

Additions to the CMS Regulations

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CENTER FOR BIOSECURITY, BIOPREPAREDNESS
AND EMERGING INFECTIOUS DISEASES

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Overview

- Changes are in **RED** in the document (found [here](#)) a link to the document is on the CoPH ECHO webpage
- We are only discussing changes/additions, not the base content
- The majority of changes relate to COVID (and/or Emerging Infectious Diseases, EIDs), and Paperwork reduction
- This is not just hospitals or LTCs....these changes relate to all CMS providers (although some changes are facility specific)
- Search for “Survey Procedures” because “Ask facility leadership...” is in here a lot

Healthcare Coalitions and Cooperation / Collaboration pp. 8, 30

- If you use HCCs to “...conduct exercises or assist in their efforts for compliance...” document it.
- Continue to engage with HCCs and the HPP (Hospital Preparedness Program) coordinators for training and guidance.
- Build relationships that allow you to “share and leverage resources”
- “While every detail of the cooperation and collaboration process is not required to be documented in writing, it is expected that the facility has documented sufficient details to support verification of the process.”
- Surveyors will ask to interview leadership and have them describe their process for ensuring cooperation/collaboration to ensure an integrated response
- <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/State-resources> is a link to the CMS page about Healthcare Coalitions

Checklists

- Use the ASPR TRACIE checklists and tools

Here is the 53 page “synopsis” of the CMS rule with updates effective November, 2019

<https://files.asprtracie.hhs.gov/documents/aspr-tracie-cms-ep-rule-long-term-care.pdf>

<https://asprtracie.hhs.gov/cmsrule> Page includes:

[California Association of Health Facilities Planning Guide](#)

[CAHF Evacuation Template](#)

[CMS Emergency Preparedness **Checklist**: Recommended Tool for Effective Health Care Facility Planning \(2013\)](#)

Survey Protocol pp.10

- Facilities have the flexibility to determine how to format the documentation of their program and are not required to have a separate policy and procedure for each type of hazard.
 - New specifics:
 - The facility should “...identify within their policies and procedures under what circumstances the facility would invoke particular procedures (e.g., evacuate or shelter)”
 - Procedures should include who would initiate the emergency preparedness response
 - Facilities should be prepared to provide CMS with written evidence of its emergency preparedness program at the time of the survey
 - There is no particular method in which the facility must document its review and updates
 - “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.”
- “We would **recommend** the surveyor review the program with the responsible facility representative and ask this representative to facilitate this review by referring the surveyor to the specific documentation requested.”

New Definitions pp. 12

- Community Partners: Emergency management officials (e.g., fire, police, emergency medical services, etc.) or those that assist in an emergency such as providers or suppliers
- Full Scale Exercise – added the recommendation that they include, at a minimum, local or state emergency officials.
- Functional Exercise – a definition and resource ([HSEEP guidance](#)) was added
- “Mock Disaster Drill” – Or....a drill
- Workshop – planning meeting, seminar or practice session
- IF you need exercise training, reach out to Kristi or Keith...we have developed an online training and will, hopefully, be offering a live version next FY.

Plan Review Frequency pp. 14, 87

- “The emergency preparedness program and its elements must be **reviewed and updated annually for LTC facilities...**” **everyone else bi-annually.**
- If there are other rules that require more frequent updates (e.g., the “Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care”), then you must also follow that timeline
- Retain at a minimum, the past 2 cycles (**generally 4 years**) of emergency training documentation for both training and exercises for surveyor verification

Plan Contents (general) pp. 18

- Plan reviews should include public health emergencies (e.g., infectious diseases).
- Plans must be in writing (electronic or paper) and must be cross walked with other policies (e.g., infection control policies and where they are located)
- End State Renal Disease plans must include, but not be limited to, emergencies of fire, equipment, or power failures, care-related emergencies, emerging infectious diseases, water supply interruption, and natural disasters likely to occur in the facility's geographic area
- Business Continuity – “...the facility’s ability to **continue operations or services** related to patient care and to ensure patient safety and quality of care is continued in an emergency event.” A good resource document is the [FEMA Continuity Guidance Circular](#).
 - Be sure to **include contracts and inventory supply needs** (e.g., PPE, equipment, transportation, etc.).
 - The plan should **account for “Plan B”** in case essential contractor are unable to meet your needs in a disaster.
- See Checklists on slide 3

