

Emergency Preparedness: PROVIDER READINESS!

CMS Consortium for Quality Improvement and Survey and Certification Operations (CQISCO),
Div. of Survey & Certification, Branch Managers/G5 Emergency Preparedness Workgroup

CMS Center for Clinical Standards and Quality (CCSQ), Quality, Safety, and Oversight Group
(QSOG)



This Webinar has Four Sections:

- The 1135 Waiver Process
- The Emergency Preparedness Final Rule
- Observations and Lessons Learned during recent emergencies and disasters
- Resources available
- Questions should be sent to SCGEmergencyPrep@cms.hhs.gov

Objectives

At the conclusion of this presentation you will be able to:

- Demonstrate knowledge of the 1135 Waiver Process and Requirements of 1135 Waivers under the Emergency Preparedness Final Rule
- Demonstrate an understanding of the Emergency Preparedness Final Rule and general requirements for providers and suppliers
- Demonstrate an awareness of how certain emergency challenges were handled during recent disasters
- Understand the resources available to you in relation to the Emergency Preparedness Rule and real-world disasters

Disclaimer

This presentation was prepared as a tool to assist providers and is not intended to grant rights or impose obligations. Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services.

This publication is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference.

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The 1135 Waiver Process



Purpose of an 1135 Waiver

- Sufficient health care items and services are available to meet the needs of Medicare, Medicaid and CHIP beneficiaries;
- Health care providers that provide such services in good faith can be reimbursed for them and not subjected to sanctions for noncompliance, absent any fraud or abuse.

1135 Waiver

- **SCOPE:** Federal Requirements only, not state licensure. Determine: Scope and severity of event with specific focus on health care infrastructure; Are there unmet needs for health care providers? Can these unmet needs be resolved within our current regulatory authority?
- **PURPOSE:** Allow reimbursement during an emergency or disaster even if providers can't comply with certain requirements that would under normal circumstances bar Medicare, Medicaid or CHIP payment.
- **DURATION:** 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.

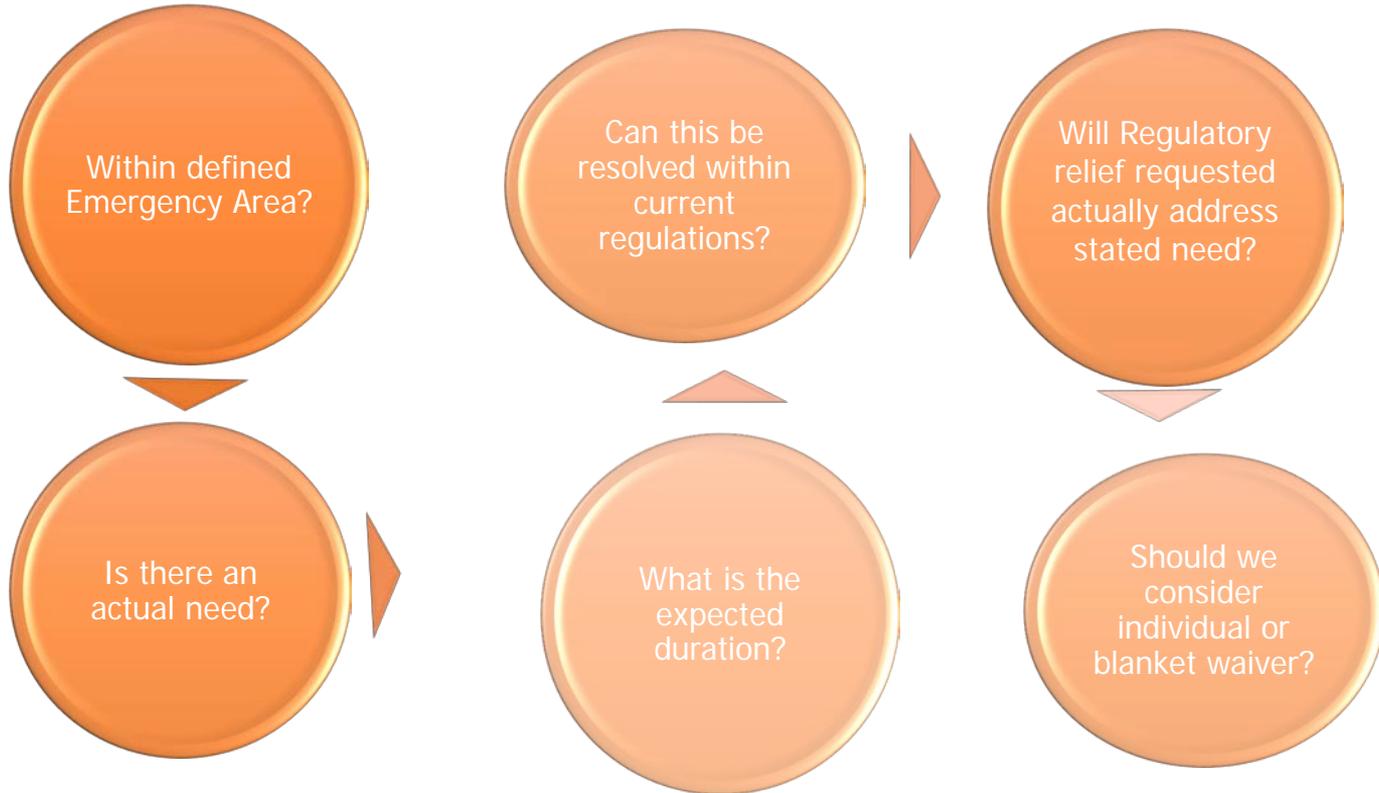
Waivers DO NOT:

