pursuant to a distribution or release from the SNS.

Further, as to doses shipped by the Centers for Disease Control and Prevention (CDC) to the Department of Defense (DOD) pursuant to the DoD/CDC Interagency Agreement (IAA) dated March 10, 2008, an additional period of time of liability protection shall extend for as long as the SNS or its successor exists and the IAA remains in effect, plus, if the additional twelve (12) months following the time period in paragraph 1 of this section has expired, an additional twelve (12) months upon expiration of the IAA.

XIV. Countermeasures Injury Compensation Program

42 U.S.C. 247d–6e

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

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The October 1, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for anthrax countermeasures was first published on October 6, 2008. This is the first amendment to that declaration.

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

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31090 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Acute Radiation Syndrome Medical Countermeasures—Amendment

ACTION: Notice of Amendment to the October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the declaration issued on October 10, 2008, (73 FR 61866) pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bbb–3a and 360bbb–3b); clarify and expand the description of covered countermeasures; extend the effective time period of the declaration; reformat the declaration; modify or clarify terms of the declaration; and republish the declaration in its entirety, as amended.

DATES: The amendment of the October 10, 2008, declaration is effective as of January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, 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:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued a declaration for countermeasures to botulinum toxin(s) and the resulting disease(s) from a manmade or natural source on October 10, 2008, and is amending the October 10, 2008 declaration.[1]

The major actions taken by this amendment to the acute radiation syndrome countermeasures declaration are the following: (1) Updating the description of covered countermeasures to include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act;[2] (2) expanding covered countermeasures to include countermeasures administered acutely during the response for delayed effects to acute radiation exposure; (3) clarifying the description of covered countermeasures to delete vaccines and antitoxins and to add biologics; (4) changing the description of qualified persons to include persons authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act; (5) clarifying that liability immunity extends to ''other transactions'' and to activities related to any federal agreements including clinical trials agreements by adding the terms ''other transactions'' and ''other federal agreements'' to the clause describing the types of federal agreements for which immunity is in effect; (6) deleting references to specific federal contracts to clarify that immunity is not limited to activities conducted under listed contracts; (7) clarifying that liability immunity extends to activities directly conducted by the Federal government by adding the phrase ''or directly conducted by the Federal Government'' to the section describing methods of distribution for which liability immunity is in effect; (8) narrowing the definition of ''administration'' to cover ''slip-and–fall'' claims only to the extent they are directly tied to the operation of a countermeasure program; (9) extending the time period for which liability immunity is in effect for the Covered Countermeasures to December 31, 2022; and, (10) changing the entire declaration to the new format that was first used with the February 29, 2012, amendment to the declaration for pandemic influenza to make the declaration easier for readers to follow. Other minor modifications and clarifications are also made, as more fully explained below.

The declaration is republished in full. We explain the substantive and format changes in this supplementary section.

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.

[1] 73 FR 61869.

[2] 21 U.S.C. 360bbb–3a and 360bbb–3b.

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 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 (the 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 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.

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 in the future constitute such an emergency.[3] This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act [4] 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. In the previous PREP Act declaration for acute radiation syndrome countermeasures (''declaration''), this determination appeared in the declaration's introduction as the conclusion to the ''whereas'' clauses. The determination is stated in the first section of the declaration. This change was made to improve readability and is not intended to have any substantive legal effect.

In addition, we made a substantive change to the determination. The determination made in the ''whereas'' clauses in the October 10, 2008 declaration stated that the Secretary ''determined there is a credible risk of an unintentional radioactive release, a deliberate detonation of a nuclear device, or other radiological nuclear incident and the resulting incidence of ARS constitutes a public health emergency.'' The Secretary is amending this determination to state that the threat may be ''in the future,'' to be consistent with language used in the PREP Act and changing ''and the resulting incidence of ARS'' to ''that could result in population exposures to radiation and resulting acute radiation syndrome and/or delayed effects to acute radiation exposure'' to more completely describe the public health risk.[5] Thus, in this amended declaration, the Secretary determines ''that there is a credible risk that an unintentional radioactive release, a deliberate detonation of a nuclear device, or other radiological or nuclear incident that could result in population exposures to radiation and resulting acute radiation syndrome and/or delayed effects of acute radiation exposure may in the future 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.[6] We previously stated these considerations in the introductory ''whereas'' clauses to the declaration. The declaration now states these considerations in section II. These changes were made to improve readability and do not intend that it have any substantive legal effect.

