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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

Ref: QSO-21-15-ALL

DATE: **March 26, 2021**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Updated Guidance for Emergency Preparedness-Appendix Z of the State Operations Manual (SOM)

Memorandum Summary

- **Burden Reduction Final Rule Interpretive Guidelines:** The Centers for Medicare & Medicaid Services (CMS) is releasing interpretive guidelines and updates to Appendix Z of the State Operations Manual (SOM) as a result of the revisions of the *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CoPs) (CMS 3346-F) Final Rule.*
- **Expanded Guidance related to Emerging Infectious Diseases (EIDs):** CMS is also providing additional guidance based on best practices, lessons learned and general recommendations for planning and preparedness for EID outbreaks.

Background

On September 30, 2019, the Centers for Medicare & Medicaid Services (CMS) published two final rules with certain provisions effective November 29, 2019. The first rule was the *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CoPs) (CMS 3346-F)* (referenced to as the Burden Reduction Final Rule 84 FR 51732) which revised requirements all providers and suppliers for Emergency Preparedness. The guidance within the SOM Appendix Z has now been updated to reflect the revisions made within this Final Rule.

Additionally, in February 2019, CMS added "emerging infectious diseases" to the definition of all-hazards approach in Appendix Z as CMS determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program. In light of events such as the Ebola Virus and Zika, we believe that facilities should consider preparedness and infection prevention within their all-hazards approach, which covers both natural and man-made disasters.

In light of the coronavirus disease 2019 (COVID-19) public health emergency (PHE), CMS is expanding the Emergency Preparedness Interpretive Guidelines to further expand on best practices, lessons learned, and planning considerations for EIDs.

Discussion

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 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 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.

Training: CMS is currently working on updates to the Emergency Preparedness Basic Surveyor Training Course to reflect the new changes. We will communicate the updated course availability at a later time.

Contact: For questions or concerns, please contact QSOG_EmergencyPrep@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/CMS Location training coordinators within 30 days of this memorandum.

State Operations Manual
Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance

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to improve the patient's safety. The individualized emergency plan should be in writing and could be as simple as a detailed emergency card to be kept with the patient. HHA personnel should document that these discussions occurred and also keep a copy of the individualized emergency plan in the patient's file as well as provide a copy to the patient and or their caregiver.

Additionally, HHAs should consider potential contingency operations within their policies. For example, how will the HHA ensure the appropriate discipline/staff perform the required initial and comprehensive assessments when access to residences may be hindered due to an emergency? While some contingency plans may include requests for Section 1135(b) emergency waiver flexibility during a declared public health emergency (requiring CMS pre-approval prior to use), HHAs are encouraged to plan ahead for the potential use of alternative staffing options/professions, acting in accordance with their state scope of practice laws.

For additional information on 1135 Waivers, please visit: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/Waivers-and-flexibilities and also the CMS Frequently Asked Questions, Emergency-Related Policies and Procedures That May Be Implemented Without § 1135 Waivers, at https://www.cms.gov/about-cms/agency-information/emergency/downloads/consolidated_medicare_ffs_emergency_qsas.pdf

Survey Procedures

- Through record review, verify that each patient has an individualized emergency plan documented as part of the patient's comprehensive assessment.
- *Does the HHA have a process related to how to continue to meet the requirements for individualized care plans?*

E-0018

(Rev.)

§403.748(b)(2), §416.54(b)(1), §418.113(b)(6)(ii) and (v), §441.184(b)(2), §460.84(b)(2), §482.15(b)(2), §483.73(b)(2), §483.475(b)(2), §485.625(b)(2), §485.920(b)(1), §486.360(b)(1), §494.62(b)(1).

[(b) Policies and procedures. The [facilities] 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 /annually for LTC *facilities]*. At a minimum, the policies and procedures must address the following:]

contract/agreement/MOU is still applicable and able to be fulfilled to provide continuity of care.

For RNHCIs, at § 403.748(b)(7), the term "non-medical" is added in order to accommodate the uniqueness of the RNHCI non-medical care.

Survey Procedures

- Ask to see copies of the arrangements and/or any agreements the facility has with other facilities to receive patients in the event the facility is not able to care for them during an emergency.
- Ask facility leadership to explain the arrangements in place for transportation in the event of an evacuation.

E-0026

(Rev.)

