

§ 409.34

related to a specific loss of function; and assistive walking do not constitute skilled rehabilitation services.

[48 FR 12541, Mar. 25, 1983, as amended at 63 FR 26307, May 12, 1998; 64 FR 41681, July 30, 1999]

§ 409.34 Criteria for “daily basis”.

(a) To meet the daily basis requirement specified in § 409.31(b)(1), the following frequency is required:

(1) Skilled nursing services or skilled rehabilitation services must be needed and provided 7 days a week; or

(2) As an exception, if skilled rehabilitation services are not available 7 days a week those services must be needed and provided at least 5 days a week.

(b) A break of one or two days in the furnishing of rehabilitation services will not preclude coverage if discharge would not be practical for the one or two days during which, for instance, the physician has suspended the therapy sessions because the patient exhibited extreme fatigue.

§ 409.35 Criteria for “practical matter”.

(a) *General considerations.* In making a “practical matter” determination, as required by § 409.31(b)(3), consideration must be given to the patient’s condition and to the availability and feasibility of using more economical alternative facilities and services. However, in making that determination, the availability of Medicare payment for those services may not be a factor. For example, if a beneficiary can obtain daily physical therapy services on an outpatient basis, the unavailability of Medicare payment for those alternative services due to the beneficiary’s non-enrollment in Part B may not be a basis for finding that the needed care can only be provided in a SNF.

(b) *Examples of circumstances that meet practical matter criteria—*(1) *Beneficiary’s condition.* Inpatient care would be required “as a practical matter” if transporting the beneficiary to and from the nearest facility that furnishes the required daily skilled services would be an excessive physical hardship.

(2) *Economy and efficiency.* Even if the beneficiary’s condition does not preclude transportation, inpatient care might be more efficient and less costly

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if, for instance, the only alternative is daily transportation by ambulance.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 85 FR 47632, Aug. 5, 2020]

§ 409.36 Effect of discharge from posthospital SNF care.

If a beneficiary is discharged from a facility after receiving posthospital SNF care, he or she is not entitled to additional services of this kind in the same benefit period unless—

(a) He or she is readmitted to the same or another facility within 30 calendar days following the day of discharge (or, before December 5, 1980, within 14 calendar days after discharge); or

(b) He or she is again hospitalized for at least 3 consecutive calendar days.

Subpart E—Home Health Services Under Hospital Insurance

§ 409.40 Basis, purpose, and scope.

This subpart implements sections 1814(a)(2)(C), 1835(a)(2)(A), and 1861(m) of the Act with respect to the requirements that must be met for Medicare payment to be made for home health services furnished to eligible beneficiaries.

[59 FR 65493, Dec. 20, 1994]

§ 409.41 Requirement for payment.

In order for home health services to qualify for payment under the Medicare program the following requirements must be met:

(a) The services must be furnished to an eligible beneficiary by, or under arrangements with, an HHA that—

(1) Meets the conditions of participation for HHAs at part 484 of this chapter; and

(2) Has in effect a Medicare provider agreement as described in part 489, subparts A, B, C, D, and E of this chapter.

(b) The certification and recertification requirements for home health services described in § 424.22.

(c) All requirements contained in §§ 409.42 through 409.47.

[59 FR 65494, Dec. 20, 1994, as amended at 85 FR 27619, May 8, 2020]

§ 409.42 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements:

(a) *Confined to the home.* The beneficiary must be confined to the home or in an institution that is not a hospital, SNF or nursing facility as defined in section 1861(e)(1), 1819(a)(1) or 1919(a)(1) of the Act, respectively.

(b) *Under the care of a physician or allowed practitioner, as defined at § 484.2 of this chapter.* The beneficiary must be under the care of a physician or allowed practitioner, as defined at § 484.2 of this chapter who establishes the plan of care. A doctor of podiatric medicine may establish a plan of care only if that is consistent with the functions he or she is authorized to perform under State law.

(c) *In need of skilled services.* The beneficiary must need at least one of the following skilled services as certified by a physician or allowed practitioner, as defined at § 484.2 of this chapter in accordance with the certification and recertification requirements for home health services under § 424.22 of this chapter.

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in § 409.32. (Also see § 409.33(a) and (b) for a description of examples of skilled nursing and rehabilitation services.) These criteria are subject to the following limitations in the home health setting:

(i) In the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications 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

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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; 85 FR 27619, May 8, 2020]

§ 409.43 Plan of care requirements.