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'').[7] In the previous declaration, we included the Recommended Activities in section I of the declaration, ''Covered Countermeasures.'' The declaration now states them in section III. We made this change to improve readability and do not intend that it have any substantive legal effect. In addition, we deleted the phrases ''as defined in section IX below'' and ''with respect to the category of disease and population described in sections II and IV below'' for consistency with formatting changes, and changed ''and usage'' to ''or use'' for consistency with the statute. These changes are not intended to have any substantive legal 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.[8] 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.'' [9] In the previous declaration, we included a statement referring to liability immunity specified under the PREP Act in section I of the declaration, ''Covered Countermeasures.'' The declaration now includes the statement that liability immunity is in effect for Recommended Activities in a separate section IV. This change was made to improve readability and is not intended to have any substantive legal effect.

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.[10] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[11]

A *manufacturer* includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research

[3] 42 U.S.C. 247d–6d(b)(1).

[4] 42 U.S.C. 247d.

[5] See 42 U.S.C. 247d–6d(b)(1).

[6] 42 U.S.C. 247d–6d(b)(6).

[7] 42 U.S.C. 247d–6d(b)(1).

[8] 42 U.S.C. 247d–6d(b)(1).

[9] 42 U.S.C. 247d–6d(a)(1).

[10] 42 U.S.C. 247d–6d(i)(2).

[11] 42 U.S.C. 247d–6d(i).

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; [12]

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; [13]

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; [14] 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 who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration.[15] 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 ''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.[16]

The provisions regarding Covered Persons previously appeared in the declaration as a definition in section IX, ''Definitions'' and in section VI, ''Qualified Persons.'' These two provisions were combined into a new section V, ''Covered Persons'' and added ''to perform an activity'' to the description of ''Other Qualified Persons'' authorized under an Emergency Use Authorization for clarity. These changes were made to improve readability and clarity and do not intend them to have any substantive legal effect.

The description of Covered Persons was also modified to include a new category of qualified persons: ''Any person authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act.'' This change ensures that persons who prescribe, administer, or dispense covered countermeasures in accordance with section 564A of the FD&C Act are Covered Persons under the declaration.

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 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 section 564, 564A, or 564B of the FD&C Act.[17]

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 [18] 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.[19]

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 [20] 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.[21]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures also must be approved or cleared under the FD&C Act; [22] licensed under the PHS Act; [23] authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.[24]

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 [25] and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, cure or 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 ten years after the Department's determination that procurement of the countermeasure is appropriate.

Provisions regarding Covered Countermeasures previously appeared in section I of the declaration, ''Covered Countermeasures'' and section IX of the declaration, ''Definitions.'' Section I included not only a description of the Covered Countermeasure but also the Secretary's recommendation, statement regarding liability immunity, and additional conditions characterizing countermeasures. Sections I and IX were combined and the language was simplified so that it now only identifies the Covered Countermeasures. The other conditions included in the ''Covered Countermeasure'' section were relocated to new sections,

[12] 42 U.S.C. 247d–6d(i)(4).
[13] 42 U.S.C. 247d–6d(i)(3).
[14] 42 U.S.C. 247d–6d(i)(6).
[15] 42 U.S.C. 247d–6d(i)(8).
[16] 42 U.S.C. 247d–6d(i)(5).
[17] 42 U.S.C. 247d–6d(i)(1). Sections 564, 564A, and 564B of the FD&C Act may be found at 21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b.
[18] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).
[19] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).
[20] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).
[21] 42 U.S.C. 247d–6d(i)(1)(B), (c)(1)(B).
[22] 21 U.S.C. 301 *et seq.*
[23] 42 U.S.C. 262.
[24] 21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b.
[25] 21 U.S.C. 355(i), 360j(g).

''Recommended Activities,'' ''Liability Immunity,'' and ''Limitations on Distribution,'' to improve readability. This change is not intended to have any substantive legal effect.

Section I of the declaration also stated that the declaration applied to Covered Countermeasures administered or used during the effective time period of the declaration. This language was deleted as it is redundant of the provisions stated in sections XII, ''Effective Time Period,'' and XIII, ''Additional Time Period of Coverage.''

Substantive changes were made to the description and definition of the Covered Countermeasure that previously appeared in sections I, ''Covered Countermeasures'' and IX, ''Definitions.'' Section I referred to the Act for the definition of ''Covered Countermeasures,'' and section IX defined the term ''Acute Radiation Syndrome Countermeasure'' as ''Any vaccine; antimicrobial/antibiotic, other drug or antitoxin; or diagnostic or device to identify, prevent or treat acute radiation syndrome or adverse events from such countermeasures (1) licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.''

The description of acute radiation syndrome countermeasures was clarified to: Delete vaccines and antitoxins, as such countermeasures are not relevant to acute radiation syndrome; explain the term ''antimicrobial'' with regard to use against acute radiation syndrome; add ''biologics'' that are relevant to acute radiation syndrome; add ''other'' before ''device''; and add references to clinical manifestations of acute radiation syndrome and delayed effects of acute radiation exposure. The description now reads: ''any antimicrobial (antibiotic, antifungal, antiviral); any other drug; any biologic; or any diagnostic or other device administered acutely during the response to identify, prevent or treat acute radiation syndrome and its associated clinical manifestations, or delayed effects of acute radiation exposure or adverse events from such countermeasures.'' These changes are intended to clarify the description of covered countermeasures and to expand countermeasures covered by the declaration to include biologics and countermeasures against delayed effects of acute radiation exposure, consistent with the statute and terms and conditions of the declaration.

