

are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. To be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the non-skilled services being provided to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service. In some cases, the condition of the patient may cause a service that would originally be considered unskilled to be considered a skilled nursing service. This would occur when the patient's underlying condition or complication requires that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. The registered nurse is ensuring that service is safely and effectively performed. However, a service is not considered a skilled nursing service merely because it is performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self administered) by non-licensed staff without the direct supervision of a nurse, the service cannot be regarded as a skilled service even if a nurse actually provides the service.

(ii) In the home health setting, skilled education services are no longer needed if it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

(2) Physical therapy services that meet the requirements of § 409.44(c).

(3) Speech-language pathology services that meet the requirements of § 409.44(c).

(4) Occupational therapy services in the current and subsequent certification periods (subsequent adjacent episodes) that meet the requirements of § 409.44(c) initially qualify for home health coverage as a dependent service as defined in § 409.45(d) 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. Subsequent to an initial covered occupational therapy service, continuing occupational therapy services which meet the requirements of § 409.44(c) are considered to be qualifying services.

(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, as amended at 74 FR 58133, Nov. 10, 2009; 76 FR 68606, Nov. 4, 2011]

§ 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 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; or
- (iii) Discharge with goals met and/or no expectation of a return to home health care and the patient returns to home health care 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; 74 FR 58133, Nov. 10, 2009; 80 FR 68717, Nov. 5, 2015]

EFFECTIVE DATE NOTE: At 82 FR 4578, Jan. 13, 2017, § 409.43 was amended in paragraph (a) by removing “§ 484.18(a)” and replacing it with “§ 484.60(a)”, in paragraph (c)(1)(i)(C) by removing “42 CFR 484.4” and replacing it with “42 CFR 484.115”, and in paragraph (d) by removing “§ 484.4” and replacing it with “§ 484.115”, effective July 13, 2017. At 82 FR 31729, July 10, 2017, the effectiveness was delayed until Jan. 13, 2018.

§ 409.44 Skilled services requirements.

(a) *General.* The Medicare Administrative Contractor'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, meet the criteria for skilled nursing services specified in § 409.32, and meet the qualifications for coverage of skilled services specified in § 409.42(c). 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 as-

pect 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.

(c) *Physical therapy, speech-language pathology services, and occupational therapy.* To be covered, physical therapy, speech-language pathology services, and occupational therapy must satisfy the criteria in paragraphs (c)(1) and (2) of this section.

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes. To be covered by Medicare, all of the requirements apply as follows:

(i) The patient's plan of care must describe a course of therapy treatment and therapy goals which are consistent