SUPPLEMENTARY INFORMATION:

A. Purpose

If it is in the best interest of the Government, the contracting officer may authorize cost-reimbursement contractors to obtain, for official purposes only, interagency motor pool vehicles and related services. Contractors’ requests for vehicles must obtain two copies of the agency authorization, the number of vehicles and related services required and period of use, a list of employees who are authorized to request the vehicles, a listing of equipment authorized to be serviced, and billing instructions and address. A written statement that the contractor will assume, without the right of reimbursement from the Government, the cost or expense of any use of the motor pool vehicles and services not related to the performance of the contract is necessary before the contracting officer may authorize cost-reimbursement contractors to obtain interagency motor pool vehicles and related services.

The information is used by the Government to determine that it is in the Government’s best interest to authorize a cost-reimbursement contractor to obtain, for official purposes only, interagency motor pool vehicles and related services, and to provide those vehicles.

B. Annual Reporting Burden

Respondents: 70.
Responses per Respondent: 2.
Annual Responses: 140.
Hours per Response: .5.
Total Burden Hours: 70.

Obtaining Copies of Proposals:
Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0032, Contractor Use of Interagency Motor Pool Vehicles, in all correspondence.


Al Matera,
Director, Acquisition Policy Division.

DEPARTMENT OF DEFENSE
GENERAL SERVICES ADMINISTRATION
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0034; Docket 2010–0083; Sequence 13]

Federal Acquisition Regulation; Information Collection; Examination of Records by Comptroller General and Contract Audit

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

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

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning the examination of records by comptroller general and contract audit.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before May 4, 2010.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden to the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street, NW., Room 4041, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Jackson, Procurement Analyst, Contract Policy Branch, GSA, (202) 208–4949 or e-mail michaelo.jackson@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The Audit and Records-Negotiation clause, 52.215–2; Contract Terms and Conditions Required to Implement Statutes or Executive Orders clause, 52.212–5(d); and Audit and Records-Sealed Bidding clause, 52.214–26, implement the requirements of 10 U.S.C. 2313, 41 U.S.C. 254, and 10 U.S.C. 2306. The statutory requirements are that the Comptroller General and/or agency shall have access to, and the right to, examine certain books, documents and records of the contractor for a period of 3 years after final payment. The record retention periods required of the contractor in the clauses are for compliance with the aforementioned statutory requirements. The information must be retained so that audits necessary for contract surveillance, verification of contract pricing, and reimbursement of contractor costs can be performed.

B. Annual Reporting Burden

Respondents: 19,142.
Responses per Respondent: 2.
Total Responses: 382,840.
Hours per Response: 0.167.
Total Burden Hours: 63,934.
Obtaining Copies of Proposals:
Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control Number 9000–0034, Examination of Records by Comptroller General and Contract Audit, in all correspondence.


Al Matera,
Director, Acquisition Policy Division.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Pandemic Influenza Vaccines—Amendment

Authority: 42 U.S.C. 247d–6d.

ACTION: Notice of amendment to the September 28, 2009 Republished Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: Amendment to declaration issued on September 28, 2009 (74 FR 51153) pursuant to section 319F–3 of the Public Health Service Act (‘‘the Act’’)
(42 U.S.C. 247d–6d) to revise covered countermeasures and extend effective date and republication of the declaration to reflect the declaration in its entirety, as amended.

DATES: The amendment of the republished declaration issued on September 28, 2009 is effective as of March 1, 2010.

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).

