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(1) If a State or local government agency's payments are delinquent 30 days or more, CMS may terminate the agreement with 30 days advance notice.

(2) If the State or local government agency fails to comply with the terms of the agreement or procedures promulgated by CMS, CMS may terminate the agreement with 30 days advance notice.

(3) If CMS finds that the State or local government agency is not acting in the best interest of the enrollees, or CMS, or for any reason other than those in paragraphs (b)(1) and (b)(2) of this section, CMS may terminate the agreement at any time.

(4) The State or local government agency must pay all outstanding premium surcharge and any interest amounts due within 30 days after the effective date of the termination.

(5) Interest will continue to accrue until all amounts due are paid in full.

(6) After the agreement is terminated, CMS will resume collection of the premium surcharge from the enrollees covered under the terminated agreement.

(7) If an agreement is terminated by CMS, the State or local government agency must wait 3 years from the effective date of the termination before it can request to enter into another SMI premium surcharge agreement.

PART 409—HOSPITAL INSURANCE BENEFITS

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AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 48 FR 12541, Mar. 25, 1983, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 409 appear at 62 FR 46037, Aug. 29, 1997.

Subpart A—Hospital Insurance Benefits: General Provisions

§ 409.1 Statutory basis.

This part is based on the identified provisions of the following sections of the Social Security Act:

(a) Sections 1812 and 1813 establish the scope of benefits of the hospital insurance program under Medicare Part A and set forth deductible and coinsurance requirements.

(b) Sections 1814 and 1815 establish conditions for, and limitations on, payment for services furnished by providers.

(c) Section 1820 establishes the critical access hospital program.

(d) Section 1861 describes the services covered under Medicare Part A, and benefit periods.

(e) Section 1862(a) specifies exclusions from coverage.

(f) Section 1881 sets forth the rules for individuals who have end-stage renal disease (ESRD), for organ donors, and for dialysis, transplantation, and other services furnished to ESRD patients.

[60 FR 50441, Sept. 29, 1995, as amended at 65 FR 62646, Oct. 19, 2000]

§ 409.2 Scope.

Subparts A through G of this part describe the benefits available under Medicare Part A and set forth the limitations on those benefits, including certain amounts of payment for which beneficiaries are responsible.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.3 Definitions.

As used in this part, unless the context indicates otherwise—

Arrangements means arrangements which provide that Medicare payment made to the provider that arranged for the services discharges the liability of the beneficiary or any other person to pay for those services.

Covered refers to services for which the law and the regulations authorize Medicare payment.

Nominal charge provider means a provider that furnishes services free of charge or at a nominal charge and is either a public provider, or another provider that (1) demonstrates to CMS's satisfaction that a significant portion of its patients are low-income, and (2) requests that payment for its services be determined accordingly.

Participating refers to a hospital or other facility that meets the conditions of participation and has in effect a Medicare provider agreement.

Qualified hospital means a facility that—

(a) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled;

(b) Is not primarily engaged in providing skilled nursing care and related services for inpatients who require medical or nursing care;

(c) Provides 24-hour nursing service in accordance with Sec. 1861(e)(5) of the Act;

(d) If it is a U.S. hospital, is licensed, or approved as meeting the standards

for licensing, by the State or local licensing agency; and

(e) If it is a foreign hospital, is licensed, or approved as meeting the standard for licensing, by the appropriate foreign licensing agency, and for purposes of furnishing nonemergency services to U.S. residents, is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or by a foreign program under standards that CMS finds to be equivalent to those of JCAHO.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 71 FR 48135, Aug. 18, 2006]

§ 409.5 General description of benefits.

