110. Christopher Reams, Auburn, California, Court of Federal Claims No: 22–1124V
111. Rita Evans, Washington, District of Columbia, Court of Federal Claims No: 22–1125V
112. Sandra Panovich Craft, Chagrin Falls, Ohio, Court of Federal Claims No: 22–1126V
113. Carolyn Olivares on behalf of G. F., Phoenix, Arizona, Court of Federal Claims No: 22–1127V
114. Michelle Smith on behalf of J. S., Phoenix, Arizona, Court of Federal Claims No: 22–1128V
115. Michael Otero, Miami Shores, Florida, Court of Federal Claims No: 22–1129V
116. Tony Campbell, Sarasota, Florida, Court of Federal Claims No: 22–1130V
117. John Theisen, Dresher, Pennsylvania, Court of Federal Claims No: 22–1131V
118. Robert Rose, Boston, Massachusetts, Court of Federal Claims No: 22–1132V
119. Adonnis Conner, Waupun, Wisconsin, Court of Federal Claims No: 22–1133V
120. Allen Moure, Norwich, Connecticut, Court of Federal Claims No: 22–1134V
121. Jill Popejoy, Pittsburg, Kansas, Court of Federal Claims No: 22–1136V
122. Elizabeth Walter, Sarasota, Florida, Court of Federal Claims No: 22–1148V
123. Tammy Musselman, Kenney, Illinois, Court of Federal Claims No: 22–1149V
124. Ashley Stevens and Nicholas Stevens on behalf of G. S., Phoenix, Arizona, Court of Federal Claims No: 22–1150V
125. Virginia Dowling, Crestview, Florida, Court of Federal Claims No: 22–1151V
126. John Patton, Boston, Massachusetts, Court of Federal Claims No: 22–1152V
127. Joanna King, East Longmeadow, Massachusetts, Court of Federal Claims No: 22–1153V

[FR Doc. 2022–21349 Filed 9–30–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recharter for the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the Council on Graduate Medical Education (COGME or Council) has been rechartered. The effective date of the renewed charter is September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Curi Kim, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA. Anyone requesting information may reach Dr. Kim by mail at 5600 Fishers Lane, 15N35, Rockville, Maryland 20857; by phone at 301–945–5827; or by email at *ckim@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on matters specified by section 762 of Title VII of the Public Health Service Act. Issues addressed by COGME include: (1) the supply and distribution of physicians in the United States; (2) current and future shortages or excesses of physicians in medical and surgical specialties and subspecialties; (3) issues relating to foreign medical school graduates; (4) appropriate federal policies with respect to the matters specified in (1), (2), and (3) above, including policies concerning changes in the financing of undergraduate and graduate medical education programs and changes in the types of medical education training in graduate medical education programs; (5) appropriate efforts to be carried out by hospitals, schools of medicine, schools of osteopathic medicine, and accrediting bodies with respect to the matters specified in (1), (2), and (3) above, including efforts for changes in undergraduate and graduate medical education programs; and (6) deficiencies in, and needs for improvements in, existing databases concerning the supply and distribution of, and postgraduate training programs for, physicians in the United States and steps that should be taken to eliminate those deficiencies. Not later than September 30, 2023, and not less than every 5 years thereafter, COGME shall submit a report on the recommendations made by the committee to the Secretary, and to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Additionally, COGME encourages entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the Council; and develops, publishes, and implements performance measures, develops and publishes guidelines for longitudinal evaluations, and recommends appropriation levels for certain programs under Title VII of the Public Health Service Act.

The renewed charter for COGME was approved on September 23, 2022. The filing date is September 30, 2022. The recharter of COGME gives authorization for the Council to operate until September 30, 2024.

A copy of the COGME charter is available on the COGME website at *https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/graduate-medical-edu/cogme-charter.pdf.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–21352 Filed 9–30–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Amendment to the January 1, 2016 Republished Declaration Under the Public Readiness and Emergency Preparedness Act

ACTION: Notice of amendment.

