

(i) Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;

(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;

(iii) Demonstrating competency with assigned tasks;

(iv) Complying with infection prevention and control policies and procedures;

(v) Reporting changes in the patient's condition; and

(vi) Honoring patient rights.

(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to:

(i) Ensuring the overall quality of care provided by an aide;

(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.

EFFECTIVE DATE NOTE: At 84 FR 51825, Sept. 30, 2019, §484.80 was amended by revising paragraphs (c)(1) and (h)(3), effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

§ 484.80 Condition of participation: Home health aide services.

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(c) * * *

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified

under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient, or with a pseudo-patient as part of a simulation.

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(h) * * *

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, retraining and a competency evaluation related to the deficient skill(s).

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Subpart C—Organizational Environment

SOURCE: 82 FR 4578, Jan. 13, 2017, unless otherwise noted.

§ 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 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 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, 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 § 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