(a) *Contents.* An individualized plan of care must be established and periodically reviewed by the certifying physician or allowed practitioner.

(1) The HHA must be acting upon a plan of care that meets the requirements of this section for HHA services to be covered.

(2) For HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment.

(3)(i) The plan of care must include all of the following:

(A) The identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in § 484.60(a) of this chapter that establish the need for such services.

(B) Any provision of remote patient monitoring or other services furnished via telecommunications technology (as defined in § 409.46(e)) or audio-only technology. Such services must be tied to the patient-specific needs as identified in the comprehensive assessment, cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for the purposes of patient eligibility or payment.

(ii) All care provided must be in accordance with the plan of care.

(b) *Physician's or allowed practitioner's orders.* The physician or allowed practitioner'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 or allowed practitioner 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 or allowed practitioner signature—(1) Request for Anticipated payment signature requirements.* If the physician or allowed practitioner 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 or allowed practitioner's orders 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 or allowed practitioner's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in 42 CFR 484.115) 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 allowed practitioner; or

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

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

(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 treat-

ment 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 the 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 rea-

sonable 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 pro-

gram 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.

(4) The home health aide also may perform services incidental to a visit that was for the provision of care as described in paragraphs (b)(3)(i) through (iii) of this section. For example, these incidental services may include changing bed linens, personal laundry, or preparing a light meal.

(c) *Medical social services.* Medical social services may be covered if the following requirements are met:

(1) The services are ordered by a physician or allowed practitioner and included in the plan of care.

(2)(i) The services are necessary to resolve social or emotional problems that are expected to be an impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(ii) If these services are furnished to a beneficiary's family member or caregiver, they are furnished on a short-term basis and it can be demonstrated that the service is necessary to resolve a clear and direct impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(3) The frequency and nature of the medical social services are reasonable and necessary to the treatment of the beneficiary's condition.

(4) The medical social services are furnished by a qualified social worker or qualified social work assistant under the supervision of a social worker as defined in § 484.115 of this chapter.

(5) The services needed to resolve the problems that are impeding the beneficiary's recovery require the skills of a social worker or a social work assistant under the supervision of a social worker to be performed safely and effectively.

(d) *Occupational therapy.* Occupational therapy services that are not qualifying services under § 409.44(c) are nevertheless covered as dependent services if the requirements of § 409.44(c)(2)(i) through (iv), as to reasonableness and necessity, are met.

(e) *Durable medical equipment.* Durable medical equipment in accordance with § 410.38 of this chapter, which describes the scope and conditions of payment for durable medical equipment under Part B, may be covered under the home health benefit as either a Part A or

Part B service. Durable medical equipment furnished by an HHA as a home health service is always covered by Part A if the beneficiary is entitled to Part A.

(f) *Medical supplies.* Medical supplies (including catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care but excluding drugs and biologicals) may be covered as a home health benefit. For medical supplies to be covered as a Medicare home health benefit, the medical supplies must be needed to treat the beneficiary's illness or injury that occasioned the home health care.

(g) *Intern and resident services.* The medical services of interns and residents in training under an approved hospital teaching program are covered if the services are ordered by the physician or allowed practitioner who is responsible for the plan of care and the HHA is affiliated with or under the common control of the hospital furnishing the medical services.

Approved means—

(1) Approved by the Accreditation Council for Graduate Medical Education;

(2) In the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association;

(3) In the case of an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association; or

(4) In the case of an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association.

[59 FR 65495, Dec. 20, 1994; 60 FR 39122, 39123, Aug. 1, 1995, as amended at 82 FR 4573, Jan. 13, 2017; 85 FR 27620, May 8, 2020]

§ 409.46 Allowable administrative costs.

Services that are allowable as administrative costs but are not separately billable include, but are not limited to, the following:

(a) *Registered nurse initial evaluation visits.* Initial evaluation visits by a registered nurse for the purpose of assessing a beneficiary's health needs, determining if the agency can meet those health needs, and formulating a plan of care for the beneficiary are allowable administrative costs. If a physician or allowed practitioner specifically orders that a particular skilled service be furnished during the evaluation in which the agency accepts the beneficiary for treatment and all other coverage criteria are met, the visit is billable as a skilled nursing visit. Otherwise it is considered to be an administrative cost.