- 1135 waivers are not a grant or financial assistance program
- Do not allow reimbursement for services otherwise not covered
- Do not allow individuals to be eligible for Medicare who otherwise would not be eligible
- Should NOT impact any response decisions, such as evacuations.
- Do not last forever. And appropriateness may fade as time goes on.

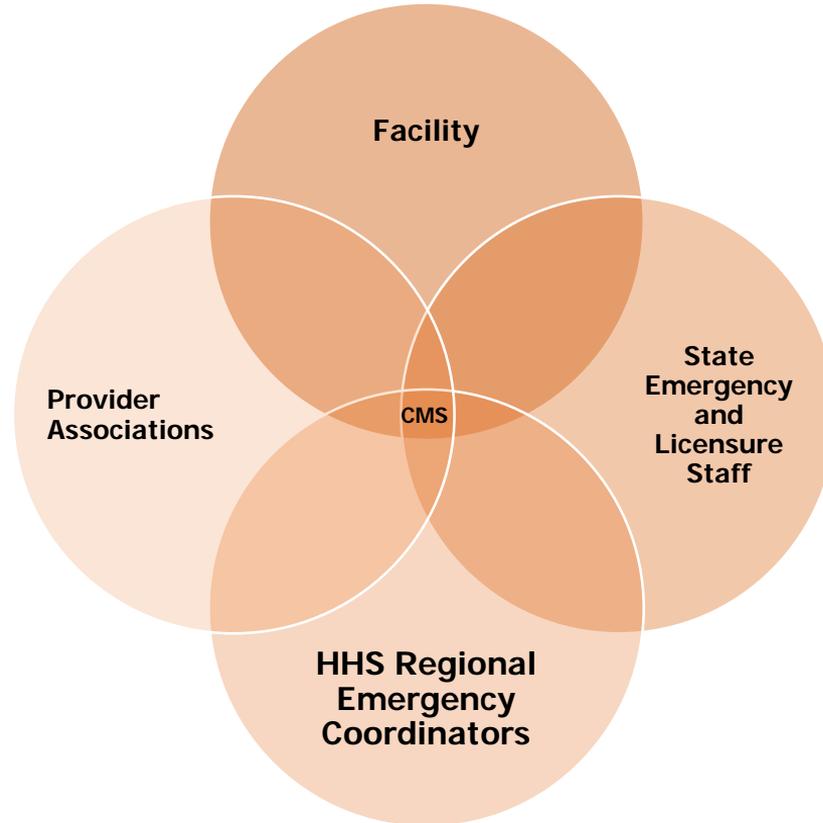
Examples of 1135 Waiver Authorities

- Conditions of Participation: For instance, CAHs require 25-bed limit and Average Patient stays of less than 96-hours or SNFs- 3-day prior hospitalization for SNF Patients
- Licensure for Physicians or others to provide services in affected state
- Emergency Medical Treatment and Labor Act (EMTALA): For instance, Request to setup Alternate Screening Locations
- Stark Self-Referral Sanctions
- Medicare Advantage out of network providers
- HIPAA (Based on OCR determination)

1135 Waiver Review Process



Waiver Review Inputs



The Final Rule and 1135 Waivers

- To be compliant with the requirement under the Emergency Preparedness Final Rule, you'll need to have a policy and procedure for addressing your facility's awareness of the 1135 Waiver Process.
- There is no specific form or document template.
- Some elements that could be considered and reflected (but not limited to) in the policies and procedures.
- Having an 1135 waiver on file is NOT possible since 1135 waivers are event & geographically specific & time limited.

