### Final Rule, Pgs. 64022-64024

<table>
<thead>
<tr>
<th>Section</th>
<th>Narrative*</th>
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<tr>
<td>§ 416.54 The Ambulatory Surgery Center (ASC) must comply with all applicable Federal, State and local emergency preparedness requirements. The ASC must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach specific to its location. The emergency preparedness program must include, but not be limited to, the following elements:</td>
<td>Three essential elements are required in the final rule to maintain access to healthcare services during emergencies: 1. Safeguarding human resources 2. Maintaining business continuity 3. Protecting physical resources</td>
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<td>§ 416.54(a) Emergency Plan</td>
<td>Preparedness planning should focus on capacities and capabilities critical to a full spectrum of emergencies or disasters and other federal, state and local laws. Examples may include care-related emergencies, equipment and power related failures, communication interruptions-including cybersecurity attacks, loss of all or part of the facility.</td>
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<td>§ 416.54(a)(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.</td>
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<td>§ 416.54(a)(2) Include strategies for addressing emergency events identified by the risk assessment.</td>
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<td>§ 416.54(a)(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.</td>
<td>At risk patient populations may need additional assistance such as those with disabilities, living in an institutionalized setting, from diverse cultures, limited English proficiency, lack of transportation, chronic medical disorders or drug dependency. At risk individuals means children, pregnant women, hospitalized patients, senior citizens, others with special needs in a public health emergency or based upon unique population and geographical areas. See the Public Health Service Act and the National Response Framework for expanded definitions.</td>
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<td>§ 416.54(a)(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, its participation in collaborative and cooperative planning efforts.</td>
<td>ASCs are expected to document their efforts to contact pertinent emergency preparedness officials, and when applicable document their participation in any collaborative and cooperative planning efforts.</td>
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### § 416.54(b) Policies and Procedures

The ASC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in section (a) Emergency Plan, in section (a)(1) Risk Assessment and section (c) Communication Plan. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

#### §416.54(b)(1) A system to track the location of on-duty staff and sheltered patients in the ASC's care during an emergency.

ASCs are required to develop and implement policies and procedures that support the successful execution of the emergency plan and risks identified during the risk assessment process.

If on-duty staff or sheltered patients are relocated during an emergency, the ASC must document the specific name and location of the receiving facility or other location.

#### §416.54(b)(2) Safe evacuation from the ASC, which includes the following:

- Consideration of care and treatment needs of evacuees
- Staff responsibilities
- Transportation
- Identification of evacuation location(s)
- Primary and alternate means of communication with external sources of assistance

State or local emergency management officials would designate such alternate care sites in collaboration with local facilities. During an emergency, if a patient requires care beyond the capabilities of the ASC, CMS expects the patient would be transferred to a hospital with which the ASC has a written transfer agreement or to a local hospital meeting the requirements of §416.41(b)(2) where the ASC physicians have admitting privileges. Also, consider in the ASC risk assessment if the hospitals may be also affected by the emergency.

#### §416.54(b)(3) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

Policies and procedures should address the criteria for selecting patients and staff sheltered in place and a description of how to ensure their safety.

#### §416.54(b)(4) A system of medical documentation that does the following:

- Preserves patient information
- Protects confidentiality of patient information
- Secures and maintains the availability of records

Policies and procedures must be in compliance with Health Insurance Portability and Accountability Act (HIPAA) Rules at 45 CFR parts 160 and 164.

#### §416.54(b)(5) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

Medical and non-medical volunteers.

#### §416.54(b)(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.

Section 1135 authorizes the Secretary to waive or modify certain Medicare, Medicaid and CHIP requirements to ensure sufficient healthcare is available in an emergency.
### §416.54(c) Communication Plan

The ASC must develop and maintain an emergency preparedness communication plan that complies with both Federal, State and local law and must be reviewed and updated at least annually. The communication plan must include all of the following:

- **§416.54(c)(1) Names and contact information for the following:**
  - **§416.54(c)(1)(i) Staff.**
  - **§416.54(c)(1)(ii) Entities providing services under arrangement.**
  - **§416.54(c)(1)(iii) Patients’ physicians.**
  - **§416.54(c)(1)(iv) Volunteers.**  
    Medical and non-medical volunteers.

