occurred in the three-month period of April through June 2018. A hyperlink to the available chapters on the OMHA website is provided below. The OMHA website contains the most current, up-to-date chapters and revisions to chapters, and will be available earlier than we publish our quarterly notice. We believe the OMHA website provides more timely access to the current OCPM chapters for those involved in the Medicare claim, organization and coverage determination and entitlement appeals processes. We also believe the website offers the public a more convenient tool for real time access to current OCPM provisions. In addition, OMHA has a listserv to which the public can subscribe to receive notification of certain updates to the OMHA website, including when new or revised OCPM chapters are posted. If accessing the OMHA website proves to be difficult, the contact person listed above can provide the information.

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the reader may determine whether any are of particular interest. We expect this notice to be used in concert with future published notices. The OCPM can be accessed at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

III. How To Use the Notice

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the reader may determine whether any are of particular interest. We expect this notice to be used in concert with future published notices. The OCPM can be accessed at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

IV. Reorganization and Revision of the OCPM

OMHA is in the process of restructuring, reorganizing, and reformatting the OCPM to make it more user friendly. As part of this ongoing process, we are drafting new OCPM chapters and revising existing OCPM chapters to conform to the new format. Previously, the OCPM contained separate divisions for each Medicare part, and most chapters were repeated in each division. New and revised chapters provide information pertaining to all appeals arising under all Medicare parts. Plain language is used where possible and guidance is provided in a user-friendly, question-and-answer format. The manual is also being revised to reflect regulatory changes made by the final rule that was published in the January 17, 2017 **Federal Register** and became effective on March 20, 2017 (82 FR 4974). New and revised chapters can be accessed at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.* Unless inconsistent with a statute, regulation, or other controlling authority, provisions of chapters that were published before May 10, 2018, remain in effect until revised, and can be accessed at: *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/2017/index.html.*

IV. OCPM Releases for April Through June 2018

The OCPM is used by OMHA adjudicators and staff to administer the OMHA program. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, and OMHA directives.

The following is a list and description of new OCPM provisions and the subject matter. For future quarterly notices, we will list only the specific updates to the list of manual provisions that have occurred in the covered 3-month period. This information is available on our website at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

OCPM Chapter 1: Manual Overview, Definition, and Governance

Chapter 1, Manual Overview, Definition, Governance. This chapter describes the OCPM's purpose and organization. It also describes how to navigate the OCPM, and when and how to cite an OCPM provision as an authority in an action issued by an OMHA adjudicator.

OMHA receives a variety of appeals, as discussed in section I above. This chapter describes when a specific OCPM provision may be read to apply to all or certain types of appeals, and describes OCPM conventions for citing to statutory, regulatory, and other applicable authorities. In addition, this chapter describes the process for updating an OCPM chapter, as well as how to determine when a revision was issued or became effective, and how to access prior versions of a chapter.

OCPM Chapter 19: Closing the Case

Chapter 19, Closing the Case. Timely notice of the disposition and closing of a case, in compliance with applicable laws and policy, is important to ensure that effectuation of a decision, or other necessary actions, can be undertaken by the parties to the appeal, CMS, CMS contractors, plans, SSA, or the Council. Receipt of the disposition package also governs the timing for parties to file an appeal, and for the Council to initiate a review of a case on its own motion. In addition, the timely transfer of the administrative record helps ensure effectuation can occur, SSA, CMS, or CMS contractors can refer cases for review by the Council, and the record can be transitioned to storage. This revised chapter describes the necessary steps to timely and accurately close appeals pending at OMHA.

OCPM Chapter 20: Post-Adjudication Actions

Chapter 20, Post-Adjudication Actions. This new chapter describes the various potential actions that may occur after an OMHA adjudicator issues a decision, dismissal, or remand, and the procedures for responding to such actions. These actions include requests to correct a clerical error, reopen a decision, vacate a dismissal, or review a remand issued by an OMHA adjudicator. OMHA adjudicators take action to grant or deny such a request, and in some instances may initiate an action on their own motion.

In addition, parties may seek Council review of decisions and dismissals. CMS and its contractors, or SSA, may also refer decisions and dismissals to the Council for possible own motion review. The chapter also describes actions the Council may take on an appealed or referred case, including remanding the case to OMHA.

Dated: July 23, 2018.

Amanda M. Axeen,

Acting Chief Advisor, Office of Medicare Hearings and Appeals.

[FR Doc. 2018–16860 Filed 8–6–18; 8:45 am]

BILLING CODE 4150–46–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary is amending a Declaration pursuant to the Public Health Service Act to provide liability immunity protection for activities related to Zika virus vaccines consistent with the terms of the Declaration.