SUMMARY: The Secretary is amending the declaration first issued on October 10, 2008, and amended and republished effective January 1, 2016 for Smallpox countermeasures and countermeasures against other orthopoxviruses pursuant to section 319F–3 of the Public Health Service Act to emphasize that the declaration applies to monkeypox virus, to expand the categories of providers authorized to administer vaccines and therapeutics against smallpox (variola virus), monkeypox virus, and other orthopoxviruses in a declared emergency, and to extend the duration of the declaration.

DATES: This amendment of the January 1, 2016 republished declaration is effective September 28, 2022.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Administration for Strategic Preparedness and Response, 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 administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued a declaration for smallpox countermeasures against variola virus or other orthopoxviruses on October 10, 2008, amended the declaration effective January 1, 2016, and is further amending this declaration.

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 in the U.S. Code as 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, 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 August 4, 2022, the Secretary determined pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, that a public health emergency exists nationwide as a result of the consequences of an outbreak of monkeypox cases across multiple states. Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus is an orthopoxvirus, part of the same family of viruses as variola virus, the virus that causes smallpox.

The Secretary is now amending this PREP Act declaration to: amend the title of the declaration to emphasize that it covers monkeypox virus; add to Section I his determination that the 2022 outbreak of monkeypox cases in the United States caused by the monkeypox virus presents a public health emergency for the purposes of the PREP Act; make more explicit in Section I that the declaration applies to public health threats arising from smallpox (variola virus), monkeypox virus, and other orthopoxviruses; authorize in section V additional qualified persons to administer vaccines and therapeutics to address the current public health emergency caused by the 2022 outbreak of monkeypox cases and the risk of future public health threats arising from smallpox (variola virus), monkeypox virus, or other orthopoxviruses; update in Section VI the definition of Covered Countermeasures to reflect amendments to the PREP Act and to refer explicitly to monkeypox; update section VIII to refer explicitly to monkeypox; extend in Section XII the effective time period of the declaration; and republish the declaration in its entirety, as amended.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Description of Amendments by Section

The Secretary is amending the title of the declaration to ''Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Countermeasures against Smallpox, Monkeypox, and other Orthopoxviruses.''

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other declarations or determinations made under other authorities of the Secretary.

The Secretary is amending this determination to clarify that a risk of future public health threats is posed by smallpox (variola virus), monkeypox virus, or other orthopoxviruses, and to state that the 2022 outbreak of monkeypox cases in the United States presents a public health emergency for purposes of the PREP Act.

Section V, Covered Persons

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States.

A ''qualified person'' is one category of ''covered person.'' A qualified person means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration. Under this definition, the Secretary can describe in the declaration other qualified persons, who are Covered Persons.

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. To the extent that any State law that would otherwise prohibit a ''qualified person'' from prescribing, dispensing, or administering Covered Countermeasures, such law is preempted.[1] A State remains free to expand the universe of individuals authorized to administer Covered Countermeasures within its jurisdiction under State law.

The Secretary anticipates that there will be a need to increase the available pool of providers should a large-scale vaccination or therapeutic administration effort be required for the current monkeypox outbreak or future public health threats arising from smallpox (variola virus), monkeypox virus, or other orthopoxviruses. Variola virus, monkeypox virus, and other orthopoxviruses have the potential to

[1] See, ''Preemption of State and Local Requirements Under a PREP Act Declaration,'' Memorandum Opinion for the General Counsel Department of Health and Human Services, January 19, 2021, available at: *https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf.*

inflict significant burden and strain on the U.S. healthcare system in their own right; and in conjunction with the ongoing COVID–19 pandemic, a spike in current monkeypox cases could overwhelm healthcare providers. The health care system capacity and the healthcare workforce are likely to become increasingly strained throughout the nation. Allowing additional healthcare providers to administer smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics in accordance with applicable Federal Food and Drug Administration (FDA) licenses, approvals, or authorizations during a declared emergency allows states maximum flexibility in limiting potential impacts of illness.