HHS Secretary’s Amendment to the September 28, 2009 Republished Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, H7, H9 and 2009–H1N1 Vaccines:

Whereas there are or may be multiple animal influenza A viruses, circulating in wild birds and/or domestic animals that cause, or have significant potential to cause, sporadic human infections or have mutated to cause pandemics in humans;

Whereas, these viruses may evolve into virus strains capable of causing a pandemic of human influenza because these viruses may cause infection in and spread among humans and because humans have little or no immunity to these viruses;

Whereas, one such virus is the 2009 H1N1 Influenza Virus; whereas, vaccination and may be effective to protect persons from the threat of pandemic influenza;

Whereas, Secretary Michael O. Leavitt issued a Declaration for the Use of the Public Readiness and Emergency Preparedness Act dated January 26, 2007 ("Original Declaration"), as amended on November 30, 2007 and October 17, 2008 with respect to certain avian influenza viruses;

Whereas, I amended the declaration on June 15, 2009 with respect to 2009 H1N1 influenza virus and 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 the declaration each time in its entirety;

Whereas, the September 28, 2009 declaration extended through February 28, 2010 for vaccines against influenza virus strains named in the Declaration other than 2009 H1N1 influenza virus;

Whereas, modifications are necessary to revise covered countermeasures and to extend the effective date of the Declaration;

Whereas, the findings made in the declaration issued on September 28, 2009 continue to apply;

Whereas, in accordance with section 319F–3(b)(6) of the Act (42 U.S.C. 247d–6d(b)), I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of additional covered countermeasures with respect to the category of disease and population described in sections II and IV of the September 28, 2009 Republished Declaration, as hereby amended, and have found it desirable to encourage such activities for these additional covered countermeasures, and;

Whereas, to encourage the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures with respect to the category of disease and population described in sections II and IV of the September 28, 2009 Republished Declaration, as hereby amended, it is advisable, in accordance with section 319F–3(a) and (b) of the Act, to provide immunity from liability for covered persons, as that term is defined at section 319F–3(c)(2) of the Act, and to include as such covered persons other qualified persons as I have identified in section VI of the September 28, 2009 Republished Declaration, as amended;

Therefore, pursuant to section 319F–3(b) of the Act, I have determined that there is a credible risk that the spread of influenza A viruses with pandemic potential and resulting disease could in the future constitute a public health emergency and that spread of one of these viruses (2009 H1N1 Influenza) has caused a disease that constitutes a public health emergency.

In order to extend the scope of covered countermeasures and to extend the effective date of the Declaration, the September 28, 2009 Republished Declaration, is hereby amended as follows:

In the title, delete “for H5N1, H2, H6, H7, H9 and 2009 H1N1 Vaccines” and replace with “for Vaccines Against Pandemic Influenza A Viruses and Those with Pandemic Potential”.

In the recitals, delete the fourth “whereas” clauses, and insert two new recitals as follows:

Whereas there are or may be multiple animal influenza A viruses circulating in wild birds and/or domestic animals that cause, or have significant potential to cause, sporadic human infections or have mutated to cause pandemics in humans;

Whereas, these viruses may evolve or have evolved into virus strains capable of causing a pandemic of human influenza because these viruses may cause infection in, and spread among, humans and because humans have little or no immunity to these viruses;

In the “whereas” clause, insert “October 1, 2009, and December 28, 2009” after “July 24, 2009”.

In the “therefore” clause, delete “avian influenza viruses and resulting disease could in the future constitute a public health emergency” and that 2009 H1N1 influenza constitutes a public health emergency” and replace with: “pandemic influenza A viruses and those with pandemic potential and resulting disease does or could constitute a public health emergency”.

In section I, first paragraph, delete “the pandemic countermeasures influenza A H5N1, H2, H6, H7, H9, and 2009 H1N1 vaccines” each time it appears and replace with “vaccines against pandemic influenza A viruses with pandemic potential”.

In section I, at the end of the second sentence, replace “IX” with “X”.

In section II, delete “the virus with (1) highly pathogenic avian influenza A (H5N1, H2, H6, H7, or H9) virus; or (2) 2009 H1N1 influenza” and replace with “animal and/or human influenza A viruses against which most humans do not have immunity, except those included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program, that are circulating in wild birds and/or domestic animals causing or having significant potential to cause sporadic human infections or have mutated to cause pandemics in humans”.

In section III, first paragraph, delete in its entirety and replace with: “The effective period of time of this Declaration commenced as described in the September 28, 2009 Republished Declaration, and extends through February 28, 2012.

