

CMS

ALTERNATE CARE SITE & 1135 WAIVER REQUIREMENTS

COMPLIANCE RECOMMENDATIONS FOR HOSPITALS

To comply with the CMS Conditions of Participation for Emergency Preparedness, a hospital's emergency management plan must include policies and procedures addressing its role in the provision of care and treatment at an alternate care site under an 1135 waiver. These policies and procedures should also demonstrate the organization's awareness of the 1135 waiver process.

This document includes a summary of these requirements, recommendations for compliance, guidance on requesting and operating under an 1135 waiver, and sample policies and procedures.

The Iroquois Healthcare Association document: [Temporary Suspension or Modification of Statutes & Regulations in NYS During Emergencies: A Guide For Healthcare Providers](#) provides additional 1135 waiver information.



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1. SUMMARY

To be compliant with the CMS Emergency Preparedness Rule, a hospital's emergency preparedness policies and procedures must address its role in the provision of care and treatment at an alternate care site under an 1135 waiver, and should demonstrate the organization's awareness of the 1135 waiver process.¹

In accordance with section 1861(e)(9) of the Social Security Act and 42 CFR 482.15(b)(8), inpatient hospital policies and procedures must address the role of the hospital under a waiver declared by the HHS Secretary, in accordance with section 1135 of the Act, for the provision of care and treatment at an alternate care site (ACS) identified by emergency management officials.

CMS states within the commentary section of the rule its expectation that state or local emergency management officials conduct joint planning with hospitals on issues related to staffing, equipment and supplies at such alternate sites. This requirement encourages health care providers to collaborate with their local emergency officials in proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted.

Under section 1135 of the Social Security Act, the Secretary is authorized to temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements for healthcare providers to ensure that sufficient healthcare items and services are available to meet the needs of individuals enrolled in these programs in an emergency area. Under an 1135 waiver, healthcare providers unable to comply with one or more waiver-eligible requirements may be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).

CMS' interpretive guidance further states that these policies and procedures should address what coordination efforts are required during a declared emergency in which an 1135 waiver is granted. Surveyors are instructed to verify that such policies and procedures are included in the hospital's emergency plan (e.g. emergency operations plan or comprehensive emergency management plan).

The Joint Commission [EM.02.01.01 EP 14] and Healthcare Facilities Accreditation Program [09.01.11] both updated their standards in 2017 to incorporate this CMS provision.

¹ This requirement also applies to: Critical Access Hospitals (CAH); Long Term Care Facilities (LTCF), Religious Nonmedical Health Care Institutions; Ambulatory Surgical Centers Hospices; Psychiatric Residential Treatment Facilities (PRTFs); Programs of All-Inclusive Care for the Elderly (PACE); Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID); Community Mental Health Centers (CMHCs); and End-Stage Renal Disease (ESRD) Facilities.



2. 1135 WAIVER INFORMATION

Purpose

- To ensure sufficient health care services and resources are available to meet the needs of Medicare, Medicaid and CHIP beneficiaries during emergencies and disasters;
- Allow health care providers to be reimbursed and not subjected to sanctions when unable to comply with certain requirements during an emergency or disaster.

Authority

- When the President declares an emergency under the Stafford Act or National Emergencies Act, and the HHS Secretary declares a public health emergency under Section 319 of the Public Health Service Act, the Secretary is granted additional authorities including waiving or modify certain Medicare, Medicaid, and CHIP requirements under section 1135 of the Social Security Act.
- Once an 1135 waiver is authorized, healthcare providers may submit requests to their State Survey Agency (DQA) to operate under the authority of the waiver.

Scope

- Applies only to waiver of federal requirements; does not waive state requirements;
- Effective up to 60 days or the end of the emergency period; may be extended up to 60 days.
- Can be issued as “blanket waivers,” which apply to all similarly-situated providers and facilities within the emergency period and geographic area based on state need;
- Does not allow reimbursement for services otherwise not covered.

Examples

- HIPAA requirements and sanctions relating to obtaining a patient privacy rights;
- Conditions of Participation or certification requirements (e.g. requirement that providers be certified as Medicaid providers before emergency declaration); and expedited provider enrollment;
- Preapproval requirements for providers, health care items, or services;
- Requirements that physicians and other health care professionals be licensed in the state;
- EMTALA requirements relating to transport for medical screening and non-stable patient transfer;
- Stark self-referral sanctions (i.e. referral to a provider in which the physician has a financial stake);
- Performance deadlines and timetables adjustments.