Hospital insurance (Part A of Medicare) helps pay for inpatient hospital or inpatient CAH services and posthospital SNF care. It also pays for home health services and hospice care. There are limitations on the number of days of care that Medicare can pay for and there are deductible and coinsurance amounts for which the beneficiary is responsible. For each type of service, certain conditions must be met as specified in the pertinent sections of this subpart and in part 418 of this chapter regarding hospice care. Conditions for payment of emergency inpatient services furnished by a nonparticipating U.S. hospital and for services furnished in a foreign country are set forth in subparts G and H of part 424 of this chapter.

[71 FR 48135, Aug. 18, 2006]

Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital Services

§ 409.10 Included services.

(a) Subject to the conditions, limitations, and exceptions set forth in this subpart, the term ''inpatient hospital or inpatient CAH services'' means the following services furnished to an inpatient of a participating hospital or of a participating CAH or, in the case of emergency services or services in foreign hospitals, to an inpatient of a qualified hospital:

(1) Bed and board.

(2) Nursing services and other related services.

(3) Use of hospital or CAH facilities.

(4) Medical social services.

(5) Drugs, biologicals, supplies, appliances, and equipment.

(6) Certain other diagnostic or therapeutic services.

(7) Medical or surgical services provided by certain interns or residents-in-training.

(8) Transportation services, including transport by ambulance.

(b) *Inpatient hospital services* does not include the following types of services:

(1) Posthospital SNF care, as described in § 409.20, furnished by a hospital or a critical access hospital that has a swing-bed approval.

(2) Nursing facility services, described in § 440.155 of this chapter, that may be furnished as a Medicaid service under title XIX of the Act in a swing-bed hospital that has an approval to furnish nursing facility services.

(3) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(5) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(6) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(7) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(8) Services of an anesthetist, as defined in § 410.69

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, May 26, 1993; 64 FR 3648, Jan. 25, 1999; 65 FR 18535, Apr. 7, 2000]

§ 409.11 Bed and board.

(a) *Semiprivate and ward accommodations.* Except for applicable deductible and coinsurance amounts, Medicare Part A pays in full for bed and board and semiprivate (2 to 4 beds), or ward (5 or more beds) accommodations.

(b) *Private accommodations*—(1) *Conditions for payment in full.* Except for applicable deductible and coinsurance amounts, Medicare Part A pays in full for a private room if—

(i) The patient's condition requires him or her to be isolated;

(ii) The hospital or CAH has no semiprivate or ward accommodations; or

(iii) The hospital's or CAH's semiprivate and ward accommodations are fully occupied by other patients, were so occupied at the time the patient was admitted to the hospital or CAH, respectively, for treatment of a condition that required immediate inpatient hospital or inpatient CAH care, and have been so occupied during the interval.

(2) *Period of payment.* In the situations specified in paragraph (b)(1) (i) and (iii) of this section, Medicare pays for a private room until the patient's condition no longer requires isolation or until semiprivate or ward accommodations are available.

(3) *Conditions for patient's liability.* The hospital or CAH may charge the patient the difference between its customary charge for the private room and its most prevalent charge for a semiprivate room if—

(i) None of the conditions of paragraph (b)(1) of this section is met; and

(ii) The private room was requested by the patient or a member of the family, who, at the time of the request, was informed what the hospital's or CAH's charge would be.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.12 Nursing and related services, medical social services; use of hospital or CAH facilities.

(a) Except as provided in paragraph (b) of this section, Medicare pays for nursing and related services, use of hospital or CAH facilities, and medical social services as inpatient hospital or inpatient CAH services only if those services are ordinarily furnished by the hospital or CAH, respectively, for the care and treatment of inpatients.

(b) *Exception.* Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is a hospital or CAH employee at the time the services are furnished.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, 30667, May 26, 1993]

§ 409.13 Drugs and biologicals.

(a) Except as specified in paragraph (b) of this section, Medicare pays for drugs and biologicals as inpatient hospital or inpatient CAH services only if—

(1) They represent a cost to the hospital or CAH;

(2) They are ordinarily furnished by the hospital or CAH for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the hospital or CAH.

