Federally Qualified Health Centers (FQHCs) & Emergency Preparedness Requirements

Overview of FQHCs and What's New based on the *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction* Final Rule

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Overview & Agenda

- Overview of the Federally Qualified Healthcare Centers (FQHCs)
- Provide an overview of the recent regulatory changes as they relate to the Emergency Preparedness Medicare Condition.
- Review each of the core elements of the Emergency Preparedness Program
- Additional clarifications made over the last few months

FQHC Overview

- FQHCs must remain in substantial compliance with all of the FQHC regulatory requirements specified in 42 CFR Part 405, Subpart X, and in 42 CFR Part 491, with the exception of Section 491.3.

- Unlike RHCs, FQHCs do not undergo initial/recertification surveys. Instead, they are subject to a filing procedure. Under this procedure, the FQHC self-attest that it is in substantial compliance and will remain in substantial compliance with all applicable Medicare regulations.

- Facilities are expected to be in compliance with the revised EP requirements effective 11/29/2019.

FQHC Conditions for Coverage

Title 42 - CFR Part 491

§491.1 - Purpose and scope
§491.2 - Definitions
§491.3 - Certification procedures **(not applicable for FQHCs)**
§491.4 - Compliance with Federal, State and local laws
§491.5 - Location of clinic
§491.6 - Physical plant and environment
§491.7 - Organizational structure
§491.8 - Staffing and staff responsibilities
§491.9 - Provision of services.
§491.10 - Patient health records.
§491.11 - Program evaluation.
§491.12 - Emergency preparedness

State Agency Survey

- If CMS receives a credible allegation(s) of noncompliance with the Medicare requirements and health and safety standards found at 42 CFR 405 and 42 CFR 491, the State Survey Agency (SA) will conduct a unannounced complaint survey investigation on behalf of CMS.

- To determine whether the FQHC is in substantial compliance with the Medicare requirements, SAs (or CMS regional offices, in the case of tribal FQHCs) follow the general complaint survey process located in Chapter 5 of our State Operations Manual (SOM), particularly §§5200 – 5240 and Appendix G. (See Chapter 5: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c05pdf.pdf and Appendix G: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf

Complaint Investigation – Compendious Review

- In general, a complaint investigation is a focused survey conducted on the specific regulatory requirement(s) related to the allegation, but the SA can expand the scope of review as necessary to determine compliance or noncompliance.

- If deficiencies are cited, the SA documents the deficiencies on the Form CMS-2567 and obtains an acceptable Plan of Correction (PoC).

- The Form CMS-2567 is the official document that communicates the determination of compliance or noncompliance with Federal requirements. Also, it is the form that the FQHC would use to submit a plan to achieve compliance, i.e., the PoC.

COVID-19 Flexibilities

- *CMS is committed* to taking critical steps to ensure America's healthcare facilities can respond to the threat of COVID-19.

- All healthcare facilities are encouraged to monitor the CDC website for information and resources and contact their local health department when needed (CDC Resources for Health Care Facilities).

RHC and FQHC Flexibilities in Response to Coronavirus Disease 2019 (COVID-19)

To assist RHCs and FQHCs in furnishing services during the COVID-19 PHE, CMS has temporarily waived regulatory requirements applicable to the following:

- 50% mid-level staffing requirement for RHCs;
- Physician supervision requirement for nurse practitioners (NPs), (*to the extent permitted by State law),* and
- Location requirements for existing RHCs and FQHC to allow additions of temporary service locations.

Details for Flexibilities

- The flexibilities are retroactively effective beginning March 1, 2020
- Expires at the end of the emergency declaration and CMS issues an end of outbreak notification.
- Only apply to existing RHCs and FQHCs

Physician Supervision of NPs

- During the PHE, NPs may function to the fullest extent possible without physician supervision, and to the extent of applicable state law.

- Physician continues to be responsible for providing the overall medical direction for the RHC/FQHC's health care activities, consultation for, and medical supervision of all other health care staff, either in person or through telehealth and other remote communications.

Temporary Locations

- During the COVID-19 PHE, CMS is allowing currently approved RHCs/FQHCs to provide patient care services in temporary expansion to help address the urgent need for supplementary care.
- The temporary site may include a parking lot.
- Temporary sites are not restricted to the rural/shortage area location requirements.
- Each location is obligated to meet the same RHC/FQHC regulations as the main site, to the extent not waived.

Temporary Locations (cont'd)

- The RHC/FQHC is expected to be operating in a manner not inconsistent with its state's emergency preparedness plan.

