

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

Activity; 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity; 21 CFR part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this information collection has not changed since the last OMB approval.

Dated: February 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-03017 Filed 2-12-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

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

ACTION: Notice of amendment.

SUMMARY: The Acting Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under section VI of this Declaration.

DATES: This amendment to the Declaration is effective as of February 16, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue

SW, Washington, DC 20201; 202-260-0365, paige.ezernack@hhs.gov.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109-148, Division C, 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 Countermeasures under the PREP Act.

On January 31, 2020, former Secretary, Alex M. Azar II, declared a

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

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID-19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID-19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary’s Declaration and

authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections; made explicit that there are substantive federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190 December 9, 2020). On January 28, 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 7872, February 2, 2021).

The Acting Secretary now amends section V of the Declaration to add a new subsection (h) to add an additional category of qualified persons covered under the PREP Act, and thus authorizes:

(h) Any Federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such employees, contractors, or volunteers are authorized to carry out under this declaration.

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a "qualified person" is a "covered person." Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. "Qualified person" includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) "a person within a category of persons so identified in a declaration by the Secretary" under subsection (b) of the PREP Act. 42 U.S.C. 247d-6d(i)(8)

By this amendment to the Declaration, the Acting Secretary identifies an additional category of persons who are qualified persons under section 247d-6d(i)(8)(B): Federal employees, contractors and volunteers authorized by their Department or agency to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of their duties or responsibilities.

The Acting Secretary has determined that there is an urgent need to expand the pool of available COVID-19 vaccinators in order to respond effectively to the pandemic. As vaccine supply is made more widely available over the coming months, health care system capacity and the vaccination workforce are likely to become increasingly strained throughout the Nation. The United States is deploying federal personnel, contractors and volunteers to assist in the national COVID-19 vaccination program. While the United States is a covered person under the PREP Act and the Declaration, this amendment clarifies that federal employees, contractors and volunteers are also qualified persons authorized by the Secretary to prescribe, dispense, or administer covered countermeasures, consistent with the terms and conditions of the Declaration.

As qualified persons, these employees, contractors and volunteers will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration in addition to the protection that is afforded to the United States as a covered person. Second, to the extent

that any State law that would otherwise prohibit the employees, contractors, or volunteers who are a "qualified person" from prescribing, dispensing, or administering COVID-19 vaccines or other Covered Countermeasures, such law is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are "qualified persons" under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID-19 diagnostic tests.¹ The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as "qualified persons" would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of "qualified persons" specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F-3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under State law.

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

¹ Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Jan. 24, 2021). See also, Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2020, available at: <https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf> (last visited Jan. 24, 2021).

Amendments to Declaration

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

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

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are “manufacturers,” “distributors,” “program planners,” “qualified persons,” and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. “Order” as used herein and in guidance issued by the Office of the Assistant Secretary for Health² means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration;³

² See Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021).

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

(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 who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy),⁴ (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA

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

⁴ Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, “State-licensed or registered intern” (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. See Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020 at 2, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage.pdf> (last visited Jan. 24, 2021).

authorized or FDA licensed COVID-19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. The licensed pharmacist must have completed the immunization training that the licensing State requires in order 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;

v. The licensed or registered pharmacy intern 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;

vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation;⁵

⁵ This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase “current certificate in basic cardiopulmonary resuscitation,” when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-qualified-pharmacy-technicians-and-state-authorized-pharmacy-interns-for-childhood-vaccines-covid-19-vaccines-and-covid-19-testing.pdf> (last visited Jan. 24, 2021).

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

viii. 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;

ix. 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

x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

(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.⁶

www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf (last visited Jan. 24, 2021).

⁶ See, e.g., Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/>

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 as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID-19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to: (i) Documentation of completion of the Centers for Disease Control and Prevention COVID-19 (CDC) Vaccine Training Modules⁷ and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID-19 vaccine(s) to be administered; and

(g) Any physician, advanced practice registered nurse, registered nurse, or practical nurse who has held an active license or certification to prescribe, dispense, or administer vaccines under the law of any State within the 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 federal, State, local, Tribal or territorial authority or by an institution in which the COVID-19

[advisory-opinion-20-02-hhs-ogc-prep-act.pdf](https://www.hhs.gov/guidance/sites/default/files/hhs-ogc-prep-act.pdf) (last visited Jan. 24, 2021).

⁷ See COVID-19 Vaccine Training Modules, available at <https://www.cdc.gov/vaccines/covid-19/training.html>.

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, subject to (i) documentation of completion of the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules and (ii) documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID-19 vaccine(s) to be administered.

(h) Any Federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such employees, contractors, or volunteers are authorized to carry out under this declaration.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa-10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

2. Effective Time Period, Section XII, Add to the End of the Section:

Liability protections for Qualified Persons under sections V(f) and V(d) of the declaration begin on February 8, 2021 and last through October 1, 2024.

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

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2021-03106 Filed 2-11-21; 4:15 pm]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Epstein-Barr Virus Antibody That Blocks Fusion And Neutralizes Virus Infection of B Cells

Description of Technology

Epstein-Barr virus (EBV) is the most common cause of infectious mononucleosis and is associated with nearly 200,000 cancers and 140,000 deaths each year. EBV-associated cancers include Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt B cell lymphoma, and EBV post-transplant lymphoproliferative disease. The latent

reservoir for EBV in the body is the B lymphocyte. Thus, blocking B cell infection is important for reducing EBV-related disease.

EBV can infect both B cells and epithelial cells; however, the method of entry differs between these two cell types. To initiate B cell infection, EBV glycoprotein 350 (gp350) binds to complement receptor 2 (CR2; also known as CD21), followed by binding of glycoprotein 42 (gp42) to HLA class II molecules, which triggers fusion of EBV with the B cell, allowing virus entry into the cell. Fusion also requires the EBV proteins gH/gL, which are found complexed with gp42 as a heterotrimer, and gB. Infection of epithelial cells is initiated by the binding of the EBV protein BMRF2 to cellular integrins, followed by binding of gH/gL to ephrin receptor A2 and integrins, which triggers fusion by EBV gB.

Monoclonal antibodies that specifically bind EBV gp42 are described by this invention. The gp42-specific antibodies are capable of neutralizing EBV infection and inhibiting fusion of EBV with B cells. The monoclonal antibodies can be used for the treatment or prophylaxis of EBV infection, prevention of EBV-associated disease or infection in immunocompromised subjects, diagnosis of EBV infection, and detection of EBV in a biological sample.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Viral diagnostics
- Viral therapeutics
- Viral prophylaxis
- Vaccine research

Competitive Advantages

- Ease of manufacture
- Strongly neutralizing antibodies
- Alternative to EBV vaccines

Development Stage

- In vivo data assessment (animal)
- Inventors:* Jeffrey Cohen (NIAID), Wei Bu (NIAID), Nathan Board (NIAID), Kennichi Dowdell (NIAID).

Intellectual Property: HHS Reference No. E-020-2020-0—U.S. Provisional Application No. 62/979,070, filed February 20, 2020.

Licensing Contact: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties

interested in collaborative research to further develop, evaluate, or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Dated: January 28, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-03045 Filed 2-12-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Renal RC2 Applications.

Date: March 19, 2021.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Room 7015, Bethesda, MD 20892-2542, 301-594-4721, ryan.morris@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)