(b) *Exception.* Medicare pays for a limited supply of drugs for use outside the hospital or CAH if it is medically necessary to facilitate the beneficiary's departure from the hospital and required until he or she can obtain a continuing supply.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.14 Supplies, appliances, and equipment.

(a) Except as specified in paragraph (b) of this section, Medicare pays for supplies, appliances, and equipment as inpatient hospital or inpatient CAH services only if—

(1) They are ordinarily furnished by the hospital or CAH to inpatients; and

(2) They are furnished to inpatients for use in the hospital or CAH.

(b) *Exceptions.* Medicare pays for items to be used beyond the hospital or CAH stay if—

(1) The item is one that the beneficiary must continue to use after he or she leaves the hospital or CAH, for example, heart valves or a heart pacemaker, or

(2) The item is medically necessary to permit or facilitate the beneficiary's departure from the hospital or CAH and is required until the beneficiary can obtain a continuing supply. Tracheostomy or draining tubes are examples.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.15 Services furnished by an intern or a resident-in-training.

Medical or surgical services provided by an intern or a resident-in-training are included as ''inpatient hospital or

inpatient CAH services'' if they are provided—

(a) By an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association, or the Bureau of Professional Education of the American Osteopathic Association;

(b) By an intern or a resident-in-training in the field of dentistry under a teaching program approved by the Council on Dental Education of the American Dental Association; or

(c) By an intern or a resident-in-training in the field of podiatry under a teaching program approved by the Council on Podiatry Education of the American Podiatry Association.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.16 Other diagnostic or therapeutic services.

Diagnostic or therapeutic services other than those provided for in §§ 409.12, 409.13, and 409.14 are considered as inpatient hospital or inpatient CAH services if—

(a) They are furnished by the hospital or CAH, or by others under arrangements made by the hospital or CAH;

(b) Billing for those services is through the hospital or CAH; and

(c) The services are of a kind ordinarily furnished to inpatients either by the hospital or CAH or under arrangements made by the hospital or CAH.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.17 Physical therapy, occupational therapy, and speech-language pathology services.

(a) *General rules.* (1) Except as specified in this section, physical therapy, occupational therapy, or speech-language pathology services must be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, or speech-language pathologists who meet the requirements specified in part 484 of this chapter.

(2) Physical therapy, occupational therapy or speech-language pathology services must be furnished under a plan that meets the requirements of paragraphs (b) through (d) of this section, or plan requirements specific to the payment policy under which the services are rendered, if applicable.

(b) *Establishment of the plan.* The plan must be established before treatment begins by one of the following:

(1) A physician.

(2) A nurse practitioner, a clinical nurse specialist or a physician assistant.

(3) The physical therapist furnishing the physical therapy services.

(4) A speech-language pathologist furnishing the speech-language pathology services.

(5) An occupational therapist furnishing the occupational therapy services.

(c) *Content of the plan.* The plan:

(1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and

(2) Indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan are implemented in accordance with the provider's policies and procedures.

[72 FR 66397, Nov. 27, 2007, as amended at 73 FR 69932, Nov. 19, 2008; 75 FR 73613, Nov. 29, 2010]

§ 409.18 Services related to kidney transplantations.

(a) *Kidney transplants.* Medicare pays for kidney transplantation surgery only if performed in a renal transplantation center approved under subpart U of part 405 of this chapter.

(b) *Services in connection with kidney donations.* Medicare pays for services related to the evaluation or preparation of a potential or actual donor, to the donation of the kidney, or to post-operative recovery services directly related to the kidney donation—

(1) If the kidney is intended for an individual who has ESRD and is entitled to Medicare benefits or can be expected to become so entitled within a reasonable time; and

(2) Regardless of whether the donor is entitled to Medicare.

Subpart C—Posthospital SNF Care

§ 409.20 Coverage of services.