Plan Content (risk assessment) pp. 24

- You must include a risk assessment. **No specific format** is specified. Examples can be found at [ASPR-TRACIE](#)
 - The **risk assessment must include EIDs**
 - If you do NOT own the structure it is your responsibility to discuss preparedness concerns with the landlord (e.g., power loss risk, heat risk assessment, security, etc.)

Plan Content (EIDs) pp. 18-20

- Emerging Infectious Diseases (Influenza, Ebola, Zika, etc.), must be added to the plan
- EID components of the plan need to include (at a minimum)
 - Increased need for **PPE**
 - **Screening** of patients/visitors/staff, to include testing, if available
 - Patient **transfers** and discharges
 - **Home based healthcare**
 - The **physical environment**, including changes in distancing, isolation and/or capacity/surge
- Facilities should engage and coordinate with their local healthcare systems, **HCCs and S/L Health Departments**

Plan Content (Survey Procedures) pp. 25

“Surveyors should...”

- Ask to see the **written documentation** of the facility’s risk assessments and associated strategies
 - **Interview** the facility leadership and ask which hazards (e.g. natural, man-made, facility, geographic) were included in the facility’s risk assessment, why they were included and how the risk assessment was conducted
 - **Verify the risk-assessment** is facility-based and community-based, and based on an all-hazards approach specific to the geographic location of the facility and encompasses potential hazards, such as EIDs
-
- Their intent should be to determine whether the assessment is **facility-based AND community-based**...the format and priority of the hazards are up to the facility

Documentation Requirements pp. 15

- Plans must be in writing (electronic or paper) and must be **cross walked** with other policies (e.g., infection control policies and where they are located)
- In order to determine compliance, surveyors will be required to review at least the **past 2 cycles** of emergency testing exercises
 - Inpatient providers – maintain documentation and records for at least 2 years
 - Outpatient providers – maintain documentation and records for at least 4 years

Surge & Staffing

pp. 27

- Need a **Succession Plan** (a person who “...is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility.”)
- Must **outline roles** and responsibilities of different individuals (e.g., incident commander, PIO, etc.) by title (e.g., Administrator, Charge nurse, etc.). **They should be able to describe their role.**

Surge & Staffing (Survey Procedures) pp. 28

“Survey Procedures. Interview the leadership and ask them the following:

- The facility’s patient populations that would be at risk during an emergency event;
- Strategies the facility (except for an ASC, hospice, PACE organization, HHA, CORF, CMHC, RHC/FQHC and ESRD facility) has put in place to **address the needs of at-risk or vulnerable** patient populations;
- Services that the facility would be able to provide during an emergency and any **plans to address services needed that cannot be provided** by the facility during an emergency as part of continuity of operations and services.
- How the facility plans to continue operations during an emergency;
- **Delegations of authority and succession plans.”**

Updating Information pp. 35

- Facilities should ensure their programs have policies in place to **update or provide additional emergency preparedness procedures to staff**. This may include a policy delegating an individual to monitor guidance by public health agencies and issuing directives and recommendations to staff such as use of PPE when entering the building; isolation of patients under investigation (PUIs); and, any other applicable guidance in a public health emergency.
- There is an emphasis on “...continuity of treatment” (this is a subset of business continuity)

Hospice and Home Health pp. 42, 43

Policies and procedures should include considerations such as but not limited to:

- **Staffing** shortages;
- Staff ability to provide **safe care**, to include any potential needs such as PPE;
- Care needs of the patients-inpatient or in home-based settings and potential **equipment needs**
- **Screening** phone calls prior to arrival and screening questions prior to entry into a home
- Ways to **decontaminate** equipment and procedures to limit equipment taken into homes
- Should outline a **contingency plan** in the event patients require evacuation but are unable to be transferred due to a community-wide impacted emergency

