Condition of Participation: Emergency Preparedness

Comparison Between Proposed Rule (78 Fed. Reg. 79082 (Dec. 27, 2013))
and
Final Rule (81 Fed. Reg. 63860 (Sept. 16, 2016))

Note: ~~Strikeout~~ indicates deleted text; underline indicates added text.

PART 403—SPECIAL PROGRAMS AND PROJECTS (Religious Nonmedical Health Care Institutions)

Sec. 403.748 Condition of participation: Emergency preparedness.

The Religious Nonmedical Health Care Institution (RNHCI) must comply with all applicable Federal and State emergency preparedness requirements. The RNHCI 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 RNHCI must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of 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, persons at-risk; the type of services the RNHCI has the ability to provide in an emergency; and, continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the RNHCI's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The RNHCI 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) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the RNHCI's care both during and after the emergency.

(3) Safe evacuation from the RNHCI, which includes the following:

(i) Consideration of care 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.

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

(5) A system of care documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Ensures records are secure and readily available.

(6) The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.

(7) The development of arrangements with other RNHCIs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of nonmedical services to RNHCI patients.

(8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care at an alternate care site identified by emergency management officials.

(c) Communication plan. The RNHCI must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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 agreement.

(iii) Next of kin, guardian or custodian.

(iv) Other RNHCIs.

(v) 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) RNHCI's staff.

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

(4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to ensure continuity of care, based on the written election statement made by the patient or his or her legal representative.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(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 RNHCI's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The RNHCI must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

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

(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 roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The RNHCI must conduct exercises to test the emergency plan. The RNHCI must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(ii) Analyze the RNHCI's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed.

PART 416—AMBULATORY SURGICAL SERVICES

Sec. 416.54 Condition for coverage: Emergency preparedness.

The Ambulatory Surgical Center (ASC) must comply with all applicable Federal and State 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 ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure 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 staff and patients in the ASC's care both during and after the emergency.

(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) Ensures records are secure and readily available.

(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 development of arrangements with other ASCs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to ASC patients.

(7) 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 both Federal and State law 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) Other ASCs.

(v) 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 ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(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 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) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The ASC must conduct exercises to test the emergency plan. The ASC must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) 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 mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) 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.

PART 418—HOSPICE CARE

Sec. 418.113 Condition of participation: Emergency preparedness.

The hospice must comply with all applicable Federal and State emergency preparedness requirements. The hospice 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 hospice 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, including the management of the consequences of power failures, natural disasters, and other emergencies that could affect the hospice's ability to provide care.

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

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospice's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The hospice 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 hospice employees and patients in the hospice's care both during and after the emergency.

(2) Procedures to inform State and local officials about hospice patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of hospice employees 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.

(5) The development of arrangements with other hospices and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospice patients.

(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

(i) A means to shelter in place for patients, hospice employees who remain in the hospice.

(ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(A) Food, water, and medical supplies.

(B) Alternate sources of energy to maintain the following:

(1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(2) Emergency lighting.

(3) Fire detection, extinguishing, and alarm systems.

(C) Sewage and waste disposal.

(iv) The role of the hospice 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 hospice must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Hospice employees.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other hospices.

(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) Hospice's employees.

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

(4) A method for sharing information and medical documentation for patients under the hospice's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(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 hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The hospice must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

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

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

(ii) Ensure that hospice employees can demonstrate knowledge of emergency procedures.

(iii) Provide emergency preparedness training at least annually.

(iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(v) Maintain documentation of all emergency preparedness training.

(2) Testing. The hospice must conduct exercises to test the emergency plan. The hospice must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the hospice experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospice's emergency plan, as needed.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLIACABLE TO SPECIFIC SERVICES (Psychiatric Residential Treatment Facilities)

Sec. 441.184 Emergency preparedness.

The Psychiatric Residential Treatment Facility (PRTF) must comply with all applicable Federal and State emergency preparedness requirements. The PRTF 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 PRTF 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 resident population, including, but not limited to, persons at-risk; the type of services the PRTF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the PRTF's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The PRTF 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) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the PRTF's care both during and after the emergency.

(3) Safe evacuation from the PRTF, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or 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.

