

§ 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period.

(d) *Under a plan of care.* The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 409.43.

(e) *By whom the services must be furnished.* The home health services must be furnished by, or under arrangements made by, a participating HHA.

[59 FR 65494, Dec. 20, 1994; 60 FR 39122, Aug. 1, 1995]

#### § 409.43 Plan of care requirements.

(a) *Contents.* The plan of care must contain those items listed in § 484.18(a) of this chapter that specify the standards relating to a plan of care that an HHA must meet in order to participate in the Medicare program.

(b) *Physician's orders.* The physician's orders for services in the plan of care must specify the medical treatments to be furnished as well as the type of home health discipline that will furnish the ordered services and at what frequency the services will be furnished. Orders for services to be provided "as needed" or "PRN" must be accompanied by a description of the beneficiary's medical signs and symptoms that would occasion the visit and a specific limit on the number of those visits to be made under the order before an additional physician order would have to be obtained. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished. If a range of visits is ordered, the upper limit of the range is considered the specific frequency.

(c) *Physician signature*—(1) *Request for Anticipated payment signature requirements.* If the physician signed plan of care is not available at the time the HHA requests an anticipated payment of the initial percentage prospective payment in accordance with § 484.205, the request for the anticipated payment must be based on—

- (i) A physician's verbal order that—
  - (A) Is recorded in the plan of care;

- (B) Includes a description of the patient's condition and the services to be provided by the home health agency;

- (C) Includes an attestation (relating to the physician's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in 42 CFR 484.4) responsible for furnishing or supervising the ordered service in the plan of care; and

- (D) Is copied into the plan of care and the plan of care is immediately submitted to the physician; or

- (ii) A referral prescribing detailed orders for the services to be rendered that is signed and dated by a physician.

(2) *Reduction or disapproval of anticipated payment requests.* CMS has the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraph (c)(1)(i) and/or a prescribing referral as specified in (c)(1)(ii) of this section and is not a Medicare claim for purposes of the Act (although it is a "claim" for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a-7a (i) (2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment.

(3) *Final percentage payment signature requirements.* The plan of care must be signed and dated—

- (i) By a physician as described who meets the certification and recertification requirements of § 424.22 of this chapter; and

- (ii) Before the claim for each episode for services is submitted for the final percentage prospective payment.

(4) *Changes to the plan of care signature requirements.* Any changes in the plan must be signed and dated by a physician.

- (d) *Oral (verbal) orders.* If any services are provided based on a physician's

#### § 409.44

#### 42 CFR Ch. IV (10–1–09 Edition)

oral orders, the orders must be put in writing and be 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. Oral orders may only be accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. The oral orders must also be countersigned and dated by the physician before the HHA bills for the care.

(e) *Frequency of review.* (1) The plan of care must be reviewed by the physician (as specified in § 409.42(b)) in consultation with agency professional personnel at least every 60 days or more frequently when there is a—

- (i) Beneficiary elected transfer;
  - (ii) Significant change in condition resulting in a change in the case-mix assignment; or
  - (iii) Discharge and return to the same HHA during the 60-day episode.
- (2) Each review of a beneficiary's plan of care must contain the signature of the physician who reviewed it and the date of review.

(f) *Termination of the plan of care.* The plan of care is considered to be terminated if the beneficiary does not receive at least one covered skilled nursing, physical therapy, speech-language pathology services, or occupational therapy visit in a 60-day period unless the physician documents that the interval without such care is appropriate to the treatment of the beneficiary's illness or injury.

[59 FR 65494, Dec. 20, 1994, as amended at 65 FR 41210, July 3, 2000]

#### § 409.44 Skilled services requirements.

(a) *General.* The intermediary's decision on whether care is reasonable and necessary is based on information provided on the forms and in the medical record concerning the unique medical condition of the individual beneficiary. A coverage denial is not made solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care.

(b) *Skilled nursing care.* (1) Skilled nursing care consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse, as defined in § 484.4 of this chapter, and meet the criteria for skilled nursing services specified in § 409.32. See § 409.33(a) and (b) for a description of skilled nursing services and examples of them.

(i) In determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice.

(ii) If the nature of a service is such that it can safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse, the service cannot be regarded as a skilled nursing service.

(iii) The fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse.

(iv) If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

(2) The skilled nursing care must be provided on a part-time or intermittent basis.

(3) The skilled nursing services must be reasonable and necessary for the treatment of the illness or injury.

(i) To be considered reasonable and necessary, the services must be consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice.

(ii) The skilled nursing care provided to the beneficiary must be reasonable within the context of the beneficiary's condition.

(iii) The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time.