By this amendment to the declaration, the Secretary identifies additional categories of persons who are qualified persons covered by the PREP Act.

Section VI, Covered Countermeasures

The Secretary is amending Section VI to update the definition as amended by the CARES Act.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary is amending the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures to include explicitly disease and disease threat resulting from exposure to monkeypox virus.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act.

The Secretary is amending the declaration to extend the period for which liability immunity is in effect. The previous amended declaration was in effect through December 31, 2022. We have extended the effective time period to December 31, 2032.

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Countermeasures Against Smallpox, Monkeypox, and Other Orthopoxviruses

This declaration amends and republishes the January 1, 2016 Amended Declaration Under the Public Readiness and Emergency Preparedness Act (''PREP Act'') for smallpox and other orthopoxvirus countermeasures. To the extent any term of the January 1, 2016 declaration is inconsistent with any provision of this republished declaration, the terms of this republished declaration are controlling.

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that smallpox (variola virus), monkeypox virus, or other orthopoxviruses and the resulting disease or conditions may in the future constitute a public health emergency and that the 2022 outbreak of monkeypox cases in the United States presents a public health emergency.

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, or use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this declaration is 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. 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, subject to the requirements of this paragraph:

The person so authorized must have documentation of completion of the Centers for Disease Control and Prevention (CDC)-provided or -recommended training for the countermeasure and any additional training required in the FDA license, approval, or authorization. In the absence of training requirements or recommendations from the CDC, other training(s) may be substituted if:

(i) it is approved or accredited training from a national or state recognized accrediting body or association, the FDA, or equivalent organization for the administration route of the medical countermeasure,

(ii) it includes hands-on instruction for the administration route as appropriate for the countermeasure, supervised by someone that administers within their normal scope of practice,

(iii) it includes clinical evaluations of indications or contraindications of smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures, and

(iv) it includes the recognition and treatment of emergency reactions to smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures;

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 smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics.

(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 Food, Drug, and Cosmetic (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) The following healthcare professionals and students in a healthcare profession training program following a declaration of an emergency as defined in section VII of this declaration, subject to the requirements of this paragraph:

1. To the extent not already licensed or authorized under state law, any dentist, advanced or intermediate emergency medical technician, licensed or certified professional midwife, nurse, advanced practice registered nurse,

registered nurse, licensed practical nurse, optometrist, paramedic, pharmacist, pharmacy intern, pharmacy technician, physician, physician assistant, podiatrist, respiratory therapist, or veterinarian who is licensed or certified to practice under the law of any state who prescribes, dispenses, or administers smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics by the route of administration and to the population specified in the relevant FDA license, approval, or authorization, including intramuscular, intradermal, or subcutaneous injection, dermal/percutaneous scarification, intranasal or oral administration, that are Covered Countermeasures under section VI of this declaration in any jurisdiction where the PREP Act applies in association with a smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccination or therapeutics effort by a State, local, Tribal or territorial authority or by an institution in which the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine or therapeutic is administered;

2. Any dentist, advanced or intermediate emergency medical technician, licensed or certified professional midwife, nurse, advanced practice registered nurse, registered nurse, licensed practical nurse, optometrist, paramedic, pharmacist, pharmacy intern, physician, physician assistant, podiatrist, respiratory therapist, 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 smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics by the route of administration and to the population specified in the relevant FDA license, approval or authorization, including intramuscular, intradermal, or subcutaneous injection, dermal/percutaneous scarification, intranasal or oral administration, that are Covered Countermeasures under section VI of this declaration in any jurisdiction where the PREP Act applies in association with a smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccination or therapeutics effort by a State, local, Tribal or territorial authority or by an institution in which the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine or therapeutic 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 dental, advanced or intermediate emergency medical technician, medical, licensed or certified professional midwife, nursing, optometry, paramedic, pharmacy, pharmacy intern, physician assistant, podiatry, respiratory therapist, or veterinary student with appropriate training in administering vaccines or therapeutics as determined by their school or training program and supervision by a currently practicing healthcare professional, experienced in the route of administration and to the population specified in the relevant FDA license, approval, or authorization, who administers smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics by the route of administration and to the population specified in the relevant FDA license, approval, or authorization, including intramuscular, intradermal, or subcutaneous injection, dermal/percutaneous scarification, intranasal or oral administration that are Covered Countermeasures under section VI of this declaration in any jurisdiction where the PREP Act applies in association with a smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccination or therapeutics effort by a State, local, Tribal or territorial authority or by an institution in which the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine or therapeutic is administered;

