Labor, and any relevant supporting data, including payroll records, that the contracting officer may reasonably require. The information is used by Government contracting officers to establish the contract price adjustment for the construction requirements of a contract, generally if the contract requirements are predominantly services subject to the Service Contract Act.

B. Annual Reporting Burden

Respondents: 842.
Responses per Respondent: 1.
Annual Responses: 842.
Hours per Response: 40.
Total Burden Hours: 33,680.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0154, Davis-Bacon Act—Price Adjustment (Actual Method), in all correspondence.

Dated: February 28, 2012

Laura Auletta,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2012–5322 Filed 3–5–12; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0163; Docket 2011–0076; Sequence 6]

Information Collection; Small Business Size Representation

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request for approval of a previously approved information collection requirement regarding small business size representation.

DATES: Submit comments on or before: May 7, 2012.

ADDRESSES: Submit comments identified by Information Collection 9000–0163, Small Business Size Representation, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by inputting ''Information Collection 9000–0163, Small Business Size Representation'' under the heading ''Enter Keyword or ID'' and selecting ''Search''. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0163, Small Business Size Representation''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0163, Small Business Size Representation'' on your attached document.

- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. Attn: Hada Flowers/IC 9000–0163, Small Business Size Representation.

Instructions: Please submit comments only and cite Information Collection 9000–0163, Small Business Size Representation, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Karlos Morgan, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA (202) 501–0044 or *karlos.morgan@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Federal Acquisition Regulation (FAR) 19.301 and the FAR clause at 52.219–28, Post-Award Small Business Program Representation implement the Small Business Administration (SBA) Final Rule (71 FR 66434), Small Business Size Regulations; Size for Purposes of Governmentwide Acquisition Contracts, Multiple Award Schedule Contracts and Other Long-Term Contracts; 8(a) Business Development/Small Disadvantaged Business; Business Status Determinations. FAR 19.301 and the FAR clause at 52.219–28, requires that contractors represent size status by updating their representations and certifications at the prime contract level in the Online Representations and Certifications Application (ORCA), and notify the contracting office that it has made the required representation.

The purpose of implementing small business rerepresentation in the FAR is to ensure that small business size status is accurately represented and reported over the life of long-term contracts. The FAR also provides for provisions designed to ensure more accurate reporting of size status for contracts that are novated, merged or acquired by another business. This information is used by the SBA, Congress, Federal agencies and the general public for various reasons such as determining if agencies are meeting statutory goals, set-aside determinations, and market research.

B. Annual Reporting Burden

Respondents: 10,000.
Responses per Respondent: 1.
Hours per Response: 0.5.
Total Burden Hours: 5,000.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0163, Small Business Size Rerepresentation, in all correspondence.

Dated: February 28, 2012.

Laura Auletta,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2012–5323 Filed 3–5–12; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Pandemic Influenza Vaccines—Amendment

ACTION: Notice of Amendment to the March 1, 2010 Republished Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: Amendment to declaration issued on March 1, 2010 (75 FR 10268) pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to extend the effective time period, reformat the declaration, modify or clarify terms of the declaration and republish the declaration in its entirety, as amended.

DATES: The amendment of the republished declaration issued on March 1, 2010 is effective as of February 29, 2012.

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 (this is not a toll-free number).

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. Using this authority, the Secretary issued a declaration for pandemic influenza vaccines, which has been amended a number of times. The original pandemic influenza vaccine declaration was published on January 26, 2007,[1] and was amended on November 21, 2007,[2] October 17, 2008,[3] June 15, 2009,[4] September 28, 2009 [5] and March 1, 2010.[6] The March 1, 2010 amendment is effective through February 28, 2012. The original declaration and its amendments, as well as additional information about the PREP Act and the Secretary's declarations for other medical countermeasures, can be found here: *http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.*