§403.748(b)(8), §416.54(b)(6), §418.113(b)(6)(C)(iv), §441.184(b)(8), §460.84(b)(9), §482.15(b)(8), §483.73(b)(8), §483.475(b)(8), §485.625(b)(8), §485.920(b)(7) §494.62(b)(7).

[(b) Policies and procedures. The [facilities] 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 /annually for LTC *facilities]*. At a minimum, the policies and procedures must address the following:]

(8) [(6), (6)(C)(iv), (7), or (9)] The role of the [facility] under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

*[For RNHCIs at §403.748(b):] **Policies and procedures. (8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care at an alternative care site identified by emergency management officials.**

Interpretive Guidelines applies to: §403.748(b)(8), §416.54(b)(6), §418.113(b)(6)(C)(iv), §441.184(b)(8), §460.84(b)(9), §482.15(b)(8), §483.73(b)(8), §483.475(b)(8), §485.625(b)(8), §485.920(b)(7), §494.62(b)(7)

NOTE: This does not apply to Transplant Programs, HHAs, CORFs, Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, OPOs, RHCs/FQHCs.

state and local public health departments. The communication plan should include how the facility interacts and coordinates with emergency management agencies and systems to protect patient health and safety in the event of a disaster. The development of a communication plan will support the coordination of care. The plan must be reviewed annually and updated as necessary. We are allowing facilities flexibility in how they formulate and operationalize the requirements of the communication plan. Although *the requirement for documentation of collaboration with state and local officials was removed (see 84 FR 51817, Sept. 30, 2019), facilities should continue to collaborate with state and local emergency officials. During the creation process for communication plans, facilities should also consult their applicable state and local emergency and pandemic plans.*

Facilities in rural or remote areas with limited connectivity to communication methodologies such as the Internet, World Wide Web, or cellular capabilities need to ensure their communication plan addresses how they would communicate and comply with this requirement in the absence of these communication methodologies. For example, if a facility is located in a rural area, which has limited or no Internet and phone connectivity during an emergency, it *should* address what alternate means are available to alert local and State emergency officials. Optional communication methods facilities may consider include satellite phones, radios and short wave radios.

Survey Procedures

- Verify that the facility has a written communication plan by asking to see the plan.
- Ask to see evidence that the plan has been reviewed (and updated as necessary) *at least every 2 years (annually for LTC facilities).*
- *Ask facility leadership or the designee responsible for the emergency program to verbally explain how they are to collaborate with Federal, State and local officials to ensure their communication plan complies with the Federal, State and local requirements.*

E-0030

(Rev.)

§403.748(c)(1), §416.54(c)(1), §418.113(c)(1), §441.184(c)(1), §460.84(c)(1), §482.15(c)(1), §483.73(c)(1), §483.475(c)(1), §484.102(c)(1), §485.68(c)(1), §485.625(c)(1), §485.727(c)(1), §485.920(c)(1), §486.360(c)(1), §491.12(c)(1), §494.62(c)(1).

[(c) The [facility 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 /annually for LTC *facilities]*. The communication plan must include all of the following:]

(1) Names and contact information for the following:
(i) Staff.

*[For ASCs at 416.54(c)]: **(7) A means of providing information about the ASC's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.**

*[For Inpatient Hospice at §418.113(c):] **(7) A means of providing information about the hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.**

Interpretive Guidelines applies to: §403.748(c)(7), §416.54(c)(7), §418.113(c)(7), §441.184(c)(7), §460.84(c)(7), §482.15(c)(7), §483.73(c)(7); §483.475(c)(7); §484.102(c)(6); §485.68(c)(5), §485.625(c)(7); §485.727(c)(5); §485.920(c)(7); §491.12 (c)(5), §494.62(c)(7).

NOTE: This does not apply to outpatient hospices or Transplant Programs.

Facilities, except for transplant *programs*, must have a means of providing information about the facility's needs and its ability to provide assistance to the authority having jurisdiction (local and State emergency management agencies, local and state public health departments, the Incident Command Center, the Emergency Operations Center, or designee).

Reporting of a Facility's Needs

Generally, in small community emergency disasters, reporting the facility's needs will be coordinated through established processes to report directly to local and state emergency officials. Reporting needs may include but are not limited to: shortages in PPE; need to evacuate or transfer patients; requests for assistance in transport; temporarily loss of part or all facility function; and, staffing shortages.

In large scale emergency disasters or pandemics, reporting of needs specific to a facility may be altered by local, state and federal public health and emergency management officials due to the potential volume of requests. Some emergency management officials at all levels of governance may require facilities to report specific data or slow reporting to manage volume. It is recommended that facilities verify their reporting requirements with their local Incident Command Structures or State Agencies.

