# The H1N1 Influenza (Swine Flu) Outbreak: HHS Emergency Authorities to Respond

Written by Thomas Barker

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The September 11, 2001, terrorist attacks on the United States underscored for the Department of Health and Human Services (HHS) and other federal agencies the inflexibility and rigidity of various HHS statutes and regulations to respond to public health emergencies. Shortly after the 9/11 attacks, former HHS Secretary Tommy Thompson urged Congress to pass legislation permitting temporary waivers of HHS statutory authority in order to address sudden, acute emergencies where the normal statutory rules that govern HHS act as a barrier to rapid response to the victims of the emergencies. Over the course of the next several years, Congress responded by enacting a series of provisions designed to permit HHS to act quickly to respond to the needs of individuals facing a public health emergency. These statutes supplemented existing authority that the Secretary of HHS already possessed to waive the otherwise applicable rules to the operation of the Medicare and Medicaid programs.

The recent outbreak of H1N1 influenza virus, or swine flu, in the United States and across the world has prompted the United States government to respond in several ways, including through the use of some of the post-9/11 statutory enactments. It is possible that the HHS Secretary will invoke additional waivers available to her as a result of this outbreak. This memorandum analyzes the statutory authorities available to the Secretary, the means by which they can be triggered, and historical precedent.

## Overview of Statutory Authorities

The Secretary of HHS can authorize the Food and Drug Administration (FDA) to permit emergency use authorizations (EUAs) for the non-approved use of drugs, devices, or medical tests. She also has other significant waiver tools at her disposal, the most important of which are sections 1115 and 1135 of the Social Security Act which permit waivers or modifications of statutory provisions affecting the Medicare, Medicaid, and CHIP programs. Finally, the Secretary has authority to waive or modify otherwise applicable payment provisions for hospital services provided to Medicare beneficiaries.

## Emergency Use Authorizations

EUAs permit the FDA to authorize the use of unapproved or uncleared medical products or unapproved or uncleared uses of approved or cleared medical products following the determination and declaration of a public health emergency.[1] The issuance of an EUA follows a general outline:

### Declaration of an Emergency

Under the Public Health Service Act, the Secretary of HHS may declare a public health emergency whenever "a disease or disorder presents a public health emergency." 42 U.S.C. § 247d(a)(1). Making such a declaration enables her to "take such action as may be necessary" to respond to the emergency. The public health emergency declaration lasts until the earlier of the date that the Secretary revokes the delegation or 90 days after the declaration. If 90 days has expired and the public health emergency still exists, however, the Secretary can renew the declaration as often as necessary.[2]

### Issuance of an EUA

The declaration of an emergency allows the Secretary to consult with the FDA and CDC and order EUAs. Not any product may be given clearance through issuance of an EUA. FDA Guidance says that the only "products and uses that are eligible for authorization are those

that 'may be effective' to prevent, diagnose, or treat in humans serious or life-threatening diseases or conditions that can be caused by the specified biological, chemical, radiological, or nuclear agent(s) that led to or caused the declared emergency."[3] Furthermore, "products are eligible for emergency use authorization if FDA determines that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product." There must also be no available alternative to the candidate product.

### Private Entity Involvement

Although an EUA may not be issued until after a public health emergency has been declared, because of the extremely limited time during which approval may take place and still be effective in allowing drugs to be released, FDA strongly encourages private involvement. Specifically, it encourages "an entity with a possible candidate product, particularly one at an advanced state of development, to contact the FDA Center responsible for the candidate product even before a determination of actual or potential emergency."[4]

### Setting of Conditions on an EUA

The FDA Commissioner may establish certain conditions on an EUA that she finds necessary to protect public health. Conditions may apply to manufacturers or others who carry out activities for which the EUA is issued.

### Revocation of EUA or Termination of Emergency

An EUA is in effect for the duration of the emergency during which it was issued, unless the Secretary revokes it earlier to protect public health.[5]

In the current H1N1 influenza outbreak, the Department of Health and Human Services declared a public health emergency on April 26 in response to human infections of the newly discovered virus. Twenty-four hours after the declaration of the state of emergency, HHS and the FDA issued EUAs for the use of certain Relenza and Tamiflu antiviral products and the rRT-PCR Swine Flu Panel diagnostic test. The text of the FDA announcement can be found here.

## §1135 of the Social Security Act

Section 1135 (42 U.S.C. § 1320b-5) was designed to give the Secretary power to waive various requirements of the Medicare, Medicaid, and State Children's Health Insurance programs during national emergencies. The statute is broken down into five main operating provisions. The first is its purpose: it is designed to ensure that, in an "emergency area," and during an "emergency period," (1) sufficient health care items and services are available to Medicare, Medicaid, and State Children's Health Insurance Plan (CHIP) enrollees in the emergency area and (2) that health care providers in the emergency area can be reimbursed for providing health care items and services to those enrollees, notwithstanding the failure of those providers to comply with otherwise-applicable rules. The statute defines "emergency area" as a geographical area in which there exists a declaration of an emergency or disaster by the President of the United States and in which the Secretary of Health and Human Services has declared a public health emergency under the Public Health Service Act. The statute defines "emergency period" as the period of time during which both the Presidential and Secretarial designations are in effect.