The major actions taken by this pandemic influenza vaccine declaration are the following: (1) Changing the format to make the declaration easier for readers to follow; (2) clarifying that liability immunity is provided not only to vaccines and adjuvants, but also to vaccine components and constituent materials used as part of a covered vaccine; (3) explicitly extending liability immunity to devices and their constituent components used in the administration of vaccines, e.g., needles (which provides for uniform coverage for devices, regardless of whether they are manufactured or packaged with the vaccine or combined later for administration by a healthcare provider); (4) clarifying that liability immunity extends to recommended activities related to any Federal agreements including e.g., clinical trials agreements by adding the term ''other Federal agreements'' to the clause describing the types of federal agreements for which immunity is in effect; (5) 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; and (6) extending the time period for which liability immunity is in effect for the Covered Countermeasures to December 31, 2015. Other 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, 119 Stat 2818. 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. 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.[7] This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act, 42 U.S.C. 247d, 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 previous PREP Act declarations (''declaration'' or ''declarations''), this determination appeared in the declarations' 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 March 1, 2010 declaration stated that the Secretary ''determined there is a credible risk that the spread of pandemic influenza A viruses and those with pandemic potential and resulting disease does or could constitute a public health emergency.'' The Secretary is amending this determination: (1) To substitute ''may in the future'' for ''could'' in order to be consistent with the language used in the PREP Act [8]; and (2) to remove the words ''the spread of'' and ''does or'' to clarify that the 2009 H1N1 Influenza virus and resulting disease are not currently causing a public health emergency. As discussed further in section VI of this supplementary information section, we also changed ''and those'' to ''and influenza A viruses with'' for clarity. We also specified that the viruses could potentially cause an influenza pandemic . Thus, in this amended declaration, the Secretary determines ''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.''

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.[9] 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

[1] 72 FR 4710 (2007).
[2] 72 FR 67731 (2007).
[3] 73 FR 61871 (2008).
[4] 74 FR 30294 (2009).
[5] 74 FR 51153 (2009).
[6] 75 FR 10268 (2010).
[7] 42 U.S.C. 247d–6d(b)(1).
[8] See 42 U.S.C. 247d–6d(b)(1).
[9] 42 U.S.C. 247d–6d(b)(6).

(''Recommended Activities'').[10] In previous declarations, we included the Recommended Activities in the introductory ''whereas'' clauses to the declaration. The declaration now states them in section III. We made this change to improve readability and do not intend that it have any substantive legal effect.

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.[11] 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.'' [12] In previous declarations, we included this statement in section I of the declaration, entitled ''Covered Countermeasures.'' The declaration now makes 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.[13] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[14]

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; [15]

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; [16]

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; [17] 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.[18] 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; [19]

The provisions regarding Covered Persons previously appeared as a definition in section X, ''Definitions'' and as section VI, ''Other 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'' for clarity. We made these changes to improve readability and clarity and do not intend them to have any substantive legal effect.

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 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[20]

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 [21], that is: 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; or 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.[22]

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 [23] that: 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 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 is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.[24]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures also must be approved or cleared under the FD&C Act; [25] licensed under the PHS Act; [26] or authorized for emergency use under the FD&C Act.[27] In addition, a qualified pandemic or epidemic product may be a Covered Countermeasure when it is exempted under the FD&C Act for use as an investigational drug or device [28] that is the object of research for

[10] 42 U.S.C. 247d–6d(b)(1).
[11] 42 U.S.C. 247d–6d(b)(1).
[12] 42 U.S.C. 247d–6d(a)(1).
[13] 42 U.S.C. 247d–6d (i)(2).
[14] 42 U.S.C. 247d–6d(i).
[15] 42 U.S.C. 247d–6d(i)(4).
[16] 42 U.S.C. 247d–6d(i)(3).
[17] 42 U.S.C. 247d–6d(i)(6).
[18] 42 U.S.C. 247d–6d(i)(8).
[19] 42 U.S.C. 247d–6d(i)(5).
[20] 42 U.S.C. 247d–6d(i)(1). Section 564 of the FD&C Act may be found at 21 U.S.C. 360bbb–3.
[21] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i)
[22] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).
[23] 21 U.S.C. 321(g)(1), (h);42 U.S.C. 262(i).
[24] 42 U.S.C. 247d–6d(i)(1)(B),(c)(1)(B).
[25] 21 U.S.C. 301 et seq.
[26] 42 U.S.C. 262.
[27] 21 U.S.C. 360bbb–3.
[28] 21 U.S.C. 355(i), 360j(g).

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 eight 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 included not only a description of the Covered Countermeasure but also additional conditions characterizing countermeasures. We have simplified this section so that it now only identifies the Covered Countermeasures. We have relocated the other conditions previously included in the ''Covered Countermeasure'' section to a new section, ''Limitations on Distribution,'' to improve readability. We do not intend for this change to have any substantive legal effect.