Dependent on the emergency event and the anticipated longevity, facilities may need to report select criteria such as in an EID outbreak or the number of patients' positive or persons under investigation (PUI). The facility's process should include monitoring by the facility's emergency management coordinator or designee of reporting requirements issued by CMS or other agencies with jurisdiction. Additional monitoring and reporting may be required by local and state public health agencies due to contact tracing requirements for extended periods of time or for time specific intervals. Facilities should identify local and state policies for reporting and contract tracing to ensure they have appropriate information to address requirements.

Facilities should actively engage with their healthcare coalitions, associations, accrediting organizations and other stakeholders during the onset of any wide-spread emergency. As state and federal emergency organizations may become overwhelmed with requests, these stakeholders may be able to reconcile needs-requests for specific providers and suppliers. In situations in which a Presidential Declaration and a Public Health Emergency (PHE) have been declared, and Section 1135 Waivers may be granted, these stakeholders (healthcare coalitions, associations, accrediting organizations and others) may have the ability to request and streamline 1135 waiver requests for their members, dependent on the severity of the emergency.

Reporting of a Facility's Ability to Provide Assistance

During widespread disasters, reporting a facility's ability to provide assistance is critical within a community. Pre-planning and collaborating with emergency officials before an emergency to determine what assistance may be necessary directly supports surge planning within a community. For instance, in preparation for a natural disaster such as a hurricane, pre-planning reporting criteria such as the facility's response-- e.g. closing the outpatient services in a forecasted natural disaster-- may facilitate the Incident Command as they would be aware of the operating status of the facility. Reporting the ability to provide assistance would also include pre-planning with public health and emergency officials in the local community to make them aware of what capabilities are available within the specific facility, e.g. number of beds, critical care equipment, staffing, etc.

During widespread disasters, facilities may be required to report the following to local officials:

- *Ability to care for patients requiring transfer from different healthcare settings;*
- *Availability of PPE;*
- *Availability of staff who may be able to assist in a mass casualty incident;*
- *Availability of electricity-dependent medical and assistive equipment, such as ventilators and other oxygen equipment (BiPAP, CPAP, etc.), renal replacement therapy machines (e.g., home and facility-based hemodialysis, peritoneal dialysis, continuous renal replacement therapy and other machines, etc.), and wheelchairs and beds.*

Occupancy Reporting

For hospitals, CAHs, RNHCIs, inpatient hospices, PRTFs, LTC facilities, and ICF/IIDs, they must also have a means for providing information about their occupancy.

Occupancy reporting is considered, but not limited to, reporting the number of patients currently at the facility receiving treatment and care or the facility's occupancy percentage. The facility should consider how its occupancy affects its ability to provide assistance. For example, if the facility's occupancy is close to 100% the facility may not be able to accept patients from nearby facilities. The types of "needs" a facility may have during an emergency and should communicate to the appropriate authority would include

Under this standard, surveyors are to assess whether or not the facility has a training and testing program based on the facility's risk assessment and has incorporated its policies and procedures, as well as its communication plan within training required for staff and its testing exercises.

Survey Procedures

- Verify that the facility has a written training and testing (and for ESRD facilities, a patient orientation) program that meets the requirements of the regulation.
- *Refer back to the facility's risk assessment to determine if the training and testing program is reflecting risks and hazards identified within the facility's program.*
- Verify the program has been reviewed and updated at least *every 2 years (annually for LTC facilities)* by asking for documentation of the annual review as well as any updates made.
- Verify that ICF/IID emergency plans also meet the requirements for evacuation drills and training at §483.470(i).

E-0037

(Rev.)

§403.748(d)(1), §416.54(d)(1), §418.113(d)(1), §441.184(d)(1), §460.84(d)(1), §482.15(d)(1), §483.73(d)(1), §483.475(d)(1), §484.102(d)(1), §485.68(d)(1), §485.625(d)(1), §485.727(d)(1), §485.920(d)(1), §486.360(d)(1), §491.12(d)(1).

*[For RNCHIs at §403.748, ASCs at §416.54, Hospitals at §482.15, ICF/IIDs at §483.475, HHAs at §484.102, "Organizations" under §485.727, OPOs at §486.360, RHC/FQHCs at §491.12:]

(1) Training program. The [facility] 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.