Additional Resources

- CMS Quality, Safety & Oversight [website](#) includes an [overview](#) document information on [waiver requests](#) and [information to provide](#). CMS Emergency Preparedness and Response [website](#) includes factsheets on policies that may be implemented [only with a waiver](#) and [without a waiver](#).
- Iroquois Healthcare Association’s [document](#) “Temporary Suspension or Modification of Statutes and Regulations in NYS During Emergencies: A Guide For Healthcare Providers” provides additional 1135 Waiver information, including a CMS FAQ document (C.12 p. 79) and examples of Public Health Emergency Declarations and 1135 Waivers (C.13 p. 119).



3. EMERGENCY PREPAREDNESS RULE PROVISIONS

Below are relevant sections of the CMS Emergency Preparedness rule, interpretive guidance and survey procedures applicable to hospitals.

§ 482.15 Condition of Participation: Emergency Preparedness

The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

- (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.
- (2) Include strategies for addressing emergency events identified by the risk assessment.
- (3) Address patient population, including, but not limited to, persons at-risk; the type of services the hospital has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
- (4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

- (8) The role of the hospital under a waiver declared by the Secretary , in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

Interpretive Guidance

Facilities must develop and implement policies and procedures that describe its role in providing care at alternate care sites during emergencies. It is expected that state or local emergency management officials might designate such alternate sites, and would plan jointly with local facilities on issues related to staffing, equipment and supplies at such alternate sites. This requirement encourages



providers to collaborate with their local emergency officials in such proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted.

Facility's policies and procedures must specifically address the facility's role in emergencies where the President declares a major disaster or emergency under the Stafford Act or an emergency under the National Emergencies Act, and the HHS Secretary declares a public health emergency. Examples of 1135 waivers include some of the existing Conditions of Participation; Licensure for Physicians or others to provide services in the affected state; EMTALA; Medicare Advantage out-of-network providers; and HIPAA.

Facilities policies and procedures should address what coordination efforts are required during a declared emergency in which a waiver of federal requirements under section 1135 of the Act has been granted by the Secretary. For example, if due to a mass casualty incident in a geographic location, an 1135 waiver may be granted to waive licensure for physicians in order for these individuals to assist at a specific facility where they do not normally practice, then the facility should have policies and procedures which outline the responsibilities during the duration of this waiver period. For instance, the policies may establish a lead person in charge for accountability and oversight of assisting physicians not usually under contract with the facility.

Additionally, facilities should also have in place policies and procedures which address emergency situations in which a declaration was not made and where an 1135 waiver may not be applicable, such as during a disaster affecting the single facility. In this case, policies and procedures should address potential transfers of patients; timelines of patients at alternate facilities, etc.

Survey Procedures

Verify the facility has included policies and procedures in its emergency plan describing the facility's role in providing care and treatment (except for RNHCI, for care only) at alternate care sites under an 1135 waiver.



4. RECOMMENDATIONS FOR COMPLIANCE

There is no specific format or template designated by CMS or accreditation agencies for developing policies and procedures to meet this requirement. Sample policies and procedures are included in Section 5 of this document.

The policy (or policies) and procedures should be included as part of the hospital's emergency operations plan or comprehensive emergency management plan.

Relevant sections of the emergency operations plan or comprehensive emergency management plan should reference the alternate care site/1135 waiver policy (or policies) and procedures. Relevant sections may include:

- Evacuation
- Alternate Triage Site
- Mass Casualty
- Continuity of Operations

Some best practices for developing a policy and procedures for identifying the role of the hospital under an 1135 waiver include the following elements and considerations:

- Determine the hospital's role in providing care and treatment at alternate site (e.g. equipment and supplies, command and control, staffing). This should be done in collaboration with emergency management, public health and other preparedness partners.
- Develop a clear delineation of authority and responsibility among partners to establish and provide quality care through the ACSs. Determinations should be made relating to pre-designated sites, staffing, equipment, supplies, and emergency credentialing procedures for providers to practice at alternate site if waiver does not cover provider licensure.
- Designate a person or group 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 hospital.
- Demonstrate that the facility has an awareness of the 1135 waiver process and what may be required in the event of needing to request a waiver. These include:
 - The procedure for applying for an 1135 waiver and contact information for the CMS Regional Office (ROPHIDSC@cms.hhs.gov) and State Survey Agency.
 - Basic hospital information including:
 - Provider name and address;
 - Provider type;
 - CCN (Medicare provider number);
 - Contact person, telephone and cell phone numbers, and email address;