- FQHCs must also have an updated Health Resource and Service Administration (HRSA) Notice of Award, expanding the scope of service to include the temporary location(s) to support response to the COVID-19 PHE.

- Providing all requirements are met, services provided at a temporary site may be provided under the permanent location's CMS Certification Number (CCN)

Temporary Locations (cont'd)
Patient's Vehicle

- During the COVID-19 PHE, to help minimize transmission, an RHC/FQHC visit can take place if:
  - the patient is in a vehicle on the premises of the RHC/FQHC and all requirements for a billable visit are met (e.g. medically-necessary, face-to-face visits with an RHC/FQHC practitioner).
  - All services provided are held to all RHC/FQHC regulations, unless otherwise waived. This includes, but is not limited to, the provisions of services as per 42 CFR 491.9(c).

Temporary Locations (cont'd)
Patient's Vehicle

  - RHCs/FQHCs must consider the clinical appropriateness of services before conducting a visit and/or treating a patient in their vehicle.

- The RHC/FQHC would provide the services using its existing CCN.

Temporary Location (cont'd)
State's Emergency Preparedness Plan.

- An RHC/FQHC seeking approval of its temporary location is not inconsistent with its state's emergency preparedness plan.
- Retain any communications with the State emergency preparedness representatives to demonstrate that its temporary location(s) are not inconsistent with the state emergency preparedness and pandemic plan for the COVID-19 PHE.
- Once the state has approved the addition of temporary location(s), there are no additional CMS enrollment or reporting requirements. The RHC/FQHC may begin utilizing the temporary expansion location throughout the duration of the COVID-19 PHE.

Temporary Location (Cont'd)
COVID-19 PHE Ends

- All waived CoPs, CfCs, requirements, and most temporarily revised regulations will terminate at the end of the PHE.

- If the RHC/FQHC wishes to continue services at the temporary expansion location after the PHE has ended, the facility must submit form 855A to begin the process of enrollment and initial certification as a RHC/FQHC under the regular process and meet all applicable requirements, including 42 CFR 491.5.

FQHC Resources

- Appendix G – Guidance for Surveyors: Rural Health Clinics
- Appendix Z – Guidance: Emergency Preparedness for All Provider and Certified Supplier Types

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Additional FQHC Resources

- Medicare FFS Billing FAQ document available at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.
- CMS MLN Article - FQHCs furnishing telehealth services during the PHE, https://www.cms.gov/files/document/se20016.pdf
- COVID-19 FAQs Non-Long Term Care facilities: https://www.cms.gov/files/document/covid-faqs-non-long-term-care-facilities-and-intermediate-care-facilities-individuals-intellectual.pdf
- Additional waiver information: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

FQHC Emergency Preparedness

Emergency Preparedness Rules

Final Rules

- Original Emergency Preparedness Final Rule: *Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers* (2016)

- Revisions to Emergency Preparedness Requirements: *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction* (2019)

Important Reminders

- The Final Rule for Emergency Preparedness published in 2016 and provisions were updated with the Burden Reduction Final Rule *published 2019*.

- Emergency Preparedness still applies to all 17 provider and supplier types

- Compliance required for participation in Medicare

- Emergency Preparedness is ONE CoP/CfC of many already required

Primary Changes as of 2019's Burden Rule

- **Review & Updates**:
  - Plans, policies and procedures, communication plan **reduced to at least every 2 years** (annually for LTC). Review/updates should still occur as needed with changes.

- **Training/Testing**
  - For outpatient providers, revised the requirement such that only one testing exercise is required annually, which may be either one community-based full-scale exercise, if available, or an individual facility-based functional exercise, every other year and in the opposite years, these providers may choose the testing exercise of their choice.

What's New- Appendix Z Updates

- On March 26, 2021, CMS has made several updates to Appendix Z of the State Operations Manual (SOM). Revisions include:
  - Recommendations during PHE's 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.
  - Added additional guidance on risk assessment considerations, to include EIDs
  - Added additional guidance/considerations for emerging infectious diseases (EID) planning to include personal protective equipment (PPE).
  - Expanded guidance on the identification and use of best practices related to reporting of facility needs, the facility's ability to provide assistance and occupancy reporting.
  - Expanded guidance for surge planning due to natural disasters and EIDs.
  - Included planning considerations for potential patient surges and staffing needs.
  - Added additional planning considerations for hospices during EIDs outbreaks.