DATES: The declaration is effective as of August 1, 2018.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

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, through publication in the **Federal Register**, amend any portion of a Declaration. Using this authority, effective August 1, 2016 (82 FR 10365 (February 10, 2017)), Acting Secretary Norris Cochran issued a Declaration to provide liability immunity to Covered Persons for activities related to the Covered Countermeasures, Zika virus vaccines as listed in Section VI of the Declaration, consistent with the terms of the Declaration. The Secretary is amending the August 1, 2016 Declaration to extend the effective time period of the declaration through December 31, 2022 and to clarify and add to the list of covered countermeasures to include all Zika virus vaccine types and technologies.

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.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug & Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products. Zika virus is a mosquito-borne flavivirus that usually causes mild symptoms but has been determined to cause microcephaly and other severe brain abnormalities in fetuses and infants born to women infected with Zika virus before birth. Zika virus has also been associated with other adverse pregnancy outcomes, including miscarriage, stillbirth, and congenital Zika syndrome, and is linked to Guillain-Barre Syndrome. Beginning in 2015, Brazil experienced the largest outbreak of disease caused by Zika infection since its discovery in Uganda in 1947. On February 1, 2016, the World Health Organization (WHO) determined that microcephaly cases and other neurologic disorders reported in Brazil constituted a Public Health Emergency of International Concern (PHEIC) in accordance with the International Health Regulations (IHR). Since 2015, Zika virus has been detected in nations throughout the world. In the United States, traveler-associated cases have been identified in all the states, and local transmission of Zika virus is occurring in Puerto Rico; American Samoa; areas of Miami, Florida; and Texas. On August 12, 2016, former Secretary Sylvia M. Burwell determined that a public health emergency of national significance existed within the Commonwealth of Puerto Rico relating to pregnant women and children born to pregnant women with Zika. Former Secretary Burwell renewed that determination on November 4, 2016; Acting Secretary Norris Cochran renewed that determination on January 31, 2017; and former Secretary Thomas E. Price renewed that declaration on April 28, 2017. The Secretary's public health emergency declaration expired on July 26, 2017. On November 18, 2016, the WHO Director-General declared the end of the PHEIC based on recommendations of the WHO Emergency Committee that Zika virus and associated consequences no longer represent a PHEIC as defined under the IHR, but remain a significant enduring public health challenge requiring intense action that should be escalated into a sustained program of work with dedicated resources to address the long-term nature of the disease and its associated consequences. In 2018, cases continue to be reported throughout the U.S. states and territories of laboratory-confirmed Zika virus disease in individuals returning from travel to affected areas, or presumed local mosquito-borne transmission, or other modes of transmission.[1]

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

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 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. Accordingly, in Section I, the Secretary determines that there is a credible risk that the spread of Zika virus and the resulting disease may constitute a public health emergency.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider 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 countermeasure. In Section II, the Secretary states that he has considered these factors.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of

[1] CDC Zika case reporting; *https://www.cdc.gov/zika/reporting/2018-case-counts.html,* accessed 23July2018, 1630.

one or more Covered Countermeasures (Recommended Activities). In Section III, the Secretary recommends activities for which the immunity is in effect.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities. These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be 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 to or use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure.'' In Section IV, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

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. The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.

A manufacturer includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to: Manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

A program planner means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's Declaration. Under this definition, a private sector employer or community group or other ''person'' can be a program planner when it carries out the described activities.

A qualified person means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered 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, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this Declaration.

The PREP Act also defines the word ''person'' as used in the Act: A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.

Section V describes Covered Persons under the Declaration, including Qualified Persons.

Section VI, Covered Countermeasures

As noted above, Section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section identifies the Covered Countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be: A ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) 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 such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.

A security countermeasure is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that: (i)(a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.

To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, or cure, or to limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device.

A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Section VI lists Zika virus vaccines that are Covered Countermeasures. The Secretary is amending the list of vaccines by: Deleting ''whole particle'' from the first category of vaccines listed to clarify that the category includes all inactivated virus vaccines; adding ''and/or polysaccharide and/or conjugate'' to the sixth category of vaccines listed to include these types of peptide vaccine; and adding a new ninth category, ''recombinant vaccines'' to include any Zika virus vaccines using this type of technology.

Section VI also refers to the statutory definitions of Covered Countermeasures

to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, the Declaration notes that Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. The Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to: (a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; 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.

Section VII defines the terms ''Authority Having Jurisdiction'' and ''Declaration of an emergency.'' We have specified in the definition that Authorities having jurisdiction include federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities.

For governmental program planners only, liability immunity is afforded only to the extent they 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. This last limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

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

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure. In Section VIII, the Secretary states that the disease threat for which he recommends administration or use of the Covered Countermeasures is Zika virus.

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX, the Secretary defines ''Administration of a Covered Countermeasure:''

Administration of a 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.

