

CMS Releases Proposed Emergency Preparedness CoP Regulations

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Hospitals and other providers should be aware of imminent changes to the Medicare conditions of participation (CoPs) that will add new emergency preparedness requirements. The Proposed Rule requires an all-hazards risk assessment, a comprehensive emergency preparedness plan, and numerous policies and procedures on significant operational issues that may arise in emergencies. Further, annual training and testing of a provider's emergency preparedness will be required as well.

The Centers for Medicare & Medicaid Services (CMS) recently published a Proposed Rule on Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers.¹ Hospitals are a significant focus because CMS recognizes that “hospitals are in the best position to coordinate emergency preparedness planning with other providers and suppliers in their communities.”² However, the proposed regulations also add emergency preparedness requirements to the CoPs or conditions for coverage (CfCs) for 16 other provider/supplier types, as CMS works to bring a more uniform and consistent approach to emergency preparedness. Those include:

- Ambulatory surgical centers (ASCs);
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services;
- Community mental health centers;
- Comprehensive outpatient rehabilitation facilities;
- Critical access hospitals (CAHs);
- End-stage renal disease facilities;
- Federally qualified health centers (FQHCs);
- Home health agencies (HHAs);
- Hospices;
- Inpatient psychiatric services for individuals under age 21 in psychiatric facilities or programs;
- Intermediate-care facilities for individuals with intellectual disabilities;
- Long term care (LTC) facilities;
- Organ procurement organizations;
- Programs of all-inclusive care for the elderly;
- Religious nonmedical health care institutions;
- Rural health clinics;

- Skilled nursing facilities (SNFs) and nursing facilities (NFs); and
- Transplant centers.

Background

CMS conducted an extensive review of the current state of emergency preparedness,³ mindful of the challenges presented to the United States in recent years by the September 11, 2001 terrorist attacks, the subsequent anthrax attacks, catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, the 2009 H1N1 influenza pandemic, tornadoes and floods in the spring of 2011, and Hurricane Sandy in 2012. The result: CMS determined that the current emergency preparedness regulatory requirements are not sufficiently comprehensive or sufficiently uniform to ensure readiness for public health emergencies.

CMS acknowledges that many hospitals already have an emergency preparedness program, and those programs have been steadily becoming more comprehensive. For example, some areas have formed community-wide coalitions where public and private entities work together to prepare for emergencies. The Proposed Rule is intended to address the need for greater uniformity and cohesiveness across the country. CMS directs that the implementation of an emergency preparedness program should have four core elements: (1) risk assessment and planning; (2) policies and procedures; (3) communication plan; and (4) training and testing.⁴



CMS begins with an extensive discussion of the new hospital CoPs, explaining that it serves as a framework on which the other CoPs and CfCs are based. A discussion follows that explains how those hospital requirements are modified for each provider/supplier type.

The Proposed CoP Changes for Hospitals

The new, proposed hospital CoP requirements, at 42 C.F.R. § 482.15, mandate that hospitals have an emergency preparedness program and emergency preparedness plan that includes the following key components:

All-Hazards Risk Assessment, Section 485.15(a)

A hospital must develop an emergency plan based on a community-based, all-hazards, risk assessment. This approach focuses on developing capabilities for a broad range of disasters, rather than concentrating on one particular threat. To assist, CMS provides a citation to the 15 all-hazards National Planning Scenarios, which range from pandemic flu to a major earthquake or hurricane to a nuclear or terrorist attack. CMS also provides information about and links to various publications to assist hospitals in developing and conducting an all-hazards risk assessment; for example, guidance from agencies such as the Federal Emergency Management Agency (FEMA) and the Agency for Healthcare Research and Quality (AHRQ).⁵ This risk assessment must include the identification of essential business functions that the hospital should continue, emergencies the hospital reasonably expects to confront, and contingencies for which the hospital should plan. Further, it should address the hospital's location, any natural or man-made emergencies that may cause it to cease or limit operations, and a determination of whether arrangements with other entities are needed to ensure that essential services can be provided. The assessment must consider the patient population such as the elderly, children, pregnant women, non-English speaking persons, and those with chronic medical disorders or a lack of transportation.

Emergency Plan, Section 485.15(a)

A hospital must develop a plan based on the all-hazards risk assessment. The plan must: (1) be based on and include the documented, risk assessment; (2) include strategies to address the emergency events identified by the risk assessment; (3) address the hospital's patient population including at-risk persons, the type of services the hospital can provide in an emergency, and continuity of operations; and (4) include a process to ensure collaboration with the efforts of local, tribal, regional, state, and federal emergency preparedness officials, including documentation of the hospital's efforts to contact those officials and of its participation in collaborative planning efforts. CMS provides citations to ten different "Emergency Planning Resources" to assist hospitals in developing an emergency plan. For instance,

a hospital can look to the Health Resources and Services Administration's "Health Care Center Emergency Management Program Expectations"; The Joint Commission's "Standing Together: An Emergency Planning Guide For America's Communities"; or "Providing Mass Medical Care With Scarce Resources: A Community Planning Guide" by the AHRQ. CMS encourages providers to work with critical partners such as emergency management, public health, and other providers, noting the importance of a community's health care coalition in addressing emergencies, sharing resources, and ensuring health care resiliency. The hospital's emergency preparedness plan must be reviewed and updated at least annually.

