**The RHC has an emergency preparedness program that addresses an emergency on-site, off-site (natural disaster) and disruption of service. (§491.12)**

Evidence of Compliance:

1. The clinic complies with all applicable Federal, State and local emergency preparedness requirements. (§491.12)
2. The clinic has an emergency preparedness plan that is reviewed and updated annually. This plan contains the following elements: (§491.12(a)
3. A documented, clinic-based and community-based risk assessment that utilizes an all hazards approach. (§491.12(a)(1))
4. Strategies for addressing emergency events identified by the risk assessment. (§491.12(a)(2)
5. Addresses patient population, including, but not limited to, the type of services the clinic has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans. (§491.12(a)(3))
6. A process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness official’s efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the clinic’s efforts to contact such officials and when, applicable, of its participation in collaborative and cooperative planning efforts. (§491.12(a)(4))

Interpretive Guidelines:

An RHC’s emergency preparedness program must describe the RHC's comprehensive approach to meeting the health, safety, and security needs of their staff and patient population during an emergency or disaster situation and address how the RHC would coordinate with other healthcare facilities, as well as the whole community during an emergency or disaster (natural, man-made). The emergency preparedness program must comply with all applicable Federal, State and local emergency preparedness requirements.

Survey Procedures:

1. Interview the RHC leadership and ask him/her/them to describe the RHC’s emergency preparedness program.
2. Ask RHC leadership to identify hazards (e.g. natural, man-made, geographic, etc.) that were identified in the RHC’s risk assessment, why they were included and how the risk assessment was conducted.
3. Interview RHC leadership and ask them to describe the following:
   1. The RHC’s patient population that would be at risk during an emergency;
   2. Services the RHC would be able to provide during an emergency; how it continues to provide operations during an emergency; and delegations of authority and succession plans.
4. Ask to see the facilities written emergency preparedness program policies and procedures and verify the RHC has an emergency preparedness plan by asking to see a copy of the plan.
5. Review the plan to verify it contains the following required elements:
   1. A documented, clinic-based and community-based risk assessment.
   2. Strategies for addressing emergency events identified by the risk assessment.
   3. Addresses patient population, including, but not limited to, the type of services the clinic has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
   4. A process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness official’s efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the clinic’s efforts to contact such officials and when, applicable, of its participation in collaborative and cooperative planning efforts.
6. Ensure the word “comprehensive” in the RHC’s emergency preparedness program considers a multitude of events (not one potential emergency) and the RHC can demonstrate that they have considered this during their development of the emergency preparedness plan.
7. Verify that the plan is reviewed and updated annually.

**The clinic has developed and implemented emergency preparedness policies and procedures that are based on its emergency preparedness plan. (42 CFR 491.12(b)**

Evidence of Compliance:

1. The policies and procedures are based on the emergency preparedness plan, risk assessment, and the communication plan. (§491.12(b))
2. The policies and procedures are reviewed and updated, at a minimum annually. (§491.12(b))
3. The policies and procedures include the following elements: (§491.12(b))
   1. Safe evacuation from the clinic, which includes appropriate placement of exit signs, staff responsibilities and needs of patients. (§491.12(b)(1))
   2. A means to shelter in place for patients, staff, and volunteers who remain in the clinic. (§491.12(b)(2))
   3. A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of patient health records. (§491.12(b)(3))
   4. The use of volunteers in an emergency or 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. (§491.12(b)(4)).
   5. How refrigerated/frozen medications such as vaccines, etc. are handled in a power outage.

Interpretive Guidelines:

RHC’s must develop policies and procedures that align with the identified hazards within the RHC’s risk assessment and the RHC’s overall emergency preparedness program.

Survey Procedures:

1. Review the written policies and procedures which address the RHC’s emergency plan and verify the following:
   1. Policies and procedures were developed based on the RHC-based and community- based risk assessment and communication plan, utilizing an all-hazards approach.
   2. Verify the RHC’s policies and procedures:
      1. Provide for the safe evacuation of patients from the RHC.
      2. Include how it will provide a means to shelter in place for patients, staff and volunteers who remain in the RHC.
      3. Ensures the medical record documentation system preserve patient information, protects confidentiality of patient and secures and maintains availability of records
      4. Includes for the use of volunteers and other staffing strategies in its emergency plan.
   3. When surveying the RHC, verify that all exit signs are placed in the appropriate locations to facilitate a safe evacuation.
2. Ask to see documentation that verifies the policies and procedures have been reviewed and updated on annual basis.

