



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-41-ALL

DATE: September 25, 2020

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

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

Memorandum Summary

- ***Emergency Preparedness Testing Exemption and Guidance*** - CMS regulations for Emergency Preparedness require specific testing exercises be conducted to validate the facility's emergency program. During or after an actual emergency, the regulations allow for an exemption to the testing requirements based on real world actions taken by providers and suppliers.
- This worksheet presents guidance for surveyors, as well as providers and suppliers, with relevant scenarios on meeting the testing requirements in light of many of the response activities associated with the COVID-19 Public Health Emergency (PHE).

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.

Testing Exercise Definitions:

CMS defines the testing exercises required under the emergency preparedness regulations in two categories. Specifically, 1) full-scale, functional and individual-facility based exercises as the “required” exercises; and, 2) mock disaster drills, table-top exercises or workshops, as the “exercises of choice”, which could also include the full-scale functional and individual-facility based exercises. CMS further defines the exercises as follows:

Full-Scale Exercise (FSE): A full scale exercise is an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional (for example, joint field office, emergency operation centers, etc.) and integration of operational elements involved in the response to a disaster event, i.e. “boots on the ground” response activities (for example, hospital staff treating mock patients).

Functional Exercise (FE): “FEs are designed to validate and evaluate capabilities, multiple functions and/or sub-functions, or interdependent groups of functions. FE are typically focused on exercising plans, policies, procedures, and staff members involved in management, direction, command, and control functions” as defined by DHS’s Homeland Security Exercise and Evaluation Program (HSEEP).

Mock Disaster Drill (Exercise of Choice Only): A drill is a coordinated, supervised activity usually employed to validate a specific function or capability in a single agency or organization. Drills are commonly used to provide training on new equipment, validate procedures, or practice and maintain current skills. For example, drills may be appropriate for establishing a community-designated disaster-receiving center or shelter. Drills can also be used to determine if plans can be executed as designed, to assess whether more training is required, or to reinforce best practices. A drill is useful as a stand-alone tool, but a series of drills can be used to prepare several organizations to collaborate in an FSE.

Table-top Exercise (TTX) (Exercise of Choice Only): A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures. A tabletop exercise is a discussion-based exercise that involves senior staff, elected or appointed officials, and other key decision making personnel in a group discussion centered on a hypothetical scenario. TTXs can be used to assess plans, policies, and procedures without deploying resources.

Workshop (Exercise of Choice Only): A workshop, for the purposes of this guidance, is a planning meeting/workshop, which establishes the strategy and structure for an exercise program as defined in HSEEP guidelines.

Changes Specific to Testing Exercise Requirements

For providers of inpatient services: The testing exercises were expanded to include workshops as an exercise of choice. However these providers are still required to conduct two emergency preparedness testing exercises annually.

Inpatient providers and suppliers include: Inpatient hospice facilities, Psychiatric Residential Treatment Facilities (PRTFs), hospitals, long-term care (LTCs) facilities, Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IIDs), and Critical Access Hospitals (CAHs).

For providers of outpatient services: These providers must continue to test their program annually, by participating in a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise every other year. In the opposite years off the full-scale exercise, the providers are required to conduct a testing exercise of their choice, which may include either a community-based full-scale exercise (if available), an individual, facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

Outpatient providers and suppliers include: Ambulatory Surgical Centers (ASCs), freestanding/home-based hospice, Program for the All-Inclusive Care for the Elderly (PACE), Home Health Agencies (HHAs), Comprehensive Outpatient Rehabilitation Facilities (CORFs), Organizations (which include Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), Community Mental Health Clinics (CMHCs), Organ Procurement Organizations (OPOs), Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), and End-Stage Renal Disease (ESRD) facilities.

Exemption Based on Actual Natural or Man-made Emergency

The emergency preparedness regulations allow an exemption for providers or suppliers that experience a natural or man-made event requiring activation of their emergency plan. On Friday, March 13, 2020, the President declared a national emergency due to COVID-19 and subsequently many providers and suppliers have activated their emergency plans in order to address surge and coordinate response activities. **Facilities that activate their emergency plans are exempt from the next required full-scale community-based or individual, facility-based functional exercise.** Facilities must be able to demonstrate, through written documentation, that they activated their program due to the emergency.