Subject to the following requirements:

(i) The vaccine or therapeutic must be authorized, approved, or licensed by the FDA;

(ii) Vaccination must be ordered and administered according to CDC's/ACIP's smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine recommendation(s);

(iii) The healthcare professionals and students must have documentation of completion of the CDC-provided or -recommended training for the countermeasure and any additional training required in the FDA licensing, approval, authorization. In the absence of training requirements or recommendations from the CDC, other training(s) may be substituted if:

(1) it is approved or accredited training from a national or state recognized accrediting body or association, the FDA, or equivalent organization for the administration route of the medical countermeasure,

(2) it includes hands-on instruction for the administration route as appropriate for the countermeasure, supervised by someone that administers within their normal scope of practice,

(3) it includes clinical evaluations of indications or contraindications of smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures, and

(4) it includes the recognition and treatment of emergency reactions to smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures;

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 smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics;

(iv) The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in the appropriate route of intradermal, subcutaneous, or intramuscular injections, dermal/percutaneous scarification, intranasal or oral administration and for whom the appropriate route of intradermal, subcutaneous, or intramuscular injections, dermal/percutaneous scarification, intranasal or oral administration is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics 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 smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics;

(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 they administer vaccines or therapeutics, 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

(viii) The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the CDC provider agreement and any other federal requirements that apply to the administration of smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics.

(e) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines or therapeutics under the law of any State as of the effective date of this amendment, or healthcare professional as authorized under the sections V(d)(1) and (2) of this declaration, who, following a declared emergency as defined in section VII of this declaration, prescribes, dispenses, or administers smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics by the route of administration and to the population specified in the relevant FDA license, approval, or authorization, including intramuscular, intradermal, or subcutaneous injection, dermal/percutaneous scarification, intranasal or oral administration 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 smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccination or therapeutics effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccine or therapeutic 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 appropriate training; CDC provided or recommended training for the countermeasure and any additional training required in the FDA license, approval, or authorization. In the absence of training requirements or recommendations from the CDC, other training(s) may be substituted if:

(1) it is approved or accredited training from a national or state recognized accrediting body or association, the FDA, or equivalent organization for the administration route of the medical countermeasure,

(2) it includes hands-on instruction for the administration route as appropriate for the countermeasure, supervised by someone that administers within their normal scope of practice,

(3) it includes clinical evaluations of indications or contraindications of smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures, and

(4) it includes the recognition and treatment of emergency reactions to smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures;

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 smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics; and

(ii) for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare in experienced in the appropriate route of intradermal, subcutaneous, or intramuscular injections, dermal/percutaneous scarification, intranasal or oral administration, and for whom the appropriate route of intradermal, subcutaneous, or intramuscular injections, dermal/percutaneous scarification, intranasal or oral administration is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics to be administered.

(f) 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 smallpox (variola virus), monkeypox virus, or other orthopoxvirus Covered Countermeasures. Such Federal government service members, employees, contractors, or volunteers are qualified persons if the following requirements are met:

(i) 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;

(ii) The Federal service member or Federal government, employee, contractor, or volunteer must have documentation of completion of the CDC provided or recommended training for the countermeasure and any additional training required in the FDA license, approval, or authorization. In the absence of training requirements or recommendations from the CDC, other training(s) may be substituted if:

(1) it is approved or accredited training from a national or state recognized accrediting body or association, the FDA, or equivalent organization for the administration route of the medical countermeasure,

(2) it includes hands-on instruction for the administration route as appropriate for the countermeasure, supervised by someone that administers within their normal scope of practice,

(3) it includes clinical evaluations of indications or contraindications of smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures, and

(4) it includes the recognition and treatment of emergency reactions to smallpox (variola virus), monkeypox virus, or other orthopoxvirus countermeasures;

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 smallpox (variola virus), monkeypox virus, or other orthopoxvirus vaccines or therapeutics.