The Final Rule and 1135 Waivers

- Facility role in providing care and treatment at alternate site – for example: equipment and supplies, command and control, staffing
- Collaboration with local officials – proactive planning, pre-designated site? Predestinated roles, emergency credentialing procedures for providers to practice at alternate site (if waiver does not cover provider licensure)
- The procedure for applying for an 1135 waiver and **contact information for Regional Office and State Survey Agency.**

Resources on 1135 Waivers

Email Addresses for CMS Regional Offices:

ROATLHSO@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee

RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, and Texas

ROPHIDSC@cms.hhs.gov (Northeast Consortium): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont

ROCHISC@cms.hhs.gov (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, and Nebraska

ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, and the Pacific Territories

Quality, Safety & Oversight Group 1135 Waiver Resource Website at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers.html>



Emergency Preparedness Final Rule

Emergency Preparedness Final Rule

- Published September 16, 2016 & applies to all 17 provider and supplier types;
Implementation date November 15, 2017
- Compliance required for participation in Medicare (and Medicaid, as applicable)
- Emergency Preparedness is one new Condition of Participation/Condition for Coverage of many already required
- Appendix Z contains Interpretive Guidance and survey procedures
- The new Emergency Preparedness Tags are E-Tags
- If facilities are non-compliant, the same general enforcement procedures will occur as is currently in place for any other conditions or requirements cited for non-compliance

Four Provisions for All Provider Types



All-Hazards Approach:

- An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters, including internal emergencies and a man-made emergency (or both) or natural disaster. This approach is specific to the location of the provider or supplier and considers the particular type of hazards most likely to occur in their areas. **These may include, but are not limited to, care-related emergencies, equipment and power failures, interruptions in communications, including cyber-attacks, loss of a portion or all of a facility, and interruptions in the normal supply of essentials such as water and food.**

General Overview

- With the exception of Transplant Programs, that are incorporated under the Transplant Hospital's Emergency Preparedness Program:
- All 17 Providers and Suppliers are required to be in compliance with the four core elements/provisions with variations
- Variations may include areas such as:
 - Accountability for missing residents
 - Subsistence needs for inpatient providers only
 - Home health agencies and hospices required to inform officials of patients in need of evacuation

Four Provision Areas At-A-Glance

- **Risk Assessment and Planning (Annually):**
 - Develop an emergency plan based on a risk assessment.
 - Perform risk assessment using an “all-hazards” approach, focusing on capacities and capabilities.

- **Policies and Procedures (Annually):**
 - Develop and implement policies and procedures based on the emergency plan and risk assessment.
 - Policies and procedures must address a range of issues including subsistence needs, evacuation plans, procedures for sheltering in place, tracking patients and staff during an emergency.
 - Update emergency plan

Policies and Procedures (cont'd)

Policies and procedures must address:

- How patients, staff and volunteers would shelter in place
- A system of medical documentation that maintains availability of records, protects confidentiality, etc.
- Staffing strategies and the use of volunteers
- Patient transfer arrangements with other facilities
- The provision of care at an alternate site (under an 1135 waiver)

Four Provision Areas *Continued*

- **Communication Plan (Annually):**

- Develop a communication plan that complies with both Federal and State laws.
- Coordinate patient care within the facility, across health care providers, and with state and local public health departments and emergency management systems

- **Training & Testing Program (Annually):**

- Develop and maintain training and testing programs, including initial training in policies and procedures.
- Demonstrate knowledge of emergency procedures and provide training at least annually.
- Conduct drills and exercises to test the emergency plan

Communication Plan

Facilities must develop and maintain a communication plan that complies with Federal, State and local laws. The plan must be reviewed and updated annually

The plan must include:

- Contact information for staff, patient physicians, volunteers, contractors, other facilities as appropriate
- A primary and alternate means for communication
- A method for sharing patient information to other providers

Training and Testing

Facilities must develop and maintain an EP training and testing program. The program must be reviewed and updated annually.

