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Dated: *December 3, 2015.*

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–30970 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Pandemic Influenza Medical Countermeasures—Amendment

ACTION: Notice of Amendment to the October 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, as amended June 11, 2009; the December 22, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, and the February 29, 2012, Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the declarations issued on October 10, 2008 (73 FR 61861), as amended June 11, 2009 (74 FR 29213); December 17, 2008 (73 FR 78362); and February 29, 2012 (77 FR 13329), pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: Cover vaccines, antivirals, diagnostics and devices used against pandemic influenza A viruses in a single declaration; extend coverage to additional antivirals and devices and to biologics and other drugs; simplify descriptions of covered diagnostics and devices; clarify the disease threat and description of pandemic influenza A viruses and influenza A viruses with pandemic potential; include coverage for 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); extend the effective time period of the prior declarations; reformat the declarations for antivirals and for diagnostics and devices; modify or clarify terms of the declarations; and republish the prior declarations as a single declaration in its entirety, as amended.

DATES: The amendment of the October 10, 2008, declaration as amended June 11, 2009, the December 17, 2008, declaration and February 29, 2012, 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 several declarations for countermeasures against pandemic influenza: (1) An October 10, 2008, declaration covering the neuraminidase class of antivirals Oseltamivir Phosphate (*e.g.,* Tamiflu) and Zanamivir (*e.g.* Relenza) (hereinafter, ''antivirals declaration''); (2) a December 17, 2008, declaration covering pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices (hereinafter ''diagnostics and other devices declaration''); and a February 29, 2012, amended declaration covering pandemic influenza vaccines (hereinafter, ''vaccines declaration'') and is amending these declarations.[1]

The major actions taken by this amendment to the pandemic influenza countermeasures declarations include the following: (1) Issuing a single declaration to cover vaccines, antivirals, diagnostics and other devices used against pandemic influenza A viruses; (2) extending coverage to additional antivirals and devices and to biologics and other drugs; (3) updating the description of Covered Countermeasures to include those authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act;[2] (4) clarifying the disease threat and the description of pandemic influenza A viruses and influenza A viruses with pandemic potential; (5) 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; (6) clarifying that liability immunity for antivirals, diagnostics and other devices 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; (7) deleting references to specific federal contracts in the antivirals declaration to clarify that immunity is not limited to activities conducted under listed contracts; (8) 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; (9) narrowing the definition of ''administration'' in the antivirals declaration and in the diagnostics and other devices declaration to cover ''slip-and-fall'' claims only to the extent they are directly tied to the operation of a countermeasure program; (10) extending the time period for which liability immunity is in effect for all of the Covered Countermeasures to December 31, 2022, and; (11) changing the antivirals declaration and the diagnostics and other devices declaration to the format used for the February 29, 2012, amendment to the declaration for pandemic influenza. Other minor modifications and clarifications are also made, as more fully explained below.

The vaccines, antivirals, and diagnostics and other devices declarations are republished as a single pandemic influenza countermeasures declaration (hereinafter, ''declaration'') in full. We explain the substantive and format changes in this supplementary section.

[1] 73 FR 61861, 73 FR 78362, 74 FR 29213, 77 FR 13329.

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

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 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 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 declarations for antivirals and for diagnostics and other devices, this determination appeared in the declarations' introduction as the conclusion to the ''whereas'' clauses. In the vaccines declaration, this determination appeared in section I. This change to the antivirals and the diagnostics and other devices declarations was made to improve readability and is not intended to have any substantive legal effect.

In addition, a substantive change was made to the determination. The determination made in the ''whereas'' clauses in the antivirals declaration and the determination made in the diagnostics and other devices declaration stated that the Secretary ''determined there is a credible risk that the spread of avian and other influenza viruses that pose a pandemic threat and resulting disease could in the future constitute a public health emergency.'' The antivirals declaration also determined that ''the spread of H1N1 swine influenza viruses and resulting disease constitutes a public health emergency.'' The Secretary is amending these determinations to refer to ''influenza A viruses'' rather than ''avian influenza viruses'' to make the determinations in the antivirals declaration and the diagnostics and other devices declaration consistent with the determination made in the more recent vaccines declaration and to ensure that the health threat is described comprehensively. The declaration now reads: ''I have determined that there is a credible risk that pandemic influenza A viruses, and influenza A viruses with pandemic potential could cause an influenza pandemic with resulting disease that may in the future constitute a public health emergency.'' This change is made for clarification and consistency.