We have also revised the definition of the Covered Countermeasure. Previously, the declaration included in section X, ''Definitions,'' a definition of the term ''Pandemic influenza A viruses and those with pandemic potential.'' In this declaration, the Secretary defines the Covered Countermeasures as ''vaccines against pandemic influenza A viruses and influenza A viruses with pandemic potential.'' We replaced the phrase ''and those'' with ''and influenza A'' before ''viruses with pandemic potential'' to clarify that the declaration covers vaccines only for influenza A viruses that have pandemic potential, not all influenza viruses that have pandemic potential. This change is made throughout the declaration wherever the phrase is used. We also changed ''and any associated adjuvants'' to ''and all components and constituent materials of these vaccines'' to clarify the Secretary's intent that all components and constituent materials, such as preservatives, diluents, antibiotics as well as adjuvants are covered as part of the vaccine. This change does not negatively affect the Secretary's view that the manufacturer of an adjuvant used in a vaccine qualifying as a covered countermeasure would qualify as a manufacturer under this declaration and would be afforded the liability immunity provided by the PREP Act. We also added ''and all devices and their constituent components used in the administration of these vaccines'' to clarify that coverage extends to these devices when used in the administration of these vaccines. Devices such as needles, syringes, and aerosols, and their components and constituent materials are an integral part of the administration of the vaccine. They are covered regardless of whether they are manufactured or packaged with the vaccine, or combined later for administration by a healthcare provider. Finally, we added a statement referencing the statutory definitions of Covered Countermeasures to indicate that certain statutory requirements must also be met. These statutory requirements are discussed in the first two paragraphs of this section of the preamble.

Finally, we moved language previously included in section VIII, ''Category of Disease, Health Condition, or Threat'' and modified previous section VI, ''Covered Countermeasures,'' to provide that vaccines (including any components and constituent materials and devices used to administer vaccines) covered under the National Vaccine Injury Compensation Program are not covered countermeasures under this declaration. This language was moved from previous section X to section VI to clarify the Secretary's determination concerning coverage of vaccines under this declaration in the event that a strain of influenza meeting the requirements set forth in section VIII is included in vaccines covered by the National Vaccine Injury Compensation Program. In such circumstances, such vaccines (those covered by the National Vaccine Injury Compensation Program) would be automatically excluded from this declaration. However, to the extent that the same strain of influenza is included in other vaccines that are not covered by the National Vaccine Injury Compensation Program, such vaccines could still qualify as covered countermeasures under this declaration (assuming they meet other requirements set forth in this declaration, including the description of the disease, health condition, or threat set forth in section VIII). Currently, the only types of influenza vaccines covered by the National Vaccine Injury Compensation Program are trivalent influenza vaccines. Thus, such vaccines are not covered by this declaration. This modification is meant to clarify that potentially one formulation of influenza vaccines (e.g., monovalent or quadrivalent vaccines) could qualify as covered countermeasures under this declaration (if such vaccines were not covered under the National Vaccine Injury Compensation Program) and, at the same time, another influenza vaccine containing the exact same strain of influenza virus (e.g., a trivalent influenza vaccine) could be covered by the National Vaccine Injury Compensation Program (and excluded from coverage under this declaration).

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.[29] These limitations on distribution previously appeared in section I, ''Covered Countermeasures,'' and section X, ''Definitions.'' We now state the limitations in a separate section and combine 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

(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 pandemic countermeasures following a declaration of an emergency.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles.

In regard to (a), we added the phrase ''other transactions'', which may be used for some Covered Countermeasure activities,[30] and the phrase ''or other Federal agreements'' to clarify that the provision is intended to cover all types of Federal agreements. 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 previous declarations was a drafting error; the Secretary's intent in those previous declarations has been the meaning conferred by the term

[29] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

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

''or''. Provisions (a) and (b) are intended to afford immunity to Federal government supported activities that precede a public health emergency and to activities in accordance with all Authorities Having Jurisdiction during a declared public health emergency.

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 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 March 1, 2010 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.[31] This information previously appeared in section II, ''Category of Disease,'' and in section X, ''Definitions.'' These provisions now are combined into a single section to improve readability. In addition, we replaced the description of the influenza A virus as it previously appeared in section II with the term ''pandemic influenza A viruses and influenza A viruses with pandemic potential'' and then followed that term with the definition that previously appeared in section X. We made these changes to remove redundancy and improve consistency and do not intend for it to alter the substantive legal effect. Finally, we removed the phrase ''except those included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program'' from this section and instead included similar language in section VI, for clarity as described above.

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 X, ''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 delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to 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: As used in section 319F–3(a)(2)(B) of the Act, 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, 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.[32] 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.[33] 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,'' and section X, ''Definitions,'' stating that the population included any person who used or was administered a Covered Countermeasure: In a clinical trial conducted or supported by the Federal Government; in a pre-pandemic phase, or in a pandemic phase. 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 encompasses all of the previously listed populations and ensures that no populations that use or are administered the Covered Countermeasures in accordance with the terms of the declaration are omitted, including those who use or are administered the Covered Countermeasures in a post pandemic

[31] 42 U.S.C. 247d–6d(b)(2)(A).

[32] 42 U.S.C. 247d–6d(a).