- Provide sufficient information to justify actual need. Include:
 - A brief but specific summary of why the waiver is needed (e.g. CAH is sole community provider without reasonable transfer options during the specified emergent event. CAH needs a waiver to exceed its bed limit by X number of beds for Y days/weeks);
 - The type of relief you are seeking or regulatory requirements or regulatory reference that the requestor is seeking to be waived; and
 - The scope of the issue, and the impact of the disaster in terms of patients needing care and the hospital’s ability to provide required services.
- Expectations for providers granted waivers:
 - Providers and suppliers will be required to keep careful records of beneficiaries to whom they provide services in order to ensure that proper payment may be made’
 - Providers must resume compliance with normal rules and regulations as soon as they are able to do so, and within the waiver’s termination date.
- Identify potential waivers that may be necessitated ahead of time (see Iroquois [document](#) “Temporary Suspension or Modification of Statutes and Regulations in New York State During Emergencies: A Guide For Healthcare Providers”).



5. SAMPLE POLICIES AND PROCEDURES

Sample Policy and Procedures 1: Requesting a Section 1135 Waiver from CMS

(Adapted from Kentucky Hospital Association Sample Procedure)

1. Prerequisites for a Section 1135 Waiver

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

- A. The President has declared an emergency or disaster under the Stafford Act or the National Emergencies Act,
- B. The Secretary of HHS has declared a Public Health Emergency (PHE) under Section 319 of the Public Health Service Act,
- C. The Secretary of HHS has invoked his authority under Section 1135 of the Social Security Act and authorized CMS to waive sanctions for certain EMTALA violations that arise as a result of the circumstances of the emergency, and
- D. The hospital in the affected area has implemented its hospital disaster protocol.

2. 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. 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 (SCHIP)
- State licenses for physicians and other healthcare professionals (this waiver is for purposes of Medicare, Medicaid, and SCHIP reimbursement only – the state determines 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 another location to receive a medical screening examination pursuant to a state emergency preparedness plan or 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 on the basis of 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 payment 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 (HIPAA) 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 HIPPA 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.

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 (SNF) 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).

3. Duration of a Section 1135 Waiver

These waivers under section 1135 of the Social Security Act typically ends 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.

4. Procedure for Obtaining a Section 1135 Waiver

Currently, there are no proscribed procedures for obtaining a Section 1135 waiver. During a disaster or emergency situation, the state survey agency and ASPR will be monitoring the situation to determine when CMS should be contacted. If a hospital has a problem potentially worthy of a Section 1135 waiver, it should contact NYSDOH and provide the relevant information. The state survey agency will then work with CMS who would then decide whether to recommend a waiver to the HHS Secretary.

The provider should submit a waiver request directly to the CMS Regional Office; they should also provide a copy to the appropriate state survey agency. When the state survey agency receives this copy, they will work with CMS to ensure there are no issues or conflicts with state laws, regulations, or requirements. The state survey agency will contact CMS and the facility to ensure communication and coordination is as smooth as possible in an emergency situation.

- Email Addresses for CMS Regional Office ROATLHSQ@cms.hhs.gov
- State survey agency:

5. 1135 Waiver Request Format

The specific provider requesting the 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 need additional clarification



- Brief summary of why the waiver is needed. For example: CAH 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.
- If a waiver is requested, the information should come directly from the impacted provider to the appropriate CMS Regional Office mailbox with a copy to the appropriate State Agency for Health Care Administration to make sure the waiver request does not conflict with any State requirements and all concerns are addressed timely.

6. Determining If Waivers Are Necessary

In determining whether to invoke an 1135 waiver (once the conditions precedent to the authority's exercise have been met), the Assistant Secretary for Preparedness and Response (ASPR) with input from relevant OPDIVS determine the need and scope for such modifications. Information considered includes requests from Governor's offices, feedback from individual healthcare providers and associations, and requests to regional or field offices for assistance.