CMS requires facilities to conduct an exercise of choice annually for inpatient providers and every two years for outpatient providers (opposite the year of the full-scale or facility-based functional exercise). For the “exercise of choice,” facilities must conduct one of the testing exercises below:

- Another full-scale exercise;
- Individual-facility-based functional exercise;
- Mock disaster drill; or
- A tabletop exercise or workshop.

Facilities may need to conduct an exercise of choice following the current PHE if they were required to conduct such an exercise this year and did not already do so. Facilities may choose to conduct a table-top exercise (TTX) which could assess the facility's response to COVID-19. This may include but is not limited to, discussions surrounding availability of personal protective equipment (PPE); isolation and quarantine areas for screening patients; or any other activities implemented during the activation of the emergency plan. The emergency preparedness provisions require that facilities assess and update their emergency program as needed. Therefore, lessons learned and challenges identified in the TTX may allow a facility to adjust its plans accordingly.

Conducting Assessments & Documentation

As a reminder, all providers and suppliers must continue to analyze their facility's response to and maintain documentation of all drills, tabletop exercises, and activation of their emergency plan. This would include documentation showing any revisions to the facility's emergency plan as a result of the after action review process.

A future release of the State Operations Manual, Appendix Z will update the guidance.

Contact: Questions about this memorandum should be addressed to QSOG_EmergencyPrep@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated to all survey and certification staff, their managers and the State/Regional Office training coordinators immediately.

/s/

David R. Wright

Attachment (s)- Emergency Preparedness Surveyor Worksheet

cc: Survey and Operations Group Management

Emergency Preparedness Surveyor Worksheet Requirements for Surveying for Testing Exercises Standard (d)(2) Exemptions

Purpose: This worksheet presents guidance relevant to determining compliance with the testing exemption following activation of emergency plans during actual emergency events. We note that the testing requirements changed for inpatient and outpatient providers with 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 published on September 30, 2019 (<https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf>).

Requirement for Outpatient Providers

Requirement & Guidance: Outpatient providers must conduct a full-scale exercise (or individual facility-based exercise when a full-scale is not available) every 2 years pursuant to standard (d)(2) of their respective “Emergency Preparedness” regulation and in opposite years conduct any one of the “exercises of choice,” which include another full-scale or individual facility-based functional exercise, table top exercise, workshop, or mock drill.

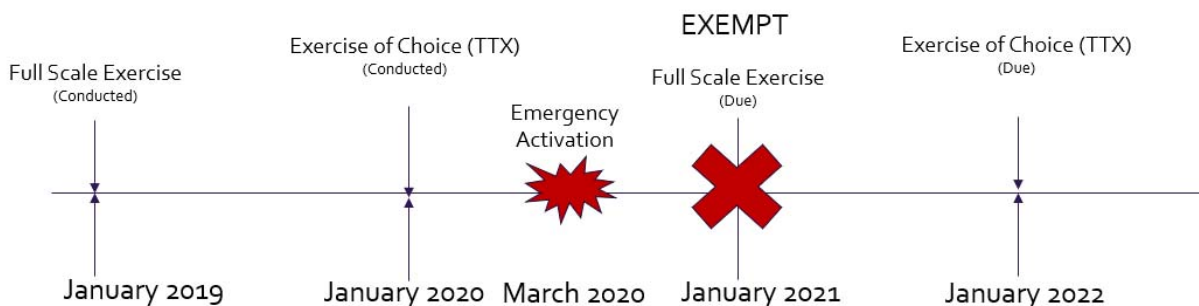
The Exemption Clause: In the event a facility activates its emergency plan due to an actual emergency, the outpatient provider would be exempt from engaging in its **next required community-based full-scale exercise or individual facility-based functional exercise following the onset of the emergency event**. Facilities must be able to demonstrate, through written documentation, that they activated their emergency plan.

Outpatient Provider Scenarios

Scenario #1. Facility X conducted a full-scale exercise in January 2019 and a table-top exercise for January 2020 (opposite year). In March 2020, Facility X activates its emergency preparedness plan due to the COVID-19 Public Health Emergency (PHE).

