§ 416.52 Conditions for coverage—Patient admission, assessment and discharge.

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

(a) *Standard: Patient assessment and admission.* (1) The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must—

(i) Include the timeframe for medical history and physical examination to be completed prior to surgery.

(ii) Address, but is not limited to, the following factors: Patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.

(iii) Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) The pre-surgical assessment must include documentation of any allergies to drugs and biologicals.

(4) The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure.

(b) *Standard: Post-surgical assessment.* (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Post-surgical needs must be addressed and included in the discharge notes.

(c) *Standard: Discharge.* The ASC must—

(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for followup care.

(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.

[73 FR 68813, Nov. 18, 2008, as amended at 84 FR 51814, Sept. 30, 2019]

§ 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 every 2 years. 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.

(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 every 2 years. 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 every 2 years. 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 every 2 years.

(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 every 2 years.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the ASC must conduct training on the updated policies and 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 every 2 years; or

(A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or

(B) 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 its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion 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.

[81 FR 64022, Sept. 16, 2016, as amended at 84 FR 51814, Sept. 30, 2019]

Subpart D—Scope of Benefits for Services Furnished Before January 1, 2008

§ 416.60 General rules.

(a) The services payable under this part are facility services furnished to