CMS will review and validate the 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.

7. How States or Individual Healthcare Providers Can Ask for Assistance On A Waiver

Once an 1135 Waiver is authorized, health care providers can submit requests to operate under that authority or for other relief that may be possible outside the authority to the CMS Regional Office with a copy to the State Survey Agency. Request can be made by sending an email to the CMS Regional Office. The Email address is listed in Section 4. Information on your facility and justification for requesting the waiver will be required.

8. Implementation Of 1135 Waiver Authority

Providers must resume compliance with normal rules and regulations as soon as they are able to do so and in any event the waivers or modifications a provider was operating under are no longer available after the termination of the emergency period. Federally certified/approved providers must operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.



Sample Policy and Procedures 2: Requesting a Section 1135 Waiver from CMS

(Adapted from Nevada Hospital Association Sample Policy and Procedures)

CMS Tag #: 0026

Manual: Emergency Management (EM)

TJC Ref: EM.02.01.01 Item # 14 (CAMH, Standard EC.4.14, EPs 10 and 11, p. EC-13d)

Policy Summary: During disasters, [hospital] may need to request an 1135 waiver to address care and treatment at an alternative care site identified by emergency management officials or to receive temporary administrative flexibility from various federal regulations. Examples of regulatory requirements that can be modified with an 1135 waiver, for a defined period of time includes Medicare, Medicaid, Children’s Health Insurance Program, Health Insurance Portability and Accountability Act.

Definitions: 1135 waivers are emergency, temporary waivers granted by the US Health and Human Services (HHS) Secretary to healthcare facilities or blanket waivers for specific disaster area, during the time of disaster. These waivers are authorized under section 1135 of the Social Security Act. Waivers can only be issued following a Presidential disaster declaration under the Stafford Act or National Emergencies Act and the HHS Secretary has declared a public health emergency under section 319 of the Public Health Service Act.

Requirements:

1. The President of the United States has declared a federal disaster that includes the service area of our facility and the HHS Secretary has declared a public health emergency within our service area.
2. The CEO, or designee, has determined that certain regulatory flexibilities are necessary to help [hospital] fulfill our mission and to service the healthcare needs of area residents, visitors and disaster victims.

Purpose: The purpose of 1135 waivers are to ensure that federal regulations do not needlessly infringe on an immediate need to provide health and medical services to individuals effected by a large-scale disaster.

Examples of the type of relief that can be requested through the 1135 waiver process are:

Hospitals and Critical Access Hospitals: Waiver of EMTALA sanctions for direction or relocation or of an individual to receive medical screening examination in an alternative location pursuant to an appropriate state emergency preparedness plan, state pandemic plan or state crisis standards of care plan or transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared emergency. Any waiver of EMTALA requirements are only effective if the actions taken under the waiver do not discriminate on the basis of the patient’s source of payment or ability to pay.

Skilled Nursing Facilities: 1812(f): Waiver of the requirement for a 3-day prior hospitalization for coverage of a skilled nursing facility stay provides temporary emergency coverage of Skilled Nursing Facility (SNF) services without a qualifying hospital stay, for those people who are evacuated, transferred, or otherwise dislocated as a result of the effect of a disaster or emergency. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start a new benefit period.

483.20: Waiver to provide relief to Skilled Nursing Facilities on the timeframe requirements for Minimum Data Set assessments and transmission.



Home Health Agencies: 484.20(c)(1): Waiver to provide relief to Home Health Agencies on the timeframes related to OASIS Transmission.

Critical Access Hospitals: Waiver of the requirements that Critical Access Hospitals limit the number of beds to 25, and that the length of stay be limited to 96 hours.

Housing Acute Care Patients in Excluded Distinct Part Units: Allow the authority to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute care inpatient. The inpatient prospective payment system (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.

Durable Medical Equipment: Allow the authority to suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) where DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable. Under this waiver, the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required for replacement. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable as a result of the disaster or emergency.

Allows CMS to temporarily extending the 10-business day deadline to provide notification of any subcontracting arrangements. During the temporary extension period, affected contract suppliers will have 30 business days to provide notice to the Competitive Bidding Implementation Contractor of any subcontracting arrangements.

