

Survey & Certification Group
Frequently Asked Questions (FAQs)
Emergency Preparedness Regulation

Documentation Requirements/ Plans

Q: Can continuity of operations, delegations of authority, succession planning be included in the Emergency Operations Plan, or do you expect to see separate plans?

A: We are not requiring a specific format for how a facility should have their Emergency Plans documented and in which order. Upon survey, a facility must be able to provide documentation of these requirements in the plan and show where the plans are located.

Q: For formatting of the documentation, the standard state policies & procedures are required. Our documents are structured as an Emergency Operations Plan with addendums. Is this allowable?

A: We are not requiring a specific format for the manner in which a facility should have their Emergency Plans documented. Upon survey, a facility must be able to provide documentation of the policies and procedures and show surveyors where the policies and procedures are located.

Q: There are repeated references in the rule to business continuity, business resilience and continuity of operations, but not much clarity is provided as to how the rule differentiates these things or specific requirements. Can you provide more detail as to what will be surveyed?

A: We did not find any references to the term “business resilience” in the final rule. *Business continuity* and *continuity of operations* have the same meaning in the context of this rule.

The Assistant Secretary for Preparedness and Response has developed a document that includes information to assist facilities in planning for continuity of operations. The document may be found at: <http://www.phe.gov/Preparedness/planning/hpp/reports/Documents/hc-coop2-recovery.pdf>

Q: How does this regulation affect facilities participating in the Hospital Preparedness Program (HPP)?

A: The regulation does not affect providers and suppliers participating in the HPP. There is no relationship between the HPP and the regulation, as HPP works with the Health Care Coalitions (HCC) and State Departments. The Assistant Secretary for Preparedness and Response (ASPR) administers the HPP which provides leadership and funding through grants and cooperative agreements to states, territories, and eligible municipalities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. For additional information, please contact ASPR’s Technical Resources, Assistance Center, and Information Exchange (TRACIE) at askasprtracie@hhs.gov.

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Q: CMS does not require an approved emergency preparedness plan from the local emergency official but must show coordination with local emergency management officials. What level of coordination will be considered acceptable for the facility emergency plan approval? Will a facility only need an approval for their emergency plan from the CMS servicing agency?

A: Providers and suppliers must document efforts made by the facility to cooperate and collaborate with emergency preparedness officials. While we are aware that the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the rule states that providers and suppliers must document efforts made by the facility to cooperate and collaborate with emergency preparedness officials. Since some aspects of collaborating with various levels of government entities may be beyond the control of the provider/supplier, we have stated that these facilities must include in their emergency plan a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials. We also encourage providers and suppliers to engage and collaborate with their local HCC, which commonly includes the health department, emergency management, first responders, and other emergency preparedness professionals. Facilities are required to coordinate with local management officials, such as with their communication plans. For instance, facilities are required to have documentation of their efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts. Facilities are required to have contact information for emergency officials and who they should contact in emergency events; maintain an emergency preparedness communication plan that complies with both federal and state law; and be able to demonstrate collaboration through the full-scale exercises. We are not requiring official “sign-off” from local emergency management officials; however, if the state requires this action, we would expect that facilities comply with their state laws.

Q: In the past, new facilities seeking licensure needed an approved Comprehensive Emergency Management Plan from local officials. Who will review and approve plans for new facilities in order for them to obtain their licensure?

A: We cannot address how the new regulation will affect state licensure laws. Facilities should contact their state licensing agencies for clarification.

Q: What is the regulation’s definition or intent behind the word “community”?

A: We did not define “community”, to afford providers the flexibility to develop disaster drills and exercises that are realistic and reflect their risk assessments. However, the term could mean entities within a state or multi-state region. The goal of the provision is to ensure that healthcare providers collaborate with other entities within a given community to promote an integrated response. In the proposed rule, we indicated that we expected hospitals and other providers to participate in healthcare coalitions in their area for additional assistance in effectively meeting this requirement. Conducting exercises at the healthcare coalition level could help to reduce the administrative burden on individual healthcare facilities and demonstrate the value of connecting

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into the broader medical response community, as well as the local health and emergency management agencies, during emergency preparedness planning and response activities.

Survey Process Requirements

Q: Which agencies will be involved in monitoring compliance? Will monitoring for compliance include State and/or local health officials and emergency management? Are there ways to coordinate monitoring and compliance with local Health/Emergency Management Officials? Will CMS ask local Health/Emergency officials to sign-off (or at least be involved in the process) verifying that these organizations have met the requirements or at least involved in the process of signing-off on?