*[For Hospices at §418.113(d):] **(1) Training. The hospice must do all of the following:**

(i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.

(ii) Demonstrate staff knowledge of emergency procedures.

(iii) Provide emergency preparedness training at least every 2 years.

E-0039
(Rev.)

§416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2), §484.102(d)(2), §485.68(d)(2), §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §491.12(d)(2), §494.62(d)(2).

*[For ASCs at §416.54, CORFs at §485.68, OPO, "Organizations" under §485.727, CMHCs at §485.920, RHCs/FQHCs at §491.12, and ESRD Facilities at §494.62]:

(2) Testing. The [facility] must conduct exercises to test the emergency plan annually. The [facility] must do all of the following:

(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 [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.

(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 [facility's] response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [facility's] emergency plan, as needed.

***[For Hospices at 418.113(d):]**

(2) Testing for hospices that provide care in the patient's home. The hospice must conduct exercises to test the emergency plan at least annually. The hospice must do the following:

(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 an individual facility based functional exercise every 2 years; or

(B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from

(d)(2) Testing. The RNHCI must conduct exercises to test the emergency plan. The RNHCI must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the RNHCI's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed.

Interpretive Guidelines applies to: §403.748(d)(2), §416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2), §484.102(d)(2), §485.68(d)(2), §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §486.360(d)(2)§491.12(d)(2), §494.62(d)(2)

NOTE: This does not apply to Transplant Programs.

Variability in Requirements

For inpatient providers *(inpatient hospice facilities, PRTFs, hospitals, LTC facilities*, ICFs/IID, and CAHs): The types of acceptable testing exercises are expanded. Inpatient providers can choose one of the two annually required testing exercises to be an exercise of their choice, which may include one community-based full-scale exercise (if available), an individual facility-based functional exercise, a mock disaster drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.*

****NOTE:*** *For LTC facilities, while the types of acceptable testing exercises was expanded, LTC facilities must continue to conduct their exercises on an annual basis.* Facilities must conduct exercises to test the emergency plan, which for LTC facilities also includes unannounced staff drills using the emergency procedures

For outpatient providers *(ASCs, freestanding/home-based hospice, PACE, HHAs, CORFs, Organizations (which include Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), CMHCs, OPOs, RHCs, FQHCs, and ESRD facilities): 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. The opposite years (every other year opposite of the full-scale exercises), these providers may choose the testing exercise of their choice, which can include either another full-scale, individual facility-based, a mock disaster drill (using mock patients), tabletop exercise or workshop which includes a facilitator.*

For OPOs and RNCHIs, these providers must at a minimum conduct either a paper-based, tabletop exercise or workshop every year, however can elect to also participate in full-scale, individual facility-based exercise.

Understanding Exercises and Terminology

Similar to the training expectations outlined under E-0037 or (d)(1), such as hospitals at 482.15(d)(1), a facility's testing exercises require they be based on the individual facility's risk assessment, policies and procedures, and communication plan and support the patient population it serves. Testing exercises should vary, based on the facility's requirements, by cycles and frequency of testing. The intent is that testing exercise provide a comprehensive testing and training for staff, volunteers, and individuals providing services under arrangement as well community partners. Testing exercises must be based on the facility's identified hazards, to include natural or man-made disasters. This should include EID outbreaks.

Facilities are expected to test their response to emergency events as outlined within their comprehensive emergency preparedness program. Testing exercises should not test the same scenario year after year or the same response processes. The intent is to identify gaps in the facility's emergency program as it relates to responding to various emergencies and ensure staff are knowledgeable on the facility's program. In the event gaps are identified, facilities should update their emergency programs as outlined within the requirements for After-Action Report (AAR).

Full-Scale and Community Based Exercises

As the term full-scale exercise may vary by sector, facilities are not required to conduct a full-scale exercise as defined by FEMA or DHS's Homeland Security Exercise and Evaluation Program (HSEEP). For the purposes of this requirement, a full scale exercise is defined and accepted as any operations-based exercise (drill, functional, or full-scale exercise) that assesses a facility's functional capabilities by simulating a response to an emergency that would impact the facility's operations and their given community. *Full-scale exercises in the industry setting are large exercises in which multiple agencies participate and may only be available every three to five years; while functional exercises are similar in nature, but may not involve as many participants and in which each agency can choose its priorities to test within the confines of the exercise. Therefore, full-scale can include what is known as a "functional" exercise or drill in the industry and according to HSEEP.* A full-scale exercise is also an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional or operational elements. There is also definition for "community" as it is subject to variation based on geographic setting, (e.g. rural, suburban, urban, etc.), state and local agency roles and responsibilities, types of providers in a given area in addition to other factors. In doing so, facilities have the flexibility to participate in and conduct exercises that more realistically reflect the risks and composition of their communities. Facilities are expected to consider their physical location, agency and other facility responsibilities and needs of the community when planning or participating in their exercises. The term could, however, mean entities within a state or multi-state region.