Replacement Prescription Fills: Medicare payment may be permitted for replacement prescription fills (for a quantity up to the amount originally dispensed) of covered Part B drugs in circumstances where dispensed medication has been lost or otherwise rendered unusable by damage due to the disaster or emergency.

Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital: Allows IPPS and other acute care hospitals with excluded distinct part inpatient psychiatric units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit. The hospital should continue to bill for inpatient psychiatric services under the inpatient psychiatric facility prospective payment system for such patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the hurricane. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.

Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital: Allows IPPS and other acute care hospitals with excluded distinct part inpatient Rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit. The hospital should continue to bill for inpatient rehabilitation services under the inpatient rehabilitation facility prospective payment system for such patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster



or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.

Ensuring Correct Processing of Home Health Disaster Related Claims: Allows MACs to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.

Procedure:

1. The CEO, or designee, has determined the need to request an 1135 waiver.
2. The CEO, or designee, delegates responsibility to draft request letter to CMS. There is no specific form or format that is required but the letter should clearly state the scope of the issue and the impact on the facility. The request letter shall at a minimum include:
 - A. Facility's Full Name and Type
 - B. Full Address
 - C. Medicare Provider (CCN) Number (s)
 - D. Authorized contact person at the facility and contact information (phone, fax, email) for follow-up and clarification questions from the CMS Region
 - E. Brief Summary of why the waiver is needed. Example: CAH is sole community provider without reasonable transfer options at this point during the specified emergency event. CAH needs a waiver to exceed its bed limit by _ number of beds for _days/weeks (be as specific as possible).
 - F. Consideration: Specify the type of relief you are seeking and/or the regulatory requirement that you are seeking to be waived.
3. The CEO, or designee, should sign the letter and forward directly to the following agencies via email:
 - A. The CMS Regional Office:
 - B. State Survey Agency:
 - C. Hospital associations: Consider copying hospital associations (or other applicable association) who can help follow the status of the waiver on your behalf, as well as provide update on the overall healthcare system.
 - D. The facility must resume compliance with normal rules and regulations as soon as possible, and in any event if the waivers or modifications extended and the facility is operating under are no longer available or expired.
 - E. The facility must operate under the normal rules and regulations, unless a waiver has been requested and granted modifications under the waiver authority, from specific requirements.



Sample Policy and Procedures 3: Requesting a Section 1135 Waiver from CMS

(Adapted from American Health Lawyers Association Sample 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 [insert], the Compliance Officer or the [insert] will submit a request to operate under an 1135 waiver authority to the CMS Regional Office and State Survey Agency via email (preferred method).

HICS Incident Commander or [insert]	1. Contact Office of Integrity and Compliance and ask them to request an 1135 waiver.
Compliance Officer or [insert]	2. Draft email to CMS Regional Office and State Survey Agency that contains: a. Facility Name; b. Full Mailing Address (including county); c. CMC Certification Number (CCN); d. Facility Contact Name and Information; e. Explanation of why the waiver is needed. [Example: Facility is sole community provider without reasonable transfer options at this point during the specified emergent event. Facility needs a waiver to exceed its bed limit by X number of beds for Y days/weeks (be specific).]; f. The scope of the issue and the impact it has on the entity; g. The type of relief the facility is seeking or the regulatory requirement(s) / reference(s) the facility is seeking to have waived Examples include: <ul style="list-style-type: none">• Requests by hospitals to provide screening/triage of patients at a location offsite from the hospital’s campus;• Hospitals housing patients in units not otherwise appropriate under the Medicare Conditions of Participation or for a duration that exceeds regulatory requirements;• Hospitals or nursing homes requesting increases in their certified bed capacity; 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; i. Return to compliance as soon as possible and by the end of the approved operational period or end of the emergency period.



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| | <ol style="list-style-type: none">3. Submit email with Request to Operate under an 1135 waiver authority to:<ol style="list-style-type: none">a. CMS Regional Officeb. State Survey Agency |
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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 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.

