

CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE



VIRTUAL WORKSHOP -- JUNE 1, 2021

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CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

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Guidance related to the Emergency Preparedness Testing Exercise Requirements- Coronavirus Disease 2019 (COVID-19)

Background

On September 30, 2019, the Centers for Medicare & Medicaid Services (CMS) published the *Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care* Final Rule (84 FR 51732) which revised the requirements for emergency preparedness.

Revisions in the Final Rule include:

- CMS removed the requirements for facilities to document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials, and for facilities to document their participation in collaborative and cooperative planning efforts;
- CMS revised cycles for review and updates requirements to the emergency preparedness program. Specifically, all applicable providers and suppliers review their emergency program biennially, except for Long Term Care (LTC) facilities, which will still be required to review their emergency program annually.
- CMS revised training program requirements, specifically, that facilities develop and maintain a training program based on the facility's emergency plan annually by requiring facilities to provide training biennially (every 2 years) after facilities conduct initial training for their emergency program, except for LTC facilities, which will still be required to provide training annually. However, additional training is required when the emergency plan is significantly updated.

Additionally, the Final Rule revised the emergency preparedness testing exercise requirements. As discussed in more detail below, the regulations allow for an exemption to the testing requirements during or after an actual emergency. If a provider experiences an actual natural or man-made emergency that requires activation of their emergency plan, inpatient and outpatient providers will be exempt from their next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the actual event. In light of the PHE, CMS is clarifying the testing exercise requirements to ensure that surveyors, as well as providers and suppliers, are aware of the exemption available based on activation of their emergency plans.



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

The centers for Medicare & Medicaid services (CMS) issued the [emergency preparedness requirements for medicare and medicaid participating providers and suppliers final rule](#) to establish consistent emergency preparedness requirements for healthcare providers participating in Medicare and Medicaid, increase patient safety during emergencies, and establish a more coordinated response to natural and human-caused disasters.

This document combines excerpts from the final rule and interpretive guidelines (as updated 3/6/19, 11/8/19, and 3/26/21) from CMS to provide a consolidated overview document for the Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) requirements. This document reflects final language as of the most recent final rule updates and interpretive guidance updates as of March 26, 2021. For a comparison of changes between past versions, please review the [interpretive guidelines published by CMS on March 26, 2021](#).

This document is meant as a reference and is NOT intended to replace your review of the Final Rule or the Interpretive Guidance documents and speaking with your surveyor or accrediting body. This document may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a resource. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

While the primary changes to Appendix Z focused on the changes as a result of the Burden Reduction Final Rule, specifically adjustment of cycles of updates required for non-long term care providers and changes to the training and testing program; CMS has also updated the guidance to reflect some of the following changes:

- Expanded surveyor guidance to ensure Life Safety Code and health surveyors communicate/collaborate surrounding potential deficiencies for alternate source energy.
- Added new definitions based on Burden Reduction Final Rule expansion of acceptable testing exercises.
- Clarified expectations surrounding documentation of the emergency program.
- Added additional guidance/considerations for EID (emerging infectious disease) planning stages, to include personal protective equipment (PPE).
- Added additional guidance on risk assessment considerations, to include EIDs.
- Included planning considerations for surge and staffing.
- Expanded guidance for surge planning-to include recommendations for natural disaster surge planning and EID surge planning.
- Included recommendations during PHE's (public health emergencies) for facilities to monitor Centers for Disease Control and Prevention (CDC) and other public health agencies which may issue event-specific guidance and recommendations to healthcare workers.
- Clarified existing guidance surrounding use of portable generators and maintaining temperature controls.
- Added additional planning considerations for hospices during EIDs outbreaks.
- Expanded guidance and added clarifications related to alternate care sites and 1135 Waivers.
- Expanded guidance and best practices related to reporting of facility needs, facility's ability to provide assistance, and occupancy reporting.
- Revised guidance related to training and testing program as the Burden Reduction Rule extensively changed these requirements, especially for outpatient providers.
- Provided clarifications related to testing exercise exemptions when a provider/supplier experiences an actual emergency event.

CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

RHC/FQHC Requirements as Written in the Final Rule and as amended by 2019 Burden Reduction (November 2019)

The following excerpt is taken from page 64041 of the Final Rule, accessible directly by this link: <https://www.federalregister.gov/d/2016-21404/p-amd-40> published September 30, 2019, and effective November 29, 2019.

Add § 491.12 to read as follows:

§ 491.12

Emergency preparedness.

The RHC/FQHC must comply with all applicable Federal, State, and local emergency preparedness requirements. The RHC/FQHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

(a) Emergency plan. The RHC/FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of 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, the type of services the RHC/FQHC 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.



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

(b) Policies and procedures. The RHC/FQHC 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 every 2 years. At a minimum, the policies and procedures must address the following:

- 1) Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.
- 2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.
- 3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.
- 4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

(c) Communication plan. The RHC/FQHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

- 1) Names and contact information for the following:
 - i. Staff.
 - ii. Entities providing services under arrangement.
 - iii. Patients' physicians.
 - iv. Other RHCs/FQHCs.
 - v. Volunteers.
- 2) Contact information for the following:
 - i. Federal, State, tribal, regional, and local emergency preparedness staff.
 - ii. Other sources of assistance.
- 3) Primary and alternate means for communicating with the following:
 - i. RHC/FQHC's staff.
 - ii. Federal, State, tribal, regional, and local emergency management agencies.
- 4) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).
- 5) A means of providing information about the RHC/FQHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

(d) Training and testing. The RHC/FQHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

- 1) **Training program.** The RHC/FQHC must do all of the following:
 - i. Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles,
 - ii. Provide emergency preparedness training at least every 2 years.
 - iii. Maintain documentation of all emergency preparedness training.
 - iv. Demonstrate staff knowledge of emergency procedures.
 - v. If the emergency preparedness policies and procedures are significantly updated, the [facility] must conduct training on the updated policies and procedures.



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

2) **Testing.** The RHC/FQHC must conduct exercises to test the emergency plan at least annually.

The RHC/FQHC must:

- i. Participate in a full-scale exercise that is community-based every 2 years; or
 - a. When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or
 - b. If the RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC is exempt from engaging in its next required community-based or individual, facility-based functional exercise for 1 year following the onset of the actual event.
- ii. Conduct an additional exercise at least every 2 years opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:
 - a. A second full-scale exercise that is community-based or individual, facility-based functional exercise; or
 - b. A mock disaster drill; or
 - c. A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
- iii. Analyze the RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

(e) Integrated healthcare systems. If a RHC/FQHC is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the RHC/FQHC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, **the unified and integrated emergency preparedness program must do all of the following:**

- 1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
- 2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.
- 3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.
- 4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:
 - i. A documented community-based risk assessment, utilizing an all-hazards approach.
 - ii. A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.
- 5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE

References and Resources:

- ✓ 42 CFR Sec. 491.12: <https://www.law.cornell.edu/cfr/text/42/491.12>
- ✓ [Rural Health Clinic / Federally Qualified Health Center Requirements: CMS Emergency Preparedness Final Rule \(Updated\)](#)
- ✓ Updated Guidance for Emergency Preparedness - [Appendix Z of the State Operations Manual](#) (SOM); see interpretive guidelines.
- ✓ CAHF DISASTER PREPAREDNESS PROGRAM – Resources: <https://www.cahfdisasterprep.com/eop>
- ✓ Everything you might need: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS EP Rule): <https://asprtracie.hhs.gov/cmsrule>



CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE



QUESTIONS ?

COMMENTS ?

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Thank you for your time !

CMS FINAL RULE - EMERGENCY PREPAREDNESS - 26 MARCH 2021 - UPDATE



VIRTUAL WORKSHOP -- JUNE 1, 2021

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