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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-10-05 -EMTALA

DATE: **November 6, 2009**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Emergency Medical Treatment and Labor Act (EMTALA) Regulation Changes *and* H1N1 Pandemic Flu and EMTALA Waivers**

Memorandum Summary

- **EMTALA Regulation at 42 CFR 489.24 (a)(2) Revised**: The Fiscal Year (FY) 2010 Inpatient Prospective Payment System (IPPS) Final Rule included technical revisions concerning the non-applicability of EMTALA sanctions under Section 1135(b)(3) of the Social Security Act (the Act). During a public health emergency, waivers under section 1135(b)(3) can provide exceptions to penalties for the otherwise impermissible redirection or relocation of individuals for a medical screening examination (MSE) and for inappropriate transfers. In this memorandum we describe the waiver process for these EMTALA-specific waivers.

- **Current Waiver Status for H1N1:** The Secretary has invoked Section 1135 and under that authority hospitals and critical access hospitals (CAHs) may apply for waiver of EMTALA sanctions as described in this guidance.

Technical Changes to EMTALA Regulations

The FY 2010 IPPS Final Rule, published on August 27, 2009 (74 FR 43919 and 44001) included technical changes to the non-applicability of sanctions for certain EMTALA violations at 42 CFR 489.24 (a)(2). These revisions were adopted to conform the regulatory language more closely to the provisions of Section 1135 of the Act. It should be noted that, even in a waiver situation, EMTALA requires screening for all individuals who come to a hospital or CAH Dedicated Emergency Department (DED), regardless of their ability to pay, even if that screening occurs off the hospital's or CAH's campus.

The revised regulation now reads as follows:

489.24(a)(2)(i) When a waiver has been issued in accordance with section 1135 of the Act that includes a waiver under section 1135(b)(3) of the Act, sanctions under this section for an inappropriate transfer or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department if the following conditions are met:

(A) The transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period.
(B) The direction or relocation of an individual to receive medical screening at an alternate location is pursuant to an appropriate State emergency preparedness plan or, in the case of a public health emergency that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan.
(C) The hospital does not discriminate on the basis of an individual's source of payment or ability to pay.
(D) The hospital is located in an emergency area during an emergency period, as those terms are defined in section 1135(g)(1) of the Act.
(E) There has been a determination that a waiver of sanctions is necessary.

(ii) A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided under section 1135(e)(1)(B) of the Act.

Background

What can be Waived under Section 1135?

In accordance with Section 1135(b)(3) of the Act, hospitals and CAHs operating under an EMTALA waiver will not be sanctioned for:

- Redirecting an individual who "comes to the emergency department," as that term is defined in §489.24(b), to an alternate location for an MSE, pursuant to a State emergency preparedness plan or, as applicable, a State pandemic preparedness plan. Even when a waiver is in effect there is still the expectation that everyone who comes to the ED will receive an appropriate MSE, if not in the ED, then at the alternate care site to which they are redirected or relocated.
- Inappropriately transferring an individual protected under EMTALA, when the circumstances of the transfer are necessitated by the circumstances of the declared emergencies. Transfers may be inappropriate under EMTALA for a number of reasons.

However, even if a hospital/CAH is operating under an EMTALA waiver, the hospital/CAH would not be exempt from sanctions if it discriminates among individuals based on their ability to pay for services, or the source of their payment for services when redirecting or relocating them for the MSE making inappropriate transfers.

All other EMTALA-related requirements at 42 CFR 489.20 and EMTALA requirements at 42 CFR 489.24 continue to apply, even when a hospital is operating under an EMTALA waiver. For example, the statute does not provide for a waiver of a recipient hospital's obligation to accept an appropriate transfer of an individual protected under EMTALA. Of course, even without a waiver a hospital is obligated to accept an appropriate EMTALA transfer only when that recipient hospital has specialized capabilities required by the individual and the requisite capacity at the time of the transfer request.

We also emphasize that an EMTALA Section 1135 waiver does not affect a hospital's or CAH's obligation to comply with State law or regulation that may separately impose requirements similar to those under EMTALA law and regulations. Facilities are encouraged to communicate with their State licensure authorities as to the availability of waivers under State law.

