

to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA complies with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(d) *Standard: Confidentiality of medical records.* The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records.

(e) *Standard: Patient liability for payment.* (1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before the care is initiated, the HHA must inform the patient, orally and in writing, of—

(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this

section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

(f) *Standard: Home health hotline.* The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advance directives requirements.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 57 FR 8203, Mar. 6, 1992; 60 FR 33293, June 27, 1995]

§ 484.11 Condition of participation: Release of patient identifiable OASIS information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

[64 FR 3763, Jan. 25, 1999]

§ 484.12 Condition of participation: Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.

(a) *Standard: Compliance with Federal, State, and local laws and regulations.* The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

(b) *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 name and address of all persons with an ownership or control 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 address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(c) *Standard: Compliance with accepted professional standards and principles.* The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

§ 484.14 Condition of participation: Organization, services, and administration.

Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable. Administrative and supervisory functions are not delegated to another agency or organization and all services not furnished directly, including services provided through subunits are monitored and controlled by the parent agency. If an agency has subunits, appropriate administrative records are maintained for each subunit.

(a) *Standard: Services furnished.* Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a pa-

tient's home. An HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

(b) *Standard: Governing body.* A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency. The governing body appoints a qualified administrator, arranges for professional advice as required under § 484.16, adopts and periodically reviews written bylaws or an acceptable equivalent, and oversees the management and fiscal affairs of the agency.

(c) *Standard: Administrator.* The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

(d) *Standard: Supervising physician or registered nurse.* The skilled nursing and other therapeutic services furnished are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person, or similarly qualified alternate, is available at all times during operating hours and participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

(e) *Standard: Personnel policies.* Personnel practices and patient care are supported by appropriate, written personnel policies. Personnel records include qualifications and licensure that are kept current.

(f) *Standard: Personnel under hourly or per visit contracts.* If personnel under hourly or per visit contracts are used