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Emergency preparedness: Medicare and Medicaid provider and supplier requirements

By Michael Kotch, CFE, CMAS, CFCE, and Jan Elezian, MS, RHIA, CHC, CHPS

Michael Kotch (michael.kotch@sunhawkconsulting.com) is a Director and Healthcare Management Consultant at SunHawk Consulting residing in Arizona. **Jan Elezian** (jan.elezian@sunhawkconsulting.com) is a Director at SunHawk Consulting and resides in Denver, Colorado.

Is your organization's emergency preparedness plan current, tested, and functioning? Earlier this year, the Department of Health & Human Services (HHS) added auditing of organizational plans for emergency preparedness planning, which now includes emerging infectious disease preparedness planning, to its Work Plan.[1] Centers for Medicare & Medicaid Services (CMS) plans to audit internal controls over hospital preparedness for an emerging infectious disease epidemic, such as coronavirus disease 2019 (COVID-19), along with hospital compliance and CMS's emergency preparedness requirements.[2] Hospitals that participate in the Medicare program must comply with federal participation requirements, including requirements that hospitals engage in all-hazards emergency preparedness planning.[3] Business continuity plans are required under 42 C.F.R. § 422.504(o) and 42 C.F.R. § 423.505(p) to ensure restoration of business operations following disruptions, including emergencies, and should be outlined in each required facility's emergency preparedness plan.

As we continue to experience the impact of COVID-19 on our healthcare system, it is a good time to reflect on lessons learned regarding emergency preparedness and response. CMS recommends that current business continuity plans include necessary planning for business operations disruption due to a public health emergency.[4]

Background

CMS published the final rule on the emergency preparedness on September 16, 2016.[5] The regulation became effective November 15, 2016, and the implementation date became effective November 15, 2017.

The CMS Emergency Preparedness Rule focuses on the development and implementation of an emergency preparedness plan, policies and procedures, a communications plan, training and testing requirements, and specialized provisions dealing with emergency and backup power supplies for certain provider and supplier types.

The regulation implies that providers and suppliers that comply with emergency planning criteria, such as standards set by The Joint Commission, may be considered compliant for some aspects of the emergency preparedness plan. However, there is significant focus directed toward the guidance and tools available through the Assistant Secretary for Preparedness and Response - Technical Resources, Assistance Center, and Information Exchange (ASPR-TRACIE) to meet compliance requirements.[6]

In addition, the Federal Emergency Management Agency (FEMA) *Guide for All-Hazard Emergency Operations Planning*[7] and the FEMA *Comprehensive Preparedness Guide*[8] are recommended resources that can be used to

help achieve the goals of the rule and meet compliance requirements.

In the annual HHS publication of the top management and performance challenges for 2019,[9] Office of Inspector General (OIG) identified emergency preparedness planning as one of the top six areas requiring attention.

While the HHS has a lead role in preventing, preparing for, and responding to the adverse health effects of public health emergencies, it important for Medicare and Medicaid providers and suppliers to be prepared to handle public health emergencies such as communicable diseases, outbreaks, and natural disasters that can severely strain the healthcare infrastructure.

The CMS Emergency Preparedness Rule emphasizes the importance of having adequate planning and mechanisms in place prior to and during a national emergency to efficiently and rapidly deploy assets and provide relief to those in need. OIG has identified a number of gaps in emergency preparedness and response planning for healthcare facilities during disasters and pandemics.[10] In one example, discussed in the OIG report titled *Hospital Emergency Preparedness and Response During Superstorm Sandy*, infrastructural gaps, including electrical and communication failures, as well as community collaboration issues over resources such as fuel, transportation, hospital beds, and public shelters were reported at healthcare facilities.[11] A concerted effort to improve preparedness and response is important and necessary to deliver healthcare services during a natural disaster, as well as support an effective recovery.

A 2019 OIG report found that HHS was deficient in several key areas, including (1) inadequate planning for coordinating global health security, (2) insufficient preparation for deployment of the resources needed for an adequate response, and (3) a lack of internal and external communication channels for responding to a public health emergency.[12] The Medicare and Medicaid provider and supplier types identified in the CMS Emergency Preparedness Rule should note the OIG findings and ensure planning and preparedness includes provisions to address coordination of security; deployment and resupply of resources such as personal protective equipment, vaccines, anti-viral drugs, antibiotics, and other medications and medical equipment; internal and external communications channels; and procedures for handling medical surge.

Applicability

The CMS Emergency Preparedness Rule is intended to safeguard human resources, protect physical resources, and maintain business continuity. It applies to the 17 Medicare and Medicaid provider and supplier types identified in Table 1.