Please note that there are many methods a hospital may use in a pandemic environment to be responsive within the requirements of EMTALA and for which the hospital does not need a waiver (e.g., use of other temporary or permanent sites on campus). Such methods are discussed in the previously-issued memorandum S&C-09-52, which may be found at: http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf).

When Can a Waiver Be Issued?

In accordance with Section 1135 of the Act, an EMTALA waiver may be issued only when:

- The President has declared an emergency or disaster pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and
- The Secretary has declared a public health emergency pursuant to Section 319 of the Public Health Service Act; and
- The Secretary has exercised her waiver authority pursuant to Section 1135 of the Act and notified Congress at least 48 hours in advance of exercising her waiver authority.

In exercising her waiver authority the Secretary may choose to delegate to the Centers for Medicare & Medicaid Services (CMS) the decision as to which Medicare, Medicaid, or CHIP requirements specified in Section 1135 should be temporarily waived or modified and for which health care providers or groups of providers such waivers are necessary. Specifically, the Secretary may delegate to CMS decision-making about whether and for which hospitals/CAHs to waive the EMTALA sanctions specified in Section 1135(b)(3).

In addition, in order for an EMTALA waiver to apply to a specific hospital or CAH:

- The hospital or CAH must activate its disaster protocol; and
- The State must have activated an emergency preparedness plan or pandemic preparedness plan in the emergency area, and any redirection of individuals for an MSE must be consistent with such plan. It is not necessary for the State to activate its plan statewide, so long as it is activated in the area where the hospital is located. It is not necessary for the State plan to identify the specific location of the alternate screening sites to which individuals will be directed, although some may do so.

How Long Does an EMTALA Waiver Last?

Except in the case of waivers related to pandemic infectious disease, an EMTALA waiver is limited in duration to 72 hours beginning upon activation of the hospital's/CAH's disaster protocol. In the case of a public health emergency involving pandemic infectious disease, the general EMTALA waiver authority will continue in effect until the termination of the declaration of the public health emergency. However, application of this general authority to specific hospital/CAH or groups of hospitals and CAHs may limit the waiver's application to a date prior to the termination of the public health emergency declaration, since case-specific applications of the waiver authority are issued only to the extent they are necessary, as determined by CMS.

Furthermore, if a State emergency/pandemic preparedness plan is deactivated in the area where the hospital or CAH is located prior to the termination of the public health emergency, the hospital or CAH no longer meets the conditions for an EMTALA waiver and that hospital/CAH waiver would cease to be in effect as of the deactivation date. Likewise, if a hospital or CAH deactivates its disaster protocol prior to the termination of the public health emergency, the hospital or CAH no longer meets the conditions for an EMTALA waiver and that hospital/CAH waiver would cease to be in effect as of the deactivation date.

What is the Process for Seeking an EMTALA Waiver?

Section 1135 provides for waivers of certain Medicare, Medicaid, or CHIP requirements, including waivers of EMTALA sanctions, but only to the extent necessary to ensure sufficient health care items and services are available to meet the needs of Medicare, Medicaid, and CHIP beneficiaries and to ensure that health care providers who provide such services in good faith but are unable to comply with one or more of the specified requirements may be reimbursed for such items and services and exempted from sanctions for noncompliance, absent any fraud or abuse.

To date, waivers exercised by the Secretary, including the waiver in effect as of the date of this memorandum, have authorized CMS to approve specific waivers. CMS policy in exercising this authority for EMTALA waivers is as follows:

> ***Localized Emergency Area:*** In the case of localized disasters, such as those related to floods or hurricanes, CMS may exercise its discretion to advise hospitals/CAHs in the affected areas that they are covered by the EMTALA waiver, without requiring individual applications for each waiver. However, hospitals or CAHs that activate their disaster protocol and expect to take advantage of the area-wide waiver must notify their State Survey Agency (SA) at the time they activate their disaster protocol.
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> ***Nationwide Emergency Area:*** In the case of a nationwide emergency area, CMS may also exercise its discretion to advise hospitals/CAHs in a specific geographical area(s) that they are covered by the EMTALA waiver *for a time-limited period*. CMS expects to do this only if the State has activated its emergency or pandemic preparedness plan in the affected area(s), and if there is other evidence of need for the waiver for a broad group of hospitals or CAHs. CMS will rely upon SAs to advise their CMS Regional Office (RO) whether and where a State's preparedness plan has been activated, as well as when the plan has been deactivated.