(7) The development of arrangements with other PRTFs and other providers to receive residents in the event of limitations or cessation of operations to ensure the continuity of services to PRTF residents.

(8) The role of the PRTF under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The PRTF must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Residents' physicians.

(iv) Other PRTFs.

(v) 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 PRTF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the PRTF's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

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

(d) Training and testing. The PRTF must develop and maintain an emergency preparedness training program that must be reviewed and updated at least annually.

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

(i) Provide 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.

(ii) After initial training, provide emergency preparedness training at least annually.

(iii) Ensure that staff can demonstrate knowledge of emergency procedures.

(iv) Maintain documentation of all emergency preparedness training.

(2) Testing. The PRTF must conduct exercises to test the emergency plan. The PRTF must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the PRTF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PRTF is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv)(A) Analyze the PRTF's response to and maintain documentation of all drills, tabletop exercises, and emergency events.

(B) Revise the PRTF's emergency plan, as needed.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

Sec. 460.84 Emergency preparedness.

The Program for the All-Inclusive Care for the Elderly (PACE) organization must comply with all applicable Federal and State emergency preparedness requirements. The PACE organization 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 PACE organization 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 participant population, including, but not limited to, the type of services the PACE organization has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the PACE's efforts to contact such officials and, when applicable, of its participation in organization's collaborative and cooperative planning efforts.

(b) Policies and procedures. The PACE organization 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 address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. 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 staff and participants under the PACE center(s) care both during and after the emergency.

(2) Safe evacuation from the PACE center, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(3) The procedures to inform State and local emergency preparedness officials about PACE participants in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric conditions and home environment.

(4) A means to shelter in place for participants, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves participant information, protects confidentiality of patient information, and ensures records are secure and readily available.

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

(7) The development of arrangements with other PACE organizations, PACE centers, or other providers to receive participants in the event of limitations or cessation of operations to ensure the continuity of services to PACE participants.

(8) The role of the PACE organization 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.

(9)(i) Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs.

(ii) Staff who know how to use the equipment must be on the premises of every center at all times and be immediately available.

(iii) A documented plan to obtain emergency medical assistance from outside sources when needed.

(c) Communication plan. The PACE organization must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for staff; entities providing services under arrangement; participants' physicians; other PACE organizations; and 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) PACE organization's staff.

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

(4) A method for sharing information and medical documentation for participants under the organization's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release participant information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of participants under the facility's care as permitted under 45 CFR 164.510(b)(4).

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

(d) Training and testing. The PACE organization must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The PACE organization 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, contractors, participants, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Ensure that staff demonstrate a knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.

(iv) Maintain documentation of all training.

(2) Testing. The PACE organization must conduct exercises to test the emergency plan. The PACE organization must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the PACE organization experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE organization is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

Sec. 482.15 Condition of participation: Emergency preparedness.

The hospital must comply with all applicable Federal and State emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The hospital 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, persons at-risk; the type of services the hospital has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The hospital 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) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the hospital's care both during and after the emergency.

(3) Safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

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

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(6) 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.

(7) The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients.

(8) The role of the hospital 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 hospital must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Other hospitals

(v) 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) Hospital'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 hospital's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(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 hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The hospital must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

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

(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.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The hospital must conduct drills and exercises to test the emergency plan. The hospital must do all of the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.

(e) Emergency and standby power systems. The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(2)(i) and (ii) of this section.

(1) Emergency generator location. (i) The generator must be located in accordance with the location requirements found in NFPA 99, NFPA 101, and NFPA 110.

(2) Emergency generator inspection and testing. In addition to the emergency power system inspection and testing requirements found in NFPA 99--Health Care Facilities and NFPA 110--Standard for Emergency and Standby Power systems, as referenced by NFPA 101--Life Safety Code (as required by 42 CFR 482.41(b)), the hospital must:

(i) At least once every 12 months, test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the hospital anticipates it will require during an emergency.

(ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation and repairs.

(3) Emergency generator fuel. Hospitals that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.

Sec. 482.78 Condition of participation: Emergency preparedness for transplant centers.

A transplant center must have policies and procedures that address emergency preparedness.