(b) *Visits by registered nurses or qualified professionals for the supervision of home health aides.* Visits by registered nurses or qualified professionals for the purpose of supervising home health aides as required at §484.80(h) of this chapter are allowable administrative costs. Only if the registered nurse or qualified professional visits the beneficiary for the purpose of furnishing care that meets the coverage criteria at §409.44, and the supervisory visit occurs simultaneously with the provision of covered care, is the visit billable as a skilled nursing or therapist's visit.

(c) *Respiratory care services.* If a respiratory therapist is used to furnish overall training or consultative advice to an HHA's staff and incidentally provides respiratory therapy services to beneficiaries in their homes, the costs of the respiratory therapist's services are allowable as administrative costs. Visits by a respiratory therapist to a beneficiary's home are not separately billable. However, respiratory therapy services that are furnished as part of a plan of care by a skilled nurse or physical therapist and that constitute skilled care may be separately billed as skilled visits.

(d) *Dietary and nutrition personnel.* If dietitians or nutritionists are used to provide overall training or consultative advice to HHA staff and incidentally provide dietetic or nutritional services to beneficiaries in their homes, the costs of these professional services are allowable as administrative costs. Visits by a dietitian or nutritionist to a beneficiary's home are not separately billable.

(e) *Telecommunications technology.* Telecommunications technology, as indicated on the plan of care, can include: remote patient monitoring, defined as the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient or caregiver or both to the home health agency; teletypewriter (TTY); and 2-way audio-video telecommunications technology that allows for real-time interaction between the patient and clinician. The costs of any equipment, set-up, and service related to the technology are allowable only as administrative costs. Visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the technology, without the provision of a skilled service, are not separately billable.

[59 FR 65496, Dec. 20, 1994, as amended at 82 FR 4578, Jan. 13, 2017; 83 FR 56627, Nov. 13, 2018; 85 FR 27620, May 8, 2020; 85 FR 70354, Nov. 4, 2020]

§ 409.47 Place of service requirements.

To be covered, home health services must be furnished in either the beneficiary's home or an outpatient setting as defined in this section.

(a) *Beneficiary's home.* A beneficiary's home is any place in which a beneficiary resides that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1), of 1919(a)(1) of the Act, respectively.

(b) *Outpatient setting.* For purposes of coverage of home health services, an outpatient setting may include a hospital, SNF or a rehabilitation center with which the HHA has an arrangement in accordance with the requirements of §484.105(e) of this chapter and that is used by the HHA to provide services that either—

(1) Require equipment that cannot be made available at the beneficiary's home; or

(2) Are furnished while the beneficiary is at the facility to receive services requiring equipment described in paragraph (b)(1) of this section.

[59 FR 65496, Dec. 20, 1994, as amended at 82 FR 4578, Jan. 13, 2017]

§ 409.48

§ 409.48 Visits.

(a) *Number of allowable visits under Part A.* To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part A for an unlimited number of covered home health visits. All Medicare home health services are covered under hospital insurance unless there is no Part A entitlement.

(b) *Number of visits under Part B.* To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part B for an unlimited number of covered home health visits. Medicare home health services are covered under Part B only when the beneficiary is not entitled to coverage under Part A.

(c) *Definition of visit.* A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service.

(1) Generally, one visit may be covered each time an HHA employee or someone providing home health services under arrangements enters the beneficiary's home and provides a covered service to a beneficiary who meets the criteria of § 409.42 (confined to the home, under the care of a physician or allowed practitioner, in need of skilled services, and under a plan of care).

(2) If the HHA furnishes services in an outpatient facility under arrangements with the facility, one visit may be covered for each type of service provided.

(3) If two individuals are needed to provide a service, two visits may be covered. If two individuals are present, but only one is needed to provide the care, only one visit may be covered.

(4) A visit is initiated with the delivery of covered home health services and ends at the conclusion of delivery of covered home health services. In those circumstances in which all reasonable and necessary home health services cannot be provided in the course of a single visit, HHA staff or others providing services under arrangements with the HHA may remain at the beneficiary's residence between visits (for example, to provide non-cov-

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ered services). However, if all covered services could be provided in the course of one visit, only one visit may be covered.

[59 FR 65497, Dec. 20, 1994, as amended at 85 FR 27620, May 8, 2020]

§ 409.49 Excluded services.

(a) *Drugs and biologicals.* Drugs and biologicals are excluded from payment under the Medicare home health benefit.

(1) A drug is any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other condition or for the relief of pain or suffering or to control or improve any physiological pathologic condition.