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 any vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antiviral; any other drug; any biologic; or any diagnostic or other device to identify, or any respiratory protective device to prevent or treat smallpox (variola virus),

monkeypox virus, or other orthopoxvirus or adverse events from such countermeasures. Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, or a respiratory protective device as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements, or activities directly conducted by the federal government; or

(b) 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 an emergency.

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 immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) 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 smallpox resulting from exposure to variola virus, monkeypox resulting from exposure to monkeypox virus, or other infectious disease resulting from exposure to other orthopoxviruses, and the threat of disease resulting from exposure to any of these viruses.

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 purpose of distributing and dispensing countermeasures.

X. Population

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

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is 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 immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

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

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2032.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a declaration and lasts through (1) the final day the emergency declaration is in effect or (2) December 31, 2032, whichever occurs first.

Liability immunity for Covered Countermeasures administered and used by additional qualified persons in sections V(d) and V(e) begins with a declaration and lasts through (1) the final day the emergency declaration is in effect or (2) December 31, 2032, whichever occurs first.

Covered Countermeasures obtained for the Strategic National Stockpile (SNS) during the effective period of this declaration for Covered Countermeasures are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(A), (B) and (C)

I have determined that an additional twelve (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.

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 serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or

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 Department of Health and Human Services. Information about the CICP is available at 855–266–2427 (toll-free) or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The October 10, 2008 declaration under the PREP Act for smallpox countermeasures was first published on October 17, 2008 and amended and republished on January 1, 2016. This is the second amendment to and republication of the declaration.

Any further amendments to this declaration will be published in the **Federal Register**.

(Authority: 42 U.S.C. 247d–6d)

Xavier Becerra,

Secretary.

[FR Doc. 2022–21412 Filed 9–30–22; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias (ADRD) on people with the disease and their caregivers. During the October 24, 2022 meeting the Advisory Council will hear presentations on access to long-term services and supports as well as end-of-life challenges for people living with ADRD. Federal agencies will provide updates including a presentation from the Administration for Community Living on the new National Strategy to Support Family Caregivers.

DATES: The meeting will be held on October 24, 2022 from 9:00 a.m. to 4:30 p.m. EST.

ADDRESSES: The meeting will be a hybrid of in-person and virtual. The meeting will be held in Room 800 of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. It will also stream live at *www.hhs.gov/live*.

Comments: Time is allocated on the agenda to hear public comments from 4:00 p.m. to 4:30 p.m. The time for oral comments will be limited to two (2) minutes per individual. In order to provide a public comment, please register by emailing your name to *napa@hhs.gov* by Thursday, October 20. Registered commenters may provide their comments either in-person or virtually on Friday, October 21. Registered commenters attending virtually will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. *Note:* There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:45 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. All participant audio lines will be muted for the duration of the meeting and only unmuted by the Host at the time of the participant's public comment. Should you have questions during the session email *napa@hhs.gov* and someone will respond to your message as quickly as possible.

In order to ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Tuesday, October 25. These comments will be shared on the website and reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Tuesday, October 25 to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202–260–6075, *helen.lamont@hhs.gov.* Note: The meeting will be available to the public live at *www.hhs.gov/live*

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. app. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: Aducanumab, dementia risk reduction, recommendations.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website when available, after the meeting.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: September 28, 2022.

Benjamin Sommers,

Senior Official Performing the Duties of the Assistant Secretary for Planning and Evaluation, Deputy Assistant Secretary for Health Policy.

[FR Doc. 2022–21396 Filed 9–30–22; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 2, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the