Policies and Procedures, Section 485.15(b)

Hospitals must develop and maintain policies and procedures in accordance with their emergency plan and communications plan (discussed below). These must be reviewed and updated annually. CMS provides a list of mandatory elements:

Subsistence

A hospital should plan to provide food, water, and medical supplies to meet the subsistence needs of its staff and patients. It should be mindful that visitors, volunteers, and other members of the community may come to the hospital for assistance. CMS does not mandate minimum levels of supplies that must be maintained, but rather gives hospitals flexibility to determine how much is adequate.

Backup Power

A hospital must plan for alternate sources of energy sufficient to maintain temperatures that protect patient health and safety and allow safe storage of provisions. It also must have sufficient backup power to provide emergency lighting, for fire detection and extinguishing, and for sewage and waste disposal. Notably, Section 482.15(e) provides specifications for the location, inspection, and testing of a hospital's emergency generator as well as requirements to maintain fuel for the emergency generator.

Tracking System

The location of patients and staff in a hospital's care should be tracked during and after an emergency. CMS suggests the Joint Patient Assessment and Tracking System as an available tool for providers.

Evacuation

The hospital's policies and procedures should address safe evacuation, including how evacuees will receive care and treatment, staff responsibilities, transportation, evacuation location, and communication with outside assistance.

Sheltering in Place

The policies should further include a plan for sheltering in place for patients, staff, and volunteers who remain. “Sheltering in place” is not explicitly defined in the Proposed Rule, but refers to the decision for patients and staff to remain in a facility during an emergency or disaster either in lieu of evacuating or until a safe evacuation is possible. The decision should include an evaluation of the risks of evacuating which can include dangers in transporting patients, availability of receiving facilities to accept patients, the destruction of the facility, and the community infrastructure. This can be a difficult decision, and CMS provides a citation to guidance from the AHRQ that can provide direction to providers/suppliers.⁶

Documentation

The policies must include the hospital’s plan to preserve patient information and maintain the security and confidentiality of the patient records, while also ensuring that records remain readily available.

Volunteers

The hospital should plan for the use of volunteers in emergency staffing and the integration of health care professionals to address surge needs resulting from the emergency.

Collaboration

The policies should reflect the development of arrangements with other hospitals and providers to receive patients if the hospital’s operations are limited or if it is unable to continue providing patient services.

Alternate Care Site

The policies should address the hospital’s role if emergency management officials direct that care and treatment be provided to patients at an alternate care site. This action would be implemented in accordance with a waiver under Section 1135 of the Social Security Act and involves collaboration among providers and governmental officials to provide staffing, equipment, and supplies at a designated, alternate location as appropriate in light of the emergency.

Communication Plan, Section 485.15(c)

A hospital’s communication plan must include the names and contact information for staff, physicians, volunteers, entities that provide service to the hospital under arrangement, and other hospitals. The hospital should have contact information for governmental emergency preparedness staff and for other sources of assistance. The hospital must maintain a primary and a back-up method of communication with its staff and with governmental agencies. It also must have a way to provide information to appropriate authorities about the hospital’s occupancy, needs, and ability to provide

assistance. With regard to patient information, the hospital must address how it will share that information with other providers to ensure continuity of care, and, in the event of an evacuation, how it will release patient information. It must have a plan to provide information about a patient’s general condition and location.

Training and Testing

The hospital must conduct initial and annual training based on its emergency preparedness policies and procedures, and it must maintain documentation of that training. It must conduct drills to test the training, including annual participation in a community mock drill in addition to an annual paper-based tabletop exercise. The hospital must analyze its response in the drills and update its emergency plan as needed. There is an exemption from the annual mock drill for a hospital that experiences an actual disaster that requires activation of the emergency plan.

Regulations for Other Providers/Suppliers

The proposed CoP/CfC requirements for other provider and supplier types are based on the comprehensive requirements for hospitals, but are tailored for each particular provider or supplier type and its patients.⁷ Like hospitals, the other provider and supplier types must address the four core elements: (1) risk assessment and planning; (2) policies and procedures; (3) communication plan; and (4) training and testing; however, some provider/supplier types have greater responsibilities than others.⁸ For example, inpatient or residential facilities such as LTC facilities, CAHs, SNFs, and NFs generally, and logically, will have greater responsibilities for their patients/residents than outpatient facilities such as ASCs, HHAs, and FQHCs. Further, while all provider and supplier types have responsibilities to staff and patients during an emergency, the implementation of those responsibilities will vary based on the type, size, and sophistication of the provider or supplier.

1 78 Fed. Reg. 79082 (Dec. 27, 2013).

2 78 Fed. Reg. 79087, 79092.

3 CMS considered guidance from and had meetings with the U.S. Food and Drug Administration, Centers for Disease Control and Prevention, Health Resources and Services Administration, and Office of the Assistant Secretary for Preparedness and Response. CMS also considered The Joint Commission standards for emergency preparedness; the American Osteopathic Association standards for disaster preparedness; the National Fire Protection Association (NFPA) standards in NFPA 101 Life Safety Code and NFPA 1600: “Standard on Disaster/Emergency Management and Business Continuity Programs”; certain state-level requirements (including California and Maryland); and policy guidance from the American College of Healthcare Executives. 78 Fed. Reg. 79084.

4 78 Fed. Reg. 79085.

5 See 78 Fed. Reg. 79092 for the complete list.

6 78 Fed. Reg. 79094.

7 78 Fed. Reg. 79090.

8 78 Fed. Reg. 79091.