In many areas of the country, State and local agencies (emergency management agencies and health departments) and some regional entities, such as healthcare coalitions may conduct an annual full-scale, community-based exercise in an effort to more broadly assess community-wide emergency planning, potential gaps, and the integration of response capabilities in an emergency. Facilities should actively engage these entities to identify potential opportunities, as appropriate, as they offer the facility the opportunity to not only assess their emergency plan but also better understand how they can contribute to, coordinate with, and integrate into the broader community's response during an emergency. They also provide a collective forum for assessing their communications plans to ensure they have the appropriate contacts and understand how best to engage and communicate with their state and local public health and emergency management agencies and other relevant partners, such as a local healthcare coalition, during an emergency.

Facilities are expected to contact their local and state agencies and healthcare coalitions, where appropriate, to determine if an opportunity exists and determine if their participation would fulfill this requirement. It is also important to note that agencies and or healthcare coalitions conducting these exercises will not have the resources to fulfill individual facility requirements and thus will only serve as a conduit for broader community engagement and coordination prior to, during and after the full-scale community-based exercise. Facilities are responsible for resourcing their participation and ensuring that all requisite documentation is developed and available to demonstrate their compliance with this requirement.

Facilities are encouraged to engage with their area Health Care Coalitions (HCC) (partnerships between healthcare, public health, EMS, and emergency management) to explore integrated opportunities. Health Care Coalitions (HCCs) are groups of individual health care and response organizations who collaborate to ensure each member has what it needs to respond to emergencies and planned events. HCCs plan and conduct coordinated exercises to assess the health care delivery systems readiness. There is value in participating in HCCs for participating in strategic planning, information sharing and resource coordination. HCC's do not coordinate individual facility exercises, but rather serve as a conduit to provide an opportunity for other provider types to participate in an exercise. HCCs should communicate exercise plans with local and state emergency preparedness agencies and HCCs will benefit the entire community's preparedness. In addition, CMS does not regulate state and local government disaster planning agencies. It is the sole responsibility of the facility to be in compliance.

Facilities which determine that a full-scale community-based exercise will be planned for the facility's exercise requirement must also ensure that the exercise scenario developed is identified within the facility's risk assessment. While generally local and state emergency officials plan emergency exercises which could occur within the geographic location or community, facilities must ensure that participation in the exercise would adequately test the facility's emergency program (specifically its policies and procedures and communication plan). For instance, in the event the local or state full-scale exercise is testing the response to a major multiple car accident requiring airlift transfers of

patients, a LTC facility or ESRD facility may not be impacted by this type of disaster or require activation of its emergency program, therefore the exercise may not be as appropriate. In this case, the facility could document that the scenario offered in this full-scale community based exercise and that the facility conducted an individual facility-based exercise to test its emergency program instead. However, if the state or local exercise is testing an EID outbreak, all facilities in the community may be impacted, therefore participation would be strongly recommended.

The intent behind full-scale and community based exercises is to ensure the facility's emergency program and response capabilities complement the local and state emergency plans and support an integrated response while protecting the health and safety of patients.

Individual Facility-Based Exercises

Facilities that are not able to identify a full-scale community-based exercise, can instead fulfill this part of their requirement by either conducting an individual facility-based exercise, documenting an emergency that required them to fully activate their emergency plan, or by conducting a smaller community-based exercise with other nearby facilities. Facilities that elect to develop a small community-based exercise have the opportunity to not only assess their own emergency preparedness plans but also better understand the whole community's needs, identify critical interdependencies and or gaps and potentially minimize the financial impact of this requirement. For example, a LTC facility, a hospital, an ESRD facility, and a home health agency, all within a given area, could conduct a small community-based exercise to assess their individual facility plans and identify interdependencies that may impact facility evacuations and or address potential surge scenarios due to a prolonged disruption in dialysis and home health care services. Those that elect to conduct a community-based exercise should make an effort to contact their local/state emergency officials and healthcare coalitions, where appropriate, and offer them the opportunity to attend as they can provide valuable insight into the broader emergency planning and response activities in their given area. *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.*

Participation

While the regulations do not specify a minimum number of staff, or the roles of staff in the exercises, it is strongly encouraged that facility leadership and department heads participate in exercises. If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, staff who work in this clinical area should participate in the exercise for a clear understanding of their roles and responsibilities. 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.