In section III, second paragraph, delete “; except that with respect to 2009 H1N1 influenza vaccine, the effective period commences on June 15, 2009 and extends through March 31, 2013” and replace with “through February 28, 2012.”

In section III, add to the end of the section as a new paragraph: “With respect to any covered countermeasure subsequently covered under the
National Vaccine Injury Compensation Program, the effective time period expires immediately upon such coverage.”

In section VII, insert “and use” after “administration in the first sentence, delete “the Act’s” from the second sentence and replace with “this”, and delete “Countermeasure” from the second sentence and replace with “Countermeasures”.

In section IX, add to the end of the first sentence: “; and 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.”

In section X, after the fifth paragraph, insert a new definition as follows:

Pandemic influenza A viruses and those with pandemic potential: Animal and/or human influenza A viruses, except those included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program, 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.

In Appendix I, title and item 32, add “H7,” after “H6”.


Republication of HHS Secretary’s September 28, 2009 Republished Declaration, as Amended, for the Use of the Public Readiness and Emergency Preparedness Act for Vaccines Against Pandemic Influenza A Viruses and Those with Pandemic Potential.

To the extent any term of the September 28 Republished Declaration, as hereinafter amended, is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

Whereas there are or may be multiple animal influenza A viruses circulating in wild birds and/or domestic animals that cause, or have significant potential to cause, sporadic human infections or have mutated to cause pandemics in humans;

Whereas, these viruses may evolve or have evolved into virus strains capable of causing pandemic of human influenza because these viruses may cause infection in, and spread among, humans and because humans have little immunity to these viruses;

Whereas, on April 26, 2009, Acting Secretary Charles E. Johnson determined under section 319 of the Public Health Service Act, (42 U.S.C. 247d), that a public health emergency exists nationwide involving the Swine Influenza A virus that affects or has significant potential to affect the national security (now called “2009–H1N1 influenza”);

Whereas, on July 24, 2009, October 1, 2009, and December 28, 2009 I renewed the determination by the Acting Secretary that a public health emergency exists nationwide involving the Swine influenza A virus (now called “2009–H1N1 influenza virus”);

Whereas, vaccination may be effective to protect persons from the threat of pandemic influenza;

Whereas, the possibility of governmental program planners obtaining stockpiles from private sector entities except through voluntary means such as commercial sale, donation, or deployment would undermine national preparedness efforts and should be discouraged as provided for in section 319F–3(b)(2)(E) of the Public Health Service Act (42 U.S.C. 247d–6(b)) (“the Act”);

Whereas, immunity under section 319F–3(a) of the Act should be available to governmental program planners for distributions of Covered Countermeasures obtained voluntarily, such as by (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;

Whereas, the extent of immunity under section 319F–3(a) of the Act afforded to a governmental program planner that obtains Covered Countermeasures except through voluntary means is not intended to affect the extent of immunity afforded other covered persons with respect to such covered countermeasures;

Whereas, to encourage the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures with respect to the category of disease and population described in sections II and IV below, and have found it desirable to encourage such activities for the Covered Countermeasures;

Therefore, pursuant to section 319F–3(b) of the Act, I have 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.

I. Covered Countermeasures (as Required by Section 319F–3(b)(1) of the Act)

Covered Countermeasures are defined at section 319F–3(i) of the Act.

At this time, and in accordance with the provisions contained herein, I am recommending the manufacture, testing, development, distribution, dispensing; and, with respect to the category of disease and population described in sections II and IV below, the administration and usage of vaccines against influenza A viruses with pandemic potential and any associated adjuvants. The immunity specified in section 319F–3(a) of the Act shall only be in effect with respect to: (1) Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding for vaccines against pandemic influenza A viruses with pandemic potential used and administered in accordance with this declaration, and (2) 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, as defined in section X below.

In accordance with section 319F–3(b)(2)(E) of the Act for governmental program planners, the immunity specified in section 319F–3(a) of the Act shall be in effect to the extent they obtain Covered Countermeasures through voluntary
means of distribution, 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. For all other covered persons, including other program planners, the immunity specified in section 319F–3(a) of the Act shall, in accordance with section 319F–3(b)(2)(E) of the Act, be in effect pursuant to any means of distribution.