References

- [CMS Emergency Preparedness Rule](#)
- [FAQ - 1135 Waiver Process](#)
- [Waiver or Modification of Requirements Under Section 1135 \(Current & Previous Waivers\)](#)
- [US DHHS Office for Civil Rights Bulletin: HIPAA Privacy in Emergency Situations](#)



Sample Policy and Procedures 4: Bylaws on Emergency and Disaster Privileges

(Adapted from American Health Lawyers Association Sample Procedure)

1. For the purposes of this Section, an “emergency” is defined as a condition in which serious or permanent harm would result to a patient or in which the life of a patient is in immediate danger and any delay in administering treatment would add to that danger. In the case of an emergency, any practitioner, to the degree permitted by his/her license and regardless of department/section, Medical Staff membership or clinical privileges or allied health professional (AHP) status or practice prerogatives, shall be permitted to do, and shall be assisted by Hospital personnel in doing, everything possible to save the life of a patient or to save a patient from serious harm. All efforts will be made to obtain a Medical Staff member with appropriate clinical privileges. Clinical privileges granted under an emergency situation shall terminate when a Medical Staff member with appropriate clinical privileges becomes available or the emergency ceases.
2. Emergency privileges in case of a disaster will be granted in accordance with the following:
 - A. Consistent with the current Hospital Disaster Credentialing Policy (Hospital Disaster Policy) clinical privileges or practice prerogatives may be granted when the Hospital Incident Command System (HICS) plan has been activated and the Hospital is unable to handle the immediate patient needs. This includes events of a bioterrorism attack or any other type of disaster situation whereby Volunteer Practitioners and AHPs, as those terms are defined in the Hospital Disaster Policy, may require disaster credentialing.
 - 1) Security will set up a satellite post in the Medical Staff Services Department or other appropriate area where non-credentialed Volunteer Practitioners and AHPs will check in.
 - 2) Emergency privileging for disaster situations is specialty-specific and Volunteer Practitioners or AHPs shall not carry out any clinical activities for which they do not already hold clinical privileges or practice prerogatives at another hospital.
 - B. Procedure:
 - 1) Upon presentation to the campus, Volunteer Practitioners and/or AHPs shall be directed to the Hospital Representative responsible for disaster credentialing under the HICS plan. Volunteer Practitioners and/or AHPs must sign in and present required identification as follows: a valid government-issued photo identification issued by a state or federal agency (e.g., driver’s license or passport), and at least one of the following:
 - a) Current hospital photo ID that clearly identifies the person’s professional designation;
 - b) Current license, certificate, or registration to practice;
 - c) Identification indicating that the individual is a member of a Disaster Medical Assistance Team (DMAT), Medical Reserve Corps (MRC), Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP), or other recognized state or federal organizations or groups;
 - d) Identification that indicates that the individual has been granted authority to render patient care, treatment, and services in disaster circumstances (such authority having been granted by a federal, state, or municipal entity); or
 - e) Identification of Volunteer Practitioners by current Hospital Medical Staff member(s) who possess personal knowledge regarding the Practitioner’s ability to act as a



practitioner during a disaster, and of Volunteer AHPs by current Hospital Medical Staff member(s) or AHPs who possess personal knowledge regarding the AHP's qualifications.

- 2) Required documentation on the Disaster Clinical Privileges/Practice Prerogative Approval Form: The Volunteer Practitioner shall include all of the following information on the Disaster Clinical Privileges/Practice Prerogative Approval Form:
 - a) Name of Practitioner or AHP (printed and signed) ;
 - b) Specialty or AHP Category;
 - c) Office Address and Phone Number;
 - d) Professional License/Certificate/Registration Number and Expiration Date;
 - e) Driver's License or Passport Number and Expiration Date;
 - f) Date of Birth;
 - g) Name of Professional Liability Insurance Carrier and Limits of Liability;
 - h) Name of Professional School and Year of Graduation;
 - i) Hospital Affiliation(s) and Staff Status.
- C. Verification Process: The Hospital Representative shall verify professional licenses, certificates, and registrations as follows:
 - 1) Primary Source Verification: Query the appropriate licensing/certification/registration board online, and print verification if possible.
 - 2) If computer access is not available, a copy (if possible) of the Practitioner's or AHP's professional license/certificate/registration and driver's license or other identification shall be made and attached to the Disaster Clinical Privileges/Practice Prerogative Approval Form. If a copier is not available, the Hospital Representative shall perform a visual verification of the above documents, and document such verification.
 - 3) If primary source verification of professional licensure/certification/registration cannot be accomplished at the time of initial credentialing, it must be performed as soon as the immediate situation is under control and completed no later than seventy-two hours from the time the Volunteer Practitioner or AHP presented to the campus. In extraordinary circumstances when primary source verification cannot be completed within seventy-two hours (e.g., no means of communication or lack of resources), it shall be accomplished as soon as possible. In this extraordinary circumstance, the following must be documented:
 - a) Why primary source verification could not be performed in the required timeframe;
 - b) Evidence of the Practitioner's or AHP's demonstrated ability to continue to provide adequate care, treatment, and services;
 - c) Attempt(s) to rectify the situation as soon as possible.
 - 4) The Medical Staff Services Department shall query the National Practitioner Data Bank and other sources as needed as soon as the emergency situation has been contained.
 - 5) Primary source verification shall not be required if the Volunteer Practitioner or AHP has not provided care, treatment and services under the Disaster Clinical Privileges/Practice Prerogative Approval Form, as appropriate.
- D. Who May Grant Disaster Clinical Privileges/Practice Prerogatives: As described in these Bylaws, the CEO or Chief of Staff or their designees may grant Disaster Clinical Privileges or Practice Prerogatives. The option to grant Disaster Clinical Privileges or Practice Prerogatives