- Initial training required for all new and existing staff, volunteers and individuals providing services under arrangement (contractors, per diem staff, etc.)
- Annual training required thereafter
- Must maintain documentation of the training
- Training may be tailored to specific staff roles

Testing: Annual Exercises

Facilities must conduct exercises on an annual basis:

- Participate in a full-scale community based or individual based exercise (when a community based exercise is not available)
- Conduct a second exercise (may be full-scale community or individual exercise or tabletop exercise)

Integrated Healthcare Systems

Facilities that are part of a system consisting of multiple, separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program (EP), may choose to participate in the system's unified and integrated EP program.

If a facility elects to participate in the unified EP program, the facility must demonstrate/include:

- Active participation in the development of the unified program
- The facility's unique circumstances, patient populations, and services are part of the program
- It is capable of utilizing the unified EP program
- A community-based and facility based risk assessment specific to the facility
- Integrated policies and procedures that meet all requirements

Facilities with Multiple Locations

All locations of a Medicare certified provider or supplier must be included in the facility's EP program (all locations operating under the same CCN).

Off-campus locations of a Medicare certified provider or supplier that are co-located with another healthcare entity must be part of **its** facility's EP program but may collaborate with the co-located entity as part of each facility's community-based risk assessments and community-based exercises.

Be Aware of Slight Differences in Requirements

- Outpatient providers are not required to have policies and procedures for the provision of subsistence needs.
- Home health agencies and hospices required to inform officials of patients in need of evacuation.
- Long-term care and psychiatric residential treatment facilities must share information from the emergency plan with residents and family members or representatives.



Observations and Lessons Learned from the Management of Emergencies and Disasters

Observations from the Management of Emergencies and Disasters

Multiple Disaster types occur throughout the nation annually

- Hurricanes
- Flooding
- Wildfires
- Mudslides
- Tornadoes
- Earthquakes
- Volcanoes
- Other natural and person-made emergencies and disasters

Observations and Lessons Learned

- Challenges evolve during different phases of a disaster
- CMS works closely with State and other Federal Agencies before, during and after the disaster to ensure safe, quality care is provided
- Communication, collaboration, and coordination among state and local emergency management, public health, and health care entities are essential to promoting effective emergency preparedness and response.
- **Remember, personal preparedness is your foundation to be best prepared!**

Observations/lessons learned affecting Providers and Suppliers- DURING THE EVENT

- The critical lesson of Emergency Preparedness is assume nothing.
- It is vital to gauge the awareness and knowledge of the emergency management community with regard to their role during emergency situations.
- Do not assume that individuals are knowledgeable or prepared simply because they have attended a training session

Observations/lessons learned affecting Providers and Suppliers- BEFORE THE EVENT

- Suddenness of onset of Emergency
- Continual readiness of Providers and Suppliers to activate robust/adequate emergency plans is essential
- Environment may already be damaged from prior events
- Geographic limitations

Observations/lessons learned affecting Providers and Suppliers- BEFORE THE EVENT

- Establish relationships, forge partnerships, and increase communication and collaboration among providers, provider organizations, your survey state agency, and emergency management services before disaster occurs.
- Maintain situational awareness of conditions and anticipate actions.

Observations/lessons learned affecting Providers and Suppliers- DURING THE EVENT

- The length of time the emergency extends creates continuing stress on healthcare operations
- Supply chains may be disrupted
- Evolving Healthcare Needs during crisis

Observations/lessons learned affecting Providers and Suppliers- DURING THE EVENT

What is the role of CMS Regional Office during an emergency?

During a disruptive event, the Regional Office's (RO) primary role is to provide guidance to affected SAs regarding health care providers' CoP/CfC and potential altered care decisions, while ensuring the health and safety of patients and residents. The RO's essential functions include the following:

- Establishing an emergency point of contact
- Ensuring communication links with designated emergency points of contact at affected State Agencies

Observations/lessons learned affecting Providers and Suppliers- DURING THE EVENT

What is the role of CMS Regional Office during an emergency? (con't.)

- Responding promptly to requests for 1135(b) waiver
- Referring questions and waiver/suspension of regulation requests to CMS Central Office, as needed.
- Requesting status reports from the State Agency regarding affected health care providers
- Assisting affected State Agencies to provide essential monitoring and enforcement activities if the State Agency is overwhelmed/unable to meet their survey and certification obligations.

