# 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.

## Equipment/Supplies

N/A

## Procedure

If the site is impacted by a disaster to a degree that compliance to CMS requirements is unavoidable, at the request of the [Insert Senior Leadership Designation] or Healthcare Incident Command System (HICS) Incident Commander, the [Office of Integrity and Compliance] will submit a request to operate under an 1135 waiver authority to the CMS Regional Office and State Survey Agency via email (preferred method).

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| [Senior Leadership] or HICS Incident Commander | 1. Contact Office of Integrity and Compliance and ask them to request an 1135 waiver.
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| [Office of Integrity and Compliance] | 1. Draft email to appropriate CMS Regional Office and State Survey Agency that contains:
2. Facility Name
3. Full Mailing Address (including county)
4. CMC Certification Number (CCN)
5. Facility Contact Name and Information
6. Explanation of why the waiver is needed.
7. 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).
8. The scope of the issue and the impact it has on the entity
9. The type of relief the facility is seeking or the regulatory requirement(s)/reference(s) the facility is seeking to have waived
10. Examples include:
11. Requests by hospitals to provide screening/triage of patients at a location offsite from the hospital’s campus;
12. Hospitals housing patients in units not otherwise appropriate under the Medicare Conditions of Participation or for a duration that exceeds regulatory requirements;
13. Hospitals or nursing homes requesting increases in their certified bed capacity.
14. Assure processes are in place to keep careful records of CMS beneficiaries to whom services are provided to assure proper payment may be made.
15. Return to compliance as soon as possible and by the end of the approved operational period or end of the emergency period.
16. Submit email with Request to Operate under an 1135 waiver authority to appropriate CMS Regional Office and State Survey Agency :
17. CMS Regional Office

1. MN/WI: ROCHIfm@cms.hhs.gov2. IA: rokcmmfm@cms.hhs.gov1. State Survey Agency

1. IA: 515.281.4233/fax: 515.242.6863 ATTN: Administrator, Health Facilities Division/email: dawn.fisk@dia.iowa.gov 2. MN: health.fpclicensing@state.mn.us /651.201.41013. WI: 608.366.0269/fax: 608.267.0352 |

## Troubleshooting

N/A

## Procedural Notes

* If the required emergency declarations have been satisfied, then 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](https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/hipaa-privacy-emergency-situations.pdf)

## Definitions

N/A

## References

[CMS Emergency Preparedness Rule](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html)

[FAQ - 1135 Waiver Process](https://www.ahcancal.org/facility_operations/disaster_planning/Documents/CMS%20Issues%20update%20to%20the%20FAQ%20for%20the%201135%20Waivers.pdf)

[Section 1135 EMTALA Waiver Toolkit](https://www.healthlawyers.org/Members/PracticeGroups/THAMC/EmergencyPreparednessToolkit/Documents/III_EMTALA/A_EMTALAWaiverToolkit.pdf)

[Waiver or Modification of Requirements Under Section 1135 of the Social Security Act (Current & Previous Waivers)](https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx)

## Owner

[Insert Policy Owner]

## Contact

[Insert Policy Owner Contact Information]

## Revision History

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| --- | --- |
| Date | Synopsis of Change |
|  |  |
|  | Approval for need to establish document:   |