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

(ii) Before the claim for each episode (for episodes beginning on or before December 31, 2019) or 30-day period (for periods beginning on or after January 1, 2020) is submitted.

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

(d) *Oral (verbal) orders.* If any services are provided based on a physician's or allowed practitioner'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 § 484.115 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 or allowed practitioner before the HHA bills for the care.

(e) *Frequency of review.* (1) The plan of care must be reviewed by the physician or allowed practitioner (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 within 60 days.

(2) Each review of a beneficiary's plan of care must contain the signature of the physician or allowed practitioner 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 or allowed practitioner 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; 82 FR 4578, Jan. 13, 2017; 83 FR 56627, Nov. 13, 2018; 84 FR 60642, Nov. 8, 2019; 85 FR 19285, Apr. 6, 2020; 85 FR 27619, May 8, 2020; 85 FR 70354, Nov. 4, 2020; 86 FR 62418, Nov. 9, 2021]

§ 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 § 484.115 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 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.

(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 or allowed practitioner) 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 with the evaluation of the patient's function, and both must be included in the clinical record. The therapy goals must be established by a qualified therapist in conjunction with the physician or allowed practitioner.

(ii) The patient's clinical record must include documentation describing how the course of therapy treatment for the patient's illness or injury is in accordance with accepted professional standards of clinical practice.

(iii) Therapy treatment goals described in the plan of care must be measurable, and must pertain directly to the patient's illness or injury, and the patient's resultant impairments.

(iv) The patient's clinical record must demonstrate that the method used to assess a patient's function included objective measurements of function in accordance with accepted professional standards of clinical practice enabling comparison of successive measurements to determine the effectiveness of therapy goals. Such objective measurements would be made by the qualified therapist using measurements which assess activities of daily living that may include but are not limited to eating, swallowing, bathing, dressing, toileting, walking, climbing stairs, or using assistive devices, and mental and cognitive factors.

(2) Physical and occupational therapy and speech-language pathology services must be reasonable and necessary. To be considered reasonable and necessary, the following conditions must be met:

(i) The services must be considered under accepted standards of professional clinical practice, to be a specific, safe, and effective treatment for the beneficiary's condition. Each of the following requirements must also be met:

(A) The patient's function must be initially assessed and periodically reassessed by a qualified therapist, of the corresponding discipline for the type of therapy being provided, using a method which would include objective measurement as described in § 409.44(c)(1)(iv). If more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must perform the assessment and periodic reassessments. The

measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record.

(B) At least every 30 calendar days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A). Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) at least every 30 calendar days.

(C) As specified in paragraphs (c)(2)(i)(A) and (B) of this section, therapy visits for the therapy discipline(s) not in compliance with these policies will not be covered until the following conditions are met:

(*1*) The qualified therapist has completed the reassessment and objective measurement of the effectiveness of the therapy as it relates to the therapy goals. As long as paragraphs (c)(2)(i)(C)(*2*) and (c)(2)(i)(C)(*3*) of this section are met, therapy coverage resumes with the completed reassessment therapy visit.

(*2*) The qualified therapist has determined if goals have been achieved or require updating.

(*3*) The qualified therapist has documented measurement results and corresponding therapy effectiveness in the clinical record in accordance with paragraph (c)(2)(i)(F) of this section.

(D) If the criteria for maintenance therapy, described at § 409.44(c)(2)(iii)(B) and (C) of this section are not met, the following criteria must also be met for subsequent therapy visits to be covered:

(*1*) If the objective measurements of the reassessment do not reveal progress toward goals, the qualified therapist together with the physician or allowed practitioner must determine whether the therapy is still effective or should be discontinued.

(*2*) If therapy is to be continued in accordance with § 409.44(c)(2)(iv)(B)(*1*) of this section, the clinical record must document with a clinically supportable statement why there is an expectation that the goals are attainable in a reasonable and generally predictable period of time.

(E) Clinical notes written by therapy assistants may supplement the clinical record, and if included, must include the date written, the signature, professional designation, and objective measurements or description of changes in status (if any) relative to each goal being addressed by treatment. Assistants may not make clinical judgments about why progress was or was not made, but must report the progress or the effectiveness of the therapy (or lack thereof) objectively.

(F) Documentation by a qualified therapist must include the following:

(*1*) The therapist's assessment of the effectiveness of the therapy as it relates to the therapy goals;

(*2*) Plans for continuing or discontinuing treatment with reference to evaluation results and or treatment plan revisions;

(*3*) Changes to therapy goals or an updated plan of care that is sent to the physician or allowed practitioner for signature or discharge;

(*4*) Documentation of objective evidence or a clinically supportable statement of expectation that the patient can continue to progress toward the treatment goals and is responding to therapy in a reasonable and generally predictable period of time; or in the case of maintenance therapy, the patient is responding to therapy and can meet the goals in a predictable period of time.

(ii) The services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified physical therapist or by a qualified physical therapy assistant under the supervision of a qualified physical therapist, by a qualified speech-language pathologist, or by a qualified occupational therapist or a qualified occupational therapy assistant under the supervision of a qualified occupational therapist (as defined in § 484.115 of this chapter). Services that do not require the performance or supervision of a physical therapist or an occupational therapist are not considered reasonable or necessary physical

therapy or occupational therapy services, even if they are performed by or supervised by a physical therapist or occupational therapist. Services that do not require the skills of a speech-language pathologist are not considered to be reasonable and necessary speech-language pathology services even if they are performed by or supervised by a speech-language pathologist.

(iii) For therapy services to be covered in the home health setting, one of the following three criteria must be met:

(A) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's or allowed practitioner's assessment of the beneficiary's restoration potential and unique medical condition.