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.[5] We stated these considerations in the introductory ''whereas'' clauses to the antivirals declaration, the diagnostics and other devices declaration, and in section II of the vaccines declaration. This change was made to the antivirals declaration and the diagnostics and other devices declaration to improve readability; it is not intended to 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'').[6] In the previous antivirals declaration and devices and other diagnostics declaration, we included the Recommended Activities in section I of the Covered Countermeasures declaration. In the vaccines declaration, Recommended Activities appeared in section III. This change was made to the antivirals and diagnostics and other devices declarations to improve readability and we 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'' from these declarations 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. We also deleted specific references to the influenza antiviral drugs Oseltamivir Phosphate (Tamiflu) and Zanamivir (Relenza) from the antivirals declaration. This change could expand coverage if new antivirals, other drugs, or biologics against pandemic influenza are developed; to the extent coverage is consistent with the statute and the terms of this declaration.

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.[7] 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.'' [8] In the previous antivirals declaration and diagnostics and other devices declaration, we included a statement

[3] 42 U.S.C. 247d–6d(b)(1).

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

[5] 42 U.S.C. 247d–6d(b)(6).

[6] 42 U.S.C. 247d–6d(b)(1).

[7] 42 U.S.C. 247d–6d(b)(1).

[8] 42 U.S.C. 247d–6d(a)(1).

referring to liability immunity specified under the PREP Act in section I of the declaration, ''Covered Countermeasures.'' The vaccines declaration included a statement regarding liability in section IV. The declaration includes the statement that liability immunity is in effect for Recommended Activities in a separate section IV. This change was made to the antivirals and diagnostics and other devices declarations to improve readability and we 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. ''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.[9] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[10]

A *manufacturer* includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.[11]

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.[12]

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.[13] Under this definition, a private sector employer or community group or other person can be a program planner when it carries out the described activities.

A *qualified person* means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration.[14] 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 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.[15]

The provisions regarding Covered Persons appeared in the antivirals declaration and diagnostics and other devices declaration as a definition in section IX, ''Definitions'' and in section VI, ''Qualified Persons.'' We combined these two provisions into a 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. The vaccine declaration included a description of Covered Persons in section V.

We also modified the description of Covered Persons in the antivirals declaration, the diagnostics and other devices declaration, and the vaccines declaration to include a new category of qualified persons in this declaration: ''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.[16]

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[17] 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.[18]

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[19] 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.[20]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures must be approved or cleared under the FD&C Act;[21] licensed under the PHS Act;[22] or authorized for emergency use

[9] 42 U.S.C. 247d–6d(i)(2).

[10] 42 U.S.C. 247d–6d(i).

[11] 42 U.S.C. 247d–6d(i)(4).

[12] 42 U.S.C. 247d–6d(i)(3).

[13] 42 U.S.C. 247d–6d(i)(6).

[14] 42 U.S.C. 247d–6d(i)(8).

[15] 42 U.S.C. 247d–6d(i)(5).

[16] 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.

[17] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[18] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).

[19] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[20] 42 U.S.C. 247d–6d(i)(1)(B),(c)(1)(B).

[21] 21 U.S.C. 301 *et seq.*

[22] 42 U.S.C. 262.

under sections 564, 564A, or 564B of the FD&C Act.[23]

A qualified pandemic or epidemic product 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 [24] 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 appeared in section I of the antivirals declaration and the diagnostics and other devices declaration, ''Covered Countermeasures'' and section IX of these declarations, ''Definitions.'' Section I of these declarations included a description of the Covered Countermeasure and 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 and for consistency with the vaccines declaration. We do not intend for this change to have any substantive legal effect.

Section I of the antivirals declaration and the diagnostics and other devices declaration also stated that the declarations 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.''

We have also revised the descriptions and definitions of the Covered Countermeasure that previously appeared in section IX, ''Definitions'' of the antivirals and the diagnostics and other devices declarations.

Section IX of the antivirals declaration defined the term ''Pandemic Countermeasures'' as: ''the neuraminidase class of Antivirals Oseltamivir Phosphate (*e.g.,* Tamiflu) and Zanamivir (*e.g.,* Relenza).'' The declaration now refers to ''any antiviral, any other drug'' and ''any biologic.'' This substantive change is made for consistency with other PREP Act declarations and to extend coverage to antiviral drugs, other drugs, and biologics that may be developed for use against pandemic influenza, to the extent coverage is consistent with the statute and terms of this declaration.