This Declaration shall subsequently refer to the countermeasures identified above as Covered Countermeasures.

This Declaration shall apply to all Covered Countermeasures administered or used during the effective time period of the Declaration.

II. Category of Disease (as Required by Section 319F–3(b)(2)(A) of the Act)

The category of disease for which I am recommending 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 animal and/or human influenza A viruses, against which most humans do not have immunity, except those included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program, that are circulating in wild birds and/or domestic animals causing or have significant potential to cause sporadic human infections or have mutated to cause pandemics in humans.

III. Effective Time Period (as Required by Section 319F–3(b)(2)(B) of the Act)

The effective period of time of this Declaration commenced as described in the September 28, 2009 Republished Declaration and extends through February 28, 2012.

With respect to Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, the effective period of time of this Declaration commences on the date of a declaration of an emergency and lasts through and includes the final day that the emergency declaration is in effect including any extensions thereof through February 28, 2012.

With respect to any covered countermeasure subsequently covered under the National Vaccine Injury Compensation Program, the effective time period expires immediately upon such coverage.

IV. Population (as Required by Section 319F–3(b)(2)(C) of the Act)

Section 319F–3(a)(4)(A) confers immunity to manufacturers and distributors of the Covered Countermeasure, regardless of the defined population.

Section 319F–3(a)(3)(C)(i) confers immunity to covered persons who could be program planners or qualified persons with respect to the Covered Countermeasure only if a member of the population specified in the Declaration administers or uses the Covered Countermeasure and is in or connected to the geographic location specified in this Declaration, or the program planner or qualified person reasonably could have believed that these conditions were met.

The populations specified in this Declaration are the following:

(1) All persons who use a Covered Countermeasure or to whom such a Covered Countermeasure is administered as an Investigational New Drug in a human clinical trial conducted directly by the Federal Government, or pursuant to a contract, grant or cooperative agreement with the Federal Government; (2) all persons who use a Covered Countermeasure or to whom such a Countermeasure is administered in a pre-pandemic phase, as defined below; and/or (3) all persons who use a Covered Countermeasure, or to whom such a Covered Countermeasure is administered in a pandemic phase, as defined below.

V. Geographic Area (as Required by Section 319F–3(b)(2)(D) of the Act)

Section 319F–3(a) applies to the administration and use of a Covered Countermeasure without geographic limitation.

VI. Other Qualified Persons (as Required by Section 319F–3(i)(8)(B) of the Act)

With regard to the administration or use of a Covered Countermeasure, Section 319F–3(i)(8)(A) of the Act defines the term “qualified person” as a licensed individual who is authorized to prescribe, administer, or dispense the countermeasure under the law of the State in which such Covered Countermeasure was prescribed, administered or dispensed. Additional persons who are qualified persons pursuant to section 319F–3(i)(8)(B) are the following: (1) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency, and (2) Any person authorized to prescribe, administer, or dispense Covered Countermeasures or who is otherwise authorized under an Emergency Use Authorization.

VII. Additional Time Periods of Coverage After Expiration of Declaration (as Required by Section 319F–3(b)(3)(B) of the Act)

A. I have determined that, upon expiration of the applicable time period specified in Section III above, an additional twelve (12) months is a reasonable period to allow for the manufacturer to arrange for disposition of the Covered Countermeasure, including the return of such product to the manufacturer, and for covered persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasure, and the liability protection of section 319F–3(a) of the Act shall extend for that period.

B. The Federal Government shall purchase the entire production of Covered Countermeasures under the contracts specifically listed by contract number in section I for the stockpile under section 319F–2 of the Act, and shall be subject to the time-period extension of section 319F–3(b)(3)(C). Production under future contracts for the same vaccine will also be subject to the time-period extension of section 319F–3(b)(3)(C).