(*1*) Material improvement requires that the clinical record demonstrate that the patient is making improvement towards goals when measured against his or her condition at the start of treatment.

(*2*) If an individual's expected restorative potential would be insignificant in relation to the extent and duration of therapy services required to achieve such potential, therapy would not be considered reasonable and necessary, and thus would not be covered.

(*3*) When a patient suffers a transient and easily reversible loss or reduction of function which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities, because the services do not require the performance or supervision of a qualified therapist, those services are not to be considered reasonable and necessary covered therapy services.

(B) The unique clinical condition of a patient may require the specialized skills, knowledge, and judgment of a qualified therapist to design or establish a safe and effective maintenance program required in connection with the patient's specific illness or injury.

(*1*) If the services are for the establishment of a maintenance program, they must include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary periodic reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment of a physical therapist, speech-language pathologist, or occupational therapist is required.

(*2*) The maintenance program must be established by a qualified therapist (and not an assistant).

(C) The unique clinical condition of a patient may require the specialized skills of a qualified therapist or therapist assistant to perform a safe and effective maintenance program required in connection with the patient's specific illness or injury. Where the clinical condition of the patient is such that the complexity of the therapy services required—

(*1*) Involve the use of complex and sophisticated therapy procedures to be delivered by the therapist or the therapist assistant in order to maintain function or to prevent or slow further deterioration of function; or

(*2*) To maintain function or to prevent or slow further deterioration of function must be delivered by the therapist or the therapist assistant in order to ensure the patient's safety and to provide an effective maintenance program, then those reasonable and necessary services must be covered.

(iv) The amount, frequency, and duration of the services must be reasonable and necessary, as determined by a qualified therapist and/or physician or allowed practitioner, using accepted standards of clinical practice.

(A) Where factors exist that would influence the amount, frequency or duration of therapy services, such as factors that may result in providing more services than are typical for the patient's condition, those factors must be documented in the plan of care and/or functional assessment.

(B) Clinical records must include documentation using objective measures that the patient continues to progress towards goals. If progress cannot be measured, and continued progress towards goals cannot be expected, therapy services cease to be covered except when—

(*1*) Therapy progress regresses or plateaus, and the reasons for lack of progress are documented to include justification that continued therapy treatment will lead to resumption of progress toward goals; or

(*2*) Maintenance therapy as described in § 409.44(c)(2)(iii)(B) or (C) is needed.

[59 FR 65494, Dec. 20, 1994, as amended at 74 FR 58133, Nov. 10, 2009; 75 FR 70461, Nov. 17, 2010; 76 FR 68606, Nov. 4, 2011; 77 FR 67162, Nov. 8, 2012; 79 FR 66116, Nov. 6, 2014; 82 FR 4578, Jan. 13, 2017; 84 FR 60642, Nov. 8, 2019; 85 FR 27619, May 8, 2020]

§ 409.45 Dependent services requirements.

(a) *General.* Services discussed in paragraphs (b) through (g) of this section may be covered only if the beneficiary needs skilled nursing care on an intermittent basis, as described in § 409.44(b); physical therapy or speech-language pathology services as described in § 409.44(c); or has a continuing need for occupational therapy services as described in § 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; and otherwise meets the qualifying criteria (confined to the home, under the care of a physician or allowed practitioner, in need of skilled services, and under a plan of care) specified in § 409.42. Home health coverage is not available for services furnished to a beneficiary who is no longer in need of one of the qualifying skilled services specified in this paragraph. Therefore, dependent services furnished after the final qualifying skilled service are not covered, except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.

(b) *Home health aide services.* To be covered, home health aide services must meet each of the following requirements:

(1) The reason for the visits by the home health aide must be to provide hands-on personal care to the beneficiary or services that are needed to maintain the beneficiary's health or to facilitate treatment of the beneficiary's illness or injury. The physician or allowed practitioner's orders must indicate the frequency of the home health aide services required by the beneficiary. These services may include but are not limited to:

(i) Personal care services such as bathing, dressing, grooming, caring for hair, nail and oral hygiene that are needed to facilitate treatment or to prevent deterioration of the beneficiary's health, changing the bed linens of an incontinent beneficiary, shaving, deodorant application, skin care with lotions and/or powder, foot care, ear care, feeding, assistance with elimination (including enemas unless the skills of a licensed nurse are required due to the beneficiary's condition, routine catheter care, and routine colostomy care), assistance with ambulation, changing position in bed, and assistance with transfers.

(ii) Simple dressing changes that do not require the skills of a licensed nurse.

(iii) Assistance with medications that are ordinarily self-administered and that do not require the skills of a licensed nurse to be provided safely and effectively.

(iv) Assistance with activities that are directly supportive of skilled therapy services but do not require the skills of a therapist to be safely and effectively performed, such as routine maintenance exercises and repetitive practice of functional communication skills to support speech-language pathology services.

(v) Routine care of prosthetic and orthotic devices.

(2) The services to be provided by the home health aide must be—

(i) Ordered by a physician or allowed practitioner in the plan of care; and

(ii) Provided by the home health aide on a part-time or intermittent basis.

(3) The services provided by the home health aide must be reasonable and necessary. To be considered reasonable and necessary, the services must—

(i) Meet the requirement for home health aide services in paragraph (b)(1) of this section;

(ii) Be of a type the beneficiary cannot perform for himself or herself; and

(iii) Be of a type that there is no able or willing caregiver to provide, or, if there is a potential caregiver, the beneficiary is unwilling to use the services of that individual.