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Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

Date November 10, 2009

AFL 09-53

TO: All Facilities

SUBJECT: 1135 Waiver Request Process

The purpose of this All Facility Letter (AFL) is to provide direction to all facilities on the process for requesting waivers under Section 1135 of the Social Security Act (42 U.S.C. 1320b-5).

Authority:

Waiver or Modification of Requirements under Section 1135 of the Social Security Act, October 27, 2009. (See Attached)

Background:

In response to the ongoing spread of the H1N1 virus, and in response to a declaration of a national public health emergency by the President of the United States, on October 27, 2009 the Secretary of Health and Human Services published the "Waiver or Modification of Requirements under Section 1135 of the Social Security Act", which provides a method for specific federal laws and/or regulations to be waived to remove barriers to facilities' response to emergent events related to the spread and treatment of the H1N1 virus. These H1N1- related waivers are herein referred to as 1135 Waivers.

1135 Waiver Process:

CMS is requiring that all 1135 Waiver requests are to be electronically submitted directly to CMS, and follow the process identified below:

1. The facility requesting the 1135 Waiver will provide to the Centers for Medicare and Medicaid Services (CMS) Regional Office (RO), at a minimum the following information, using this email address: rosfoso@cms.hhs.gov and copy the respective local CDPH District Office.
 - A letter delineating all specific, relevant federal laws or regulations for which a waiver is being sought.
 - Clear reasons and justifications for the request. (See the attached matrix for an example of types of waivers and criteria, provided by CMS.)

1135 Waiver requests for EMTALA regulations require the following verification.

- The State must have activated an emergency preparedness plan or pandemic preparedness plan in the area where the hospital is located, and
- The facility's Emergency Operations Plan (EOP) must have been activated for the specific H1N1 Waiver being requested. (Note: Activation of the facility's EOP constitutes an unusual occurrence, which must be reported to the L&C DO as required by 22 CCR 70737.)

CMS has advised the California Department of Public Health (CDPH), Licensing and Certification Program (L&C) that L&C will be included in the review process and will be tasked with providing CMS with a recommendation for each 1135 Waiver request. In order to expedite the 1135 Waiver request process, L&C asks that all facilities electronically copy their L&C District Office with all the above information at the time it is sent to CMS, and asks facilities to include all other background documentation necessary to support the 1135 Waiver request. Because L&C will be involved in the review process it is possible that a representative from the L&C District Office or CMS may contact the facility to verify and/or clarify information in the request.

2. The facility's 1135 Waiver request will undergo an expedited review process by the CMS National Validation Team, a committee established for the review of these requests, which will evaluate each request and make a determination as to whether the request will be approved or denied. CMS will track each request to ensure decisions are promptly returned to the requesting facility.
3. CMS will contact the facility directly to inform the facility of CMS's decision to approve or deny all or parts of the 1135 Waiver request, and will also notify L&C of their decision.

CMS has provided a Frequently Asked Questions (FAQ) document on the CMS H1N1 website. This FAQ document contains answers to questions from facilities across the nation, and also includes updates to this 1135 Waiver request process. All facilities are advised to review this FAQ document on a regular basis to ensure that they are current on answers to questions they may have, and that they are using the most current process for submitting 1135 Waivers. The link to the CMS website that contains this FAQ document is <http://www.cms.hhs.gov/h1n1/> .

Note: At this time CMS will not approve anticipatory waivers (waiver requests prior to an actual need) or any blanket waivers (waivers for whole regions or waivers for all facilities of a particular provider type).

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Note: All HIPAA related 1135 Waiver requests must be sent to:

Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHH Bldg.
Washington, D.C. 20201

If you have questions about this AFL, please contact your local L&C District Office.

Sincerely,

ORIGINAL SIGNED BY KATHLEEN BILLINGSLEY, R.N.

Kathleen Billingsley, R.N.
Deputy Director
Center for Health Care Quality

Attachments