The operative provision of the statute is its second provision. It lists the statutory and regulatory provisions of the Medicare, Medicaid and CHIP programs that the Secretary may "temporarily waive or modify" if the waiver or modification will "accomplish the purpose" of making health care items and services available and permitting payment for those items and services. 42 U.S.C. § 1320b-5(b). There are seven:

- Medicare conditions of participation for providers, program participation requirements, and pre-approval requirements;
- Requirements that providers be licensed to practice medicine in the State in which they perform services;
- Limited provisions of the Emergency Medical Treatment and Labor Act (EMTALA) for a period of 72 hours after the implementation of a hospital disaster protocol (or longer, in the event of a pandemic infectious disease);
- Prohibitions on physician referrals to entities in which they or their families have a financial interest (the so-called "Stark" self-referral prohibitions);
- Deadlines and timetables for the performance of certain required activities, although these timetables can only be modified, not waived;

- Payment by Medicare Advantage plans for services provided to enrollees by out-of-network providers;
- Limited provisions of HIPAA.

Third, the statute grants the Secretary authority to issue retroactive waivers, solely at the discretion of the Secretary. This may be necessary where, for example, the Presidential or Secretarial declarations happen a few days after the outbreak of the public health emergency, but providers took actions in the first hours of the emergency to ensure adequate health care to enrollees. Next, the Secretary must notify Congress of her use of the waiver authorities.

The statute also specifies the length of time during which the waivers can be in effect. Generally, waivers expire on the expiration of the Presidential declaration of a disaster or emergency, the expiration of the public health emergency, or 60 days after the first invocation of the section 1135 waiver. The 60 day period can be extended as necessary.

Waivers under section 1135 of the Social Security Act and public health emergency declarations were not uncommon during the Bush Administration. Examples of their use included Hurricanes Katrina and Rita in 2005 and the Midwest flooding in the late spring of 2008. The waivers and declarations were of assistance to Medicare, Medicaid and CHIP beneficiaries in obtaining needed health care services. The most significant need for waivers involved conditions of participation, EMTALA, and the modifications of deadlines (typically, for reporting requirements to HHS).

## Section 1115 Waiver Authority

Section 1115 of the Social Security Act (42 U.S.C. § 1315) permits the Secretary of HHS to waive the various requirements that State Medicaid plans must meet, as well as to permit certain State expenditures to qualify as Medicaid expenditures (and therefore receive federal matching funds), as long as the waivers will, in the judgment of the Secretary, "assist in promoting the objectives of" the Medicaid and CHIP programs. The Secretary may wish to invoke these authorities in an emergency to rapidly provide health care coverage to people who do not have it (or who may have lost evidence of coverage). In the alternative, the Secretary may wish to invoke these authorities to expand the benefits available under a State Medicaid plan in a State in which an emergency has occurred. It should be noted, with respect to section 1115 waivers, that there is no requirement for a Presidential or Secretarial declaration – the sole basis for granting a waiver is the Secretary's judgment that granting the waiver will "assist in promoting the objectives of" Medicaid or CHIP.

HHS liberally used its § 1115 waiver authority during the aftermath of Hurricane Katrina to provide Medicaid coverage to former Louisiana residents who evacuated to other States and to pay providers in those other States who treated the Katrina evacuees. To ease the ability of States to take advantage of these waivers, HHS developed a model template that enabled States applying for waivers to check-the-box and submit the waiver request. HHS typically approves these requests within 24 hours.

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[1] Other grounds for declaring an emergency include declaration of a military emergency by the Secretary of Defense or a domestic emergency by the Secretary of Homeland Security.

[2] The Secretary will generally publish in the Federal Register notice of the declaration of public health emergency, advance notice of the termination, and renewal of a declaration of emergency.

[3] See "Guidance on the Emergency Use Authorization of Medical Products," Food and Drug Administration, July 2007, available here

[4] *Id.*, FDA also includes a list of recommended datat to support a request for consideration.

[5] Another important provision is that dealing with liability or compensation. Section 564 of the Federal Food, Drug and Cosmetic Act does not establish a liability protection scheme for manufacturers who carry out any activity for which an EUA is issued. However, they may be eligible under other statutes such as the National Vaccine Injury Compensation Program, the Public Readiness and Emergency Preparedness Act (Pub. L. 109-148) or others.

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