(2) A biological is any medicinal preparation made from living organisms and their products including, but not limited to, serums, vaccines, antigens, and antitoxins.

(b) *Transportation.* The transportation of beneficiaries, whether to receive covered care or for other purposes, is excluded from home health coverage. Costs of transportation of equipment, materials, supplies, or staff may be allowable as administrative costs, but no separate payment is made for them.

(c) *Services that would not be covered as inpatient services.* Services that would not be covered if furnished as inpatient hospital services are excluded from home health coverage.

(d) *Housekeeping services.* Services whose sole purpose is to enable the beneficiary to continue residing in his or her home (for example, cooking, shopping, Meals on Wheels, cleaning, laundry) are excluded from home health coverage.

(e) *Services covered under the End Stage Renal Disease (ESRD) program.* Services that are covered under the ESRD program and are contained in the composite rate reimbursement methodology, including any service furnished to a Medicare ESRD beneficiary that is directly related to that individual's dialysis, are excluded from coverage under the Medicare home health benefit.

(f) *Prosthetic devices.* Items that meet the requirements of § 410.36(a)(2) of this

chapter for prosthetic devices covered under Part B are excluded from home health coverage. Catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care are not considered prosthetic devices if furnished under a home health plan of care and are not subject to this exclusion from coverage.

(g) *Medical social services provided to family members.* Except as provided in § 409.45(c)(2), medical social services provided solely to members of the beneficiary's family and that are not incidental to covered medical social services being provided to the beneficiary are not covered.

(h) *Services covered under the home infusion therapy benefit.* Services that are covered under the home infusion therapy benefit as outlined at § 486.525 of this chapter, including any home infusion therapy services furnished to a Medicare beneficiary that is under a home health plan of care, are excluded from coverage under the Medicare home health benefit. Excluded home infusion therapy services pertain to the items and services for the provision of home infusion drugs, as defined at § 486.505 of this chapter. Services for the provision of drugs and biologicals not covered under this definition may continue to be provided under the Medicare home health benefit.

[59 FR 65497, Dec. 20, 1994; 60 FR 39123, Aug. 1, 1995; 85 FR 70354, Nov. 4, 2020]

§ 409.50 Coinsurance for durable medical equipment (DME) and applicable disposable devices furnished as a home health service.

The coinsurance liability of the beneficiary or other person for the following home health services is:

(a) DME—20 percent of the customary (insofar as reasonable) charge.

(b) An applicable disposable device (as defined in section 1834(s)(2) of the Act)—20 percent of the payment amount for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device (as that term is defined in § 484.202 of this chapter).

[81 FR 76796, Nov. 3, 2016]

Subpart F—Scope of Hospital Insurance Benefits

§ 409.60 Benefit periods.

(a) *When benefit periods begin.* The initial benefit period begins on the day the beneficiary receives inpatient hospital, inpatient CAH, or SNF services for the first time after becoming entitled to hospital insurance. Thereafter, a new benefit period begins whenever the beneficiary receives inpatient hospital, inpatient CAH, or SNF services after he or she has ended a benefit period as described in paragraph (b) of this section.

(b) *When benefit periods end—*(1) A benefit period ends when a beneficiary has, for at least 60 consecutive days not been an inpatient in any of the following:

(i) A hospital that meets the requirements of section 1861(e)(1) of the Act.

(ii) A CAH that meets the requirements of section 1820 of the Act.

(iii) A SNF that meets the requirements of sections 1819(a)(1) or 1861(y) of the Act.

(2) For purposes of ending a benefit period, a beneficiary was an inpatient of a SNF if his or her care in the SNF met the skilled level of care requirements specified in § 409.31(b) (1) and (3).

(c) *Presumptions.* (1) For purposes of determining whether a beneficiary was an inpatient of a SNF under paragraph (b)(2) of this section—

(i) A beneficiary's care met the skilled level of care requirements if inpatient SNF claims were paid for those services under Medicare or Medicaid, unless:

(A) Such payments were made under § 411.400 or Medicaid administratively necessary days provisions which result in payment for care not meeting the skilled level of care requirements, or

(B) A Medicare denial and a Medicaid payment are made for the same period, in which case the presumption in paragraph (c)(2)(ii) of this section applies;

(ii) A beneficiary's care met the skilled level of care requirements if a SNF claim was paid under section 1879(e) of the Social Security Act;

(iii) A beneficiary's care did not meet the skilled level of care requirements if a SNF claim was paid for the services under § 411.400;