(a) Standard: Agreement with at least one Medicare approved transplant center. A transplant center or the hospital in which it operates must have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and related care for its patients during an emergency. The agreement must address the following, at a minimum:

(1) Circumstances under which the agreement will be activated.

(2) Types of services that will be provided during an emergency.

(b) Standard: Agreement with the Organ Procurement Organization (OPO) designated by the Secretary. The transplant center must ensure that the written agreement required under Sec. 482.100 addresses the duties and responsibilities of the hospital and the OPO during an emergency.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

Sec. 483.73 Emergency preparedness.

The LTC facility must comply with all applicable Federal and State emergency preparedness requirements. The LTC facility 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 LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing residents;

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

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the LTC facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the LTC facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The LTC facility 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) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to:

(i) Food, water, and medical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems, and;

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the LTC facility's care both during and after the emergency.

(3) Safe evacuation from the LTC facility, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the LTC facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and ensures records are secure and readily available.

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

(7) The development of arrangements with other LTC facilities and other providers to receive residents in the event of limitations or cessation of operations to ensure the continuity of services to LTC residents.

(8) The role of the LTC facility 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 LTC facility must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Residents' physicians.

(iv) Other LTC facilities.

(v) Volunteers.

(2) Contact information for the following:

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

(ii) The State Licensing and Certification Agency.

(iii) The Office of the State Long-Term Care Ombudsman.

(iv) Other sources of assistance.

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

(i) LTC facility's staff.

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

(4) A method for sharing information and medical documentation for residents under the LTC facility's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the LTC facility's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives.

(d) Training and testing. The LTC facility must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The LTC facility must do all of the following:

(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 roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The LTC facility must conduct drills and exercises to test the emergency plan, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the LTC facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the LTC facility's emergency plan, as needed.

(e) Emergency and standby power systems. The LTC facility must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) Emergency generator location. (i) The generator must be located in accordance with the location requirements found in NFPA 99 and NFPA 100.

(2) Emergency generator inspection and testing. In addition to the emergency power system inspection and testing requirements found in NFPA 99--Health Care Facilities and NFPA 110--Standard for Emergency and Standby Power Systems, as referenced by NFPA 101--Life Safety Code as required under paragraph (a) of this section, the LTC facility must do the following:

(i) At least once every 12 months test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the LTC facility anticipates it will require during an emergency.

(ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation and repairs.

(3) Emergency generator fuel. LTC facilities that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.

Sec. 483.475 Condition of participation: Emergency preparedness.

The Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) must comply with all applicable Federal and State emergency preparedness requirements. The ICF/IID 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 ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing clients.

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

(3) Address the special needs of its client population, including, but not limited to, persons at-risk; the type of services the ICF/IID has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the ICF/IID efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The ICF/IID 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) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the ICF/IID's care both during and after the emergency.

(3) Safe evacuation from the ICF/IID, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves client information, protects confidentiality of client information, and ensures records are secure and readily available.

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

(7) The development of arrangements with other ICF/IIDs or other providers to receive clients in the event of limitations or cessation of operations to ensure the continuity of services to ICF/IID clients.

(8) The role of the ICF/IID 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 ICF/IID must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other ICF/IIDs.

(v) Volunteers.

(2) Contact information for the following:

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

(ii) Other sources of assistance.

(iii) The State Licensing and Certification Agency.

(iv) The State Protection and Advocacy Agency.

(3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the ICF/IID's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ICF/IID's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives.

(d) Training and testing. The ICF/IID must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. The ICF/IID must meet the requirements for evacuation drills and training at Sec. 483.470(h).

(1) Training program. The ICF/IID must do all the following:

(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 roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The ICF/IID must conduct exercises to test the emergency plan. The ICF/IID must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

PART 484—HOME HEALTH SERVICES

Sec. 484.22 Condition of participation: Emergency preparedness.

The Home Health Agency (HHA) must comply with all applicable Federal and State emergency preparedness requirements. The HHA 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 HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must:

(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 HHA has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the HHA's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The HHA 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) The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at Sec. 484.55.

(2) The procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) A system to track the location of staff and patients in the HHA's care both during and after the emergency.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

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

(6) The development of arrangements with other HHAs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to HHA patients.