(a) *Included services.* Subject to the conditions and limitations set forth in this subpart and subpart D of this part, ''posthospital SNF care'' means the following services furnished to an inpatient of a participating SNF, or of a participating hospital or critical access hospital (CAH) that has a swing-bed approval:

(1) Nursing care provided by or under the supervision of a registered professional nurse.

(2) Bed and board in connection with the furnishing of that nursing care.

(3) Physical therapy, occupational therapy, and speech-language pathology services.

(4) Medical social services.

(5) Drugs, biologicals, supplies, appliances, and equipment.

(6) Services furnished by a hospital with which the SNF has a transfer agreement in effect under § 483.70(j) of this chapter.

(7) Other services that are generally provided by (or under arrangements made by) SNFs.

(b) *Excluded services*—(1) *Services that are not considered inpatient hospital services.* No service is included as posthospital SNF care if it would not be included as an inpatient hospital service under §§ 409.11 through 409.18.

(2) *Services not generally provided by (or under arrangements made by) SNFs.* Except as specifically listed in §§ 409.21 through 409.27, only those services generally provided by (or under arrangements made by) SNFs are considered as posthospital SNF care. For example, a type of medical or surgical procedure that is ordinarily performed only on an inpatient basis in a hospital is not included as ''posthospital SNF care,'' because such procedures are not generally provided by (or under arrangements made by) SNFs.

(c) *Terminology.* In § 409.21 through § 409.36—.

(1) The terms *SNF* and *swing-bed hospital* are used when the context applies to the particular facility.

(2) The term *facility* is used to mean both SNFs and swing-bed hospitals.

(3) The term *swing-bed hospital* includes a CAH with swing-bed approval under subpart F of part 485 of this chapter.

(4) The term *post-hospital SNF care* includes SNF care that does not follow a hospital stay when the beneficiary is enrolled in a plan, as defined in § 422.4 of this chapter, offered by a Medicare + Choice (M + C) organization, that includes the benefits described in § 422.101(c) of this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30667, May 26, 1993; 63 FR 26306, May 12, 1998; 64 FR 3648, Jan. 25, 1999; 64 FR 41681, July 30, 1999; 68 FR 46070, Aug. 4, 2003; 68 FR 50854, Aug. 22, 2003; 69 FR 35529, June 25, 2004; 75 FR 73613, Nov. 29, 2010; 82 FR 32258, July 13, 2017]

§ 409.21 Nursing care.

(a) *Basic rule.* Medicare pays for nursing care as posthospital SNF care when provided by or under the supervision of a registered professional nurse.

(b) *Exception.* Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is an SNF employee at the time the services are furnished.

[63 FR 26306, May 12, 1998]

§ 409.22 Bed and board.

(a) *Semiprivate and ward accommodations.* Except for applicable deductible and coinsurance amounts Medicare Part A pays in full for semiprivate (2 to 4 beds), or ward (5 or more beds) accommodations.

(b) *Private accommodations*—(1) *Conditions for payment in full.* Except for applicable coinsurance amounts, Medicare pays in full for a private room if—

(i) The patient's condition requires him to be isolated;

(ii) The SNF has no semiprivate or ward accommodations; or

(iii) The SNF semiprivate and ward accommodations are fully occupied by other patients, were so occupied at the time the patient was admitted to the SNF for treatment of a condition that required immediate inpatient SNF care, and have been so occupied during the interval.

(2) *Period of payment.* In the situations specified in paragraph (b)(1) (i) and (iii) of this section. Medicare pays for a private room until the patient's

condition no longer requires isolation or until semiprivate or ward accommodations are available.

(3) *Conditions for patient's liability.* The facility may charge the patient the difference between its customary charge for the private room furnished and its most prevalent charge for a semiprivate room if:

(i) None of the conditions of paragraph (b)(1) of this section is met, and

(ii) The private room was requested by the patient or a member of the family who, at the time of request was informed what the charge would be.

§ 409.23 Physical therapy, occupational therapy, and speech-language pathology services.