There are significant additions for Hospice and Home Health...if these apply to you, refer to pages 42 - 48

Surge Planning

pp. 56-58

- Healthcare facilities **MUST** have policies and procedures in place for **emergency staffing** strategies. They should encompass business continuity needs and patient care needs
- Facilities **MUST** have policies that allow them to respond to a surge in patients (as aligned with your risk assessment and including EIDs)
- EID surge planning should address the following goals
 - Reduce morbidity and mortality
 - Minimize disease transmission
 - Protect healthcare personnel
 - Preserve healthcare system functioning
- Numerous strategies are provided for managing non-essential healthcare visits (e.g., telehealth, patient portals, triage protocols, etc.)
- **Volunteer usage** also needs to be considered (e.g., Who will you use? How? Where? Credentialing?). A [guidance document](#) is available from ASPR-TRACIE

Transfer Agreements and Alternate Care Sites pp. 61

- The facility must describe how they would provide care in an alternate setting. This may include
 - Patient populations
 - Supplies
 - Equipment
 - Staffing
 - Physical environment
- Facilities should have **more than one transfer agreement** in place (in case the 'usual' transfer facility is also affected by the disaster)
- ICFs/IID and LTC facilities are also responsible for **tracking residents**. They need to “account for the patient population, number of patients and the ability for the receiving facility or facilities to continue care to the residents/patients.”
- These agreements (including other **MOUs**) should be **reviewed every two years** (annually for LTCs)

Alternate Care Sites and 1135 waivers pp. 61

- The [1135 waiver](#) is discussed in the context of Alternate Care Sites (ACS). “...emergency preparedness program **must** include policies and procedures which outline the facility’s role in the provision of care and treatment under section 1135 waivers during a declared public health emergency in alternate care sites.”
- There is a lot of explanatory language (what is an 1135 waiver? How are they issued? How long do they last? What types of things do they do? Etc.).
- “While the establishment and use of an ACS are generally acceptable only during an emergency and **require CMS approval**, the facility’s program must **address the facility’s ability to provide care in an alternate setting.**”

Other Stuff

- Maintain **contact information** for emergency management officials (fire, police, EMS, S/L/T public health, state survey agency, “FEMA, ASPR, DHS, CMS, etc.”). pp 71
- In the communications plan, **primary and alternate modes** should be identified. pp 72
- “Reporting of a Facility’s Needs” (pp 76, 77). How, and to whom do you report:
 - data (PUI, positives, etc.),
 - needs (PPE, evacuation assistance, etc.) ,
 - ability to assist

Training

pp. 81-

- **“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.” pp 81**
- Training must complement the risk assessment
- Facilities must “...maintain documentation of the training so that surveyors are able to clearly identify staff training and testing conducted.”

Training

pp. 86

- Training must be based on the risk assessment, policies/procedures, and communication plan
- Training should include **individual level activities** (e.g., what actions do you take when the tornado siren rings?)
- Should include shelter-in-place or evacuation
- “After the initial training has been conducted for staff, facilities must provide training on their facility’s emergency plan at least every 2 years (except for LTC facilities which will still be required to provide training annually).”
- “Facilities must also be able to **demonstrate additional training when the emergency plan is significantly updated.**”

Testing

pp. 15, 81 - 82,
95

- Inpatient facilities must conduct **two** exercises annually
 - The choices of exercises for one of the exercises has been expanded to include community based FSX, and facility-based functional, a drill, a tabletop or a workshop
- Outpatient facilities must conduct **one** exercise annually, one out of every two years must be a full-scale exercise or a facility based functional exercise
 - Years opposite the FSX/FX, outpatient facilities can choose a full-scale, functional, drill, tabletop, or workshop
- Facilities should include **all staff, in all departments, in all shifts in exercises “...over a period of time”**
- Must be related to your HVA (risk assessment)

Surveyors:

- “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.”

