

Services) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a-1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

(j) *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 FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, 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.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 56 FR 51334, Oct. 11, 1991; 57 FR 7136, Feb. 28, 1992; 66 FR 32778, June 18, 2001]

§ 484.16 Condition of participation: Group of professional personnel.

A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with appropriate representation from other professional disciplines, establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner nor an employee of the agency.

(a) *Standard: Advisory and evaluation function.* The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program. The meetings are documented by dated minutes.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

(a) *Standard: Plan of care.* The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a

patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

(b) *Standard: Periodic review of plan of care.* The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

(c) *Standard: Conformance with physician orders.* Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications. Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991; 64 FR 3784, Jan. 25, 1999; 65 FR 41211, July 3, 2000; 67 FR 61814, Oct. 2, 2002]

§ 484.20 Condition of participation: Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with § 484.55.

(a) *Standard: Encoding OASIS data.* The HHA must encode and be capable of transmitting OASIS data for each

agency patient within 7 days of completing an OASIS data set.

(b) *Standard: Accuracy of encoded OASIS data.* The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

(c) *Standard: Transmittal of OASIS data.* The HHA must—

(1) Electronically transmit accurate, completed, encoded and locked OASIS data for each patient to the State agency or CMS OASIS contractor at least monthly;

(2) For all assessments completed in the previous month, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section;

(3) Successfully transmit test data to the State agency or CMS OASIS contractor beginning March 26, 1999, and no later than April 26, 1999; and

(4) Transmit data using electronic communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

(d) *Standard: Data Format.* The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

[64 FR 3763, Jan. 25, 1999]

Subpart C—Furnishing of Services

§ 484.30 Condition of participation: Skilled nursing services.

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

(a) *Standard: Duties of the registered nurse.* The registered nurse makes the initial evaluation visit, regularly re-evaluates the patient's nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, counsels the patient and family in meeting nursing and related needs,