What's New- Appendix Z Updates *(Cont.)*

- Expanded guidance and added clarifications related to alternate care sites and 1135 Waivers.
- Added new definitions based on the Omnibus Burden Reduction Final Rule expansion of acceptable testing exercises.
- 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.
- Clarified expectations surrounding documentation of the emergency program.
- Expanded surveyor guidance to ensure Life Safety Code and health surveyors communicate/collaborate surrounding potential deficiencies for alternate source energy.
- Clarified existing guidance

Four Provisions for All Provider Types

Risk Assessment and Planning

- Develop an emergency plan based on a risk assessment.
- Perform risk assessment using an “all-hazards” approach, focusing on capacities and capabilities.
- Facilities must still have a process for cooperation and collaboration with local, tribal (as applicable), regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.
- Update emergency plan at **least every 2 years** (annually for LTC)

All-Hazards Approach:

- An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters.

- This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is 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; and emerging infectious disease (EID) threats.

Additional Guidance for EID Planning

- CMS does not specifically define infectious disease or which types to include in the risk assessment/plan.

- Some examples of EID's may include, but are not limited to:
  - Potentially infectious Bio-Hazardous Waste
  - Bioterrorism
  - Pandemic Flu
  - Highly Communicable Diseases (such as Ebola, Zika Virus, SARS, or novel COVID-19 or SARS-CoV-2)

Additional Guidance for EID Planning

- EID's should be identified within a facility's risk assessment.
- EID's may be localized to a certain community or be widespread (as seen with the COVID-19 PHE) and therefore plans for coordination with local, state, and federal officials are essential.
- Consider having infection prevention personnel involved in the planning, development and revisions to the EP program, as these individuals would likely be coordinating activities within the facility during a potential surge of patients.

Policies and Procedures

- Develop and implement policies and procedures based on the emergency plan and risk assessment, and the communication plan.

- 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.

- Review and update policies and procedures at **least every 2 years** (annually for LTC).

P&P Additional Clarifications/Guidance

- Appendix Z provides additional guidance related to incorporating EID's into the facility's policies and procedures. This included overarching themes of:
  - Surge Planning Considerations
  - Reporting of Facility Needs and Ability to Provide Assistance
  - Contingency of Services and Operations
- For example, facilities must have policies which address their ability to respond to a surge in patients requiring care. As required, these policies and procedures must be aligned with a facility's risk assessment, and should include planning for EIDs.

Reminders and Important Notes

- When developing transfer agreements, facilities must take into account the patient population and the ability for the receiving facility to provide continuity of services.

- If a facility has a transfer arrangement with another facility and this facility could not accommodate all patients, then the facility should plan accordingly to provide continuity of services with another facility who could receive the remaining residents.

Reminders and Important Notes

Continued

- Facilities should also take into account the availability of contracted resources during an emergency event. For instance, a facility has a written arrangement with a transportation company, yet during an emergency the transportation company is unable to reach the facility due to flooding and/or having other arrangements with the community.

- The facility is responsible to ensure these areas are discussed and managed within their policy and procedure to ensure availability of resources during an emergency event.

- It would be appropriate for the facility to have discussions with transportation vendors about their competing contracts during an emergency and the vendor's continuity of business plans in the event of an emergency.

Communication Plan

- 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.
- Review and update plan at **least every 2 years** (annually for LTC).
- Updated Appendix Z also provides additional considerations for facility's on reporting occupancy and sharing information with emergency management systems.

Training and Testing Program

- Develop and maintain a training and testing program including initial training in policies and procedures, based on the emergency plan, risk assessment, policies & procedures and the communication plan.

- Review and update the training and testing program at **least every 2 years.**

Training Requirements

- Conduct initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers
- After initial training, provide emergency preparedness training **every 2 years** (Annually for LTC)
- Demonstrate staff knowledge of emergency procedures.
- Maintain documentation of all emergency preparedness training.
- If the emergency preparedness policies and procedures are significantly updated, conduct training on the updated policies and procedures.

Additional Guidance for Training Program

- Training refers to a facility's responsibility to provide education and instruction to staff, contractors, and facility volunteers to ensure all individuals are aware of the emergency preparedness program.

- For training requirements, the facility must have a process outlined within its emergency preparedness program which encompasses staff and volunteer training complementing the risk assessment.

- The training for staff should at a minimum include training related to the facility's policies and procedures.

New Definitions for Testing

- **Functional Exercise (FE):** "FEs are designed to validate and evaluate capabilities, multiple functions and/or sub-functions, or interdependent groups of functions. FEs are typically focused on exercising plans, policies, procedures, and staff members involved in management, direction, command, and control functions" as defined by HSEEP. We have attempted to align our definitions with those guidelines.