Observations/lessons learned affecting Providers and Suppliers- DURING THE EVENT

- Training and information dissemination efforts should be designed to equip individuals and organizations to be able to handle 90 percent of an emergency situation out of habit, allowing them to focus energies on addressing the 10 percent unexpected.
- It is valuable for you as a provider to establish open lines of communication with your local Office of Emergency Management and first responders, while also ensuring that you are as self-sufficient as possible.
- It is difficult to predict issues and obstacles that may arise during an emergency situation.

Observations/lessons learned affecting Providers and Suppliers- DURING THE EVENT

Evacuation and tracking

- In the event that evacuation may be necessary, it is essential to be able to track evacuees.
- Establish a stable information system that is designed for concurrent use by multiple users.
- It is important to consider confidentiality issues, particularly in a database with multiple end users, although it can be tempting to track individual residents by name.

Observations/lessons learned affecting Providers and Suppliers- AFTER THE EVENT

- New gaps in health care continuum may occur
- Emergent mental health issues/stress rooted in the trauma of the event
- 1135 Waivers/ CMS and State Agency considerations
- Flexibility vs Waiver

Observations/lessons learned affecting Providers and Suppliers- AFTER THE EVENT

CMS Flexibility vs Waiver

- Question: What is the difference between a “flexibility” and a “waiver?”
- Answer: A flexibility is either a sub-regulatory policy or procedure or a policy or procedure that can be amended under the terms of the implementing statute or regulation and that, in either case, CMS can amend at will without reprogramming its systems. A waiver or a modification is generally thought of as a waiver or modification of a statutory requirement of the Social Security Act (Act) that may be waived or modified under the authority of § 1135 of the Act.

Observations/lessons learned affecting Providers and Suppliers- AFTER THE EVENT

Examples of Two Flexibilities

- Special Purpose Renal Dialysis Facility (SPRDF) – Serves ESRD patients on an emergency basis when approved permanent facilities close due to natural disasters.
- Temporary Closure – Allows facilities to retain CMS CCN while the facility is temporarily closed to complete repairs of physical structures.

Observations/lessons learned affecting Providers and Suppliers- AFTER THE EVENT

Provider Relocation

- If a provider who has been adversely impacted by a declared public health emergency, is unable to restart full operations, can they maintain their existing Medicare or Medicaid provider agreement while the facility is closed? Can a provider relocate, and what are the procedures for program certification if relocation is necessary?
- Reviewed on a case by case basis
- Relocation?

Observations/lessons learned affecting Providers and Suppliers- AFTER THE EVENT

Provider Relocation (cont'd)

- To retain the current provider certification, the entity must demonstrate to the RO that it is functioning as essentially the same provider serving the same community.
 - The provider remains in the same State and complies with the same State licensure requirements.
 - The provider remains the same type of Medicare provider after relocation.
 - The provider maintains at least 75 percent of the same medical staff, nursing staff and other employees, and contracted personnel.

Observations/lessons learned affecting Providers and Suppliers- AFTER THE EVENT

Temporary Facilities

- In the event of extensive damage, use of temporary, mobile facilities may be necessary



EP Resources/ web links

- Centers for Medicare & Medicaid (CMS) Survey and Certification Emergency Preparedness Website: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html>
- Assistant Secretary for Preparedness and Response (ASPR) TRACIE Website: <https://asprtracie.hhs.gov/>
- State Operations Manual Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Advanced-Copy-SOM-Appendix-Z-EP-IGs.pdf>

CMS Rule Health Sector Emergency Preparedness Course

The Center for Domestic Preparedness (CDP) at FEMA is offering a Health Sector Emergency Preparedness Course that will provide healthcare providers and suppliers with training in achieving the four core emergency preparedness elements outlined in the CMS Rule.

Course Goals: Understand specific emergency preparedness requirements as outlined in the CMS Rule and develop knowledge and skill in achieving these requirements.

