these health professions programs is collected in the HRSA Performance Report for Grants and Cooperative Agreements. Specific performance measurement requirements for each program may be found on the HRSA website at *https://bhw.hrsa.gov/grants/reportonyourgrant.* Data collection activities consist of two reports—an annual progress report and annual performance report—that are submitted by awardees to comply with statutory and programmatic requirements for performance measurement and evaluation (including specific Title III, VII and VIII requirements), as well as the Government Performance and Results Act of 1993 (GPRA) and the GPRA Modernization Act of 2010 requirements. The performance measures were last revised in 2016 to ensure they addressed programmatic changes, met evolving program management needs, and responded to emerging workforce concerns. As these changes successfully enabled BHW to demonstrate accurate outputs and outcomes associated with the health professions programs, BHW will continue with its current performance management strategy and make only minor changes that reflect new HHS and HRSA priorities with the addition of a question asking awardees how many trainees received training in telehealth, substance use treatment, and/or medication-assisted treatment.

Need and Proposed Use of the Information: The purpose of the proposed data collection is to continue analysis and reporting of awardee training activities and educational programs, identify intended practice locations and report outcomes of funded initiatives. Data collected from these grant programs will also provide a description of the program activities of approximately 1,500 reporting grantees to inform policymakers on the barriers, opportunities, and outcomes involved in health care workforce development. The proposed measures focus on five key outcomes: (1) Increasing the workforce supply of well-educated practitioners in needed professions; (2) increasing the number of practitioners that practice in underserved and rural areas; (3) enhancing the quality of education; (4) increasing the recruitment, training, and placement of under-represented groups in the health workforce; and (5) supporting educational infrastructure to increase the capacity to train more health professionals in high demand areas.

Likely Respondents: Respondents are awardees of BHW health professions grant programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Direct Financial Support Program	500	1	500	3.1	1,550
Infrastructure Program	100	1	100	4.5	450
Multipurpose or Hybrid Program	900	1	900	4.3	3,870
Total	1,500		1,500		5,870

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–00402 Filed 1–30–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Ebola Virus Disease Therapeutics—Amendment

ACTION: Notice of Amendment to the February 27, 2015, Declaration under the Public Readiness and Emergency Preparedness Act for Ebola Virus Disease Therapeutics, as amended.

SUMMARY: The Secretary is amending the February 27, 2015, Declaration issued pursuant to the Public Health Service Act, amended December 9, 2015 and December 2, 2016, to update the term ''Ebola Virus Disease'' to ''Ebola disease'' (EBOD) throughout the declaration and to clarify the definition of EBOD. The amendment also expands the Covered Countermeasures beyond the single therapeutic listed in prior declarations but limit coverage to Covered Countermeasures that are directly supported by the United States (U.S.) Federal Government, consistent with the terms of the Declaration, and is republishing the Declaration in its entirety as amended.

DATES: The Amended Declaration is applicable beginning December 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 Secretary is amending the February 27, 2015, Declaration issued pursuant to the Public Health Service Act, amended December 9, 2015 (80 FR 76536) and December 2, 2016, (81 FR 89476) to extend the effective time period through December 31, 2023; to update the term ''Ebola Virus Disease'' to ''Ebola disease'' (EBOD) throughout the declaration and to clarify the definition of EBOD; and to expand the Covered Countermeasures beyond the single therapeutic listed in prior declarations but limit coverage to Covered Countermeasures that are directly supported by the United States (U.S.) Federal Government, consistent with the terms of the Declaration, and is republishing the Declaration in its entirety as amended.

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services 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, the Secretary is amending the Declaration that provides liability immunity to Covered Persons for activities related to the

Covered Countermeasures, EBOD therapeutics as listed in Section VI of the Declaration to extend the effective time period through December 31, 2023; to update the term used to identify the disease and clarify the definition of ''Ebola disease''; and to expand the Covered Countermeasures beyond the single therapeutic listed in prior declarations but limit coverage to Covered Countermeasures that are directly supported by the U.S. Federal Government, consistent with the terms of 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.

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, and Cosmetic (FD&C) Act to provide 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.