Provider/Supplier type	Statutory and regulatory citations
Ambulatory surgical centers	Social Security Act (SSA) § 1832(a)(2)(F)(i) (Title XVIII) and42 C.F.R. §§ 416.2, 416.40–416.52
Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services	SSA § 1861(p) (Title XVIII) and42 C.F.R. §§ 485.701–485.729

Community mental health centers	SSA § 1861(ff)(3)(B)(i)(ii) (Title XVIII),42 U.S.C. § 300x–2 (c)(1) , and42 C.F.R. § 410.110
Comprehensive outpatient rehabilitation facilities	SSA § 1861(cc)(2) (Title XVIII) and42 C.F.R. §§ 485.50–485.74
Critical access hospitals	SSA §§ 1820 and 1861(mm) (Title XVIII) and42 C.F.R. §§ 485.601–485.647
End-stage renal disease facilities	SSA §§ 1881(b), 1881(c), 1881(f)(7) (Title XVIII) and42 C.F.R. §§ 494.1–494.180
Home health agencies	SSA §§ 1861(o), 1891 (Title XVIII) and42 C.F.R. §§ 484.1–484.55
Hospices	SSA § 1861(dd)(1) (Title XVIII) and42 C.F.R. §§ 418.52–418.116
Hospitals	SSA § 1861(e)(9) (Title XVIII) and42 C.F.R. §§ 482.1–482.66
Inpatient psychiatric services for individuals under age 21 in psychiatric residential treatment facilities (PRTFs)	SSA §§ 1905(a) and 1905(h) (Title XIX) and42 C.F.R. §§ 441.150–441.182 and 42 C.F.R. §§ 483.350–483.376 ; SSA §§ 1905(a) and 1905(h) (Title XIX) and42 C.F.R. §§ 441.150–441.182 and 42 C.F.R. §§ 483.350–483.376
Intermediate care facilities for individuals with intellectual disabilities	SSA § 1905(d) (Title XIX) and42 C.F.R. §§ 483.400–483.480
Long-term care facilities and skilled nursing facilities	Long-term care facilities under SSA § 1819 (Title XVIII); skilled nursing facilities under SSA § 1919 (Title XIX) and 42 C.F.R. §§ 483.1–483.180
Organ procurement organizations	SSA § 1138 (Title XI), 42 U.S.C. § 273 , and42 C.F.R. §§ 486.301–486.348
Programs of All-Inclusive Care for the Elderly	SSA §§ 1894 (Title XVIII), 1905(a), and 1934 (Title XIX) and42 C.F.R. §§ 460.2–460.210
Religious nonmedical health care institutions	SSA § 1821 (Title XVIII) and42 C.F.R. §§ 403.700–403.756

Rural health clinics and federally qualified health centers	Rural health clinics: SSA § 1861(aa) (Title XVIII) and42 C.F.R. §§ 491.1–491.11; and federally qualified health centers: SSA § 1861(aa) (Title XVIII) and 42 C.F.R. §§ 491.1–491.11 (except 491.3)
Transplant centers	SSA §§ 1861(e)(9) and 1881(b)(1) (Title XVIII) and42 C.F.R. §§ 482.68–482.104

Table 1: Medicare and Medicaid provider and supplier types the CMS Emergency Preparedness Rule applies to

While all 17 Medicare and Medicaid provider and supplier types are affected by the CMS Emergency Preparedness Rule, requirements may differ between each provider and supplier type.

General requirements of the CMS Emergency Preparedness Rule

There are five general requirements of the emergency preparedness rule. Specific requirements are dependent on the provider or supplier type. A list and brief synopsis of the general requirements includes the following.

Emergency preparedness plan

Requires development, documentation, and implementation of a formalized emergency preparedness plan based on a risk assessment using an integrated all-hazards approach. This approach is used to identify capacities and capabilities that are critical to preparedness, and the plan must do all of the following:

- Be based on and include a documented facility-based and community-based risk assessment;
- Include strategies for addressing emergency events identified by the risk assessment;
- Address patient population, including, but not limited to:
    - Persons at risk,
    - The type of services the plan has the ability to provide in an emergency, and
    - Continuity of operations, including delegations of authority and succession plans; and
- Include a process for cooperation and collaboration with local, state, and federal emergency preparedness and response officials. The plan must be reviewed and updated at least annually.

Policies and procedures

Development and implementation of emergency preparedness policies and procedures are to be based on the risk assessment, emergency plan, and communications plan outlined in the rule. The policies and procedures must address:

- The provision of subsistence needs (i.e., food, water, and supplies) and alternative sources of energy to maintain temperature, lighting, fire detection and extinguishing, and sewerage and waste disposal for staff and patients;
- A system to track the location of on-duty staff and sheltered patients;

- Safe evacuation when necessary to protect staff and patients;
- A means to shelter in place;
- A system of care for documentation that preserves patient information, protects confidentiality of patients, and secures and maintains records;
- Emergency staffing strategies;
- Development of arrangements with other providers and suppliers to receive patients in the event of limitations or cessation of operations; and
- The role and responsibility of the provider or supplier under a section 1135 waiver[13] when declared by the HHS secretary during a declared emergency. The policies and procedures must be reviewed and updated at least annually.