(c) Communication plan. The HHA must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Other HHAs.

(v) Volunteers.

(2) Contact information for the following:

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

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the HHA's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to ensure continuity of care.

(5) 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).

(6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The HHA must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

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

(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 roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(ii) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The HHA must conduct drills and exercises to test the emergency plan. The HHA must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

Sec. 485.68 Condition of participation: Emergency preparedness.

The Comprehensive Outpatient Rehabilitation Facility (CORF) must comply with all applicable Federal and State emergency preparedness requirements. The CORF 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 CORF must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(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 CORF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CORF's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts;

(5) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) Policies and procedures. The CORF 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) Safe evacuation from the CORF, which includes staff responsibilities, and needs of the patients.

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

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

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

(c) Communication plan. The CORF must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Other CORFs.

(v) 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 CORF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CORF's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means of providing information about the CORF's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The CORF must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

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

(i) Provide 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.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The CORF must ensure that staff can demonstrate knowledge of emergency procedures. All new personnel must be oriented and assigned specific responsibilities regarding the CORF's emergency plan within two weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and fire fighting equipment.

(2) Testing. The CORF must conduct drills and exercises to test the emergency plan. The CORF must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CORF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CORF is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the CORF's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CORF's emergency plan, as needed.

Sec. 485.625 Condition of participation: Emergency preparedness.

The Critical Access Hospital (CAH) must comply with all applicable Federal and State emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) Emergency plan. The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(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, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CAH's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The CAH 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) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to:

(i) Food, water, and medical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the CAH's care both during and after the emergency.

(3) Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

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

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

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

(7) The development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to CAH patients.

(8) The role of the CAH 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 CAH must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Other CAHs.

(v) 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) CAH'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 CAH's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(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 CAH's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The CAH must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

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

(i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with fire fighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The CAH must conduct exercises to test the emergency plan. The CAH must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

(e) Emergency and standby power systems. The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) Emergency generator location. (i) The generator must be located in accordance with the location requirements found in NFPA 99 and NFPA 100.

(2) Emergency generator inspection and testing. In addition to the emergency power system inspection and testing requirements found in NFPA 99--Health Care Facilities and NFPA 110--Standard for Emergency and Standby Power Systems, as referenced by NFPA 101--Life Safety Code (as required by 42 CFR 485.623(d)), the CAH must do all of the following:

(i) At least once every 12 months test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the CAH anticipates it will require during an emergency.

(ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation, and repairs.

(3) Emergency generator fuel. Hospitals that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.

Sec. 485.727 Condition of participation: Emergency preparedness.

The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (``Organizations'') must comply with all applicable Federal and State emergency preparedness requirements. The Organizations 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 Organizations must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of 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 Organizations have the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Address the location and use of alarm systems and signals; and methods of containing fire.

(5) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation.

(6) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) Policies and procedures. The Organizations 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) Safe evacuation from the Organizations, which includes staff responsibilities, and needs of the patients.

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

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of volunteers in an emergency or 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.

(c) Communication plan. The Organizations must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Other Organizations.

(v) 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) Organizations' staff.

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

(4) A method for sharing information and medical documentation for patients under the Organizations' care, as necessary, with other health care providers to ensure continuity of care.

(5) A means of providing information about the Organizations' needs, and their ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The Organizations must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

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

(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 roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The Organizations must ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The Organizations must conduct drills and exercises to test the emergency plan. The Organizations must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the Organizations experience an actual natural or man-made emergency that requires activation of the emergency plan, they are exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the Organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed.

Sec. 485.920 Condition of participation: Emergency preparedness.

The Community Mental Health Center (CMHC) must comply with all applicable federal and state emergency preparedness requirements. The CMHC 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 CMHC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of 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 client population, including, but not limited to, the type of services the CMHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CMHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The CMHC 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 staff and clients in the CMHC's care both during and after the emergency.

(2) Safe evacuation from the CMHC, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

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

(4) A system of medical documentation that preserves client information, protects confidentiality of client information, and ensures records are secure and readily available.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other CMHCs or other providers to receive clients in the event of limitations or cessation of operations to ensure the continuity of services to CMHC clients.