Testing for Home Health Agencies pp. 94

- Must test the emergency plan at least annually
 - Participate in a community-based full-scale or....
 - When not accessible, conduct a facility functional exercise or
 - If there is an actual emergency they are exempt from the testing requirement for that year
 - Conduct an additional exercise every two years (opposite the FSX or FX)
 - Maintain and document all exercise, events and plans

Testing Exemptions pp. 100 – 101

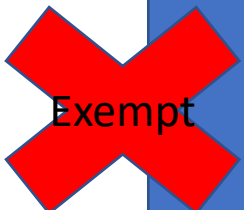
- Real world events only exempt you from the **next FSX**...NOT from the next exercise
- You must document that you activated your emergency program through and 1135 waiver OR a document alerting staff of the emergency OR documentation of facility closure OR meeting minutes with time and event specific information OR some other clear documentation.
- Facilities must also **complete an after action meeting and execute corrective actions**

Outpatient Facility
Exercise Calendar
Example 1

January 2019
Required FSX

January 2020
Exercise of Choice

March 2020
Real World



January 2021
Required FSX

Testing
Exemptions
pp. 100

Outpatient Facility
Exercise Calendar
Example 2

January 2020
Required FSX

March 2020
Real World

January 2021
Exercise of Choice

~~Exempt~~ January 2022
Required FSX

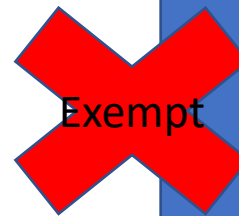
Testing
Exemptions
pp. 100

Testing
Exemptions
pp. 100

January 2020
Required FSX

March 2020
Real World

November 2020
Exercise of Choice



Exempt

January 2021
~~Required FSX~~

Exercise of Choice

November 2020
Exercise of Choice

Inpatient Facility Exercise Calendar Example 1

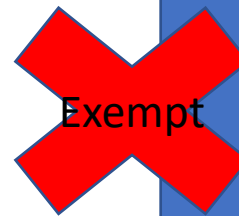
Testing
Exemptions
pp. 100

Inpatient Facility Exercise Calendar Example 2

January 2020
Required FSX

November 2020
Exercise of Choice

December 2020
Real World



Exempt

~~January 2021
Required FSX~~

Exercise of Choice

November 2020
Exercise of Choice

In Conclusion

Upcoming:

Exercise Development Class through the College of Public Health....registration forthcoming.

A longer version of this presentation will be available on the AHEPP webinar on May 19th, 1100 Central.

Links

CMS Emergency Preparedness Guideline Revision
<https://www.cms.gov/files/document/qso-21-15-all.pdf>

CMS link to Healthcare Coalitions <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/State-resources>

California Association of Health Facilities Planning Guide.
<https://www.cahfdisasterprep.com/eop>

California Association of Health Facilities Evacuation Template.
http://www.cahf.org/Portals/29/DisasterPreparedness/Evac/TTXevac_final_FDF.pdf

CMS Emergency Preparedness Checklist: Recommended Tool for Effective Health Care Facility Planning (2013).
<https://www.lifespan-network.org/sites/default/files/EmergencyPreparednessChecklist.pdf>

Links

Homeland Security Exercise Evaluation Program (HSEEP) guidance.
https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revision_Apr13_Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da

FEMA Continuity Guidance Circular.
https://www.fema.gov/sites/default/files/2020-07/Continuity-Guidance-Circular_031218.pdf

Hazard Vulnerability Assessment Tools from ASPR-TRACIE.
<https://files.asprtracie.hhs.gov/documents/aspr-tracie-evaluation-of-hva-tools-3-10-17.pdf>

ASPR TRACIE guidance on using temporary volunteers in healthcare facilities to manage patient surge.
<https://asprtracie.s3.amazonaws.com/documents/aspr-tracie-considerations-for-the-use-of-temporary-care-locations-for-managing-seasonal-patient-surge.pdf>

Links

1135 Waiver. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>