A statement referencing the statutory definitions of Covered Countermeasures was added to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, it was noted they 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.'' By referencing the statutory provisions, the revised definition also incorporates changes to the PREP Act definitions of covered countermeasure and qualified pandemic or epidemic product made by PAHPRA.

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.[26] These limitations on distribution previously appeared in section I, ''Covered Countermeasures,'' and section IX, ''Definitions.'' We now state the limitations in a separate section and combine them with relevant definitions for improved readability.

The declaration now 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 activities directly conducted by the federal government; or,

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

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.

In regard to (a), we, added the phrase ''other transactions,'' which may be used for some Covered Countermeasure activities,[27] added the phrase ''or other Federal agreements'' to clarify that the provision is intended to cover all types of federal agreements, and added the phrase ''or activities directly conducted by the Federal Government'' to clarify that activities such as manufacture of vaccines for clinical trials by the HHS National Institutes of Health Vaccine Research Center or distribution of countermeasures by federal employees are covered. We changed the conjunction ''and'' to ''or'' between (a) and (b) to clarify that immunity is available under either of these circumstances; the activities do not have to both relate to a federal award or agreement and be used in a public health and medical response in order for immunity to apply. The conjunction ''and'' used in the previous declaration was a drafting error; the Secretary's intent in that previous declaration has been the meaning conferred by the term ''or.'' Provisions (a) and (b) are intended to afford immunity to federal government conducted and supported activities that precede a public health emergency and to activities in accordance with all Authorities Having Jurisdiction during a declared public health emergency. These changes are intended as clarifications and to improve readability, and are not intended as substantive changes.

In regard to (b), the meaning of the terms ''Authority Having Jurisdiction'' and ''Declaration of an Emergency'' are unchanged.

Finally, the last limitation was slightly modified by deleting extraneous statutory references and other language and by replacing the final sentence with the word ''only'' after ''planners'' to improve readability. The changes to this provision are not intended to alter its substantive legal effect. As stated in the ''whereas'' clauses of the prior declaration, this 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

[26] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

[27] See, *e.g.,* 42 U.S.C. 247d–7d(c)(5).

recommends the administration or use of the countermeasure.[28] This information previously appeared in section II, ''Category of Disease.'' The category of disease threat was modified to include delayed effects of acute radiation exposure. This change is intended to clarify and expand the category of disease, health condition or health threat caused by exposure to acute radiation.

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. This definition previously appeared in section IX, ''Definitions.'' It was moved to a separate section to improve readability. The Secretary also narrowed the definition of ''administration'' that was previously provided in the declaration. The declaration previously defined the term ''administration'' to include physical provision of a Covered Countermeasure, as well as management and operation of systems and locations at which Covered Countermeasures may be provided to recipients.

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to patients/recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

The definition has been revised as follows:

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.

As clarified, *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.[29] 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 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.[30] 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. These provisions previously appeared in section IV, ''Population.'' The previous declaration stated that the population specified in the declaration included:

The populations specified in this declaration are all persons who use a Covered Countermeasure or to whom a Covered Countermeasure is administered in accordance with this declaration, including, but not limited to: (1) Any person conducting research and development of Covered Countermeasures directly for the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government; (2) any person who receives a Covered Countermeasure from persons 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 Countermeasure, and their officials, agents, employees, contractors, and volunteers following a declaration of an emergency; (3) any person who receives a Covered Countermeasure from a person authorized to prescribe, administer or dispense the countermeasure or who is otherwise authorized to prescribe, administer or dispense the countermeasure under an Emergency Use Authorization; (4) any person who receives a Covered Countermeasure as an investigational new drug in human clinical trials being conducted directly by the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government.

The declaration was amended to provide that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the declaration.'' We believe this broad statement accurately encompasses all of the previously listed populations given as examples of that phrase and ensures that no populations that use or are administered the Covered Countermeasures in accordance with the terms of the declaration are omitted.

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.[31] These statutory conditions were included in the declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in

[28] 42 U.S.C. 247d–6d(b)(2)(A).

[29] 42 U.S.C. 247d–6d(a).

[30] 42 U.S.C. 247d–6d(b)(2)(C).

[31] 42 U.S.C. 247d–6d(a)(4).

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.[32] This section previously appeared in section V, ''Geographic Area.''

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.[33] These statutory conditions were included 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.[34] This section previously appeared as section III, ''Effective Time Period.''

