It is further ordered that the Commission's Bureau of Enforcement be made a party to this proceeding;

It is further ordered that rebuttal affidavits and memoranda of law shall be filed by the Bureau of Enforcement and any intervenors in opposition to the Respondent no later than October 5, 2009;

It is further ordered that reply affidavits and memoranda of law shall be filed by the Respondent and intervenors in support no later than October 20, 2009;

It is further ordered that:

(a) Should any party believe that an evidentiary hearing is required, that party must submit a request for such a hearing together with a statement setting forth in detail the facts to be proved, the relevance of those facts to the issues in this proceeding, a description of the evidence which would be adduced, and why such evidence cannot be submitted by affidavit;

(b) Should any party believe that an oral argument is required, that party must submit a request specifying the reasons therefor and why argument by memorandum is inadequate to present the party's case; and

(c) Any request for evidentiary hearing or oral argument shall be filed no later than October 5, 2009;

It is further ordered that notice of this proceeding be published in the **Federal Register** and that a copy thereof be served upon Respondent at his last known address;

It is further ordered that all documents submitted by any party of record in this proceeding shall be filed in accordance with Rule 118 of the Commission's Rules of Practice and Procedure, 46 CFR 502.118, as well as being mailed directly to all parties of record;

Finally, it is ordered that pursuant to the terms of Rule 61 of the Commission's Rules of Practice and Procedure, 46 CFR 502.61, the final decision of the Commission in this proceeding shall be issued by February 17, 2010.

By the Commission.

Karen V. Gregory,

Secretary.

[FR Doc. E9–18601 Filed 8–3–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination and Declarations Regarding Emergency Use of Certain In vitro Diagnostic, Antiviral, and Personal Respiratory Products Accompanied by Emergency Use Information

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 360bbb–3(b)(4). On April 26, 2009, the Acting Secretary of HHS determined that a public health emergency exists nationwide involving Swine Influenza A (now known as 2009–H1N1 Influenza A, or 2009–H1N1 influenza) that affects or has significant potential to affect national security. On the basis of this determination, on April 26 and April 27, 2009, the Acting Secretary declared emergencies justifying the authorization of emergency use of certain *in vitro* diagnostic, antiviral, and personal respiratory protection products accompanied by emergency use information subject to the terms of any authorization issued by the Commissioner of Food and Drugs (Commissioner) under 21 U.S.C. 360bbb–3(a). The Acting Secretary also specified that these declarations are declarations of emergency as defined by former Secretary Michael O. Leavitt in the October 10, 2008 Declaration under the Public Readiness and Emergency Preparedness (PREP) Act for Influenza Antivirals Oseltamivir Phosphate and Zanamavir, as amended, and the December 17, 2008 Declaration under the PREP Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices.

DATES: The declaration of an emergency justifying the authorization of emergency use of certain *in vitro* diagnostic products is effective April 26, 2009. The declaration of an emergency justifying the authorization of certain antiviral products is effective April 26, 2009. The declaration of an emergency justifying the authorization of emergency use of certain respiratory protection products is effective April 27, 2009.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, M.D., 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:

I. Background

Under Section 564 of the FFDCA, the Commissioner, acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product, or an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare an emergency justifying the authorization based on one of three determinations: a determination of a domestic emergency, or a significant potential for a domestic emergency, by the Secretary of Homeland Security; a determination of a military emergency, or a significant potential for a military emergency, by the Secretary of Defense; or a determination of a public health emergency by the Secretary of HHS. *See* 21 U.S.C. 360bbb–3(b)(1). In the case of a determination by the Secretary of HHS (as was made here), the Secretary must determine that a public health emergency exists under section 319 of the Public Health Service (PHS) Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. Based on such a determination, the Secretary of HHS may then declare an emergency that justifies the EUA, at which point the Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FFDCA are met.

The Centers for Disease Control and Prevention (CDC), HHS, requested that the Food and Drug Administration (FDA) issue EUAs for certain *in vitro* diagnostic, antiviral, and personal respiratory protection products accompanied by emergency use information. The determination of a public health emergency by the Acting Secretary of HHS and the declarations of an emergency by the Acting Secretary of HHS based on that determination, as described below, enabled the Acting Commissioner to issue EUAs for certain *in vitro* diagnostic, antiviral, and personal respiratory protection products

for emergency use under section 564(a) of the FFDCA, 21 U.S.C. 360bbb-3(a).

An *in vitro* diagnostic, CDC Human Influenza Virus Real-time RT–PCR Detection and Characterization Panel (rRT–PCR Flu Panel), is cleared by FDA for detection of seasonal Influenza A and subtype determination. CDC sought an EUA to allow this test to be used with specimen types and reagents additional to those of the cleared test as a first tier test for patients suspected of having 2009–H1N1 influenza. CDC also sought an EUA to allow an *in vitro* diagnostic that has not been previously approved or cleared by the FDA, Swine Influenza Virus Real-time RT–PCR Detection Panel (rRT–PCR Swine Flu Panel), to be used in detecting 2009–H1N1 influenza.