Facilities can use a sign-in roster for the exercise to substantiate staff participation. 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.

Facilities that conduct an individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment. For example, an inpatient facility might test their policies and procedures for a flood that may require the evacuation of patients to an external site or to an internal safe "shelter-in-place" location (e.g. foyer, cafeteria, etc.) and include requirements for patients with access and functional needs and potential dependencies on life-saving electricity-dependent medical equipment. An outpatient facility, such as a home health provider, might test its policies and procedures for a flood that may require it to rapidly locate its on-duty staff, assess the acuity of its patients to determine those that may be able to shelter-in-place or require hospital admission, communicate potential evacuation needs to local agencies, and provide medical information to support the patient's continuity of care. *If the facility uses fire drills based on their risk assessment (e.g. wild fires) as a full-scale community based exercise in one given year (which is also a requirement for some providers/suppliers under Life Safety Code), the facility is encouraged to choose in the following year a different hazard in their risk assessment to conduct an exercise in order to ensure variability in the training and testing program. The intent of the requirements under the emergency preparedness condition for participation/condition for coverage, or requirement for LTC, is to test the facility's ability to respond to any emergency outlined within their risk assessment. The purpose of testing the facility's emergency program is to identify gaps in response which could result in adverse events for patients and staff and to adjust plans, policies and procedures to ensure patient and staff safety is maintained regardless of the type of emergency which occurs.*

Table-Top Exercise and Workshops

Facilities are also required to conduct an "exercise of choice" or, for some, only conduct a table-top exercise (TTX) or workshop. Please refer back to the definition section above. TTX's or workshops are expected to be group discussions led by a facilitator. We are not defining whether or not the facilitator must be a staff member or contracted service. Some facilities may find that a specific department lead may be best suited dependent on the scenario being tested, while other facilities may find an outside facilitator may be more appropriate to facilitate.

The intent behind TTX's or workshops is to test an exercise based on the facility's risk assessment. Some facilities may find it prudent to conduct a TTX or workshop prior to a full-scale or individual-facility based exercise in order to identify potential gaps or challenges and then update the policies and procedures accordingly to resolve the potential issue. This would allow for facilities to test their adjustments during a full-scale or individual facility-based exercise to determine if the corrective action was appropriate.

After-Action Reviews

Each facility is responsible for documenting their compliance and ensuring that this information is available for review at any time for a period of no less than three (3) years. Facilities should also document the lessons learned following their tabletop and full-scale exercises and real-life emergencies and demonstrate that they have incorporated any necessary improvements in their emergency preparedness program. Facilities may complete an after action review process to help them develop an actionable after action report (AAR). The process includes a roundtable discussion that includes leadership, department leads and critical staff who can identify and document lessons learned and necessary improvements in an official AAR. The AAR, at a minimum, should determine 1) what was supposed to happen; 2) what occurred; 3) what went well; 4) what the facility can do differently or improve upon; and 5) a plan with timelines for incorporating necessary improvement. Lastly, facilities that are a part of a healthcare system, can elect to participate in their system's integrated and unified emergency preparedness program and exercises. However, those that do will still be responsible for documenting and demonstrating their individual facility's compliance with the exercise and training requirements.

Exemption based on Actual Emergency

Finally, an actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the *full-scale* exercise requirement and exempts the facility for engaging in *their next required community-based full-scale exercise or individual, facility-based exercise* for following the actual event; and facilit*ies* must be able to demonstrate this through written documentation. *With the changed requirements as a result of the 2019 Burden Reduction final rule (81 FR 63859) for outpatient providers required to conduct full-scale exercises only every other year, opposite of their exercises of choice, these facilities are exempt from their next required full-scale or individual facility-based exercise. For inpatient providers, the full-scale exercise would be annually. The intent is to ensure that facilities conduct at least one exercise per year.*

For example, in the event an outpatient provider conducts a required full-scale community based exercise in January 2019, and completed the optional exercise of its choice in January 2020, and experiences an actual emergency in March 2020, the outpatient provider is exempt from next required full-scale community based or individual facility based exercise in January 2021. If the outpatient provider conducts a required full-scale community based exercise in January 2020, and has the optional exercise of its choice scheduled for January 2021, and experiences an actual emergency in March 2020, the outpatient provider is exempt from next required full-scale community based or individual facility based exercise in January 2022, but must still conduct the required exercise of choice in January 2021. The exemption is based on the facility's required full-scale exercise, not the exercise of choice, therefore the exemption may not be applicable until two years following the activation of the emergency plan, dependent on the cycle the facility has determined and the actual emergency event.

