countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

**X. Population**


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**


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)

For any Covered Countermeasure subsequently covered under the National Vaccine Injury Compensation Program, liability immunity under this declaration expires immediately upon such coverage.

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 or until a Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, as applicable, whichever occurs first.

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; (2) December 31, 2022; or (3) until a Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, as applicable, 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 other appropriate actions 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 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 toll-free at 1–855–266–2427 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 pandemic influenza antivirals was first published on October 17, 2008, and amended on June 11, 2009. This is the second amendment to that declaration.

The December 17, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for diagnostics and other devices was first published on December 22, 2008. This is the first amendment to that declaration.

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 vaccines was first published on January 26, 2007. The declaration was amended on November 30, 2007, to add H7 and H9 vaccines; amended on October 17, 2008, to add H2 and H6 vaccines; amended on June 15, 2009, to add 2009 H1N1 vaccines and republished in its entirety; amended on March 1, 2010, to revise the Covered Countermeasures to include countermeasures against pandemic influenza A viruses, extend the effective date and republished in its entirety; and amended on February 29, 2012, to extend the effective time period, reformat the declaration, and republish the declaration.

This declaration incorporates all amendments to these declarations prior to the date of its publication in the Federal Register. 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.

[PR Doc. 2015–31087 Filed 12–8–15; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Anthrax Medical Countermeasures—Amendment**

**ACTION:** Notice of Amendment to the October 1, 2008, Declaration under the Public Readiness and Emergency Preparedness Act.
SUMMARY: The Secretary is amending the declaration issued on October 1, 2008 (73 FR 58239) 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); revise the description of covered countermeasures and the disease threat; 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 1, 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 anthrax countermeasures against the agent Bacillus anthracis (“B. anthracis”) on October 1, 2008 and is amending this declaration.

The major actions taken by this amendment to the anthrax 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) revising the description of covered countermeasures to clarify that coverage for vaccines includes all components and constituent materials of the vaccines, and all devices and their constituent components used in the administration of the vaccines and to accurately describe the types of countermeasures used against anthrax by deleting “antitoxin” and adding “biologic” to the section describing covered countermeasures; (3) revising the description of the disease threat and category of disease to refer to the “spread of Bacillus anthracis and/or spores of Bacillus anthracis;” (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 e.g., 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 both 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. 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 1, 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 anthrax countermeasures (“declaration”), this determination appeared in the declaration’s introduction as the conclusion to the “whereas” clauses. The determination is now 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 1, 2008, declaration stated that the Secretary “determined there is a credible risk that the threat of exposure of B. anthracis and the resulting disease constitutes a

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1 73 FR 58239.
4 42 U.S.C. 247d.
public health emergency.” The Secretary is amending this determination: (1) To clarify that the threat posed is the spread of Bacillus anthracis and/or the spores of Bacillus anthracis and the resulting disease or condition; (2) to state that the threat may be in the future in order to be consistent with the language used in the PREP Act. Thus, in this amended declaration, the Secretary determines “that there is a credible risk that the spread of Bacillus anthracis and/or the spores of Bacillus anthracis and the resulting disease or conditions may in the future constitute a public health emergency.” This change is provided for clarification.

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. We previously stated these considerations in the introductory “whereas” clauses to the declaration. The declaration now states these considerations in section II. We made this change 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”). In the previous declaration, we included the Recommended Activities in section I of the declaration, “Covered Countermeasures.” The declaration now states these activities under an Emergency Use Authorization (EUA) as a definition in section IX, “Persons previously appeared in the agency or department.” We made this change to improve readability and do not intend that it 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. 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 the previous declaration, we included a statement referring to liability immunity 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. We made this change to improve readability and do not intend that it 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. 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 licensor 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 who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary’s declaration. Under this definition, the Secretary can describe in the declaration other qualified persons, 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.

The provisions regarding Covered Persons previously appeared in the declaration as a definition in section IX, “Definitions” and in section VI, “Qualified Persons.” We combined these two provisions 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. We made these changes to improve readability and clarity and do not intend them to have any substantive legal effect.