CMS is currently waiving 42 C.F.R. § 482.12(f)(3) requirements for emergency services, with respect to *surge facilities only*.[14] "[W]ritten policies and procedures for staff to use when evaluating emergencies are not required for surge facilities." This action temporarily removes "the burden on facilities to develop and establish additional policies and procedures at their surge facilities … related to the assessment, initial treatment and referral of patients. These flexibilities [can] be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan."

Communications plan

This involves the development and maintenance of an emergency communication plan that complies with federal, state, and local laws and that includes:

- Names and contact information for all staff and all federal, state, regional, and local emergency preparedness organizations and responders;
- A primary and alternate means for communicating with staff and federal, state, regional, and local emergency preparedness organizations and responders;
- A method for sharing information and care documentation for patients with care providers to maintain the continuity of care;
- A means, in the event of an evacuation, to release patient information as permitted;
- A means of providing information about the general condition and location of patients receiving care; and
- A means of providing information about provider or supplier regarding occupancy, needs, and its ability to provide assistance. The communications plan must be reviewed and updated at least annually.

Training and testing

A training and testing program that is based on the emergency plan, policies and procedures, and communications plan is required. The training component must include initial training for new staff and training for all staff at least annually and documentation of all emergency preparedness training. The testing component requires:

- A paper-based, tabletop exercise 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; and

- Documentation of all tabletop exercises and emergency events. The training and testing program must be reviewed and updated at least annually.

Emergency standby power

Implementation of emergency and standby power systems based on the emergency plan is required. Key components include:

- Meeting the emergency generator location requirements,
- Mandatory emergency generator inspection and testing, and
- A plan for keeping emergency power systems operational during the emergency.

Organization

Emergency preparedness requires a high degree of organization. Everyone in the organization should understand their roles and responsibilities in an emergency situation, and everyone should actively participate in emergency preparedness training and testing. Don't wait for an emergency situation to occur before assigning specific roles and responsibilities.

Consider establishing an emergency preparedness committee with representation from each functional area or department of the organization. We recommend assigning overall responsibility and accountability to a senior leader, with committee members placed under the senior leader's operational control for the duration of the development and implementation of the emergency preparedness plan, communications plan, and training and testing. This structure may also be useful as a command, communications, and control group during an actual emergency.

We recommend development and implementation of policies and procedures at department level to engage staff and leadership in a team process.

Use a project management professional to assist the emergency preparedness committee with a project plan to keep track of tasks, activities, timelines, deliverables, and milestones. The project manager should also report delays, missed milestones, adjustments, and other issues to the committee for mitigation and/or resolution.

We recommend that the compliance officer monitor, audit, and report the status of all aspects of the emergency preparedness plan, policies and procedures, communications plan, and, in particular, training and testing, to senior leadership and the board of directors.

Important last words

There is no such thing as being too prepared for an emergency. Whether it is a natural disaster, a pandemic, an act of terrorism, or some other unplanned event, preparation and planning are key and essential for successful action and mitigation.

As a first step, we recommend going to the "Emergency Preparedness Rule" page[15] for information pertaining to the rule. Learn from the experts and adapt concepts and methodologies to meet organizational needs. Take time to do things right the first time.

At present, there are a number of CMS waivers that temporarily modify certain provisions of the emergency preparedness plan regulation. These waivers are in place only until the end of the national emergency is declared. When the national emergency ends, we recommend taking time to conduct a comprehensive after-action review, including a risk vulnerability assessment, a thorough review of your emergency preparedness plan, and a review of lessons learned during the emergency. Update your plan, training, and testing accordingly.

ASPR-TRACIE, FEMA, and CMS, along with first responders at the local, state, and federal government, are valuable resources that can assist with emergency preparedness planning, training, and testing.

Takeaways

- The U.S. Department of Health & Human Services added auditing of organizational plans for emergency preparedness planning, which includes emerging infection disease preparedness, to its Work Plan.
- The Centers for Medicare & Medicaid Services published the final rule on emergency preparedness on September 16, 2016. The regulation became effective November 15, 2016, with an implementation date of November 15, 2017.
- The Emergency Preparedness Rule is intended to safeguard human resources, protect physical resources, and maintain business continuity, and it applies to 17 Medicare and Medicaid provider and supplier types.
- Emergency preparedness requires a high degree of organization. Consider establishing an emergency preparedness committee. Everyone in the organization should understand their roles and responsibilities in an emergency situation, and everyone should actively participate in training and testing.
- The compliance officer should monitor, audit, and report the status of all aspects of the emergency preparedness plan, policies and procedures, communication plan, and, in particular, training and testing to senior leadership and the board of directors.

1 "CMS's Internal Controls Over Hospital Preparedness for Emerging Infectious Disease Epidemics Such as Coronavirus Disease 2019," HHS OIG, last accessed September 15, 2020, https://bit.ly/35J0wvG.
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8 FEMA, *Developing and Maintaining Emergency Operations Plans: Comprehensive Preparedness Guide (CPG) 101*, Version 2.0, November 2010, https://bit.ly/3konyvZ.
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15 "Emergency Preparedness Rule," CMS.