to Volunteer Practitioners and/or AHPs shall be made on a case-by-case basis in accordance with the immediate needs of the Hospital's patients, based on the qualifications of the Volunteer Practitioners and/or AHPs.

- E. Temporary Badges: So that they may be readily identified, Volunteer Practitioners and/or AHPs shall be issued badges containing the following information:
 - 1) Name
 - 2) Licensure
 - 3) Specialty or AHP category
 - 4) Practicing with Disaster Clinical Privileges or Practice Prerogatives, as appropriate
- F. Oversight: The Medical Staff shall oversee the care, treatment, and services provided by a Volunteer Practitioner or AHP who has been granted Disaster Clinical Privileges or Practice Prerogatives. Oversight shall be accomplished whenever possible by partnering the Practitioner or AHP with a credentialed Hospital Medical Staff member or AHP, as appropriate, to observe or mentor the Practitioner or AHP. If partnering is not possible, oversight shall be by clinical record review. A Volunteer Practitioner or AHP may be assigned additional responsibilities by the Medical Staff Officer designated under the HICS plan.
- G. Continuation of Disaster Clinical Privileges/Practice Prerogatives: The Hospital shall make a decision within seventy-two hours regarding the continuation of a Volunteer Practitioner's or AHP's Disaster Clinical Privileges or Practice Prerogatives, based on information obtained regarding the professional performance of the Volunteer Practitioner or AHP.
- H. Termination of Disaster Clinical Privileges/Practice Prerogatives: A Practitioner's or AHP's Disaster Clinical Privileges or Practice Prerogatives shall be terminated immediately in the event that any information received through the verification process or otherwise indicates adverse information or suggests the Practitioner or AHP is not capable of exercising Disaster Clinical Privileges or Practice Prerogatives. Disaster Clinical Privileges and Practice Prerogatives are time-limited and shall expire automatically at the time the CEO or designee declares the disaster to be over, or that the services of Volunteer Practitioners or AHPs are no longer required.



Sample Policy and Procedures 5: EMTALA Policy on Section 1135 Waivers

(Adapted from American Health Lawyers Association Sample Procedure)

1. This amendment should be placed at the end of a Hospital's hospital-wide EMTALA policy.
2. Conditions of Amendment to EMTALA Policy: it applies when a major disaster or emergency is declared and the Secretary of HHS has declared a public health emergency.
 - A. Hospital must implement its disaster protocol.
 - B. Hospital must notify CMS through the appropriate State Survey Agency when it implements its disaster protocol.
 - C. The Secretary exercises his or her waiver power under Section 1135 to cover the area in which the Hospital is located.
 - D. The waiver is either limited to a seventy-two-hour period beginning with the implementation of the Hospital's disaster protocol or, in the case of a pandemic infectious disease, until the termination of the declaration of the public health emergency.
3. Amendment Language: "This EMTALA policy does not apply when the Secretary of HHS declares a public health emergency and a waiver of EMTALA requirements for the area in which the Hospital is located. The waiver of the Hospital's EMTALA requirements applies only for the period during which the waiver is in effect."

