President Obama Signs Emergency Declaration for H1N1 Flu

On October 24, 2009, President Obama signed a proclamation declaring the 2009 H1N1 influenza pandemic a National Emergency to facilitate our ability to respond to the pandemic by enabling – if warranted – the waiver of certain statutory Federal requirements for medical treatment facilities. In particular, this proclamation is aimed at providing HHS the ability to waive legal requirements that could otherwise limit the ability of our nation's health care system to respond to the surge of patients with the 2009 H1N1 influenza virus.

Authority

Section 1135 of the Social Security Act [42 USC §1320b–5] permits the Secretary of Health and Human Services to waive certain requirements for healthcare facilities in response to emergencies. Two conditions must be met for the Secretary to be able to issue such "1135 waivers": first, the Secretary must have declared a Public Health Emergency; second, the President must have declared an emergency or major disaster either through a Stafford Act Declaration or National Emergencies Act Declaration. If these conditions are met, then the Secretary may waive or modify Federal requirements as listed in section 1135. After the Secretary invokes section 1135, healthcare facilities may petition for 1135 waivers in response to particular needs, and only within the geographic and temporal limits of the emergency declarations.

Under Section 1135:

The Secretary will issue waivers or modifications under section 1135 for specific requirements to match the specific situational needs. The requirements that may be waived include certain requirements related to Medicare, Medicaid or the Children's Health Insurance Program (CHIP), the Emergency Medical Treatment and Labor Act (EMTALA), and the Health Insurance Portability and Accountability Act (HIPAA). 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. For example, requirements under the Emergency Medical Treatment and Labor Act (EMTALA) prohibit hospitals from sending an individual to an off-campus location for an appropriate screening.

- Waivers are permitted 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 as discussed below.

- Permitted actions include the waiver or modification of conditions of participation, other certification requirements, and program participation requirements for health care providers, pre-approval requirements; waiver of sanctions for certain directions or relocations and transfers that otherwise would violate EMTALA; waiver of sanctions related to Stark self-referral prohibitions; modifications to deadlines and timetables for the performance of required activities; and waiver of sanctions and penalties arising from noncompliance with certain HIPAA privacy regulations.

Examples of waiver requests:

- Hospitals request to set up an alternative screening location for patients away from the hospital's main campus (requiring waiver of sanctions for certain directions, relocations or transfers under EMTALA).

- Hospitals request to facilitate transfer of patients from ERs and inpatient wards between hospitals (requiring waiver of sanctions under EMTALA regulations).

- Critical Access Hospitals requesting waiver of 42 CFR 485.620, which requires a 25-bed limit and average patient stays less than 96 hours.

- Skilled Nursing Facilities requesting a waiver of 42 CFR 483.5, which requires CMS approval prior to increasing the number of the facility's certified beds.

Past instances where the Secretary invoked the Section 1135 waiver authority for recent disaster events include:

- Hurricane Katrina (2005)
- Hurricanes Ike and Gustav (2008)
- North Dakota flooding (2009)

Q: Why declare a National Emergency for the 2009 H1N1 pandemic now; why can't we wait until a hospital or region needs these 1135 Waivers?

A: The H1N1 epidemic is moving rapidly. By the time regions or healthcare systems recognize they are becoming overburdened, they need to implement disaster plans quickly. When the Secretary of HHS invokes section 1135, HHS has in past practice accepted requests from affected healthcare facilities, providers, and/or States for specific waivers or modifications. HHS will be requiring such requests in connection with this emergency and will need to process such requests quickly. Adding a potential delay by requiring HHS to wait for a National Emergency Declaration before it could issue necessary 1135 waivers is not in the best interest of the public, particularly if this step can be done proactively as the President has done.

Q: Do 1135 waivers affect State laws or regulations?

A: Under section 1135, only certain Federal requirements relating to Medicare, Medicaid, CHIP, and HIPAA may be waived or modified as listed in section 1135. An 1135 waiver does not affect State laws or regulations.