**The clinic develops and maintains an emergency communication plan that complies with Federal, State, and local laws. (42 CFR 491.12(c))**

Evidence of Compliance:

1. The clinic’s emergency preparedness communication plan is reviewed and updated, at a minimum, annually. (§491.12(c))
2. The clinic’s communication plan includes the following elements: (§491.12(c))
   1. Names and contact information for the following: (§491.12(c)(1)
      1. Staff. (§491.12(c)(1)(i)
      2. Entities providing services under arrangement. (§491.12(c)(1)(ii)
      3. Patient’s physicians. (§491.12(c)(1)(iii)
      4. Other RHCs. (§491.12(c)(1)(iv)
      5. Volunteers. (§491.12(c)(1)(v)
   2. Contact information for the following: (§491.12(c)(2)
      1. Federal, State, tribal, regional, and local emergency preparedness staff. (§491.12(c)(2)(i)
      2. Other sources of assistance. (§491.12(c)(2)(ii)
   3. Primary and alternate means for communicating with the following: (§491.12(c)(3)
      1. RHC (§491.12(c)(3)(i)
      2. Federal, State, tribal, regional, and local emergency management agencies. (§491.12(c)(3)(ii)
   4. A means of providing information about the general condition and location of patients under the RHC’s care as permitted under 45 CFR 164.510(b)(4). (§491.12(c)(4))
   5. A means of providing information about the clinic’s needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee. (§491.12(c)(5)
3. The clinic’s communication plan contains an organized process for handling an on-site emergency which addresses the following:
   1. How employees will be notified of emergency.
   2. Staff responsible for calling the Fire Department.
   3. Location of where employees should meet outside the building.
   4. Staff person responsible to do head count upon evacuation of the building.
4. The clinic’ communication plan has an organized process for handling an off-site emergency (e.g. Snowstorm, flood, hurricane, etc.)
   1. How employees will be notified of emergency.
   2. Staff responsible for notification and triaging of patient services.
   3. Contingency plan that includes alternative provider in the event the clinic cannot service its own customers.

Interpretive Guidelines:

RHCs must have a written communication plan that contains how the RHC coordinates patient care within the RHC, across healthcare providers, and with State and local public health departments. The plan should include how the RHC interacts and coordinates with emergency management agencies and systems to protect health and safety in the event of a disaster.

Surveyor Procedures:

1. Verify that the RHC has a written communication plan by asking to see the plan.
2. Ask to see evidence that the plan has been reviewed (and updated as necessary) on an annual basis.
3. Verify that all required contacts are included in the communication plan by asking to see a list of the contacts with their contact information.
4. Verify the communication plan includes primary and alternate means for communicating with RHC staff, Federal, State, tribal, regional and local emergency management agencies by reviewing the communication plan (i.e., pagers, cellular telephones, walkie-talkies, HAM radio, etc.)
5. Ask to see the communications equipment or communication systems listed in the plan.
6. Verify the RHC has developed policies and procedures that address the means the RHC will use to release patient information to include the general condition and location of patients, by reviewing the communication plan
7. Verify the communication plan includes a means of providing information about the RHC’s needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee by reviewing the communication plan.

**Training Program: The clinic develops and maintains an emergency preparedness training and testing program that is based on the emergency preparedness plan, risk assessment, policies and procedures, and the communication plan. (42 CFR 491.12(d)(1))**

Evidence of Compliance:

* 1. The training and testing program is reviewed and updated, at a minimum, annually. (§491.12(d))
  2. The training program includes all of the following: (§491.12(d)(1))
     1. 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 roles. (§491.12(d)(1)(i))
     2. Provide emergency preparedness training, at a minimum, annually. (§491.12(d)(1)(ii)
     3. Emergency preparedness training of staff, individual providing services under arrangement, and volunteers is documented. This documentation demonstrates knowledge of emergency procedures. (§491.12(d)(1)(iii), (§491.12(d)(1)(iv))

Interpretive Guidelines:

An emergency preparedness training and testing program must be documented and reviewed and updated on at least an annual basis. The training and testing program must reflect the risks identified in the RHC’s risk assessment and be included in their emergency plan.