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

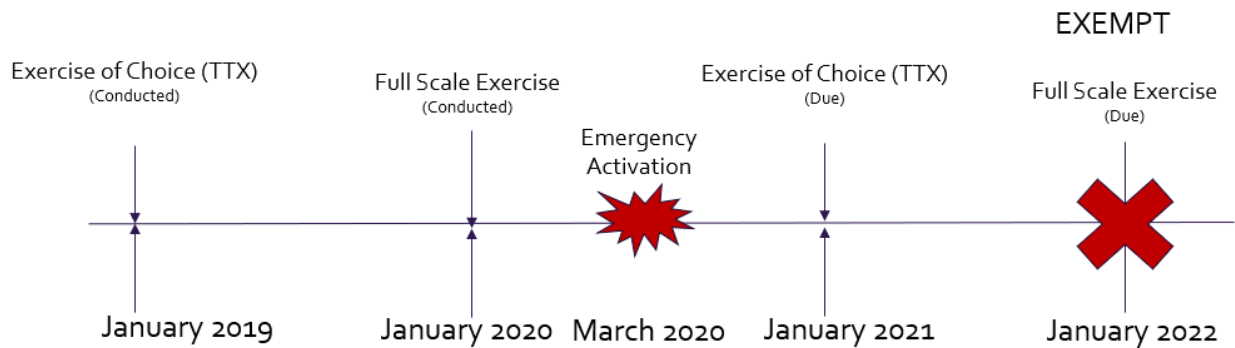
Answer: The facility is exempt from the next scheduled exercise (January 2021 full-scale exercise). It would then be required to complete their opposite year exercise of choice by January 2022.



Scenario #2. Facility Y conducted a table top exercise in January 2019 as the exercise of choice and conducted a full-scale exercise in January 2020. In March 2020, Facility Y activates its emergency preparedness program due to the COVID-19 PHE.

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

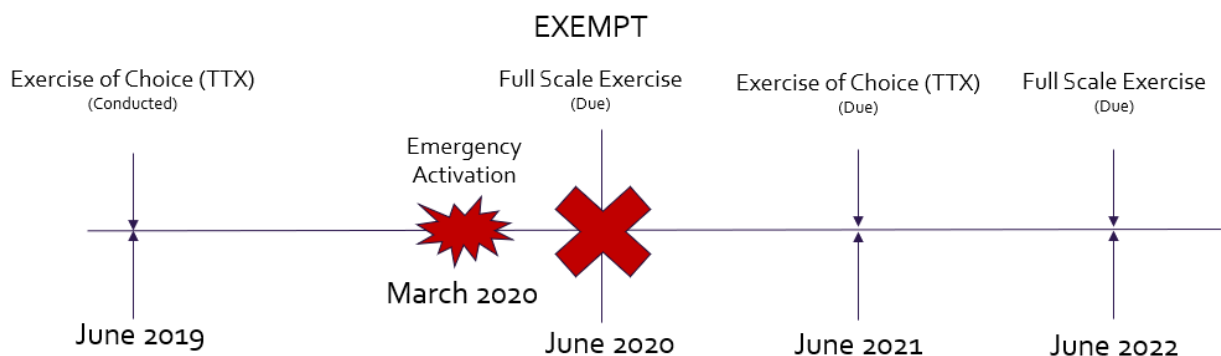
Answer: The facility is exempt from the January 2022 full-scale exercise for that “annual year”. However, the facility must conduct its exercise of choice by January 2021, and again in January 2023.



Scenario #3. Facility Z conducted a table-top exercise in June 2019 (based on its annual cycle). It is scheduled to conduct a full-scale exercise in June 2020. In March 2020, Facility Z activates its emergency preparedness program due to the COVID-19 PHE.

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

Answer: The facility is exempt from the June 2020 scheduled full-scale exercise for that “annual year” and is required to complete an exercise of choice in June 2021, and a following full-scale exercise in June 2022. It is exempt from its **next required** full-scale or individual facility-based exercise which would have been in June 2020.



Survey Steps for Determining Use of the Exemption Clause:

- Determine the facility's annual cycle.
- For outpatient providers, ensure the facility has conducted one full-scale/functional exercise within the 12-month period followed by an exercise of choice on opposite years, dependent on the scenarios above.
- Ask the facility to describe the exemption to ensure understanding that exemption is based on the scheduled next-required full-scale exercise, not the exercise of choice.
- Verify documentation evidence that the facility activated its emergency plan (in order to determine whether the testing exemption is acceptable for use). Documentation may include, but is not limited to, the following:
 - Notice of activation to staff via electronic systems (alerts);
 - Proof of patient transfers and changes in daily operations based on the emergency;
 - Initiation of additional safety protocols, for example, mandate for use of personal protective equipment (PPE) for staff, visitors and patients as applicable;
 - Coordination with state and local emergency officials;
 - Minutes of board/facility meetings;
 - 1135 Waiver (individual or use of blanket flexibilities); or,
 - Incident command system related reports, such as situation reports or incident action plans.
- Determine, based on the above examples, whether the facility is compliant with the exemption clause and has conducted the appropriate required exercises.

