

**2009-H1N1 Questions Posed by the American Hospital Association (AHA)
HHS Response—October 27, 2009**

Overview:

Under the established National Response Framework process for the Interagency, ASPR has an established process for accepting requests for medical and public health assistance as well as requesting assistance from other Departments under the Economy Act. If needed, requests for assistance from local institutions would be made through the state health department to the ASPR Regional Emergency Coordinator (REC) and then to HHS/ASPR. Potential requests could be for a variety of assistance including clinical staff, temporary medical facilities, equipment, supplies, evacuation of patients, or laboratory.

The goal of Federal assistance via ASPR is to contain healthcare system failures locally and prevent any failures from spreading to a regional level. With that underlying strategy, an escalating response capability is necessary. Where possible, federal resources may be deployed in response to a state request. Maintaining maximal flexibility in the implementation of available options is also necessary.

When there is a National Emergencies Act Declaration (or declaration of a major disaster or an emergency under the Stafford Act) by the President and a Public Health Emergency Declaration by the Secretary, HHS, the Secretary may invoke her authority under section 1135 of the Social Security Act to waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements.

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.

HHS may receive requests to waive or modify requirements specified in section 1135. Requests for waivers will be evaluated by a cross-regional, multidisciplinary Waiver Validation Team. The Waiver Validation Team will review waiver requests to ensure they are justified and supportable. Sources of information would include specific providers, provider associations, state health departments, local and federal emergency response personnel, and others. The strategy is to receive and validate requests for assistance from local institutions made through the states. Common requests for modifications may include:

- **Emergency Medical Treatment and Active Labor Act (EMTALA):** Waiver of EMTALA will permit health care facilities to transfer an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared emergency and direct or relocate an individual to receive medical screening in an alternative location pursuant to a state pandemic preparedness plan or state emergency preparedness plan. A hospital must also activate its disaster response plan to operate under an EMTALA waiver. A waiver of these requirements is available only if the facility's actions do not discriminate on the basis of an individual's source of payment or ability to pay.

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- Critical Access Hospitals (CAH): Waiver of CAH caps on the number of beds and lengths of stay to quickly will enable them to provide in-patient care to a larger number of patients.
- Skilled Nursing Facility Center (SNF): Waiver of the requirement for SNFs to obtain prior approval from CMS to increase their number of beds. Allowing SNFs to increase the number of patients quickly will enable them to provide in-patient care to a larger number of patients.

Questions and Answers:

Q: Approximately how long will the process take for approving/denying a waiver?

A: 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. HHS anticipates that requests to operate under 1135 Waiver flexibilities should be responded to within three business days of receipt.

Q: Can a healthcare system apply for a waiver of regulations at all or some of its hospitals, or can only a hospital apply?

A: HHS anticipates that healthcare systems or corporations may apply on behalf of their facilities. However, they should include the information necessary to allow the CMS regional office to appropriately justify the flexibility requested for each facility.

Q: Can a county health department apply on behalf of several hospitals in its county or must each hospital apply individually?

A: HHS anticipates that a county may apply on behalf of facilities in their county, but they should include the information necessary to allow the CMS regional office to appropriately justify the flexibility requested for each facility.

Q: Critical Access Hospitals (CAH) anticipate that they will exceed their licensed bed capability using the 1135 waiver. Is there a source available to address how an 1135 waiver is applied for and what the process is?

A: HHS is unable to implement specific 1135 waivers in anticipation of an actual need. Rather, once the need arises, a waiver may be granted. The waiver can be retroactive to the date the need actually arose (back to the beginning of the waiver period, or in the case of this emergency, no earlier than October 23, 2009). The process for submitting a waiver requests is posted at <http://www.cms.hhs.gov/H1N1/>

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Q: Can a State petition the Federal government for a waiver covering all Critical Access Hospitals (CAH) and if so, to whom?

A: Health care providers can submit requests to operate under that authority (or for other relief that may be possible under other 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. Information on your facility and justification for requesting the waiver will be required.

Q: Can the 72 hour waiver time frame be extended if the disaster plan is still in effect?

A: These waivers under section 1135 of the Social Security Act typically end no later than the termination of the emergency period. Waivers for EMTALA (for public health emergencies that do not involve a pandemic disease) and HIPAA requirements are limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. Waiver of EMTALA requirements for emergencies that involve a pandemic disease last until the termination of the pandemic-related public health emergency.

Q: Are there mechanics for requesting such a waiver proactively?

A: Health care providers are asked to submit supported and justifiable requests reflecting actual need. Information to support the request should be clear and concise to ensure that the Waiver Validation Team can validate the request quickly.

Q: How will we receive the declaration or expect to receive it from (Federal, State or local)?

A: HHS will release all declaration information the information on www.flu.gov and additionally at <http://www.cms.hhs.gov/H1N1/>. Facilities requesting specific waivers of Medicare, Medicaid, CHIP requirements or EMTALA sanctions will receive a written response from CMS, which may be transmitted via e-mail or otherwise.

Q: To whom and in what form should a hospital “petition” for an 1135 waiver?

A: Health care providers can submit requests to operate under that authority (or for other relief that may be possible under other 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.

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

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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.

Q: Must a State or locality declare its own public health emergency (PHE) before it may request that an 1135 be put into place for one or more of its healthcare facilities? If so, is it possible for a hospital in a State that has not declared a PHE to petition directly to HHS for an 1135 waiver? If so, what is the process?

A: An 1135 waiver may be issued regardless of whether a State or locality has declared its own public health emergency or state of emergency. Health care providers can submit requests to operate under that authority (or for other relief that may be possible under other 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. Information on your facility and justification for requesting the waiver will be required.

Q: Is there a mechanism for submitting 1135 waiver questions that have not been addressed on the CMS website?

A: Additional Questions regarding 1135 that are not addressed at the <http://www.cms.hhs.gov/H1N1/> website can be sent to the following mailbox: Pandemic@cms.hhs.gov. Healthcare providers can also send 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.

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

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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.