

CMS SECTION 1135 WAIVER REQUESTS

PREREQUISITES FOR A SECTION 1135 WAIVER

There are four requirements that must be met before a hospital or other health care facility can obtain a waiver under Section 1135 of the Social Security Act.

1. The President has declared an emergency or disaster under the Stafford Act or the National Emergencies Act.
2. The Secretary of U.S. Department of Health and Human Services (HHS) has declared a Public Health Emergency (PHE) under Section 319 of the Public Health Service Act.
3. The Secretary of HHS has invoked authority under Section 1135 of the Social Security Act and authorized the Centers for Medicare & Medicaid Services (CMS) to waive sanctions for certain regulations that arise as a result of the circumstances of the emergency.
4. The hospital in the affected area has documented implementation of its hospital disaster protocol.

WAIVERS AVAILABLE UNDER SECTION 1135

When the President declares a major disaster or an emergency and the HHS Secretary declares a public health emergency, the Secretary is authorized to take certain actions in addition to his regular authorities. The Secretary has the authority to waive or modify certain federal laws and regulations. Examples of these 1135 waivers or modifications include:

- Conditions of participation or certification under Medicare, Medicaid and State Children's Health Insurance Program (SCHIP)
- Preapproval requirements under Medicare, Medicaid and State Children's Health Insurance Program
- State licenses for physicians and other health care professionals (this waiver is for purposes of Medicare, Medicaid and SCHIP reimbursement only — the state determines whether a nonfederal provider is authorized to provide services in the state without state licensure)
- Emergency Medical Treatment and Labor Act (EMTALA) sanctions for:
 - redirection of an individual to another location to receive a medical screening examination
 - pursuant to a state emergency preparedness plan
 - in the case of a public health emergency that involves a pandemic infectious disease, pursuant to a state pandemic preparedness plan
 - transfer of an individual who has not been stabilized if the transfer arises out of emergency circumstances.

A waiver of EMTALA requirements is effective only if actions under the waiver do not discriminate based on a patient's source of payment or ability to pay.

- Stark self-referral sanctions
- Performance deadlines and timetables may be adjusted (but not waived).

- Limitations on payments for health care items and services to permit Medicare+Choice enrollees to use out-of-network providers in an emergency situation

In addition, the Secretary may waive Health Insurance Portability and Accountability Act sanctions and penalties relating to the following:

- Obtaining a patient’s consent to speak with family members or friends
- Honoring a patient’s request to opt out of the facility directory
- Distributing a note of privacy practices
- Honoring the patient’s right to request privacy restrictions or confidential communications

The waiver of HIPAA requirements is effective only if actions under the waiver do not discriminate based on a patient’s source of payment or ability to pay.

In addition to the 1135 waiver authority, Section 1812(f) of the Social Security Act (the Act) authorizes the Secretary to provide for skilled nursing facility coverage in the absence of a qualifying hospital stay, as long as this action does not increase overall program payments and does not alter the SNF benefit’s “acute care nature” (that is, its orientation toward relatively short-term and intensive care).

DURATION OF A SECTION 1135 WAIVER

These waivers under Section 1135 of the Social Security Act typically end with the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the Secretary of HHS extends the waiver by notice for additional periods of up to 60 days.

Waivers for EMTALA (for 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 emergency. The waiver for licensure applies only to federal requirements and does not automatically apply to state requirements for licensure or conditions of participation.

A waiver or modification of requirements may, at the Secretary’s discretion, be made retroactive to the beginning of the emergency period or any subsequent date in such period specified by the Secretary.

PROCEDURE FOR OBTAINING A SECTION 1135 WAIVER

Blanket Waivers

According to CMS, when CMS issues a national “blanket waiver” there is nothing else the state or health care provider must do to be considered a part of the waiver and for the waiver to be considered in-effect.

Individual CMS Waiver Requests

Once a Section 1135 Waiver authority is authorized, states or individual 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.

In Missouri, there are no formal procedures for obtaining a Section 1135 Waiver. The Missouri Department of Health and Senior Services monitors the situation to determine when CMS should be contacted. Individual providers and hospital requests can be made by sending an email request to DHSS/state agency or sending an email to the designated CMS contact overseeing Missouri, or by calling the CMS Regional Office. Information on your facility and justification for requesting the waiver will be required (see below). Providers and hospitals making a request to CMS also should copy the DHSS/state agency. CMS will review and validate the Section 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.

- email addresses for CMS Midwest Consortium: ROCHISC@cms.hhs.gov
- Missouri Department of Health and Senior Services, Regulation and Licensures:
William.Koebel@health.mo.gov or David.Lanigan@health.mo.gov
912 Wildwood
P.O. Box 570
Jefferson City, MO 65102
Phone: 573-751-6400
Fax: 573-751-6010

1135 Waiver Request Format

The provider or hospital requesting the Section 1135 Waiver should provide responses to the following basic questions:

- Provider Name/Type
- Full Address (including county/city/town/state)
- CCN (Medicare provider number)
- Contact person and his or her contact information for follow-up questions should the region/department need additional clarification
- Brief summary of why the waiver is needed. For example: Waving the three-night qualifying stay for a transfer to a SNF. Another example would be critical access hospital is sole community provider without reasonable transfer options at this point during the specified emergent event (e.g., flooding, tornado, fires or flu outbreak). CAH needs a waiver to exceed its bed limit by X number of beds for Y days/weeks (be specific).
- Consideration — Type of relief you are seeking or regulatory requirements or regulatory reference that the requestor is seeking to be waived.
- There is no specific form or format that is required to submit the information, but it is helpful to clearly state the scope of the issue and the impact.

Determining If Waivers Are Necessary

In determining whether to invoke a Section 1135 Waiver (once the conditions precedent to the authority's exercise have been met), the Assistant Secretary for Preparedness and Response with input from relevant OPDIVS determine the need and scope for such modifications. Information considered includes requests from governor's offices, feedback from individual health care providers and associations, and requests to regional or field offices for assistance. CMS will review and validate the Section 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.

Resources

- Further information on the Section 1135 Waiver process can be found at: [CMS 1135 Waivers at A Glance](#)
- For information on the waivers CMS has granted: www.cms.gov/emergency
- The email address to submit questions about Section 1135 Waivers: 1135waiver@cms.hhs.gov