Q: Has the authority to grant 1135 waivers been granted before?

A: Yes, there are several instances where 1135 Waiver authority has been granted under the Stafford Disaster Relief and Emergency Assistance Act (as opposed to the National Emergencies Act) to help healthcare facilities cope with large patient burdens. Recent examples include Hurricane Katrina (2005), Hurricanes Ike and Gustav (2008), and the North Dakota flooding (2009). The Secretary was also prepared and able to invoke the 1135 waiver authority in connection with the 56th Presidential Inauguration (2009) in the event that 1135 waivers became necessary.

Q: Specifically, what will this National Emergency Act (NEA) Declaration enable? What will 1135 waivers allow hospitals to do if a waiver is requested and granted?

A: An NEA Declaration fulfills the second of the two conditions required for the Secretary of HHS to be able to grant 1135 waivers. Healthcare facilities that receive specific waivers or modifications under section 1135 will be able to continue to provide care even if they are out of compliance with certain Medicare, Medicaid and CHIP requirements.

Q. How does the President's National Emergency declaration under the National Emergencies Act differ from a Stafford Act declaration? How does the request process for assistance under the Stafford Act differ from the request process for 1135 waivers?

A: Presidential proclamation of a national emergency under the National Emergencies Act and a Presidential declaration of an emergency or major disaster under the Stafford Act are distinct and separate declarations.

The National Emergencies Act allows the President to issue a proclamation to invoke particular emergency authorities as needed. The President's proclamation that the 2009 H1N1 influenza pandemic constitutes a national emergency fulfills the second of the two conditions required for the Secretary of HHS to be able to grant 1135 waivers. The President's proclamation coupled to the HHS Secretary's prior public health emergency declaration for 2009 H1N1 influenza enables the HHS Secretary to issue waivers or

modifications under section 1135 of the Social Security Act for certain Medicare, Medicaid, CHIP, and HIPAA requirements as discussed above. The President's proclamation does not trigger a Stafford Act declaration or provide financial or other resources.

In general, when an incident overwhelms or is anticipated to overwhelm State resources, the Governor may request Federal assistance, including assistance under the Stafford Act. The Stafford Act authorizes the President to provide financial and other assistance to State and local governments, certain private nonprofit organizations, and individuals to support response, recovery, and mitigation efforts following Presidential emergency or major disaster declarations under the Stafford Act. The Stafford Act is triggered by a Presidential declaration of a major disaster or emergency under that Act, when an event causes damages of sufficient severity and magnitude to warrant Federal disaster assistance to supplement the efforts and available resources of States, local governments, and the disaster relief organizations in alleviating the damage, loss, hardship, or suffering.

Most incidents are not of sufficient magnitude to warrant a Presidential declaration. However, if State and local resources are insufficient, a Governor may ask the President to make such a declaration. Ordinarily only a Governor can initiate a request for a Presidential emergency or major disaster declaration. In extraordinary circumstances, the President may unilaterally declare a major disaster or emergency. In order to assist States in assessing impacts and evaluating the need for Federal assistance in a pandemic influenza, FEMA has developed a fact sheet for requesting Stafford Act assistance from the Federal government: http://www.fema.gov/pdf/emergency/pandemic_influenza_fact_sheet.pdf.

As noted above, the H1N1 epidemic is moving rapidly. By the time regions or healthcare systems recognize they are becoming overburdened, they need to implement disaster plans quickly. The President's proclamation of a national emergency under the National Emergencies Act, coupled to the HHS Secretary's prior public health emergency declaration for 2009 H1N1 influenza will allow the Secretary of HHS maximum flexibility to issue waivers or modifications under section 1135 of the Social Security Act nationwide as needed. The process for requesting specific waivers or modifications under section 1135 is discussed below. As the 2009 H1N1 pandemic evolves, if State and local resources become insufficient, then states may request assistance under the Stafford Act through the usual Stafford Act process.

Q: Is the HIPAA Privacy Rule suspended during a national or public health emergency?