VIII. Compensation Fund

In addition to conferring immunity to manufacturers, distributors, and administrators of the Covered Countermeasures, the Act provides benefits to certain individuals who sustain a covered injury as the direct result of the administration or use of the Covered Countermeasure. The Countermeasures Injury Compensation Program (CICP) within the Health Resources and Services Administration (HRSA) administers this compensation program. Information about the CICP is available at 1-888-275-4772 or http://www.hrsa.gov/countermeasurescomp/default.htm.

IX. Amendments

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 was published on January 26, 2007; 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; and 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. This Declaration incorporates all amendments prior to the date of its publication in the Federal Register. Any future amendment to this Declaration will be published in the Federal Register, pursuant to section 319F–2(b)(4) of the Act.

X. Definitions

For the purpose of this Declaration, including any claim for loss brought in accordance with section 319F–3 of the PHS Act against any covered persons defined in the Act or this Declaration, the following definitions will be used:

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.

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.

Covered Persons: As defined at section 319F–3(i)(2) of the Act, include the United States, manufacturers, distributors, program planners, and qualified persons. The terms “manufacturer,” “distributor,” “program planner,” and “qualified person” are further defined at sections 319F–3(i)(3), (4), (6), and (8) of the Act.

Declaration of Emergency: A 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 pandemic countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

Pandemic influenza A viruses and those with pandemic potential: Animal and/or human influenza A viruses, except those included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program, 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.

Pandemic Phase: The following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (1) First Human Case in North America; (2) Expansion Within United States; (3) Pandemic Phase: The following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas.


Kathleen Sebelius,
Secretary.

APPENDIX

I. List of U.S. Government Contracts—Covered H5N1, H2, H6, H7, H9, and 2009–H1N1 Vaccine Contracts

1. HHSN266200400031C
2. HHSN266200400032C
3. HHSN266200300039C
4. HHSN266200400045C
5. HHSN266200205459C
6. HHSN266200205460C
7. HHSN266200300451C
8. HHSN266200205462C
9. HHSN266200205463C
10. HHSN266200205464C
11. HHSN266200205465C
12. HHSN266200300057C
13. HHSN266200300068C
14. HHSN2662003005413C
15. HHSO100200600021C (formerly 20020049981)
16. HHSO100200500004C
17. HHSO100200500005I
18. HHSO100200700026I
19. HHSO100200700027I
20. HHSO100200700028I
21. HHSO100200600010C
22. HHSO100200600011C
23. HHSO100200600012C
24. HHSO100200600013C
25. HHSO100200600014C
26. HHSO100200600022C (formerly 200200511758)
27. HHSO100200600023C (formerly 200200410431)
28. CRADA No. AI–0155 NIAID/Immuno/200200511758
29. HHSO100200700029C
30. HHSO100200700030C
31. HHSO100200700031C
32. All present, completed and future Government H5N1, H2, H6, H7, H9, and 2009–H1N1 vaccine contracts not otherwise listed.

SUMMARY: Section 602 of Public Law 102–585, the “Veterans Health Care Act of 1992” enacted Section 340B of the Public Health Service Act (PHS). Section 340B implements a drug pricing program by which manufacturers who sell covered outpatient drugs to particular covered entities listed in the statute must agree to charge a price that will not exceed the amount determined under a statutory formula. The purpose of this Final Notice is to inform interested parties of final guidelines regarding the utilization of multiple contract pharmacies and suggested contract pharmacy provisions, which had been previously limited to the Alternative Methods Demonstration Project program.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Rockville, Maryland 20857 or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

DATES: Effective Date: April 5, 2010.

SUPPLEMENTARY INFORMATION:

A. Background

Proposed guidelines for contract pharmacy services were announced in the Federal Register at 72 FR 1540 on January 12, 2007. A comment period of 60 days was established to allow interested parties to submit comments. HRSA, HSB, acting through the OPA, received 32 comments concerning the proposal.

In 1996, HRSA issued guidelines that permitted covered entities participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the covered entity’s patients (61 FR 43549, August 23, 1996). Those guidelines permitted a covered entity to use a single point for pharmacy services, either an in-house pharmacy or an