Policies and Procedures and Documentation

Q: If a large health system has operating guidelines which include language described in the policies and procedures section, but does not have formal policies as approved by the hospital board etc., are healthcare facilities required to have formal policies or are official operating guidelines sufficient?

A: The regulation is clear that facilities must have “policies and procedures” in place as opposed to “operating guidelines.” Policies are considered a more formal, definite method or course of action to be adhered to. Therefore facilities must develop and maintain “policies” and procedures to meet the requirements of the regulation. Facilities may choose to include relevant language from their “operating guidelines” in their policies and procedures as appropriate. Facilities should be aware that surveyors may ask to see a copy of the facilities “policies” and not “operating guidelines.”

Q: If we choose to conduct a functional versus a community based test of the plan, what kind of justification do we have to provide on why we chose one over the other? Do we have to demonstrate that we tested our coordination with referrers and hospitals and community providers under a functional assessment?

A: We are not specifying the format of documentation to allow for flexibility. However, we would encourage facilities who chose a functional versus community based test to show why this approach was more favorable- i.e. community based testing is not available due to the rural area/geographic location of the facilities.

Q: The rule implies that facilities need to ensure their vendors have a business continuity plan to continue to provide a supply source during times of emergency. Do you have any guidance as to what vendors need to have or what they should provide to these facilities that will make the facilities compliant?

A: Facilities are required to provide subsistence needs for staff and patients, whether they evacuate or shelter in place. Those provisions include but are not limited to: food, water, medical supplies and pharmaceutical supplies.

Training and Testing

Q: Regarding fulfilling the testing needs: Do we indeed to conduct two tests a year? And minimally one of them needs to be a community based test? If an emergency presents itself between November 15, 2017 and December 31, 2017, would that satisfy one testing need? Would that be the community based need? And would that cover us for the period until November 15, 2018 or until the end of the calendar year 2017?

A: Facilities are required to participate in a full-scale exercise that is community-based or when a an individual facility-based exercise when a community-based exercise is not accessible AND
conduct an additional exercise that may include a second full-scale community or facility-based exercise or a tabletop exercise (as described in the regulations.) So yes, a facility is required to conduct two tests annually. If the facility experienced an emergency and had to activate its emergency plan between November 15, 2017 and December 31, 2017 that would satisfy one of the annual testing requirements and would exempt the facility from engaging in a community or facility based exercise for one year following the date of the actual emergency event. The “annual” testing requirement will not be measured on a calendar year basis which is January 1 through December 31. The annual requirement will be measured from the date of the last actual emergency event or the date the exercise/testing took place.

**Alternative Sources of Energy- Revised June 2017**

**Q:** What are the requirements for facilities regarding HVAC systems and alternate source energy?

**A:** The following providers have a mandatory requirement based on the new EP regulation to have an alternate source of energy to maintain temperatures to protect [patient, resident, participant, client] health and safety and for the safe and sanitary storage of provisions: RNHCI, Hospice (inpatient), PRTF, PACE, Hospitals, LTC, ICF/IIDs, and CAH.

During an emergency situation, the providers listed above with a mandatory requirement for alternate sources of energy, must be able to maintain temperatures. Maintaining temperatures could involve heating or cooling the facility to maintain temperature levels within the facility to protect the individual’s health and safety, as well as the safe and sanitary storage of provisions.

During the risk assessment a provider will need to determine how they will be able to maintain temperatures that will protect the health and safety of (patient, resident, participant, client) and the safe and sanitary storage of provisions if their facility loses power. The provider needs to determine how they will provide heating or cooling to their facility, if required, to maintain temperatures during an emergency situation, if they lose power.

We recommend facilities also review the preamble at Page 63882 Federal Register / Vol. 81, No. 180/ Friday, September 16, 2016. Additional guidance will be forthcoming in the Interpretive Guidelines.

**Q:** Do generator requirements apply to the following provider types: Small ICF/IID’s; Home and Community Based Waiver (1915(c))?  

**A:** The regulation does not make a distinction between ICF/IIDs and “small” ICF/IIDs. According to §483.475(b)(ii) ICF/IIDs have a mandatory requirement to provide alternate sources of energy to maintain the following items:

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*As of December 2016, Revised 6-1-2017
Note: The FAQs will be updated on a continuous basis.*
Survey & Certification Group
Frequently Asked Questions (FAQs)
Emergency Preparedness Regulation

§483.475(b)(ii) Alternate sources of energy to maintain the following:
(A) Temperatures to protect client health and safety and for the safe and sanitary storage of provisions.
(B) Emergency lighting.
(C) Fire detection, extinguishing, and alarm systems.
(D) Sewage and waste disposal.

As per the previous FAQs posted (11-18-16), the above provision does not specify or require that a facility must have a generator.

Additionally, the Home and Community Based Waiver (1915(c)) participate in Medicaid only and are not surveyed for the emergency preparedness requirements.

Q: The regulation states: (ii) Alternate sources of energy to maintain the following: (A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. (B) Emergency lighting. (C) Fire detection, extinguishing, and alarm systems. (D) Sewage and waste disposal. What is meant by “provisions” in (ii)(a)?

A: Provisions include: food, water, pharmaceuticals or medications and medical supplies. At §482.15(b)(1)(ii)(D), we proposed that the hospital develop policies and procedures to address the provisions of sewage and waste disposal including solid waste, recyclables, chemical, biomedical waste, and waste water. This provision also includes policies and procedures which address ‘pharmaceuticals or medications/medical supplies (Reference Page 63880 Federal Register / Vol. 81, No. 180).

Misc.

Q: Some vendors are telling healthcare facilities that they need to purchase certain quantities of medically related supplies in order to be in compliance with the new Emergency Preparedness rule. What supplies and quantities (if any) do healthcare facilities need to purchase to be in compliance?

A: The regulation does not require any specific items and quantities that facilities must have to be in compliance with the rule. It is up to each individual facility to conduct an assessment of its facility’s supply needs during an emergency and make purchases based on its assessment.