Ebola disease is a severe and often fatal illness in humans caused by several highly virulent viruses that are members of the family *Filoviridae.* Disease in people has been observed due to four viruses classified in a filoviral genus currently called *Ebolavirus*—Bundibugyo virus, Ebola virus, Sudan virus, and Taï Forest virus. With an average EBOD case fatality rate of around 42 percent, ebolaviruses pose a high risk to public health and national security.

From 2013 to 2016, Western Africa experienced the largest EBOD outbreak since the first two ebolaviruses (Ebola virus and Sudan virus) were discovered in 1976, and the unprecedented size of the outbreak complicated global health response. The outbreak affected populations in multiple Western African countries and travelers from Western Africa to the U.S. and other countries. The World Health Organization (WHO) declared the EBOD outbreak as a Public Health Emergency of International Concern under the framework of the International Health Regulations (2005). In March 2016, WHO determined that the EBOD outbreak no longer constituted a Public Health Emergency of International Concern but emphasized the crucial need for continued support to prevent, detect, and respond rapidly to any new EBOD outbreak in Western Africa. During the 2013 to 2016 outbreak widespread transmission was limited to Western African countries; however, ebolaviruses present a real threat to national security, because the U.S. experienced travel-associated cases of EBOD diagnosed within U.S. borders and transmission to health care workers within U.S. borders. The recurrent but unpredictable and variable nature of EBOD outbreaks and the transmission profile make ebolaviruses threats to the public health security of the American people, requiring vigilance and a continuing need for development of medical countermeasures.

Ebola disease is an ongoing public health risk, as the Democratic Republic of the Congo (COD) continues to experience EBOD outbreaks and there is a risk of extension to surrounding countries. Days after announcing the end of the outbreak of EBOD from April to July of 2018 in COD's Équateur Province, the COD Ministry of Health declared a new EBOD outbreak in Nord-Kivu Province on August 1, 2018. The Ministry of Health, WHO and U.S. Government partners are responding to this incident as new cases occur across the densely populated province. As demonstrated by the 2013–2016 EBOD outbreak, that resulted in disease in several Americans including transmission within the U.S., the risk to the U.S. population from EBOD outbreaks in Africa presents a national health security issue. Thus, there is a continuing need for development of therapeutics against EBOD.

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

To be consistent with the most current World Health Organization International Classification of Diseases, the Secretary is amending the declaration throughout to use the term EBOD to refer to the disease, health condition or threat to health that constitutes or may constitute a public health emergency. This change in terminology is not intended to have any substantive effect on coverage under the amended Declaration.

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

In section I, the Secretary also amends the Declaration to clarify the definition of Ebola disease, providing that for the purposes of this Declaration, Ebola disease (EBOD) is defined as the illness resulting from infection by the following viruses of the filoviral *Ebolavirus* genus:

- Bundibugyo virus
- Ebola virus
- Sudan virus
- Taï Forest virus
- ebolaviruses with undefined pathogenicity in humans

This amendment is intended to clarify that the Declaration covers EBOD and all therapeutics against viruses and variants of all viruses of the *Ebolavirus*

genus consistent with the terms of the Declaration.

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 one or more Covered Countermeasures (''Recommended Activities''). In Section III, the Secretary recommends activities for which the immunity is in effect under the conditions stated in the Declaration. The Secretary is amending the Declaration to remove the condition that Recommended Activities only include those that relate to clinical trials permitted to proceed after review by the Food and Drug Administration (FDA) that administer or use the Covered Countermeasure under an investigational new drug application (IND). This amendment continues that coverage, and expands liability immunity beyond activities related to clinical trials permitted to proceed after review by the FDA, that administer or use the Covered Countermeasure under an IND. Section VI of the Declaration retains the limitation that Covered Countermeasures are limited to those activities involving Covered Countermeasures directly supported by the U.S. Federal Government.

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 U.S. 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 of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drug, 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 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.

The Secretary is amending the Declaration to include the following as qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, 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; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act. In addition, the Secretary is amending the declaration to remove the following category of qualified persons: Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity to carry out clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the U.S. These changes are intended to expand qualified persons to those who may administer Covered Countermeasures directly supported by the U.S. Federal Government in an emergency response, or under an Emergency Use Authorization issued by the FDA or other emergency authority of the FDA, and to any individuals carrying out activities under clinical trials within the scope of the statutory definitions provided in this section that involve countermeasures directly supported by the U.S.

