

November 2, 2009



H1N1 Section 1135 Waiver for Hospitals

Effective 5:00 pm (EST) October 29, 2009, healthcare providers may now petition the Department of Health and Human Services (DHHS) for Section 1135 Waivers to ensure that sufficient healthcare items and services are available to meet the needs of individuals enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) as a result of the 2009 H1N1 influenza pandemic.

I. Section 1135 Waiver

Since Spring 2009, the nation has been preparing for the 2009 H1N1 influenza pandemic. On April 26, 2009, former Acting Secretary of Health and Human Services, Charles E. Johnson, determined that a Public Health Emergency existed nationwide involving Swine Influenza (now called 2009 H1N1 flu). This declaration was renewed by the current Secretary of Health and Human Services (the "Secretary"), Kathleen Sebelius, on July 24, 2009 and October 1, 2009. Just last week, on October 24, 2009, President Obama signed a proclamation declaring the 2009 H1N1 influenza pandemic a National Emergency. This provided the Secretary with the authority to issue a waiver of certain statutory federal requirements for medical treatment facilities in an effort to appropriately respond to the H1N1 pandemic.¹

At 5:00 pm on October 29, 2009, the Secretary invoked a Section 1135 Waiver "to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to

ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the 2009-H1N1 influenza pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse."² The Section 1135 Waiver applies to the following requirements:

- certain conditions of participation, certification, and program participation requirements;
- requirements that physicians or other health care professionals hold licenses in the State in which they provide services if they have an equivalent license from another State;
- sanctions for certain directions, relocations or transfers that would otherwise violate EMTALA if conducted pursuant to an appropriate state emergency preparedness plan or a state pandemic preparedness plan;
- sanctions related to Stark self-referral prohibitions;
- limitations on payments for health care items and services furnished to individuals enrolled in a Medicare Advantage plan;
- for hospitals that have hospital disaster protocols in operation, sanctions and penalties arising from noncompliance with certain provisions of the HIPAA privacy regulations; and

¹ Section 1135 of the Social Security Act (42 USC §1320b-5) permits the Secretary to waive certain requirements for healthcare facilities in response to emergencies if the following two conditions are met: (1) the Secretary must have declared a Public Health Emergency; and (2) the President must have declared an emergency or major disaster either through a Stafford Act Declaration or National Emergencies Act Declaration.

² Waiver or Modification of Requirements Under Section 1135 of the Social Security Act, Department of Health and Human Services, Office of Secretary, Oct. 27, 2009, available at http://www.flu.gov/professional/federal/h1n1_1135waiver_10272009.html.



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- deadlines and timetables for the performance of required activities, as determined necessary by CMS.

The Section 1135 Waiver became effective at 5:00 pm (EST) on October 29, 2009, but was retroactive to October 23, 2009, and will remain in effect during the duration of the declared Public Health Emergency for 2009 H1N1 influenza. In order to take advantage of the Section 1135 Waiver, however, providers must seek individual approval from DHHS.

To request a Section 1135 Waiver, healthcare providers must submit a request to either the State Survey Agency or the CMS Regional Office. Requests to the Regional Office can be made by email or telephone. Providers will need to be prepared to provide information about the facility and justification for the request. Once a Section 1135 Waiver request is received, the CMS Waiver Validation Team will review the request and determine whether it is justified. Examples of possible waiver requests include:

- a request to set up an alternative screening location away from the hospital's main campus
- a request to facilitate transfer of patients from ERs and inpatient wards between hospitals
- a request to waive the 25-bed limit and 96 hour average length of stay requirement for a critical access hospital

II. Waiver Limitations

It is important for healthcare providers to keep in mind that the following limitations apply:

- Federally certified providers must operate under normal rules and regulations, unless they have sought and have been granted a waiver or modification from a specific requirement.

- 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 nationwide during the declared Public Health Emergency for 2009 H1N1 influenza.

- A Section 1135 Waiver only applies to Federal requirements and does not apply to State laws or regulations. Depending on the requested waiver, providers will need to determine whether there are any state law implications and whether a corresponding waiver request needs to be submitted to the Virginia Department of Health, Office of Licensure and Certification.

- Providers must resume compliance with normal rules and regulations as soon as they are able to comply and no later than the termination of the emergency.