The declaration is amended to clarify when liability takes effect for different means of distribution. These changes are intended to have no legal effect. The declaration is also amended to extend the period for which liability immunity is in effect. The previous declaration was in effect through December 31, 2015. The effective time period is extended to December 31, 2022.

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.[35] 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.

The provision for additional time periods previously appeared as section VII, ''Additional Time Periods of Coverage After Expiration of the Declaration.'' The provision is amended to clarify the statutory provisions as they apply to manufacturers and to other covered persons, and to clarify that extended coverage applies to any products obtained for the SNS during the effective period of the declaration. The statutory provision was included for clarity.

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.[36] 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,[37] and the statute.[38] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' [39] 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'' was added to explain the types of injury and standard of evidence needed to be considered for compensation under the CICP. This information was included to inform readers of this Program.

Section XV, Amendments

The Secretary may amend any portion of a declaration through publication in the **Federal Register**.[40] This section previously appeared in section VIII, ''Amendments.'' The section has been updated to reflect that the Republished Declaration amends the prior October 10, 2008, declaration.

Deleted Sections

The prior declaration included a number of ''whereas'' clauses as introductory to the declaration. As described above, we have incorporated ''whereas'' clauses that made necessary findings under the PREP Act into the text of the declaration itself. We have deleted the remaining ''whereas'' clauses. This change is not intended to have legal effect.

The prior declaration contained a definitions section. These definitions have been incorporated into the relevant sections of the declaration as noted above, and modified or deleted where indicated above.

An appendix previously appeared in the declaration that listed federal government contracts for research, development, and procurement of Covered Countermeasures. This appendix was deleted to clarify that liability immunity under the provisions of the PREP Act and terms of the declaration is not limited to the contracts listed in the appendix. Coverage is available for any award or agreement that meets the description provided in section VII of the declaration. In addition, deleting the appendix relieves the Department of the need to periodically update the appendix.

These deletions were made for clarity and do not intend them to have legal effect.

Republished Declaration

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Acute Radiation Syndrome Countermeasures

This declaration amends and republishes the October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for acute radiation syndrome countermeasures. To the extent any term of the October 10, 2008, Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

[32] 42 U.S.C. 247d–6d(b)(2)(D).

[33] 42 U.S.C. 247d–6d(a)(4).

[34] 42 U.S.C. 246d–6d(b)(2)(B), (b)(6).

[35] 42 U.S.C. 247d–6d(b)(3).

[36] 42 U.S.C. 247d–6e.

[37] 42 CFR part 110.

[38] 42 U.S.C. 247d–6e.

[39] 42 U.S.C. 247d–6e(b)(4).

[40] 42 U.S.C. 247d–6d(b)(4).

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 an unintentional radioactive release, a deliberate detonation of a nuclear device, or other radiological or nuclear incident that could result in population exposures to radiation and resulting acute radiation syndrome and/or delayed effects of acute radiation exposure 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, or use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

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

Covered Persons who are afforded liability immunity under this declaration are manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency; (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 any antimicrobial (antibiotic, antifungal, antiviral); any other drug; any biologic; or any diagnostic or other device administered acutely during the response to identify, prevent or treat acute radiation syndrome and its associated clinical manifestations, or delayed effects of acute radiation exposure or adverse events from such countermeasures.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

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

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

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

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

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

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is acute radiation syndrome or delayed effects of acute radiation exposure resulting from an unintentional radioactive release, a deliberate detonation of a nuclear device, or other radiological or nuclear incident.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

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

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

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and

qualified persons when the countermeasure is used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

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

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

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

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

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

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

Covered Countermeasures obtained for the SNS during the effective period of this declaration for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction 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 serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at 855–266–2427 (toll-free) or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for botulinum toxin countermeasures was first published on October 17, 2008. This is the first amendment to that declaration.

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

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31094 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Botulinum Toxin Medical Countermeasures—Amendment

ACTION: Notice of Amendment to the October 10, 2008, Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the declaration issued on October 10, 2008 (73 FR 61864) pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: Include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bbb–3a and 360bbb–3b); clarify the description of covered countermeasures; extend the effective time period of the declaration; reformat the declaration; modify or clarify terms of the declaration; and republish the declaration in its entirety, as amended.

DATES: The amendment of the October 10, 2008, declaration is effective as of January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, 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:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued a declaration for countermeasures to botulinum toxin(s) and the resulting disease(s) from a manmade or natural source on October 10, 2008, and is amending this declaration.[1]

The major actions taken by this amendment to the botulinum toxin countermeasures declaration are the following: (1) Updating the description of covered countermeasures to include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act;[2] (2) revising the description of covered countermeasures to clarify that coverage for vaccines includes all components and

[1] 73 FR 61869.

[2] 21 U.S.C. 360bbb–3a and 360bbb–3b.