Section VI. Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities

for which liability immunity is in effect. Section VI identifies the 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 the EBOD therapeutics that are Covered Countermeasures. The Secretary is expanding the types of Covered Countermeasures covered under this Declaration to include classes or categories of therapeutics for mitigation or treatment of EBOD as defined in section I of this Declaration, including all components and constituent materials of these therapeutics, and all devices and their constituent components used in the administration of these therapeutics.

This change is intended to expand the types of EBOD therapeutics that are included as Covered Countermeasures consistent with the terms of this Declaration, including the limitations stated in the Section VII of this Declaration. The Declaration continues coverage for EBOD therapeutics previously covered under this declaration, ZMapp® monoclonal antibody therapeutic, and extends coverage to encompass all categories of EBOD therapeutics.

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 PHS 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 Secretary is amending the Declaration to state that liability immunity is afforded to Covered Persons for Recommended Activities involving Covered Countermeasures that are directly supported by the U.S. Federal Government through past, present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or arrangements. The Secretary defines the term ''directly support'' to mean that the U.S. has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing.

This amendment is intended to expand liability immunity beyond the prior limitation to activities that are related to clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND, but the amendment retains the limitation that the activities must be directly supported by the U.S. Federal Government as described and defined in this section.

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 EBOD.

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 Act. Under the Secretary's definition; these liability claims are precluded if the claims 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 therapeutic, 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 to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population and 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 X. 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 Africa or other locations 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 identifies the effective time period. Section XII is amended to extend the effective time period to December 31, 2023.

Section XIII. Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective 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 SNS. 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 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 always 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 that if countermeasures are administered or used outside the U.S., 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 U.S. may not be eligible for CICP benefits.

Section XV. Amendments

This is the third amendment to the February 27, 2015, Declaration (80 FR 73314). The first amendment was issued December 9, 2015 (80 FR 76536), the second amendment was issued December 2, 2016 (81 FR 89476). The Secretary may amend any portion of a Declaration through publication in the **Federal Register**.

Republished Declaration

Declaration, as Amended, Public Readiness and Emergency Preparedness Act Coverage for Ebola Disease Therapeutics

This Declaration amends and republishes the February 27, 2015 for coverage under the Public Readiness and Emergency Preparedness (PREP) Act for Ebola Disease Therapeutics, as amended December 9, 2015 and December 2, 2016. To the extent any term of the February 27, 2015 Declaration, as amended on December 9, 2015 and December 2, 2016, 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 the spread of ebolaviruses and the resulting disease or conditions, constituting EBOD may in the future constitute a public health emergency. For the purposes of this Declaration, EBOD is the illness resulting from infection by viruses of any of the following viruses of the *Ebolavirus* genus:

- Bundibugyo virus
- Ebola virus
- Sudan virus
- Taï Forest virus
- ebolaviruses with undefined pathogenicity in humans

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

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 U.S.

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 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; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

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.

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 EBOD therapeutics:

All classes or categories of therapeutics for mitigation or treatment of EBOD as defined in section I of this Declaration, including all components and constituent materials of these therapeutics, and all devices and their constituent components used in the administration of these therapeutics.

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 directly supported by the U.S. Federal Government, through past, present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements or arrangements. The term ''directly supported'' in this Declaration means that the U.S Federal Government has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing.

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 Ebola disease (EBOD).

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 began on February 27, 2015 and extends through December 31, 2023.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

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

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

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 (toll-free) or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

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

Authority: 42 U.S.C. 247d–6d.

Dated: January 24, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–00261 Filed 1–30–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1803–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—October Through December 2018

AGENCY: Office of Medicare Hearings and Appeals (OMHA), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists the OMHA Case Processing Manual (OCPM) instructions that were published from October through December 2018. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

FOR FURTHER INFORMATION CONTACT: Jason Green, by telephone at (571) 777–2723, or by email at *jason.green@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary within the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals under sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicare Advantage organizations (MAOs), Medicaid State agencies, and applicable plans, have a fair and impartial forum to address disagreements with Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors (PDPSs), and determinations related to Medicare eligibility and entitlement, Part B late enrollment penalty, and income-related