

ELECTRONIC CODE OF FEDERAL REGULATIONS

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Title 42: Public Health
PART 416—AMBULATORY SURGICAL SERVICES
Subpart C—Specific Conditions for Coverage

§416.54 Condition for coverage—Emergency preparedness.

The Ambulatory Surgical Center (ASC) must comply with all applicable Federal, State, and local requirements. The ASC must establish and maintain an emergency preparedness program that meets this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The ASC must develop and maintain an emergency preparedness plan that is updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the ASC has to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency and documentation of the ASC's efforts to contact such officials and, when applicable, of its participatory cooperative planning efforts.

(b) *Policies and procedures.* The ASC 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 (3) of this section, the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of on-duty staff and sheltered patients in the ASC's care during an emergency. If staff or sheltered patients are relocated during the emergency, the ASC must document the specific receiving facility or other location.

(2) Safe evacuation from the ASC, which includes the following:

(i) Consideration of care and treatment needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the ASC.

(4) A system of medical documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

(5) The use of volunteers in an emergency and other staffing strategies, including the process State and Federally designated health care professionals to address surge needs during an emerg

(6) The role of the ASC under a waiver declared by the Secretary, in accordance with section provision of care and treatment at an alternate care site identified by emergency management offic

(c) *Communication plan.* The ASC must develop and maintain an emergency preparedness co complies with Federal, State, and local laws and must be reviewed and updated at least annually. must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) ASC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the ASC's other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 4

(6) A means of providing information about the general condition and location of patients unde

permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ASC's needs, and its ability to provide assistance in the jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The ASC must develop and maintain an emergency preparedness training program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (b) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The ASC must do all of the following:

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

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The ASC must conduct exercises to test the emergency plan at least annually. The exercises must include:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not feasible, an individual, facility-based. If the ASC experiences an actual natural or man-made emergency that requires the use of the emergency plan, the ASC is exempt from engaging in an individual, facility-based exercise for the year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, written scenario, and a set of problem statements, directed messages, or prepared questions designed to test the emergency plan.

(iii) Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and full-scale exercises. Revise the ASC's emergency plan, as needed.

(e) *Integrated healthcare systems.* If an ASC is part of a healthcare system consisting of multiple healthcare facilities that elects to have a unified and integrated emergency preparedness program, the ASC must participate in the healthcare system's coordinated emergency preparedness program. If elected, the ASC's emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraph section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph coordinated communication plan and training and testing programs that meet the requirements of paragraph section, respectively.

[81 FR 64022, Sept. 16, 2016]

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