

## **Interplay between the Emergency Declarations issued by the President and the Secretary of Health and Human Services Regarding the H1N1 Pandemic**

Secretary Sebelius continued a Public Health Emergency (PHE) under the Public Health Service Act (PHSA) on July 26, 2009 and October 1, 2009 (the original declaration was made by the Acting Secretary on April 26, 2009). PHE declarations have a duration of 90 days, may be extended as necessary, or terminated when the SEC/HHS declares the emergency no longer exists. Under this declaration alone, the Secretary of HHS may, if necessary, and consistent with other authorities, take appropriate actions to respond to the emergency such as: making grants; entering into contracts; making temporary hiring appointments; conduct/support an investigation into the cause, treatment, or prevention of the disease or disorder; and make disbursements from the Public Health Emergency Fund.

The Secretary may grant also extensions or waive sanctions relating to submission of data or reports required under HHS laws. In addition, a Public Health Emergency declaration can be a necessary step in enabling the secretary to take a variety of discretionary actions under other authorities to respond to the PHE. For example, she may: waive certain prescription and dispensing requirements; exempt for up to 30 days a person from select agents requirements; adjust Medicare reimbursement for certain Part B drugs; waive certain Ryan White HIV/AIDS grant program requirements; and declare an emergency justifying emergency use of an investigational product under section 564 of the Federal Food Drug and Cosmetic Act.

- The President proclaimed a National Emergency under the National Emergencies Act (NEA) on October 23, 2009. This proclamation, which has a duration of one year, coupled with Secretary Sebelius' PHE declaration will enable her to:
  - Temporarily waive or modify certain requirements of the Medicare, Medicaid, the Children's Health Insurance Program (CHIP), the Emergency Medical Treatment and Active Labor Act (EMTALA), and the Health Insurance Portability and Accountability Act (HIPAA) as necessary to respond to the pandemic throughout the duration of the PHE.
  - These requirements provide important protections for patients during normal day-to-day operations, but they may impede the ability of healthcare facilities to fully implement disaster operations plans that enable appropriate care during emergencies.
  - The waivers are known as "1135 waivers" because the authority for them is found in section 1135 of the Social Security Act.
- 1135 waivers might be used, for example, to enable healthcare facilities to establish alternate care sites away from the facility's main campus; facilitate transfer of patients from ERs and inpatient wards between hospitals; exceed critical access hospital 25-bed limit and average patient stays less than 96 hours; waive Skilled Nursing Facilities need for HHS approval prior to increasing the number of certified beds in a distinct part

- 1135 waivers are not novel. They have been issued in a number of recent disasters to enable healthcare facilities to effectively cope with large patient burdens. Examples: Hurricanes Katrina/Rita (2005); Hurricanes Ike and Gustav (2008); and the North Dakota flooding of 2009.
- 1135 waivers” issued by HHS under the Social Security Act generally last for the duration of the public health emergency; HIPAA (and non-pandemic related EMTALA) waivers under section 1135 last 72 hours after a hospital implements its disaster response plan.
  - Each request for an 1135 waiver will be carefully reviewed before a decision is made by HHS. The Secretary may issue specific waivers or modifications under section 1135 only to the extent they ensure that sufficient health care items and services are available to meet the needs of Medicare, Medicaid, and CHIP beneficiaries in the emergency area during the emergency period. The “emergency area” and the “emergency period” are the geographic area, in which, and the time period, during which, the dual declarations exist. For this event, the emergency area is nationwide and the emergency period begins on October 23, 2009, and will last through duration of the declared Public Health Emergency for 2009-H1N1 influenza. HIPAA waivers are subject to special time limits
- No Stafford Act declarations (Emergency or Major Disaster) have yet been made.
  - A Stafford Act declaration could be combined with a PHE declaration to provide the same 1135 waiver authority as provided by the NEA.
  - FEMA’s new Fact Sheet for Pandemic Influenza signed October 21, 2009, (attached) explains what FEMA and the other federal agencies will provide should the President make a Stafford Act emergency declaration. It provides a series of emergency protective measures that federal agencies would make available to the states and local governments. The states would have a 25 per cent cost share for these federal assets.
- The Stafford Act options discussed above remain available to the President under appropriate circumstances.