020, and lasts through December 31, 2029, regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

iv. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, seasonal influenza vaccines to individuals aged nineteen and above begins on August 4, 2021, and lasts through December 31, 2029, regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

v. Liability protections for Qualified Persons under section V(e) of the Declaration begin on February 4, 2020.

vi. Liability protections for Qualified Persons under section V(f) of the Declaration begin on February 2, 2021.

vii. Liability protections for Qualified Persons under section V(g) of the Declaration begin on February 16, 2021, and last through December 31, 2029.

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

ix. 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 identified in section VII(d) of the Declaration begin on September 9, 2021,

and last through December 31, 2029, regardless of time periods stated in paragraphs (c)–(d) of this section or limitations on distribution stated in section VII (a)–(b) of this Declaration.

x. 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 identified in section VII(c) of the Declaration begin on September 9, 2021.

xi. Liability protections for Qualified Persons under section V(j) of the Declaration begin on December 30, 2021.

xii. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference, to administer COVID–19 tests who are licensed pharmacists begin April 8, 2020, and last until December 31, 2029, regardless of any limitations stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

xiii. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference, to administer COVID–19 tests who are licensed or registered pharmacy interns or qualified pharmacy technicians begin October 20, 2020, and last until December 31, 2029, regardless of any limitations stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

xiv. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference, who are pharmacies when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer COVID–19 vaccines to individuals aged three and above, seasonal influenza vaccines to individuals aged three through eighteen, seasonal influenza vaccines to individuals aged nineteen and above, COVID–19 tests, and COVID–19 therapeutics identified in section VII(d) of the Declaration begin October 29, 2020, and last until December 31, 2029, regardless of any limitations stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

xv. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference, who are pharmacies when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer CDC/ACIP recommended vaccines for persons aged three through 18 (other than seasonal influenza vaccines and COVID–19 vaccines) and countermeasures identified in section VII(c) of the Declaration begin October 29, 2020.

xvi. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference to prescribe or administer point-of-care COVID–19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities across the Nation who are licensed healthcare practitioners begin August 31, 2020, and last until December 31, 2029, regardless of any limitations stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the Strategic National Stockpile (SNS) during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS, including NIOSH Approved® respirators that have been rescinded or are beyond their manufacturers' declared shelf life.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical, and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the U.S. Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: December 6, 2024.

Xavier Becerra,

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

[FR Doc. 2024–29108 Filed 12–10–24; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Public Comments on the Scientific Report of the 2025 Dietary Guidelines Advisory Committee

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS); Food, Nutrition, and Consumer Services (FNCS), U.S. Department of Agriculture (USDA).

ACTION: Notice and request for public comments on the Scientific Report of the 2025 Dietary Guidelines Advisory Committee (Scientific Report).

SUMMARY: The Departments of Health and Human Services and Agriculture invite the public to provide written comments and virtual oral comments on the Scientific Report.

DATES: The written and oral comment collection dates are scheduled as follows:

- Once the Scientific Report is published online, the public will have 60 days to provide written comments to HHS and USDA; this public comment period closes on the 60th calendar day