Section IX of the diagnostics and other devices declaration included the following definitions:

> ''Pandemic Influenza Diagnostics: Means diagnostics to identify avian or other animal influenza A viruses that pose a pandemic threat, or to otherwise aid in the diagnosis of pandemic influenza, when (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.''
>
> ''Pandemic Influenza Personal Respiratory Protection Devices: Means personal respiratory protection devices for use by the general public to reduce wearer exposure to pathogenic biological airborne particulates during public health medical emergencies, such as an influenza pandemic, when (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.''
>
> ''Pandemic Influenza Respiratory Support Devices: Means devices to support respiratory function for patients infected with highly pathogenic influenza A H5N1 viruses or other influenza viruses that pose a pandemic threat when (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 declaration now refers to ''any diagnostic and any other device.'' This change is intended to extend coverage to any diagnostic or other device used as Covered Countermeasures against pandemic influenza to the extent consistent with the statute and the terms of the declaration.

The vaccines declaration included the following description of Covered Countermeasures in section VI:

> Covered Countermeasures are vaccines against pandemic influenza A viruses and influenza A viruses with pandemic potential, all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines, except that influenza A vaccines and their associated components, constituent materials and devices covered under the National Vaccine Injury Compensation Program are not Covered Countermeasures.

This description of vaccines is unchanged but has been combined with the description of antivirals and other drugs, biologics, and diagnostics and other devices into a single description.

The description of covered countermeasures in this declaration now reads:

> Covered countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine used against pandemic influenza A viruses and influenza A viruses with pandemic potential, all components and constituent materials of vaccines, and all devices and their constitution components used in the administration of vaccines, except that vaccines against influenza A and their associated components, constitute materials and devices covered under the National Vaccine Injury Compensation Program are not Covered Countermeasures.

Section I of the antivirals and diagnostics and other devices declarations also referred to the Act for the definition of ''Covered Countermeasures.'' We include a statement in the declaration referencing the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, we note that 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

[23] 21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b.

[24] 21 U.S.C. 355(i), 360j(g).

Covered Countermeasures obtained through a particular means of distribution.[25] These limitations on distribution previously appeared in section I, ''Covered Countermeasures,'' and section IX, ''Definitions'' of the antivirals and diagnostics and other devices declaration, and in section VII of the vaccines declaration. This declaration states the limitations in a separate section and combines them with relevant definitions for improved readability.

The declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or 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 to the antivirals declaration and the diagnostics and other devices declaration the phrase ''other transactions,'' which may be used for some Covered Countermeasure activities,[26] and added the phrase ''or other Federal agreements'' to clarify that the provision is intended to cover all types of federal agreements. We also added to the antivirals declaration, the diagnostics and other devices declaration, and the vaccines declaration 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. In the antivirals and diagnostics and other devices declarations, we also 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 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, we slightly modified the last limitation in the antivirals declaration and the diagnostics and other devices declaration 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 declarations, 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.[27] This information appeared in section II, ''Category of Disease'' of the antivirals and diagnostics and other devices declarations, and in section VIII of the vaccines declaration.

In addition, we have made the following substantive changes. The antivirals declaration described the category of disease as ''the threat of or actual human influenza that results from the infection of humans with highly pathogenic avian H5N1 influenza A viruses or other animal Influenza A viruses (including, but not limited to, H1N1 swine influenza) that are, or may be capable of developing into, a pandemic strain.'' The diagnostics and other devices declaration described the threat as: ''The threat of or actual human influenza that results from the infection of humans with highly pathogenic avian H5N1 influenza A viruses or other animal influenza A viruses that are, or maybe capable of developing into, a pandemic strain.'' These descriptions have been modified to delete references to specific viral strains and to animal influenza viruses, to instead refer to ''pandemic influenza A viruses and influenza A viruses with pandemic potential.'' This change is made to the antivirals and diagnostics and other devices declarations to ensure that the category of disease is described comprehensively and for consistency with the vaccines declaration.

We have also revised the description of pandemic influenza A viruses and influenza A viruses with pandemic potential that appeared in the vaccines declaration to clarify that viruses circulating in humans are included in the definition, and added the revised definition to the antivirals and diagnostics and other devices declarations: Pandemic influenza A viruses and influenza A viruses with pandemic potential mean: Animal viruses and/or human influenza A viruses that are circulating in wild birds, domestic animals and/or humans that cause or have significant potential to cause sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naive.

