

# Waiver 1135 Toolkit

Waivers may be administered during an emergency by regulatory agencies. Waivers allow health care providers to temporarily streamline their work and ensure patients continue to have safe access to care. Waivers are time limited in scope and allow for flexibility to meet deadlines and offer the possibility of extending deadlines but not eliminating them.

In an emergency an 1135 Waiver an emergency may be declared by the Federal government and can be requested by a State for an individual provider. An 1135 waiver happens when the following occur:

1. The U.S. President declares a disaster or emergency under the Stafford Act and the National Emergencies Act.
2. The U.S. Department of Health and Human Services declares a public health emergency.

The 1135 waiver is for waiving or modifying the regulations that speak to the *provision of care* and does not apply to *conditions of payment*. An example of this is the face to face encounter does not fall under the 1135 waiver because it is considered a condition of payment. If the hospice is not able to meet these types of requirements they should contact the CMS regional office to look to have this tracked and modified. For Minnesota the Regional CMS Office is in Chicago and can be reached at [ROCHlfm@cms.hhs.gov](mailto:ROCHlfm@cms.hhs.gov). Conditions of care that may be waived under an 1135 include:

Conditions of care provisions that may be waived or modified under the 1135 Waiver include:

- Certain conditions of participation certification requirements, program participation or similar requirements for individual health care providers or types of health care providers.
- Requirements that physicians and other health care professionals hold licenses in the state in which they provide services if they have a license from another state (and are not affirmatively barred from practice in that state or any state in the emergency area) for purposes of Medicare, Medicaid, and CHIP reimbursement only.

- Deadlines and time tables for performance of required activities to allow timing of such deadlines to be modified.
- Sanctions and penalties arising from noncompliance with HIPAA privacy regulations relating to:
  - Obtaining a patient's agreement to speak with family members or friends
  - Honoring a patient's request to opt out of the facility directory

The 1135 waiver is limited in scope in respect to time. The waiver usually ends when the disaster or emergency situation is over, or in 60 days from the original issuance of the waiver unless additional 60 day periods are required to be added.

### **Best Practices**

Hospices need to have in place policies and procedures that address the role of the hospice under a situation where the Secretary declares a disaster or emergency in which an 1135 waiver applies. An example of a policy and procedure for an 1135 waiver is included in the procedure template below. Best practices for an 1135 waiver includes identifying potential waivers that may be necessitated for the hospice ahead of time. The hospice should also designate a person or better, a group of people who would be responsible for submitting and tracking waiver requests. This lead person(s) would also be in charge of physicians or other health care providers who are covered by the waiver and not under the employ of the hospice.

## **Example Procedure: Request to Operate Under a CMS 1135 Waiver Procedure**

### **Scope**

Applies to employees at any site located in a county included in a presidential declaration of emergency or disaster and 1135 waiver scope when unable to operate in compliance with Centers for Medicare and Medicaid Services (CMS) requirements due to impact of a disaster.

### **Purpose**

To provide instructions for submitting a request to operate under a CMS 1135 waiver when the President of the United States declares a disaster or emergency under the Stafford Act or National Emergencies Act and the Secretary of Department of Health and Human Services (HHS) declares a public health emergency under Section 319 of the Public Health Service Act.

## Procedure

If the site is impacted by a disaster to a degree that compliance to CMS requirements is not possible, at the request of the Healthcare Incident Command System (HICS) Incident Commander or the [ ], the Compliance Officer or the [ ] will submit a request to operate under an 1135 waiver authority to the CMS Regional Office and State Survey Agency via email (preferred method).

<p>HICS Incident Commander or [ ]</p>	<p>1. Contact Office of Integrity and Compliance and ask them to request an 1135 waiver.</p>
<p>Compliance Officer or [ ]</p>	<p>2. Draft email to appropriate CMS Regional Office and State Survey Agency that contains:</p> <ul style="list-style-type: none"> <li>a. Facility Name</li> <li>b. Full Mailing Address (including county)</li> <li>c. CMC Certification Number (CCN)</li> <li>d. Facility Contact Name and Information</li> <li>e. Explanation of why the waiver is needed. <ul style="list-style-type: none"> <li>• Example: Facility is sole community provider without reasonable transfer options at this point during the specified emergent event (e.g. flooding, tornado, fires, or flu outbreak). Facility needs a waiver to exceed its bed limit by X number of beds for Y days/weeks (be specific).</li> </ul> </li> <li>f. The scope of the issue and the impact it has on the entity</li> <li>g. The type of relief the facility is seeking or the regulatory requirement(s)/reference(s) the facility is seeking to have waived <ul style="list-style-type: none"> <li>• Examples include: <ul style="list-style-type: none"> <li>a. Requests by hospitals to provide screening/triage of patients at a location offsite from the hospital's</li> </ul> </li> </ul> </li> </ul>

