

dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

(a) *Standards: Retention of records.* Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

(b) *Standards: Protection of records.* Clinical record information is safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 65498, Dec. 20, 1994]

**§ 484.52 Condition of participation: Evaluation of the agency's program.**

The HHA has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

(a) *Standard: Policy and administrative review.* As a part of the evaluation process the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appro-

priate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

(b) *Standard: Clinical record review.* At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

[54 FR 33367, Aug. 14, 1989; 66 FR 32778, June 18, 2001]

**§ 484.55 Condition of participation: Comprehensive assessment of patients.**

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.

(a) *Standard: Initial assessment visit.* (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either

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within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(b) *Standard: Completion of the comprehensive assessment.* (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) *Standard: Drug regimen review.* The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

(d) *Standard: Update of the comprehensive assessment.* The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's

health status, but not less frequently than—

(1) The last five days of every 60 days beginning with the start-of-care date, unless there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition resulting in a new case-mix assignment; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;

(3) At discharge.

(e) *Standard: Incorporation of OASIS data items.* The OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

[64 FR 3784, Jan. 25, 1999, as amended at 65 FR 41211, July 3, 2000]

**Subpart D [Reserved]**

**Subpart E—Prospective Payment System for Home Health Agencies**

SOURCE: 65 FR 41212, July 3, 2000, unless otherwise noted.

**§ 484.200 Basis and scope.**

(a) *Basis.* This subpart implements section 1895 of the Act, which provides for the implementation of a prospective payment system (PPS) for HHAs for portions of cost reporting periods occurring on or after October 1, 2000.

(b) *Scope.* This subpart sets forth the framework for the HHA PPS, including the methodology used for the development of the payment rates, associated adjustments, and related rules.

**§ 484.202 Definitions.**

As used in this subpart—