CDC also sought EUAs for certain antiviral drug products, which are approved by FDA for use in treatment and prophylaxis of influenza for adult and pediatric use. Relenza® (zanamivir) is approved to treat acute uncomplicated illnesses due to influenza in adults and children 7 years and older who have been symptomatic for less than two days, and for the prevention of influenza in adults and children 5 years and older. Tamiflu® (oseltamivir phosphate) is approved for the treatment of acute uncomplicated illness due to influenza in patients 1 year and older who have been symptomatic for less than two days, and for the prevention of influenza in patients 1 year and older. The EUA for Tamiflu allows for Tamiflu to also be used to treat and prevent influenza in children under one year, to treat influenza in patients who have been symptomatic for more than 2 days, and to provide alternate dosing recommendations for certain pediatric populations. The EUA for Tamiflu also authorizes distribution of Tamiflu deployed from the Strategic National Stockpile (SNS) and that has had its expiration date extended under the Federal government's Shelf Life Extension Program (SLEP). In addition, under the EUAs, both Tamiflu and Relenza may be distributed to large segments of the population without complying with certain prescription label requirements otherwise applicable to dispensed drug. Under the EUAs, Tamiflu and Relenza are authorized to be accompanied by certain written information pertaining to the emergency. The EUAs note that there may be distribution of these products by a broader range of health care workers, including some public health officials and volunteers, in accordance with applicable State and local laws and/or the public health and medical emergency response of the authority having jurisdiction, subject to the terms and conditions of the EUA.

Finally, certain personal respiratory protection devices certified by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR part 84, as non-powered air-purifying particulate respirators with a minimum filtration efficiency classification of N95 (known as N95 respirators) have been cleared by FDA for use by the general public in public health medical emergencies, such as an influenza pandemic. Other N95 respirators have been cleared by FDA for use in certain workplace settings. The disposable N95 respirators for which CDC sought an EUA were either not previously cleared or approved by FDA or were cleared by FDA but only for use in certain workplace settings. The EUA authorized the emergency use, by the general public,[1] of these products, as deployed from the SNS and accompanied by emergency use information, to help reduce wearer exposure to airborne germs during this emergency. The specific products covered by the EUA are identified in the EUA by manufacturer and model number; fifteen different models of disposable N95 respirators are covered.

With issuance of the EUAs for certain *in vitro* diagnostic products, laboratories may receive certain *in vitro* diagnostics covered by the EUAs for use in detection of 2009–H1N1 influenza, and patients and health care professionals may receive emergency use information regarding these *in vitro* diagnostic products during this public health emergency involving 2009–H1N1 influenza. With issuance of the EUAs for certain antiviral products and issuance of the EUA for certain personal respiratory products, members of the general public may receive certain antiviral and personal respiratory protection products covered by the EUAs, accompanied by emergency use information, for immediate use by them during this 2009–H1N1 influenza emergency. These products and accompanying information may help to detect the spread of 2009–H1N1 influenza, protect individuals against contracting 2009–H1N1 influenza, and treat individuals who are ill following exposure to 2009–H1N1 influenza.

[1] For purposes of this EUA, the term ''general public'' is broad and includes people performing work-related duties. This EUA affects only requirements applicable under the Federal Food, Drug, and Cosmetic Act. It does not affect requirements arising from other sources of law, such as Occupational Safety and Health Administration (OSHA) requirements.

In this public health emergency involving 2009–H1N1 influenza, time is of the essence in detecting, preventing, and treating illness and death by getting *in vitro* diagnostic, antiviral and personal respiratory protection products, accompanied by emergency use information, to the general public, laboratories, and public health and health care professionals. By distributing certain *in vitro* diagnostic products accompanied by emergency use information, public health and health care professionals can ensure that spread of the 2009–H1N1 influenza is quickly and accurately detected. By dispensing certain personal respiratory products accompanied by emergency use information, the appropriate State and/or public health authority(ies) can ensure that the products are provided quickly, as appropriate, to help reduce wearer exposure to airborne germs. By dispensing certain antiviral products accompanied by emergency use information, public health and medical professionals and the authorities having jurisdiction to respond to the emergency in each locality can ensure that the products are provided quickly, as appropriate, to those who may have been exposed or are ill, accompanied by the information most important to their emergency use.

This is one part of the Federal Government's strategy to encourage preparedness at all levels of government to enable the nation to respond effectively in response to this public health emergency.