The definition of ''administration'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the definition, these liability claims are precluded if they allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a Declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure. This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. Section X provides that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the Declaration.''

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population. Section X includes these statutory conditions in the Declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the Declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the Declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI provides that liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation. This could include claims related to administration or use in

countries outside the U.S. It is possible that claims may arise in regard to administration or use of the Covered Countermeasures outside the U.S. that may be resolved under U.S. law.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas. Section XI includes these statutory conditions in the Declaration for clarity.

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. Section XII extends the effective period for different means of distribution of Covered Countermeasures through December 31, 2022.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective time period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure. In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a Declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d–6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the stockpile. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the Declaration, plus the ''Additional Time Period'' described under Section XIII of the Declaration.

Section XIII provides for 12 months as the additional time period of coverage after expiration of the Declaration. Section XIII also explains the extended coverage that applies to any products obtained for the SNS during the effective period of the Declaration.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure. Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this Declaration, the administrative rules for the Program, and the statute. To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not align with the requirements for liability immunity provided under the PREP Act. Section XIV, ''Countermeasures Injury Compensation Program'' explains the types of injury and standard of evidence needed to be considered for compensation under the CICP.

Further, the administrative rules for the CICP specify if countermeasures are administered or used outside the United States, only otherwise eligible individuals at American embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed may be considered for CICP benefits. Other individuals outside the United States may not be eligible for CICP benefits.

Section XV, Amendments

The Secretary may amend any portion of this Declaration through publication in the **Federal Register**.

Declaration

Declaration for Public Readiness and Emergency Preparedness Act Coverage for Zika Virus Vaccines.

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 the spread of Zika virus and the resulting disease or conditions may in the future constitute 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, and 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; (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.

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 the following Zika virus vaccines, all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines:

(1) Inactivated virus vaccines
(2) Live-attenuated vaccines
(3) mRNA vaccines
(4) DNA vaccines
(5) Subunit vaccines
(6) Peptide and/or polysaccharide and/or conjugate vaccines
(7) Virus-like particles vaccines
(8) Nanoparticle vaccines
(9) Recombinant vaccines

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, 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,

(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 Zika virus.

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 any designated geographic area; liability immunity is 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.

XII. Effective Time Period

42 U.S.C. 247d-6d(b)(2)(B)

Liability immunity for Covered Countermeasures through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction and extends through December 31, 2022.

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, 2022, whichever occurs first.

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 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.

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 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**.

Authority: 42 U.S.C. 247d–6d.

Dated: August 1, 2018.

Alex M. Azar II

Secretary, Department of Health and Human Services.

[FR Doc. 2018–16856 Filed 8–6–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Initial Review Group; Clinical Aging Review Committee NIA–C.

Date: September 27–28, 2018.

Time: 3:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: Alicja L. Markowska, Ph.D., DSC, National Institute on Aging, National Institutes of Health, Gateway Building 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *markowsa@nia.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 1, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16787 Filed 8–6–18; 8:45 am]

BILLING CODE 4140–01–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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve commercialization of results of federally-funded research and development.

Technology description follows.

Neuroendocrine Tumor Evans Blue Containing Radiotherapeutics

The invention pertains to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors. The subject radiotherapeutic covered by the subject patent estate includes a somatostatin (SST) peptide derivative like octreotate (TATE), conjugated to an Evans Blue (EB) analog, and further chelated via DOTA to therapeutic radionuclide ^{177}Lu, a beta emitter. The EB analog reversibly binds to circulating serum albumin and improves the pharmacokinetics of SST peptide derivatives and reduce peptide-receptor radionuclide therapy toxicity. EB analog conjugated to octreotate (EB–DOTATATE) has been shown by the inventors to provide reversible albumin binding in vivo and extended half-life in circulation. When EB–TATE is slowly released into the tumor microenvironment, tumor uptake and internalization into SSTR positive tumors resulted in delivery of radioactive particles and tumor cell killing. EB–TATE displayed significantly more favorable pharmacokinetics than TATE alone by achieving higher tumor to non-tumor penetration as evidenced by positron emission tomography.

Potential Commercial Applications:

- Cancer therapeutics
- Higher stability/Lower toxicity

Development Stage:

- Early stage

Inventors: Xiaoyuan Chen and Orit Jacobson Weiss (both of NIBIB).

Intellectual Property: HHS Reference No. E–150–2016–1; International Patent Application PCT/US2017/031696.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@mail.nih.gov*.

Dated: July 20, 2018.

Michael Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2018–16839 Filed 8–6–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Treatment of Type I Diabetes and its Comorbidities

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent License to Inversago Pharma, Inc., located in Montreal, Quebec, Canada, to practice the inventions embodied in the patent applications