- For additional details, please visit HSEEP guidelines located at https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revision_Apr13_Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da

New Definitions for Testing

- ***Mock Disaster* Drill:** 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.

New Definitions for Testing

- Workshop: 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 by HSEEP. We have attempted to align our definitions with those guidelines.

- For additional details, please visit HSEEP guidelines.

Testing Changes with Burden Reduction

- **For outpatient providers:** Facilities are required to only conduct one testing exercise on an annual basis, which may be either one community-based full-scale exercise, if available, or an individual facility-based functional exercise, every other year and in the opposite years, these providers may choose the testing exercise of their choice.

- These outpatient providers are required to conduct one full-scale or individual facility based exercise every two years, and in the opposite years, the providers can conduct testing exercise of choice, which can include either a full-scale, individual facility-based, drill, tabletop exercise/workshop which includes a facilitator.

Testing Exercises- Reminder

- CMS is not specifying a minimum number of staff which must attend these exercises, however facility leadership and department heads should participate in each exercise.

- A sufficient number of staff should participate in the exercise to test the scenario and thoroughly assess the risk, policy, procedure, or plan being tested

- If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, the expectation is that staff who work in this clinical area participate in the exercise for a clear understanding of their roles and responsibilities.

Testing Exercises- Reminder

- Additionally, facilities can review which members of staff participated in the previous exercise, and include those who did not participate in the subsequent exercises to ensure all staff members have an opportunity to participate and gain insight and knowledge.

- CMS added additional clarification to Appendix Z related to testing exercises and defined “community partners” in relation to facility exercises.

- Community partners are considered any emergency management officials (fire, police, emergency medical services, etc.) for full-scale and community-based exercises, however can also mean community partners that assist in an emergency, such as surrounding providers and suppliers.

Testing Exercise- Exemption

- If a facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the facility is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.

- Exemption only applies to the NEXT REQUIRED full-scale exercise.

- Facilities must demonstrate activation of the emergency plan.

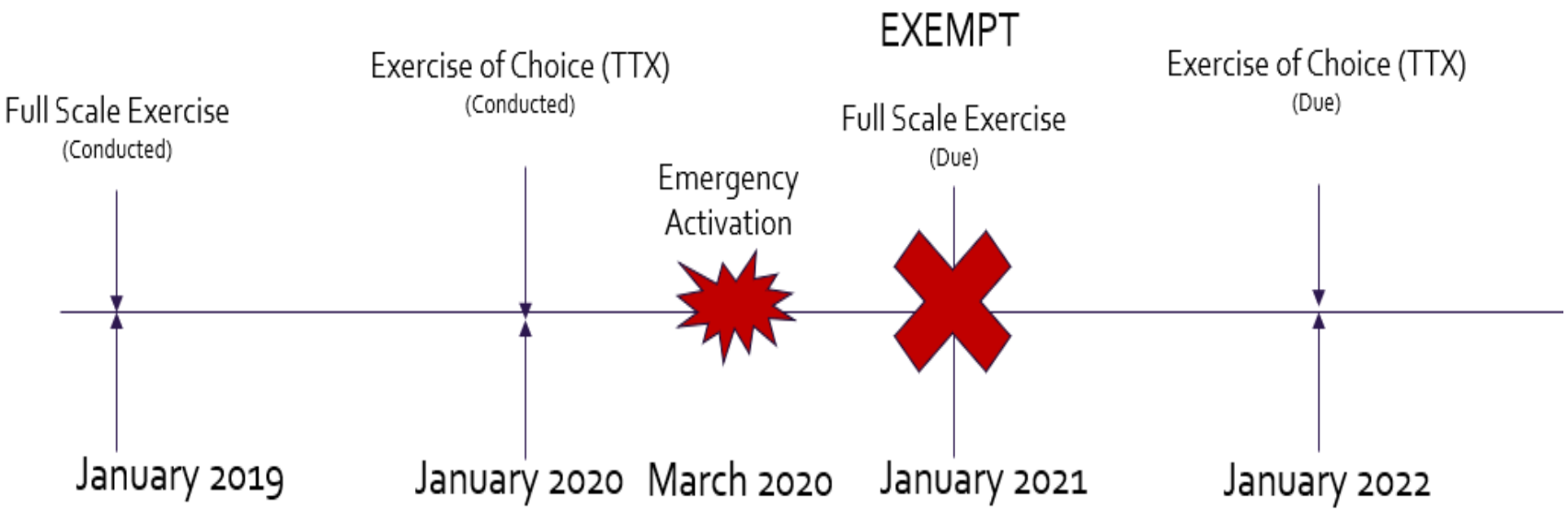
Outpatient Provider Scenarios

- **<u>Scenario #1</u>.** Facility X conducted a full-scale exercise in January 2019 and a table-top exercise as their exercise of choice for January 2020 (opposite year). In March 2020, Facility X activates its emergency preparedness program due to the COVID-19 Public Health Emergency (PHE).