Requirement for Inpatient Providers

Requirement & Guidance: Inpatient providers must conduct a full-scale exercise (or individual facility-based exercise when a full-scale is not available) annually pursuant to standard (d)(2) of their respective “Emergency Preparedness” regulation, and also conduct any one exercise of the “exercises of choice” which include another full-scale or individual facility-based exercise, table top exercise, workshop or mock drill annually.

The Exemption Clause: In the event a facility activates its emergency program due to an actual emergency, the inpatient provider would be exempt from engaging in its **next required** community-based full-scale exercise or individual facility-based exercise following the onset of the emergency event. Facilities must be able to demonstrate through written documentation, that they activated their program due to the emergency.

Inpatient Provider Scenarios

Scenario #1. Facility X conducted a full-scale exercise in January 2019 and a table-top exercise as their exercise of choice in November 2019. It also conducted another full-scale exercise in January 2020, and is scheduled to conduct its workshop in November 2020. In March 2020, Facility X activates its emergency preparedness program due to the COVID-19 Public Health Emergency (PHE).

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

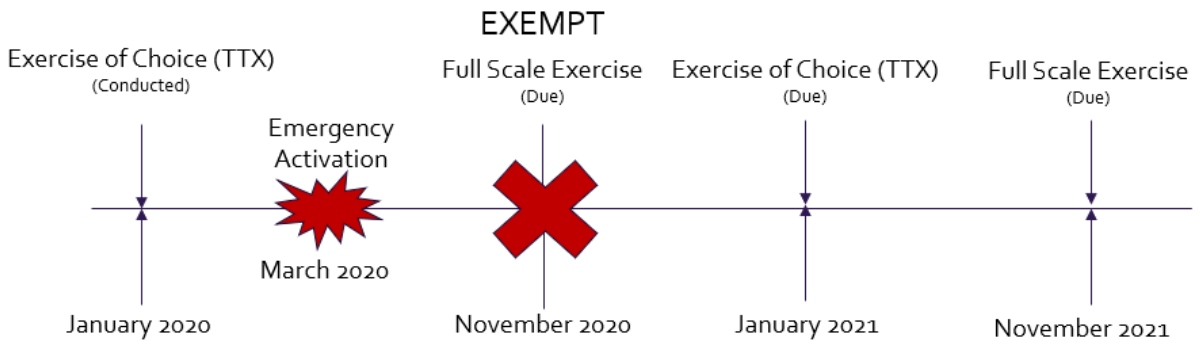
Answer: Since the facility already conducted its full-scale requirement for 2020, it is only required to conduct the scheduled workshop for November 2020. The facility is exempt from its next required full-scale, in January 2021. However, the facility must still complete an exercise of choice by November 2021.



Scenario #2. Facility Y conducted a table-top exercise in January 2020 as the exercise of choice and is scheduled to conduct its full-scale exercise in November 2020. In March 2020, Facility Y activates its emergency preparedness program due to the COVID-19 PHE.

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

Answer: The facility is exempt from the November 2020 scheduled full-scale exercise for that “annual year”. However, the facility must conduct both the full-scale and exercise of choice in 2021 based on its defined cycle (January 2021 and November 2021).



Survey Steps for Determining Use of the Exemption Clause:

- Determine the facility’s annual cycle.
- For inpatient providers, ensure the facility has conducted two required exercises within the 12-month period, dependent on the scenarios above.
- Ask the facility to describe the exemption to ensure understanding that exemption is based on the scheduled next-required full-scale exercise, not the exercise of choice.
- Verify documentation evidence that the facility activated its emergency plan in order to determine whether the testing exemption is acceptable for use. Documentation may include, but is not limited to, the following:
 - Notice of activation to staff via electronic systems (alerts);
 - Proof of patient transfers and changes in daily operations based on the emergency;
 - Initiation of additional safety protocols, for example, mandate for use of personal protective equipment (PPE) for staff, visitors and patients as applicable;
 - Coordination with state and local emergency officials;
 - Minutes of board/facility meetings;
 - 1135 Waiver (individual or use of blanket flexibilities); or,
 - Incident command system related reports, such as situation reports or incident action plans.
- Determine based on the above examples, whether the facility is compliant with the exemption clause and has conducted the appropriate required exercises.