For inpatient providers, the exemption would apply for the next required full-scale exercise as well, however, it may be the same year or following year, as inpatient providers are required to perform two exercises per year. If an inpatient provider completed the full-scale exercise in January 2020 and is scheduled to conduct an exercise of choice in November 2020, but experiences an actual emergency in March 2020 which required activation of its emergency plan, the inpatient provider is exempt from the next required full-scale exercise in January 2021, but must complete the exercise of choice. If the inpatient provider conducted an exercise of choice prior to the actual emergency and had a full-scale exercise scheduled for November 2020, then the inpatient provider would be exempt from that full-scale exercise as it would not be the exercise of choice.

The exercises of choice, which allow facilities to choose one (e.g., another full-scale/individual facility based; mock disaster drill; or table top exercises) are not considered as the required full-scale community based or individual facility based exercises. Facilities which may have schedule full-scale exercises annually as part of their licensure or accrediting organizations requirements, would be exempt from their next required annual full-scale exercise. Facilities which have a full-scale exercise scheduled as part of their exercise of choice for the opposite years would be exempt from their next scheduled exercise following an emergency, which would still be July 2021 (using the above example).

Facilities must document that they had activated their emergency program based on an actual emergency. Documentation may include, but is not limited to: a section 1135 waiver issued to the facility (time limited and event-specific); documentation alerting staff of the emergency; documentation of facility closures; meeting minutes which addressed the time and event specific information. The facility must also complete an after action review and integrated corrective actions into their emergency preparedness program.

Resources

For additional information and tools, please visit the CMS *Quality, Safety & Oversight Group* Emergency Preparedness website at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html or ASPR TRACIE.

Survey Procedures

- *Ask facility leadership to explain the participation of management and staff during scheduled exercises.*
- Ask to see documentation of the exercises (which may include, but is not limited to, the exercise plan, the AAR, and any additional documentation used by the facility to support the exercise). *Documentation must demonstrate the facility has conducted the exercises described in the standard.*
- Ask to see the documentation of the facility's efforts to identify a full-scale community based exercise if they did not participate in one (i.e. date and personnel

and agencies contacted and the reasons for the inability to participate in a community based exercise).

- Request documentation of the facility's analysis and response and how the facility updated its emergency program based on this analysis.

NOTE: We recommend facilities to retain, at a minimum, the past 2 cycles (generally 2 years for inpatient providers and 4 years for outpatient providers of emergency testing exercise documentation. This would allow surveyors to assess compliance on the cycle of testing required for outpatient providers.

E-0040

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§494.62(d)(3) Condition for Coverage:
Patient orientation: Emergency preparedness patient training. The dialysis facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

Interpretive Guidelines for §494.62(d)(3).

ESRD facilities are required to implement an orientation and training program which educates patients on the emergency preparedness policies and procedures of the facility, including the requirements of the ESRD facility's emergency preparedness training program under §494.62(d)(1). For instance, the orientation and training program should include how patients would be notified of an emergency; what particular procedures they are expected to follow; communication protocols for contacting the ESRD facility and identifying an alternate location for their treatment in the event of a facility closure as well as shelter-in place.

Additionally, patients should be oriented to how they would evacuate the facility (if required) and the location of potential transfer sites or services. For instance, if an emergency situation required evacuation during a dialysis treatment, the facility must train the patient on how to safely disconnect from the machine. Additionally, in this example, if the patient was disconnected, the patient should be informed that he or she will be transferred to another facility or hospital to complete the dialysis (if required).

Ultimately, the emergency preparedness orientation and training for patients should adequately address scenarios which were identified in the ESRD facility's risk assessment and address specific actions required for the emergency situation. The orientation and training program is intended to ensure patients are informed, ready to assist themselves, and are aware of the facility procedures and resources (e.g. KCER) that can provide up to date information during and after an emergency.

Survey Procedures