	<p>campus;</p> <p>b. Hospitals housing patients in units not otherwise appropriate under the Medicare Conditions of Participation or for a duration that exceeds regulatory requirements;</p> <p>c. Hospitals or nursing homes requesting increases in their certified bed capacity.</p> <p>h. Assure processes are in place to keep careful records of CMS beneficiaries to whom services are provided to assure proper payment may be made.</p> <p>i. Return to compliance as soon as possible and by the end of the approved operational period or end of the emergency period.</p> <p>3. Submit email with Request to Operate under an 1135 waiver authority to appropriate CMS Regional Office and State Survey Agency :</p> <p>a. CMS Regional Office</p> <ul style="list-style-type: none"> <li>• Minnesota: <a href="mailto:ROCHlfm@cms.hhs.gov">ROCHlfm@cms.hhs.gov</a></li> </ul> <p>b. State Survey Agency</p> <ul style="list-style-type: none"> <li>• Minnesota: <a href="mailto:health.fpc-licensing@state.mn.us">health.fpc-licensing@state.mn.us</a>/651.201.4101</li> </ul>
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## Procedural Notes

- If the required emergency declarations have been satisfied, the HHS assistant secretary for preparedness and response will coordinate with HHS and Centers for Medicare and Medicaid Services (CMS) offices to determine the need for and scope of the 1135 waiver. The assistant secretary considers requests from governors' offices, individual healthcare providers and associations, and regional and field HHS and CMS offices.
- At least two days before formally exercising Section 1135 waiver authority, the secretary must provide a certification and notice to Congress that describes the specific provision to be waived or modified, the healthcare providers to whom the waiver will apply, the geographic area in which the waiver or modification will apply,

the period of time the modification will be in effect, and a statement that the waiver or modification is necessary to achieve the purposes of the Social Security Act.

- Social Security Act Section 1135 does not provide immunity from liability.
  - Section 1135 provides for waivers and modifications of certain SSA program requirements, which are limited in time and geographic scope during an emergency event declared by the HHS secretary and the president.
  - Section 1135 waivers are intended to temporarily reduce administrative burdens and increase flexibility of service providers during a declared emergency with the goal of promoting greater access to care by individuals affected by the emergency
- Once the 1135 waiver has been authorized, service providers' requirements are not automatically waived or modified.
  - CMS implements the waiver by determining on a case-by-case basis whether and the extent to which sufficient grounds exist for waiving requirements with respect to a particular provider, a group or class of providers, or a geographic area.
    - CMS reviews specific 1135 waiver requests with a cross-regional waiver validation team.
    - Absent a waiver, other SSA provisions and CMS regulations can provide flexibility to providers during emergencies.
- Only certain federal requirements relating to Medicare, Medicaid, SCHIP, and HIPAA may be waived or modified under Section 1135. A waiver does not affect state laws or regulations, including those for licensure and conditions of participation.
- Examples of 1135 waiver or modifications include:
  - Conditions of participation or other certification requirements
  - Program participation and similar requirements
  - Preapproval requirements
  - Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State (this waiver is for purposes of Medicare, Medicaid, and CHIP reimbursement only – state law governs whether a non-Federal 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 receive a medical screening examination in an alternative location pursuant to a state emergency preparedness plan (or in the case of a public health emergency involving pandemic infectious disease, a state pandemic preparedness plan) or transfer of an individual who has not been stabilized if 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.
  - HIPAA—Sanctions arising from noncompliance with HIPAA privacy regulations relating to: 1) obtaining a patient's agreement to speak with family or friends or honoring a patient's request to opt out of the facility directory; 2) distributing a

notice of privacy practices; or 3) the patient's right to request confidential communications.

- The waiver is effective only if actions under the waiver do not discriminate as to source of payment or ability to pay.
- Physician self-referral sanctions (Stark)
- Performance deadlines and timetables may be adjusted (but not waived).
- Limitations on payment to permit Medicare enrollees to use out of network providers in an emergency situation
- Waivers typically end no later than 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, up to the end 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.
- The 1135 waiver authority applies only to Federal requirements and does not apply to State requirements for licensure or conditions of participation.

## Related Document(s)

[US DHHS Office for Civil Rights Bulletin: HIPAA Privacy in Emergency Situations](#)

## References

[CMS Emergency Preparedness Rule](#)

[FAQ - 1135 Waiver Process](#)

[Section 1135 EMTALA Waiver Toolkit](#)

[Waiver or Modification of Requirements under Section 1135 of the Social Security Act \(Current & Previous Waivers\)](#)

## Owner

Jane Doe

## Contact

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## Revision History

Date	Synopsis of Change

- Distributing a notice of privacy practices
- Honoring the patient's right to request privacy restrictions or confidential communications