(7) The role of the CMHC under a waiver declared by the Secretary of Health and Human Services, in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The CMHC must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Clients' physicians.

(iv) Other CMHCs.

(v) 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) CMHC's staff.

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

(4) A method for sharing information and medical documentation for clients under the CMHC's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

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

(d) Training and testing. The CMHC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training. The CMHC must provide 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, and maintain documentation of the training. The CMHC

must ensure that staff can demonstrate knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least annually.

(2) Testing. The CMHC must conduct drills and exercises to test the emergency plan. The CMHC must:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CMHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CMHC is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the CMHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CMHC's emergency plan, as needed.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

Sec. 486.360 Condition of participation: Emergency preparedness.

The Organ Procurement Organization (OPO) must comply with all applicable Federal and State emergency preparedness requirements. The OPO 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 OPO must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually.

The plan must do all of 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 the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the OPO's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The OPO 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 staff during and after an emergency.

(2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and ensures records are secure and readily available.

(c) Communication plan. The OPO must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Volunteers.

(iv) Other OPOs.

(v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).

(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) OPO's staff.

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

(d) Training and testing. The OPO must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training. The OPO must do all of the following:

(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 roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The OPO must ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The OPO must conduct exercises to test the emergency plan. The OPO must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(ii) Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the OPO's emergency plan, as needed.

(e) Agreements with other OPOs and hospitals. Each OPO must have an agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's Donation Service Area in the event that the OPO cannot provide such services due to an emergency. Each OPO must include within the hospital agreements required under Sec. 486.322(a) and in the protocols with transplant programs required under Sec. 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

Sec. 491.12 Condition of participation: Emergency preparedness.

The Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) must comply with all applicable Federal and State emergency preparedness requirements. The RHC/FQHC 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 RHC/FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(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 RHC/FQHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the RHC/FQHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The RHC/FQHC 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) Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.

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

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of volunteers in an emergency or 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.

(c) Communication plan. The RHC/FQHC must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Other RHCs/FQHCs.

(v) 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) RHC/FQHC's staff.

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

(4) 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).

(5) A means of providing information about the RHC/FQHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The RHC/FQHC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The RHC/FQHC must do all of the following:

(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 roles,

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The RHC/FQHC must conduct exercises to test the emergency plan. The RHC/FQHC must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

Sec. 494.62 Condition of participation: Emergency preparedness.

The dialysis facility must comply with all applicable Federal and State emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The dialysis facility 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 dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least annually. The plan must:

(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 dialysis facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. The dialysis facility must contact the local emergency preparedness agency at least annually to ensure that the agency is aware of the dialysis facility's needs in the event of an emergency.

(b) Policies and procedures. The dialysis facility 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. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and patients in the dialysis facility's care both during and after the emergency.

(2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.

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

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

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

(6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to dialysis facility patients.

(7) The role of the dialysis facility 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.

(8) A process to ensure that emergency medical system assistance can be obtained when needed.

(9) A process ensuring that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

(c) Communication plan. The dialysis facility must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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) Other dialysis facilities.

(v) Volunteers.

(2) Contact information for the following:

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

(ii) Other sources of assistance.

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

(i) Dialysis facility's staff.

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

(4) A method for sharing information and medical documentation for patients under the dialysis facility's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(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 dialysis facility's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training, testing, and orientation. The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that must be evaluated and updated at least annually.

(1) Training program. The dialysis facility must do all of the following:

(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 roles.

(ii) Provide emergency preparedness training at least annually.

Staff training must:

(A) Ensure that staff can demonstrate knowledge of emergency procedures, including informing patients of--

(1) What to do;

(2) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(3) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(4) How to disconnect themselves from the dialysis machine if an emergency occurs.

(B) Ensure that, at a minimum, patient care staff maintain current CPR certification; and

(C) Ensure that nursing staff are properly trained in the use of emergency equipment and emergency drugs.

(D) Maintain documentation of the training.

(2) Testing. The dialysis facility must conduct drills and exercises to test the emergency plan. The dialysis facility must:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the dialysis facility is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is 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.

(iv) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

(3) Patient orientation. Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.