Question #1: When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

Outpatient Provider Scenarios

Answer #1: The facility is exempt from the January 2021 full-scale exercise for that "annual year" and is required to complete an exercise of choice by January 2022.



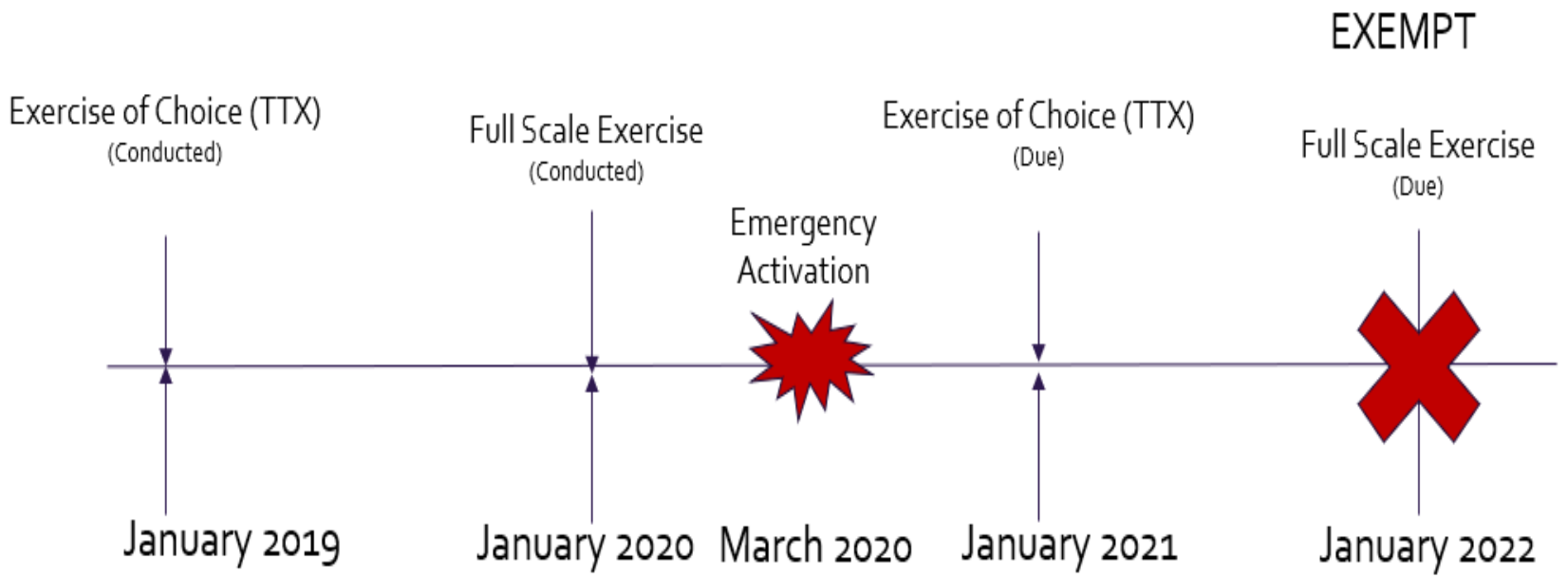
Outpatient Provider Scenarios

- **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.