II. Determination of the Acting Secretary of Health and Human Services

On April 26, 2009, pursuant to section 564(b)(1)(C) of the FFDCA, 21 U.S.C. 360bbb–3(b)(1)(A), and section 319 of the PHS Act, 42 U.S.C. 247d, the Acting Secretary of HHS determined, as a consequence of confirmed cases of Swine Influenza A (swH1N1) (now called ''2009–H1N1 influenza'') in California, Texas, Kansas, and New York, and after consultation with public health officials as necessary, that a public health emergency exists nationwide involving 2009–H1N1 influenza that affects or has significant potential to affect national security.

III. Declarations of the Acting Secretary of Health and Human Services

On April 26, 2009, on the basis of the Acting Secretary's determination on April 26, 2009, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, that a public health emergency exists involving 2009–H1N1 influenza that affects or has significant

potential to affect national security, and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb–3(b), the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain *in vitro* diagnostics for detection of Swine Influenza A (now called ''2009–H1N1 influenza'') accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). The Secretary further specified that the declaration is a declaration of emergency, as defined in the December 17, 2008, Declaration under the PREP Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, published at 73 FR 78362 (December 22, 2008).

Also, on April 26, 2009, on the basis of the Acting Secretary's determination on April 26, 2009, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, that a public health emergency exists involving Swine Influenza A that affects or has significant potential to affect national security, and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb–3(b), the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals oseltamivir phosphate and zanamivir accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). The Secretary further specified that the declaration is a declaration of emergency, as defined in the October 10, 2008, Declaration under the PREP Act for Influenza Antivirals Oseltamivir Phosphate and Zanamivir, published at 73 FR 61861 (October 17, 2008), as amended. The Acting Secretary's April 26, 2009, amendment to the October 10, 2008 Declaration under the PREP Act for Influenza Antivirals Oseltamivir Phosphate and Zanamivir is separately published elsewhere in this issue of the **Federal Register**.

On April 27, 2009, on the basis of the Acting Secretary's determination on April 26, 2009, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, that a public health emergency exists involving Swine Influenza A that affects, or has significant potential to affect, national security; and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb–3(b), the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain personal respiratory protection devices, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). The Secretary further specified that the declaration is a declaration of emergency, as defined in the December 17, 2008, Declaration under the PREP Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, 73 FR 78362 (December 22, 2008).

Notice of the authorizations issued by the FDA Commissioner under 21 U.S.C. 360bbb–3 is provided elsewhere in this **Federal Register**.

Dated: July 28, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–18432 Filed 8–3–09; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office for Civil Rights; Delegation of Authority

Notice is hereby given, that I have delegated to the Director of the Office for Civil Rights (OCR), with authority to redelegate, the following authority vested in the Secretary of Health and Human Services:

1. The authority under section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, as amended, to the extent that these actions pertain to the ''Security Standards for the Protection of Electronic Protected Health Information,'' at 45 CFR part 160 and part 164, subparts A and C, to

A. Impose civil money penalties under section 1176 of the Social Security Act for a covered entity's failure to comply with certain requirements and standards;

B. Issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation or compliance review for failure to comply with certain requirements and standards; and

C. Make exception determinations, under section 1178(a)(2)(A) of the Social Security Act, concerning when provisions of State laws that are contrary to the Federal standards are not preempted by the Federal provisions.

2. The authority under section 262 of HIPAA, as amended, to administer the regulation ''Security Standards for the Protection of Electronic Protected Health Information,'' at 45 CFR part 160 and part 164, subparts A and C, and General Administrative Requirements, 45 CFR Part 160, as these requirements pertain to part 164, subparts A and C, and to make decisions regarding the interpretation and enforcement of these Standards and General Administrative Requirements.

This delegation shall be exercised under the Department's existing delegation of authority and policy relating to regulations.

This delegation supersedes the memorandum from the Secretary to the Administrator, Centers for Medicare & Medicaid Services, dated October 7, 2003, titled ''Delegation of Authority for Certain Provisions Under Part C of Title XI of the Social Security Act.''

I hereby affirm and ratify any actions taken by the Director of OCR or his/her subordinates which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

This delegation is effective immediately.

Dated: July 27, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–18557 Filed 8–3–09; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Implementation of Section 5001 of the American Recovery and Reinvestment Act of 2009 (ARRA) for Adjustments to the Third Quarter of Fiscal Year 2009 Federal Medical Assistance Percentage (FMAP) Rates for Federal Matching Shares for Medicaid and Foster Care and Adoption Assistance

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice with comment period.

SUMMARY: This notice with comment period describes the methodology for calculating the higher federal matching funding that is made available under Section 5001 of the American Recovery and Reinvestment Act of 2009 (ARRA). Section 5001 of the ARRA provides for temporary increases in the Federal Medical Assistance Percentage (FMAP) rates to provide fiscal relief to States and to protect and maintain State Medicaid programs in a period of economic downturn. The increased FMAP rates apply during a recession adjustment period that is defined as the period beginning on October 1, 2008 and ending on December 31, 2010.