A: No. The HIPAA Privacy Rule is not suspended during a national or public health emergency. However, the Secretary of HHS may waive sanctions and penalties against a covered hospital that does not comply with certain provisions of the HIPAA Privacy Rule under the Project Bioshield Act of 2004 (PL 108-276) and section 1135(b)(7) of the Social Security Act.

Specifically, the Secretary of HHS may waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule: (1) the requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care (45 CFR 164.510(b)); (2) the requirement to honor a request to opt out of the facility directory (45 CFR 164.510(a)); (3) the requirement to distribute a notice of privacy practices (45 CFR 164.520); (4) the patient's right to request privacy restrictions (45 CFR 164.522(a)); and (5) the patient's right to request confidential communications (45 CFR 164.522(b)).

Q: When and to what entities does the HIPAA 1135 waiver granted in response to the 2009 H1N1 influenza pandemic apply?

A: The HIPAA waiver only applies to hospitals nationwide that have instituted a disaster response plan and for up to 72 hours from the time the hospital implements its disaster response plan. In addition, hospitals may only operate under such a HIPAA waiver during the emergency period beginning on October 23, 2009 through the duration of the HHS Secretary's public health emergency declaration for 2009 H1N1 influenza.

When the Presidential or Secretarial declaration terminates, a hospital must then comply with all the requirements of the Privacy Rule for any patient still under its care, even if 72 hours has not elapsed since implementation of its disaster protocol. HIPAA waivers are only effective if taken in a manner that does not discriminate among individuals on the basis of their source of payment or their ability to pay.

Regardless of the activation of an emergency waiver, the HIPAA Privacy Rule permits disclosures for treatment purposes and certain disclosures to disaster relief organizations. For instance, the Privacy Rule

allows covered entities to share patient information with the American Red Cross so it can notify family members of the patient's location. See 45 CFR 164.510(b)(4).

Learn More: * Visit the weblink below for information on sharing information in emergency situations.
http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/katrinanhipaa.pdf

Q. When and where are 1135 waivers (not related to HIPAA) in effect?

A: 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 as discussed above.

Q: What are practical implementation steps States and Individual Healthcare Providers need to consider?

Determining if Waivers Are Necessary

In determining whether to invoke an 1135 waiver (once the conditions precedent to the authority's exercise have been met), the Assistant Secretary for Preparedness and Response (ASPR) with input from relevant HHS Operating Divisions will determine the need and scope for such modifications. Information considered includes requests from Governors' offices, feedback from individual healthcare providers and associations, and requests to regional or field offices for assistance.

How States or Individual Healthcare Providers Can Ask for Assistance or a Waiver

Once an 1135 Waiver is authorized, health care providers can submit requests to operate under that authority or for other relief that may be possible outside the authority to either the State Survey Agency or CMS Regional Office. Requests can be made by sending an email to the CMS Regional Office in their service area, or by calling the State or CMS Regional Office. Email addresses are listed below. Information on your facility and justification for requesting the waiver will be required.

Review of 1135 Waiver requests

CMS will review and validate the 1135 waiver requests utilizing a cross-regional Waiver Validation Team. The cross-regional Waiver Validation Team will review waiver requests to ensure they are justified and supportable.

Implementation of 1135 Waiver Authority

Providers must resume compliance with normal rules and regulations as soon as they are able to do so and, in any event, the waivers or modifications a provider was operating under are no longer available after the termination of the emergency period.

Federally certified/approved providers must operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.

Frequently Asked Questions

Further information on the 1135 Waiver process can be found at: http://www.cms.hhs.gov/H1N1/

Questions regarding 1135 that are not addressed at the above website can be sent to the following mailbox: Pandemic@cms.hhs.gov

Email Addresses for CMS Regional Offices

ROATLHSQ@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, Texas

ROPHIDSC@cms.hhs.gov (Northeast Consortium): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

ROCHISC@cms.hhs.gov (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska

ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, Pacific Territories.