[33] 42 U.S.C. 247d–6d(b)(2)(C).

phase during the disposition period, discussed below in section XII. We deleted definitions of ''pre-pandemic phase'' and ''pandemic phase'' as those descriptions and distinctions did not prove to be useful or necessary in practice. These definitions presumed the first outbreak would be outside of the United States, which will not necessarily be the case.

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.[34] 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.[35] This section previously appeared in section V, ''Geographic Area.''

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas.[36] 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.[37] This section previously appeared as section III, ''Effective Time Period.''

The declaration is amended to clarify when liability takes effect for different distribution methods, and to extend the period for which liability immunity is in effect. Rather than referring to the September 28, 2009 declaration as defining when the effective period commenced, we have incorporated language from that declaration. We also clarified that for any Covered Countermeasure that becomes covered under the National Vaccine Injury Compensation Program after the declaration is issued, liability immunity expires under the PREP Act immediately upon such coverage. We made these changes for clarity and do not intend them to have legal effect.

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.[38] 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 previously appeared as section VII, ''Additional Time Periods of Coverage After Expiration of the Declaration''. The provision is amended to clarify the statutory provision 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.[39] 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,[40] and the statute.[41] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' [42] 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. This section previously appeared as section VIII, ''Compensation Fund.'' We have added language to explain the type of injury and standard of evidence needed to be considered for compensation under the CICP. We included this information for clarity.

Section XV, Amendments

The Secretary may amend any portion of a declaration through publication in the **Federal Register**.[43] This section previously appeared in section IX, ''Amendments.'' The section has been updated to reflect that this declaration amends the prior March 1, 2010 declaration and that the declaration incorporates all prior amendments.

Deleted Sections

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 is not limited to the contracts listed in

[34] 42 U.S.C. 247d–6d(a)(4).

[35] 42 U.S.C. 247d–6d(b)(2)(D).

[36] 42 U.S.C. 247d–6d(a)(4).

[37] 42 U.S.C. 246d–6d(b)(2)(B), (b)(6).

[38] 42 U.S.C. 247d–6d(b)(3).

[39] 42 U.S.C. 247d–6e.

[40] 42 CFR Part 110.

[41] 42 U.S.C.247d–6e.

[42] 42 U.S.C.247d–6e(b)(4).

[43] 42 U.S.C. 247d–6d(b)(4).

the appendix. Coverage is available for any award or agreement that meets the description provided in section I 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 Vaccines Against Pandemic Influenza A Viruses and Influenza A Viruses With Pandemic Potential

This declaration amends and republishes the March 1, 2010 Republished Declaration, as Amended, for coverage under the Public Readiness and Emergency Preparedness (''PREP'') Act for Pandemic Influenza Vaccines, 42 U.S.C. 247d–6d, 247d–6e. To the extent any term of the March 1, 2010 Republished Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

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

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that 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.

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 Federal Food, Drug, and Cosmetic Act (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 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.

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

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

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

(a) Present or future Federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other Federal agreements;

or

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

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

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

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

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is 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.

(a) Pandemic influenza A viruses and influenza A viruses with pandemic potential mean: animal and/or human influenza A viruses that are circulating in wild birds and/or domestic animals 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 naïve.

(b)

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 expires immediately upon such coverage.

Liability immunity began June 15, 2009 for Covered Countermeasures against the 2009 H1N1 pandemic influenza and is provided through December 31, 2015 or until the Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, whichever occurs first.

Liability immunity for countermeasures against other pandemic influenza A viruses and influenza A viruses with pandemic potential for means of distribution other than those in accordance with the public health and medical response of the Authority Having Jurisdiction begins on December 1, 2006 and lasts through December 31, 2015 or until the Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, whichever occurs first.

Liability immunity for Covered Countermeasures against other pandemic influenza A viruses or influenza A viruses with pandemic potential administered or 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 that the emergency declaration is in effect, (2) December 31, 2015, or (3) until the Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 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 Strategic National Stockpile (SNS) during the effective period of this declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes a Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals who sustain a serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and benefits to survivors or estates 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 (HRSA), within the Department of Health and Human Services. Information about the CICP is available at the toll free number 1–888–275–4772 or at *http://www.hrsa.gov/countermeasurescomp/default.htm.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 was first published on January 26, 2007. That declaration provided liability immunity for vaccines against H5N1 pandemic influenza under the terms and conditions stated in the declaration. 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; and amended on March 1, 2010 to revise the Covered Countermeasures and extend the effective date and republished in its entirety. This declaration incorporates all amendments prior to the date of its publication in the **Federal Register**.

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

Authority: 42 U.S.C. 247d–6d.

Dated: February 28, 2012.

Kathleen Sebelius,

Secretary.

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