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(c) *Supervision of skilled professional assistants.* (1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of § 484.115(k).

(2) Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of § 484.115(f) or (h), respectively.

(3) Medical social services are provided under the supervision of a social worker that meets the requirements of § 484.115(m).

§ 484.80 Condition of participation: Home health aide services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

(a) *Standard: Home health aide qualifications.* (1) A qualified home health aide is a person who has successfully completed:

(i) A training and competency evaluation program as specified in paragraphs (b) and (c) respectively of this section; or

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section; or

(iii) A nurse aide training and competency evaluation program approved by the state as meeting the requirements of § 483.151 through § 483.154 of this chapter, and is currently listed in good standing on the state nurse aide registry; or

(iv) The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section.

(2) A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services for compensation, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

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(b) *Standard: Content and duration of home health aide classroom and supervised practical training.* (1) Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Classroom and supervised practical training must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

(3) A home health aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection prevention and control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of instituting emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—

- (A) Bed bath;
- (B) Sponge, tub, and shower bath;
- (C) Hair shampooing in sink, tub, and bed;
- (D) Nail and skin care;
- (E) Oral hygiene;
- (F) Toileting and elimination;

(x) Safe transfer techniques and ambulation;

(xi) Normal range of motion and positioning;

(xii) Adequate nutrition and fluid intake;

(xiii) Recognizing and reporting changes in skin condition; and

(xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law.

(xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.

(c) *Standard: Competency evaluation.* An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

(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. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as "unsatisfactory," and has successfully completed a subsequent evaluation. A home health aide is not considered to have successfully passed a competency evaluation if the aide has an "unsatis-

factory" rating in more than one of the required areas.

(5) The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.

(d) *Standard: In-service training.* A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

(1) In-service training may be offered by any organization and must be supervised by a registered nurse.

(2) The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

(e) *Standard: Qualifications for instructors conducting classroom and supervised practical training.* Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home health care, or by other individuals under the general supervision of the registered nurse.

(f) *Standard: Eligible training and competency evaluation organizations.* A home health aide training program and competency evaluation program may be offered by any organization except by an HHA that, within the previous 2 years:

(1) Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section; or

(2) Permitted an individual who does not meet the definition of a "qualified home health aide" as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); or

(3) Was subjected to an extended (or partially extended) survey as a result of having been found to have furnished substandard care (or for other reasons as determined by CMS or the state); or

(4) Was assessed a civil monetary penalty of \$5,000 or more as an intermediate sanction; or

(5) Was found to have compliance deficiencies that endangered the health and safety of the HHA's patients, and had temporary management appointed

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to oversee the management of the HHA; or

(6) Had all or part of its Medicare payments suspended; or

(7) Was found under any federal or state law to have:

(i) Had its participation in the Medicare program terminated; or

(ii) Been assessed a penalty of \$5,000 or more for deficiencies in federal or state standards for HHAs; or

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or

(iv) Operated under temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(v) Been closed, or had its patients transferred by the state; or

(vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.

(g) *Standard: Home health aide assignments and duties.* (1) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).

(2) A home health aide provides services that are:

(i) Ordered by the physician;

(ii) Included in the plan of care;

(iii) Permitted to be performed under state law; and

(iv) Consistent with the home health aide training.

(3) The duties of a home health aide include:

(i) The provision of hands-on personal care;

(ii) The performance of simple procedures as an extension of therapy or nursing services;

(iii) Assistance in ambulation or exercises; and

(iv) Assistance in administering medications ordinarily self-administered.

(4) Home health aides must be members of the interdisciplinary team, must report changes in the patient's

condition to a registered nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

(h) *Standard: Supervision of home health aides.* (1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech-language pathology services, a registered nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in § 484.80(g), must make an onsite visit to the patient's home no less frequently than every 14 days. The home health aide does not have to be present during this visit.

(ii) If an area of concern in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(2) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, the registered nurse must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each aide while he or she is performing care.

(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 a competency evaluation in accordance with paragraph (c) of this section.

(4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

(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:

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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.

* * * * *

(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.