In the absence of CMS notification of area-wide applications of the waiver, hospitals/CAHs must contact CMS and request that the waiver provisions be applied to their facility. In all cases, the Act envisions that individuals protected under EMTALA will still receive appropriate MSEs somewhere (even if the MSE is not conducted not at the hospital or CAH where they present), and that individuals who are transferred for stabilization of their emergency medical condition will be sent to a facility capable of providing stabilizing services, regardless of whether a waiver is in effect.

Unless CMS advises otherwise, hospitals/CAHs in areas covered by time-limited, area-wide applications of the EMTALA waiver that seek to extend the waiver's application to a later date must submit individual requests for extension. The requests must demonstrate their need for continued application of the waiver. Such requests must be received at least three calendar days prior to expiration of the time-limited waiver.

Waiver Request Process

Hospitals or CAHs seeking an EMTALA waiver must demonstrate to CMS that application of the waiver to their facility is necessary, and that they have activated their disaster protocol. CMS will confirm with the SA whether the State's preparedness plan has been activated in the area where the hospital or CAH is located. CMS will also seek to confirm when the hospital activated its disaster protocol, whether other measures may address the situation in a manner that does not require a waiver, and other factors important to the ability of the hospital to demonstrate that a waiver is needed.

Requests for EMTALA waivers should be submitted electronically to the appropriate CMS Regional Office address indicated in the attachment. Additional information concerning the process for submitting all types of Section 1135 waiver requests to CMS may be found at: http://www.cms.hhs.gov/H1N1/Downloads/RequestingAWaiver101.pdf

What will CMS do in Response to EMTALA Complaints?

EMTALA enforcement is a complaint-driven process. CMS will assess any complaints/allegations related to alleged EMTALA violations concerning the medical screening examination or transfer during the period of the public health emergency to determine whether the hospital or CAH in question was operating under an EMTALA waiver at the time of the complaint, and, if so, whether the nature of the complaint involves actions or requirements not covered by the EMTALA waiver and warrants further on-site investigation.

Current situation regarding H1N1

On October 16, 2009 the CDC reported that cases of H1N1 influenza have been confirmed in all 50 States with widespread activity in 41 States. On October 1, 2009 Secretary Sebelius renewed the declaration of a public health emergency that had first been issued in April, 2009 when H1N1 initially emerged. President Obama declared a H1N1 influenza national emergency on October 23, 2009. Secretary Sebelius then exercised her Section 1135 waiver authority with a retroactive effect to October 23, 2009. The Secretary has delegated to CMS decisions as to which requirements to waive, for which providers.

We encourage hospitals and CAHs to be in very close communication with other area health care facilities and their local and State health departments to continue to monitor and update the status of their ability to appropriately screen, treat and stabilize and/or transfer individuals with emergency medical conditions.

For additional updates and guidance, continue to visit the CMS Emergency Preparedness Web site: www.**cms**.hhs.gov/H1N1

Questions about this guidance should be addressed to CDR Frances Jensen, M.D., at frances.jensen@cms.hhs.gov.

Effective Date: This information is effective immediately. It supercedes any conflicting guidance concerning EMTALA waivers found in Appendix V of the State Operations Manual, or in any prior S&C memorandum, including S&C-08-05, S&C-08-15, S&C-09-26, and S&C-09-52. Appendix V will be updated to correspond to the provisions of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators within thirty days.

/s/
Thomas E. Hamilton

Attachment: (1)

cc: Survey and Certification Regional Office Management

Attachment

E-mail Addresses – Section 1135 Waiver Requests

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.