Surveyor Procedures:

1. Verify the RHC has an emergency preparedness training and testing program.
2. Verify the program has been reviewed and updated on, at least, an annual basis by asking for documentation of the annual review as well as any updates made.
3. Ask for copies of the RHC’s initial emergency preparedness training and annual emergency preparedness training offerings.
4. Interview various staff and ask questions regarding the RHC’s initial and annual training course, to verify staff knowledge of emergency procedures.
5. Review a sample of staff training files to verify staff has received initial and annual emergency preparedness training.

**Testing Program: The clinic conducts exercises to test the emergency plan, at a minimum, annually. (42 CFR 491.12(d)(2))**

Evidence of Compliance:

1. The clinic conduct exercises to test the emergency plan, at a minimum, annually. (§491.12(d)(2))
2. The clinic must do the following: (§491.12(d)(2))
3. Participate in a full-scale exercise that is community-based or when a community-based exercise is not assessable, an individual, facility based. If the clinic experiences an actual natural, or man-made emergency that requires activation of the emergency plan, the clinic is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event. (§491.12(d)(2)(i))
4. Conduct an additional exercise that may include, but is not limited to the following: (§491.12(d)(2)(ii)
5. A second full-scale exercise that is community-based or individual, facility based. (§491.12(d)(2)(ii)(A))
6. 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. (§491.12(d)(2)(ii)(B))
7. Analyze the clinic’s response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the clinic’s emergency plan, as needed. (§491.12(d)(2)(iii))

Interpretive Guidelines:

RHCs must on an annual basis conduct exercises to test the emergency plan, specifically RHCs are required to conduct a tabletop exercise and participate in a full-scale community-based exercise or conduct an individual facility exercise if the community-based exercise is not available. For the purposes of this requirement, a full scale exercise is defined and accepted as any operations-based exercise (drill, functional, or full-scale exercise) that assesses a facility’s functional capabilities by simulating a response to an emergency that would impact the facility’s operations and their given community.

RHCs are expected to contact their local and state agencies and healthcare coalitions, where appropriate, to determine if an opportunity exists and determine if their participation would fulfill this requirement. In doing so, they are expected to document the date, the personnel and the agency or healthcare coalition that they contacted.

RHCs that are not able to identify a full-scale community-based exercise, can instead fulfill this part of their requirement by either conducting an individual facility-based exercise, documenting an emergency that required them to fully activate their emergency plan, or by conducting a smaller community-based exercise with other nearby facilities.

Surveyor Procedures:

1. Ask to see documentation of the annual tabletop and full-scale exercises (which may include, but is not limited to, the exercise plan, the AAR, and any additional documentation used by the RHC to support the exercise.
2. Ask to see the documentation of the RHC’s efforts to identify a full-scale community based exercise if they did not participate in one (i.e. date and personnel and agencies contacted and the reasons for the inability to participate in a community based exercise).
3. Request documentation of the RHC’s analysis and response and how the facility updated its emergency program based on this analysis.

**If a clinic that is part of a healthcare system consisting of multiple separately certified healthcare facilities elects to have a unified and integrated emergency preparedness program, the clinic may choose to participate in the healthcare system’s coordinated emergency preparedness program. (42 CFR 491.12(e))**

Evidence of Compliance

* 1. If the clinic elects to participate in the healthcare system’s emergency preparedness plan, the unified and integrated emergency preparedness program must do all of the following: (§491.12(e))
     1. Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program. (§491.12(e)(1))
     2. Be developed and maintained in a manner that takes into account each separately certified facility’s unique circumstances, patient populations, and services offered. (§491.12(e)(2))
     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. (§491.12(e)(3))
     4. Include a unified and integrated emergency plan that meets the requirements of 42 CFR 491.12(a)(2), (3), and (4). The unified and integrated emergency plan must also include the all of the following elements: (§491.12(e)(4))
        + 1. A documented community-based risk assessment, utilizing an all hazards approach. (§491.12(e)(4)(i))
          2. A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. (§491.12(e)(4)(ii))
     5. Include integrated policies and procedures that meet the requirements at 42 CFR 491.12(b), a coordinated communication plan, and training and testing programs that meet the requirements of 42 CFR 491.12(c) and 491.12(d).