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'' of the antivirals declaration and diagnostics and other devices declaration. We have moved it to a separate section to improve readability. The Secretary has also narrowed the definition of ''administration'' that was provided in these declarations. These declarations previously defined ''administration'' to include physical provision of a Covered Countermeasure, as well as management and operation of systems and locations

[25] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

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

[27] 42 U.S.C. 247d–6d(b)(2)(A).

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 for the antivirals declaration and the diagnostics and other devices declaration 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 in the antivirals declaration and the diagnostics and other devices declaration, 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.[28] 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 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.[29] 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,'' of the antivirals declaration and the diagnostics and other devices declaration and section X of the vaccines declaration. The antivirals declaration and diagnostics and other devices 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 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.

We have amended the antivirals declaration and the diagnostics and other devices 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 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.[30] 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.[31] This section previously appeared in section V, ''Geographic Area'' of the antivirals declaration and diagnostics and other devices declaration, and section XI of the vaccines declaration.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program

[28] 42 U.S.C. 247d–6d(a).

[29] 42 U.S.C. 247d–6d(b)(2)(C).

[30] 42 U.S.C. 247d–6d(a)(4).

[31] 42 U.S.C. 247d–6d(b)(2)(D).

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.[32] 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.[33] This section appeared in the antivirals declaration and the diagnostics and other devices declaration as section III, ''Effective Time Period'' and in the vaccines declaration in section XII.

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 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.[34] 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 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 appeared as section VII, ''Additional Time Periods of Coverage After Expiration of the Declaration'' in the antivirals declaration and the diagnostics and other devices declaration, and in section XIII of the vaccines declaration. The provision is amended in the antivirals declaration and the diagnostics and other devices declaration 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 Strategic National Stockpile 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 a 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.[35] 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,[36] and the statute.[37] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' [38] 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 the antivirals and diagnostics and other devices declarations 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**.[39] This section appeared in section VIII, ''Amendments'' of the antivirals declaration and the diagnostics and other devices declaration, and section XV of the vaccines declaration. The section has been updated to reflect that the Republished Declaration amends the prior October 10, 2008 (as amended June 11, 2009), December 17, 2008, and February 29, 2012 declarations.

Deleted Sections

The prior antivirals declaration and diagnostics and other devices 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 antivirals declaration and diagnostics and other devices 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 antivirals 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 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.

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 Pandemic Influenza Countermeasures

This declaration amends the October 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, as amended on June 11, 2009; the December 22, 2008, Declaration under the Public Readiness and Emergency Preparedness Act; and the February 29, 2012, Declaration under the Public Readiness and Emergency Preparedness

[32] 42 U.S.C. 247d–6d(a)(4).

[33] 42 U.S.C. 246d–6d(b)(2)(B), (b)(6).

[34] 42 U.S.C. 247d–6d(b)(3).

[35] 42 U.S.C. 247d-6e.

[36] 42 CFR part 110.

[37] 42 U.S.C.247d–6e.

[38] 42 U.S.C.247d–6e(b)(4).

[39] 42 U.S.C. 247d–6d(b)(4).

Act. It republishes these prior declarations as a single declaration. To the extent any term of the prior declarations are inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined there is a credible risk that pandemic influenza A viruses and influenza A viruses with pandemic potential could cause an influenza pandemic with resulting disease that may 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, and; (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 antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine used against pandemic influenza A viruses and influenza A viruses with pandemic potential, all components and constituent materials of vaccines, and all devices and their constitution components used in the administration of vaccines, except that vaccines against influenza A and their associated components, constitute materials and devices covered under the National Vaccine Injury Compensation Program are not Covered 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 the threat of or actual human influenza that results from the infection of humans following exposure to pandemic influenza A viruses or influenza A viruses with pandemic potential.

Pandemic influenza A viruses and influenza A viruses with pandemic potential mean: Animal viruses and/or human influenza A viruses circulating in wild birds, domestic animals and/or humans that cause or have significant potential to cause sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naive.

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)

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 September 28, 2009, to provide targeted liability protections for pandemic countermeasures to enhance distribution and to add provisions consistent with other declarations 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.

[FR 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.