We also modified the description of Covered Persons to include a new category of qualified persons: “Any person authorized to prescribe,

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administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act.17 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 Act18 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) 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 that is: (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.20

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures also must be approved or cleared under the FD&C Act;21 licensed under the PHS Act;22 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 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 10 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. We have combined sections I and IX and simplified the language so that it now only identifies the Covered Countermeasures. We have relocated the other conditions previously included in the “Covered Countermeasure” section to new sections, “Recommended Activities,” “Liability Immunity,” and “Limitations on Distribution,” to improve readability. We do not intend for this change 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. We have deleted this language as it is redundant of the provisions stated in sections XII, “Effective Time Period,” and XIII, “Additional Time Period of Coverage.” Section I also stated that it applied to

18 21 U.S.C. 321(g)(1), [h]; 42 U.S.C. 262(i).
19 42 U.S.C. 247d–6(i)(1)(A), [B].
20 21 U.S.C. 321(g)(1), [h]; 42 U.S.C. 262(i).
21 42 U.S.C. 247d–6(i)(1)(B), [C](1)(B).
22 21 U.S.C. 301 et seq.
23 42 U.S.C. 262.
25 21 U.S.C. 355(i), 360(g).
“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. 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 memorandum 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 deleted a reference to Appendix I, 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 declarations 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 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” remain unchanged.

Finally, we slightly modified the last limitation by deleting extraneous statutory references and other language and by replacing the final sentence with the word “only” after “planners” to improve readability. We do not intend for the changes to this provision 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 recommends the administration or use of the countermeasure.28 This information previously appeared in section II, “Category of Disease.” We have modified the category of disease, health condition, or threat to also refer to exposure to Bacillus anthracis and/or to Bacillus anthracis spores.” This change is intended as clarification, and is not intended to be substantive.

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.” We have moved it to a separate section to improve readability. The Secretary has 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 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 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.

As clarified, the definition of “administration” extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are
losses caused by, arising out of, relating to, or resulting from the administration
to or use by an individual of a Covered
Countermeasure consistent with the
terms of a declaration issued under the
Act.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—collectively, 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
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: Department of Defense military
personnel and supporting civilian
employee and contractor personnel; any
person conducting research and
development of Covered
Countermeasures directly by the Federal
government or pursuant to a contract,
grant, or cooperative agreement with the
Federal government; 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; 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 (EUA);
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.

We have amended the declaration
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
complements 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 We included these
statutory conditions in the declaration
for clarity.

Section XI. Geographic Area

The Secretary must identify, for each
Covered Countermeasure specified in
the declaration, the geographic area or
areas for which liability immunity is in
effect with respect to administration or
use of the countermeasure, including, as
appropriate, whether the declaration
applies only to individuals physically
present in the area or, in addition,
 applies to individuals who have a
described connection to the area.32 This
section previously appeared in section
V, “Geographic Area.”

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 individuals
in the geographic areas and 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 We
included 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.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. We have extended the effective
time period 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
delivery of the Covered
Countermeasure, including return of the
product to the manufacturer, 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

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34 42 U.S.C. 246d-6d(b)(2)(B), (b)(6).
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. We included the statutory provision 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. 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. We have added section XIV, “Countermeasures Injury Compensation Program” to explain the types of injury and standard of evidence needed to be considered for compensation under the CICP. We included this information to inform readers of this Program.

Section XV, Amendments

The Secretary may amend any portion of a declaration through publication in the Federal Register. This section previously appeared in section VIII, “Amendments.” The section has been updated to reflect that the Republished Declaration amends the prior October 1, 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. We do not intend this change 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. We deleted this appendix to clarify that liability immunity under the provisions of the PREP Act and terms of the declaration are 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, including those under which Covered Countermeasures are administered or used by the Department of Defense. In addition, deleting the appendix relieves the Department of the need to periodically update the appendix.

We made these deletions 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 Anthrax Countermeasures

This declaration amends and republishes the October 1, 2008, Declaration Under the PREP Act for anthrax countermeasures. To the extent any term of the October 1, 2008, Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.
volunteers, following a declaration of an emergency; (c) 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; (d) 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 vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antimicrobial/antibiotic; any other drug or biologic; or any diagnostic or other device to identify, prevent or treat anthrax 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, memorandum 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 anthrax, which may result from exposure to Bacillus anthracis and/or to Bacillus anthracis spores.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasures 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 countermeasures programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population


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


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.

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]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Acute Radiation Syndrome Medical Countermeasures—Amendment


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 61866.