

(ii) Supervising aide services as described in paragraphs (h)(1) and (2) of this section; and

(iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.

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Subpart C—Organizational Environment

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§ 484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.

(a) *Standard: Disclosure of ownership and management information.* The HHA must comply with the requirements of part 420 subpart C, of this chapter. The HHA also must disclose the following information to the state survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The names and addresses of all persons with an ownership or controlling interest in the HHA as defined in § 420.201, § 420.202, and § 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in § 420.201, § 420.202, and § 420.206 of this chapter.

(3) The name and business address of the corporation, association, or other company that is responsible for the management of the HHA, and the names and addresses of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(b) *Standard: Licensing.* The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.

(c) *Standard: Laboratory services.* (1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

(2) If the HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

§ 484.102 Condition of participation: Emergency preparedness.

The Home Health Agency (HHA) must comply with all applicable Federal, State, and local 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 every 2 years. 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 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 cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The 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 every 2 years. 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 § 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) The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient

information, and secures and maintains the availability of records.

(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.

(c) *Communication plan.* The HHA must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, 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 maintain the 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 is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at

paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program.* The 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 every 2 years.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the HHA must conduct training on the updated policies and procedures.

(2) *Testing.* The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:

(i) Participate in a full-scale exercise that is community-based; or

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

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

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

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

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

(e) *Integrated healthcare systems.* If a HHA is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the HHA may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

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

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

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

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

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

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