- **Course Length:** 8 hours
- **Course Delivery Means:** Non-resident at a coordinated host location
- **Course Host Responsibilities:**
 - Provide a classroom or auditorium capable of seating the expected audience
 - Support recruitment of an appropriate audience from the 17 CMS identified providers and suppliers
 - Provide a point of contact to coordinate the class(es) with the FEMA Center for Domestic Preparedness Non-Resident Training Coordinator

The Quality, Safety & Oversight EP Website

Home > Medicare > Survey & Certification - Emergency Preparedness > Emergency Preparedness Rule

Survey & Certification - Emergency Preparedness

[Home Survey Access](#)
[Guidance](#)
[Health Care Provider](#)
[Guidance](#)
[Lessons Learned/Archives](#)

Emergency Preparedness Rule

[Core EP Rule Elements](#)
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[Earthquakes](#)
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[Flooding](#)
[Wild Fires and Fires, General](#)
[Influenza and Viruses](#)
[Biomedical Security Threats](#)
[Templates & Checklists](#)

Emergency Preparedness Rule

Survey & Certification - Emergency Preparedness Regulation Guidance

Guidance for Surveyors, Providers and Suppliers Regarding the New Emergency Preparedness (EP) Rule

On September 8, 2016 the Federal Register posted the final rule, Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers. The regulation goes into effect on November 16, 2016. Health care providers and suppliers affected by this rule must comply and implement all regulations one year after the effective date, on November 16, 2017.

Purpose: To establish national emergency preparedness requirements to ensure adequate planning for both natural and man-made disasters, and coordination with federal, state, tribal, regional and local emergency preparedness systems. The following information will apply upon publication of the final rule:

- Requirements will apply to all 17 provider and supplier types.
- Each provider and supplier will have its own set of Emergency Preparedness regulations incorporated into its set of conditions or requirements for certification.
- Must be in compliance with Emergency Preparedness regulations to participate in the Medicare or Medicaid program. The below downloadable sections will provide additional information, such as the background and overview of the final rule and related resources.

Additional information has been provided on the left side hyperlinks, categorized by information from the EP Rule, such as the Emergency Preparedness Plan, Communication Plan, Policies and Procedures and Testing.

Note: For Medicaid-only facilities (other than ICF-IICs and PRTFs), please contact your State Medicaid Agency to determine whether you are required to meet the Emergency Preparedness requirements under the Final Rule.

If you have questions as to whether your healthcare facility is required to comply with the final rule, please refer to the downloads section below and the attachment labeled 17 Facility-Provider/Supplier Types Impacted. Additionally, please contact your specific facility CFO, CEO, Human Resources Staff, etc. to determine what Medicare certified provider number you are associated/certified under, which will determine which requirements you need to comply with.

The below downloadable sections will provide additional information, such as the background and overview of the final rule and related resources.

Downloads

- [By Name By State Healthcare Conditions - Updated 1-12-17 \(PDF, 351KB\)](#)
- [Facility Transfer Agreement - Example \(PDF, 56KB\)](#)
- [17 Facility-Provider/Supplier Types Impacted \(PDF, 69KB\)](#)
- [Frequently Asked Questions \(FAQs\) Round One \(PDF, 312KB\)](#)
- [Frequently Asked Questions \(FAQs\) Round Two Revised 6-1-17 \(PDF, 40KB\)](#)
- [Frequently Asked Questions \(FAQs\) Round Three Revised 6-1-17 \(PDF, 35KB\)](#)
- [Frequently Asked Questions \(FAQs\) Round Four \(PDF, 24KB\)](#)
- [Frequently Asked Questions Round Four Definitions \(PDF, 48KB\)](#)
- [General Presentation - Overview of EP \(PPTX, 3MB\)](#)
- [Advanced Copy-Emergency Prep Interpretive Guidelines \(PDF, 733KB\)](#)
- [Surveyor Tool-EP Tags \(XLSX, 62KB\)](#)

Related Links

Look at the Resources

- QSO Emergency Preparedness Website has an area with FAQs and resources available to the stakeholders
- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html>
- ISTW EP Training Module: <https://surveyortraining.cms.hhs.gov/>.
NOTE: Surveyor Training is available to the public. Just select “I’m a Provider” upon logging into the system.

SUMMARY & WRAP UP

Be prepared... it could happen to US...

We are all working together to protect our communities and save lives by assessing the emergency preparedness of our providers and suppliers

... through our solid examination of emergency preparedness in selected key areas (our risks, policy and procedures, communications, training, and testing), based on the CMS EP rule.

... using the EP survey process to strengthen emergency preparedness of our healthcare providers and suppliers.

Questions ?

Send to email: SCGEmergencyPrep@cms.hhs.gov



THANKS!

We appreciate and would like to acknowledge the contributions of the CMS CQISCO Division of Survey & Certification Branch Managers-G5 EP Workgroup and the CCSQ Quality, Safety, and Oversight Group:

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Thank You for your Participation