

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.

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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.

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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.