



## **PART 416--AMBULATORY SURGICAL SERVICES**

4. The authority citation for part 416 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

### **§ 416.41 [Amended]**

5. Amend § 416.41 by removing paragraph (c).

6. Add § 416.54 to subpart C to read as follows:

### **§ 416.54 Condition for coverage--Emergency preparedness.**

**The Ambulatory Surgical Center (ASC)** must comply with all applicable Federal, State, and local emergency preparedness requirements. The ASC must establish and maintain an emergency preparedness program that meets the requirements of 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 must be reviewed, and 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, utilizing an all-hazards 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 the ability 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 situation, including documentation of the ASC's efforts to contact such officials and, when applicable, of its participation in collaborative and 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 (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must

be reviewed and updated at least 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 on-duty staff or sheltered patients are relocated during the emergency, the ASC must document the specific name and location of the 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 and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.
- (6) The role of the ASC under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

### **(c) Communication plan**

The ASC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least **annually**. The communication plan 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 care, as necessary, with 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 45 CFR 164.510(b)(1)(ii).
- (6) A means of providing information about the general condition and location of patients under the facility's care as 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, to the authority having jurisdiction, the Incident Command Center, or designee.

#### **(d) Training and Testing**

The ASC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) 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 staff, individuals providing on-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 ASC must do the following:

- (i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, individual, facility-based. If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in an community-based or individual, facility-based full-scale exercise for 1 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, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
- (iii) Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the ASC's emergency plan, as needed.

### **(e) Integrated healthcare systems**

If an ASC is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the ASC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must:

- (1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
- (2) Be developed and maintained in a manner that takes into account each separately certified facility's unique 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 paragraphs (a)(2), (3), and (4) of this 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 within the health system, utilizing an all-hazards approach.

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