- **§416.54(c)(2) Contact information for the following:**
  - **§416.54(c)(2)(i) Federal, State, tribal, regional, and local emergency preparedness staff.**
  - **§416.54(c)(2)(ii) Other sources of assistance.**

- **§416.54(c)(3) Primary and alternate means for communicating with the following:**
  - **§416.54(c)(3)(i) ASC’s staff.**
  - **§416.54(c)(3)(ii) Federal, State, tribal, regional, and local emergency management agencies.**

- **§416.54(c)(4) A method for sharing information and medical documentation for patients under the ASC’s care, as necessary, with other health care providers to ensure continuity of care.**

- **§416.54(c)(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(iii).**

- **§416.54(c)(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).**

- **§416.54(c)(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.**

- **HIPAA Rule.** ASC should establish a communication system to generate timely, accurate information to be disseminated as permitted to family members and others regarding patient’s location, general condition or death in compliance with federal and state laws.

- **Relevant patient information includes but not limited to:** patient’s presence or location in the facility, patient billing and demographics, or the patient’s medical condition.

- **Uses and disclosures for disaster relief purposes rule.** The communication plan should include what types of information is releasable, and who is authorized to release this information during an emergency.

- **ASCs are encouraged to engage in their HCC for assistance in broadening awareness and collaboration as well as identifying best practices that can assist them to effectively meet this requirement.”**
§ 416.54(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 section (a) Emergency Plan, in section (a)(1) Risk Assessment, section (b) Policies and Procedures and section (c) Communication Plan. The training and testing program must be reviewed and updated at least annually.

ASCs must conduct drills and exercises to test the emergency plan to identify gaps and areas for improvement.

| §416.54(d)(1) Training program. The ASC must do all of the following: |
| §416.54(d)(1)(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role. |
| §416.54(d)(1)(ii) Provide emergency preparedness training at least annually. |
| §416.54(d)(1)(iii) Maintain documentation of the training |
| §416.54(d)(1)(iv) Demonstrate staff knowledge of emergency procedures. |

| §416.54(d)(2) Testing. The ASC must conduct exercises to test the emergency plan at least annually. The ASC must do all of the following: |
| §416.54(d)(2)(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. |
| Include in the planning a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials and regional HCCs. The ASC should document efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts. |
| §416.54(d)(2)(ii) Conduct an additional exercise that may include, but is not limited to the following: |
| (A) A second full-scale exercise that is community-based or 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. |
| 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 a community or individual, facility-based full-scale exercise for 1 year following the onset of the actual event. The ASC must maintain documentation of the emergency event and be able to demonstrate how the emergency plan was put into action. |
| §416.54(d)(2)(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. |

A.____________________________________________

B.__________________

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§ 416.54 Integrated Health Systems

Healthcare systems consisting of multiple separately certified healthcare facilities may elect to have a unified and integrated emergency preparedness program. If elected, the unified and integrated emergency program must do all of the following:

- **§416.54(e)(1)** Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

- **§416.54(e)(2)** Be developed and maintained in a manner that takes into account each separately certified facility’s unique circumstances, patient populations and services offered.

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

- **§416.54(e)(4)** Include a unified and integrated emergency plan that meets the requirements of paragraphs (a) (2), (3) and (4) of this rule. The unified and integrated emergency plan must also be based and include:
  - **§416.54(e)(4)(i)** A documented community-based risk assessment, utilizing an all-hazards approach.
  - **§416.54(e)(4)(ii)** A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing the all-hazards approach.

- **§416.54(e)(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 the rule, respectively.

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KHA 2016 – ASC CIC
August 8, 2017