III. EMTALA Waivers

Due to the nature of the H1N1 pandemic, waiver of particular EMTALA requirements will likely be the most prevalent.³ In anticipation of the significant increase in demand for emergency services due to H1N1 influenza and concerns about compliance with EMTALA requirements, CMS issued a Survey and Certification Memorandum (S&C-09-52, August 14, 2009) clarifying options that are permissible under EMTALA (without a waiver) and summarizing the provisions governing EMTALA waivers. To reassure the provider community that there is existing flexibility under EMTALA, the memorandum specifically provides, "Surveyors and managers responsible for EMTALA enforcement are expected to be aware of the flexibilities hospitals are currently afforded under EMTALA and ... to keep these flexibilities in mind when assessing hospital compliance with

³ EMTALA requires all Medicare-participating hospitals with dedicated EDs to provide an appropriate medical screening exam (MSE) to determine if the person has an Emergency Medical Condition (EMC) for all individuals who come to their EDs, regardless of ability to pay. If there is no EMC, the hospital's EMTALA obligations end. If there is an EMC, the hospital must: treat and stabilize the EMC within its capability (including inpatient admission when necessary); OR transfer the individual to a hospital that has the capability and capacity to stabilize the EMC.



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EMTALA during a survey.”

A brief summary of the clarification provided in the memorandum is outlined below:⁴

No Waiver Required

- The MSE does not have to take place in the ED.
 - Hospitals may set up alternative screening sites on campus (e.g., within 250 yards of the main hospital).
 - Individuals may be redirected to these sites after being logged in. The redirection and logging can even take place outside the entrance to the ED.
 - The person doing the directing should be qualified (e.g., an RN) to recognize individuals who are obviously in need of immediate treatment in the ED.
- The content of the MSE varies according to the individual’s presenting signs and symptoms – it can be as simple or as complex, as needed, to determine if an EMC exists.
 - MSEs must be conducted by qualified personnel, which may include physicians, NPs, PAs, or RNs trained to perform MSEs.
- Hospitals may set up screening at off-campus, hospital-controlled sites.
 - Hospitals may encourage the public to go to these sites instead of the hospital for screening for influenza-like illness; however, a hospital may not tell individuals who have already come to its ED to go to the off-site location for the MSE.
 - The hospitals should not hold the site out to the public as a

place that provides care for EMCs in general, but rather, as an influenza screening center.

EMTALA Waivers

- An EMTALA waiver allows hospitals to:
 - direct or relocate individuals who come to the ED to an alternative off-campus site for an MSE in accordance with a State emergency or pandemic preparedness plan;
 - effect transfers, normally prohibited under EMTALA, of individuals with unstable EMCs so long as the transfer is necessitated by the circumstances of the declared emergency.
- A waiver of EMTALA requirements is effective only if actions under the waiver do not discriminate on the basis of a patient’s source of payment or ability to pay.

Additional information regarding the H1N1 influenza pandemic and Section 1135 Waivers can be found at www.flu.gov or <http://www.cms.hhs.gov/H1N1/>. Should you have any questions about the recently issued Section 1135 Waivers; would like assistance obtaining a waiver for your facility; or wish to discuss any associated compliance issues or concerns, please contact Mary C. Malone, Emily W.G. Towey, or Michelle E. Calloway by telephone at (804) 967-9604 or by email at mmalone@hdjn.com, etowey@hdjn.com, or mcalloway@hdjn.com. Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available on the firm’s website at www.hdjn.com.

⁴ The full memorandum is available at http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf.



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www.hdjn.com

Richmond 4701 Cox Road Suite 400 Glen Allen, VA 23060 PO Box 72050 Richmond, VA 23255-2050 ○ (804) 967-9604	Fairfax 3975 Fair Ridge Road Suite 475 South Fairfax, VA 22033 ○ (703) 591-3440
Harrisonburg 3210 Peoples Drive Harrisonburg, VA 22801 ○ (866) 967-9604	Virginia Beach One Columbus Center 283 Constitution Drive Suite 301 Virginia Beach, VA 23462 ○ (757) 321-6555
Lewisburg, WV 210 West Randolph Street Lewisburg, WV 24901 ○ (866) 967-9604	Franklin, TN 725 Cool Springs Blvd. Suite 600 Franklin, TN 37067 ○ (866) 967-9604