A: The State Survey Agencies (SA), Accreditation Organizations (AOs), and CMS Regional Offices (ROs) will be involved in monitoring for compliance as is the case with all other requirements for participation in Medicare. Facilities may choose to work with local health and emergency management officials to review the facility's plan to meet local requirements. The facility has the option of choosing to seek approval of its plan from state/local emergency preparedness officials. We do not regulate state and local emergency management officials.

Q: What are the consequences for not meeting these new requirements? Will any leniency be given for organizations that have started this type of planning but didn't complete by November 15, 2017? Will any warnings be issued before any actions taken against a particular organization?

A: Providers/suppliers have one year to implement the emergency preparedness requirements. Surveying for compliance to these requirements will begin in November 15, 2017. There will be no exceptions for the requirements and non-compliance will follow the same process non-compliance with any other Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) for the facility at hand.

Q: Will this be an incentive - penalty such as those associated with Meaningful Use? Will it just be a penalty? How will surveys be conducted? When will we have access to the survey tool?

A: The implementation of this new regulation is not linked to an incentive program. Facilities found to be out of compliance with the requirements will follow the same enforcement process as with any other CoP/CfC that is found to be out of compliance. These new regulations are a condition or requirement to participate in Medicare. We anticipate releasing the Interpretive Guidelines and Survey Procedures in spring of 2017. In the interim, we are posting helpful tools and relevant information on the Survey and Certification Group (SCG) Emergency Preparedness Website to assist facilities in meeting the requirements.

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Q: What process/documentation/resources will SA surveyors use to assure compliance with the various facility types?

A: As always, surveyors will use the Interpretive Guidelines and Survey Procedures in the State Operations Manual (SOM). Surveyors will also be trained on the requirements before implementation.

Accrediting Organizations (AOs)

Q: Could CMS provide a listing to the different Accrediting Organizations?

A: Please see: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf>

Q: How are AOs expected to implement the new rule into their programs?

A: AOs will follow the same process for developing standards that will meet or exceed CMS requirements of the new rule.

Q: If an AO already has emergency preparedness standards or emergency preparedness program requirements, how does the new rule affect their current standards?

A: AOs will need to submit their emergency preparedness standards/programs to CMS for review. AOs are required to meet or exceed the CMS CoPs/CfCs requirements; therefore the AOs must demonstrate to CMS that their standards meet or exceed all CMS' new emergency preparedness requirements.

Testing and Training

Q: What does the term “training” encompass? Is the content and the extent of the training at the discretion of the facility?

A: A well organized, effective training program must include initial training for new and existing staff in emergency preparedness policies and procedures as well as annual refresher trainings. The facility must offer annual emergency preparedness training in which staff can demonstrate knowledge of emergency procedures. The facility must also conduct drills and exercises to test the emergency plan to identify gaps and areas for improvement. We expect facilities to delineate responsibilities for all of their facility's workers in their emergency preparedness plans and to determine the appropriate level of training for each professional role. Therefore facilities will have discretion in determining what encompasses appropriate training for the different staff positions/roles.

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Q: Please define “all-employees” in the term of being able to demonstrate knowledge of emergency plans and procedures.

A: Employee’s or the term “staff” refers to all individuals that are employed directly by a facility. The phrase “individuals providing services under arrangement” means services furnished under arrangement that are subject to a written contract conforming with the requirements specified in section 1861(w) of the Act. We refer providers back to the regulation text for further information (81 FR. 63891).

Q: What kind of training will be developed specifically for providers and suppliers to prepare for implementation of the rule?

A: CMS does not expect to develop training specifically for providers and suppliers. Healthcare associations and state, local and other Federal healthcare agencies may provide training for providers and suppliers. However, training provided by these organizations is only a tool to assist facilities in preparing for implementation of the rule and does not mean that a provider or supplier is in compliance by having received the training.

Miscellaneous

Q: Does the Final Rule apply to pharmacies (both community as well as hospital)?

A: No, the regulation does not apply to stand alone, community pharmacies. The rule does apply to pharmacies that are considered a department of a Medicare participating facility (hospital, ASC, CAH, etc.).

Q: Does this regulation apply to physician offices?

A: The new Emergency Preparedness requirements do not apply to physician offices that are not part of a certified Medicare participating facility. Physicians’ offices or practices that are considered part of a certified Medicare participating facility would be required to meet the regulations.

Q: Does the rule apply to providers/suppliers participating in Medicaid?

A: If a Medicaid provider is required to meet the requirements for participation in Medicare in order to receive Medicaid payment, that provider is required to comply with the Emergency Preparedness requirements, along with all of the other Medicare CoPs or CfCs for that provider. For example, Medicaid only hospitals must meet the Medicare requirements so they must comply with all of the hospital CoPs, including the Emergency Preparedness requirements. Note that not all provider types have a provision requiring them to meet the Medicare requirements in order to be Medicaid participating.