Question #2: When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

Outpatient Provider Scenarios

Answer #2: 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



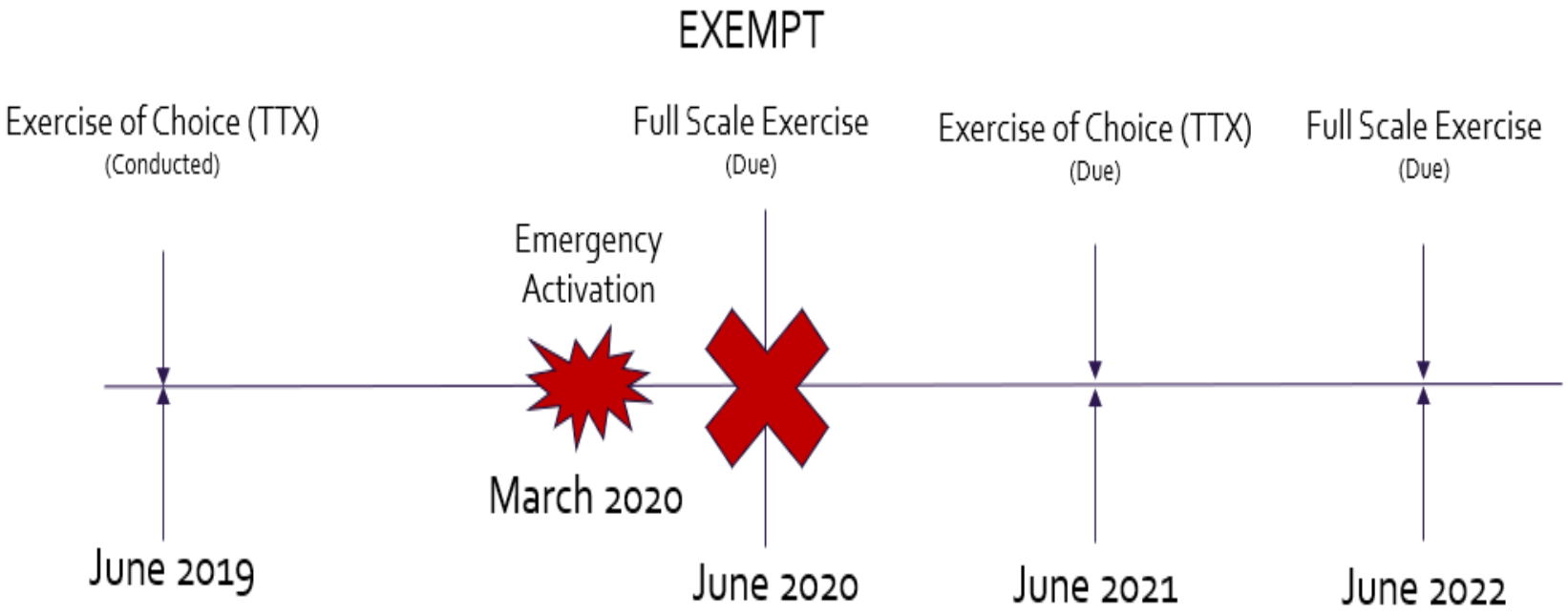
Outpatient Provider Scenarios

- **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.

Question #3: When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

Outpatient Provider Scenarios

Answer #3: 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.



Documentation Requirements

- Facilities must be able to demonstrate, through written documentation, that they activated their program due to the emergency.

- During natural disasters, facilities generally show activation by providing notice of imminent weather to staff; showing documentation of evacuations; closures etc.

- There is no need to submit any documentation.

Reminders and Important Notes

- While we encourage the use of healthcare coalitions, we recognize this is not always feasible for all providers and suppliers.

- For facilities participating in coalitions, we are not specifying the "level" of participation. However, if facilities use healthcare coalitions to conduct exercises or assist in their efforts for compliance, we ask this would be documented and in writing.

State & Accrediting Organization Requirements

- The Emergency Preparedness Rule does not specify quantities within any provisions. The rule is broad and overarching.

- Facilities should check with their State Survey Agencies and Accrediting Organizations (as applicable) for any additional requirements which may exceed the CMS requirements.

- During public health emergencies such as pandemics, the Centers for Disease Control and Prevention (CDC) and other public health agencies may issue event-specific guidance and recommendations. Facilities are recommended to have a process to ensure monitoring of event-specific guidance.

Where are we now?

- Changes are effective upon implementation of the Burden Reduction Final Rule - November 29, 2019, no grace period.
- Our Surveyor Training (available publically) is under development to reflect the Burden Reduction Final Rule changes as well as CMS's additional guidance added to Appendix Z.
- We would recommend facilities use the checklists developed by ASPR to help guide them to their specific requirements. Review the checklists under Facility-Specific Requirement Overviews at https://asprtracie.hhs.gov/cmsrule.
- Consider annotating on the checklist, the location of each of your elements of the plan to assist surveyors reviewing on-site

The QSOG EP Website

- Providers and Suppliers should refer to the resources on the CMS website for assistance in developing emergency preparedness plans.

- The website also provides important links to additional resources and organizations who can assist. We will be working on revisions to FAQs and other resources for the next several months to reflect the new changes

- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html

Thank you!