Interpretive Guidelines:

Healthcare systems that include multiple facilities that are separately certified as a Medicare-participating provider or supplier have the option of developing a unified and integrated emergency preparedness program that includes all of the facilities within the healthcare system instead of each facility developing a separate emergency preparedness program.

If a healthcare system elects to have a unified emergency preparedness program, the integrated program must demonstrate that each separately certified facility within the system that elected to participate in the system’s integrated program actively participated in the development of the program.

Each separately certified facility must be capable of demonstrating during a survey that it can effectively implement the emergency preparedness program and demonstrate compliance with all emergency preparedness requirements at the individual facility level. Compliance with the emergency preparedness requirements is the individual responsibility of each separately certified facility.

The unified emergency preparedness program must include a documented community– based risk assessment and an individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. Lastly, the unified program must have a coordinated communication plan and training and testing program.

Surveyor Procedures:

1. Verify whether or not the facility has opted to be part of its healthcare system’s unified and integrated emergency preparedness program. Verify that they are by asking to see documentation of its inclusion in the program.
2. Ask to see documentation that verifies the facility within the system was actively involved in the development of the unified emergency preparedness program.
3. Ask to see documentation that verifies the facility was actively involved in the annual reviews of the program requirements and any program updates.
4. Ask to see a copy of the entire integrated and unified emergency preparedness program and all required components (emergency plan, policies and procedures, communication plan, training and testing program).
5. Ask facility leadership to describe how the unified and integrated emergency preparedness program is updated based on changes within the healthcare system such as when facilities enter or leave the system.

**Definitions:**

Emergency/Disaster: An event that can affect the facility internally as well as the overall target population or the community at large or community or a geographic area.

Emergency: A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. It requires a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) to meet the expected outcome, and commonly requires change from routine management methods to an incident command process to achieve the expected outcome (see “disaster” for important contrast between the two terms).

Disaster: A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. Despite a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) and change from routine management methods to an incident command/management process, the outcome is lower than expected compared with a smaller scale or lower magnitude impact.

Emergency Preparedness Program: The Emergency Preparedness Program describes a facility’s comprehensive approach to meeting the health, safety and security needs of the facility, its staff, their patient population and community prior to, during and after an emergency or disaster. The program encompasses four core elements: an Emergency Plan that is based on a Risk Assessment and incorporates an all hazards approach; Policies and Procedures; Communication Plan; and the Training and Testing Program.

Emergency Plan: An emergency plan provides the framework for the emergency preparedness program. The emergency plan is developed based on facility- and community-based risk assessments that assist a facility in anticipating and addressing facility, patient, staff and community needs and support continuity of business operations.

All-Hazards Approach: An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is not limited to: care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water and food. All facilities must develop an all-hazards emergency preparedness program and plan.

Facility-Based: We consider the term “facility-based” to mean the emergency preparedness program is specific to the facility. It includes but is not limited to hazards specific to a facility based on its geographic location; dependent patient/resident/client and community population; facility type and potential surrounding community assets- i.e. rural area versus a large metropolitan area.

Risk Assessment: The term risk assessment describes a process facilities use to assess and document potential hazards that are likely to impact their geographical region, community, facility and patient population and identify gaps and challenges that should be considered and addressed in developing the emergency preparedness program. The term risk assessment is meant to be comprehensive, and may include a variety of methods to assess and document potential hazards and their impacts. The healthcare industry has also referred to risk assessments as a Hazard Vulnerability Assessments or Analysis (HVA) as a type of risk assessment commonly used in the healthcare industry.

Full-Scale Exercise: A full scale exercise is an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional (for example, joint field office, emergency operation centers, etc.) and integration of operational elements involved in the response to a disaster event, i.e. ‘‘boots on the ground’’ response activities (for example, hospital staff treating mock patients).

Table-top Exercise (TTX): A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures. A tabletop exercise is a discussion-based exercise that involves senior staff, elected or appointed officials, and other key decision making personnel in a group discussion centered on a hypothetical scenario. TTXs can be used to assess plans, policies, and procedures without deploying resource.

Staff: The term "staff" refers to all individuals that are employed directly by a facility. The phrase "individuals providing services under arrangement" means services furnished under arrangement that are subject to a written contract conforming with the requirements specified in section 1861(w) of the Act.