Medicare pays for physical therapy, occupational therapy, or speech-language pathology services as posthospital SNF care if they are furnished—

(a) By (or under arrangements made by) the facility and billed by (or through) the facility;

(b) By qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, or speech-language pathologists as defined in part 484 of this chapter; and

(c) In accordance with a plan that meets the requirements of § 409.17(b) through (d) of this part.

[75 FR 73613, Nov. 29, 2010]

§ 409.24 Medical social services.

Medicare pays for medical social services as posthospital SNF care, including—

(a) Assessment of the social and emotional factors related to the beneficiary's illness, need for care, response to treatment, and adjustment to care in the facility;

(b) Case work services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and

(c) Assessment of the relationship of the beneficiary's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care.

[63 FR 26306, May 12, 1998]

§ 409.25 Drugs, biologicals, supplies, appliances, and equipment.

(a) *Drugs and biologicals.* Except as specified in paragraph (b) of this section, Medicare pays for drugs and biologicals as posthospital SNF care only if—

(1) They represent a cost to the facility;

(2) They are ordinarily furnished by the facility for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the facility.

(b) *Exception.* Medicare pays for a limited supply of drugs for use outside the facility if it is medically necessary to facilitate the beneficiary's departure from the facility and required until he or she can obtain a continuing supply.

(c) *Supplies, appliances, and equipment.* Except as specified in paragraph (d) of this section, Medicare pays for supplies, appliances, and equipment as posthospital SNF care only if they are—

(1) Ordinarily furnished by the facility to inpatients; and

(2) Furnished to inpatients for use in the facility.

(d) *Exception.* Medicare pays for items to be used after the individual leaves the facility if—

(1) The item is one that the beneficiary must continue to use after leaving, such as a leg brace; or

(2) The item is necessary to permit or facilitate the beneficiary's departure from the facility and is required until he or she can obtain a continuing supply, for example, sterile dressings.

[63 FR 26307, May 12, 1998]

§ 409.26 Transfer agreement hospital services.

(a) *Services furnished by an intern or a resident-in-training.* Medicare pays for medical services that are furnished by an intern or a resident-in-training (under a hospital teaching program approved in accordance with the provisions of § 409.15) as posthospital SNF care, if the intern or resident is in—

(1) A participating hospital with which the SNF has in effect an agreement under § 483.70(j) of this chapter for the transfer of patients and exchange of medical records; or

(2) A hospital that has a swing-bed approval, and is furnishing services to an SNF-level inpatient of that hospital.

(b) *Other diagnostic or therapeutic services.* Medicare pays for other diagnostic or therapeutic services as posthospital SNF care if they are provided—

(1) By a participating hospital with which the SNF has in effect a transfer agreement as described in paragraph (a)(1) of this section; or

(2) By a hospital or a CAH that has a swing-bed approval, to its own SNF-level inpatient.

[63 FR 26307, May 12, 1998; 82 FR 32258, July 13, 2017]

§ 409.27 Other services generally provided by (or under arrangements made by) SNFs.

In addition to those services specified in §§ 409.21 through 409.26, Medicare pays as posthospital SNF care for such other diagnostic and therapeutic services as are generally provided by (or under arrangements made by) SNFs, including—

(a) Medical and other health services as described in subpart B of part 410 of this chapter, subject to any applicable limitations or exclusions contained in that subpart or in § 409.20(b);

(b) Respiratory therapy services prescribed by a physician for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies and abnormalities of cardiopulmonary function; and

(c) Transportation by ambulance that meets the general medical necessity requirements set forth in § 410.40(e)(1) of this chapter.

[63 FR 26307, May 12, 1998, as amended at 64 FR 41681, July 30, 1999; 84 FR 63187, Nov. 15, 2019]

Subpart D—Requirements for Coverage of Posthospital SNF Care

§ 409.30 Basic requirements.

Posthospital SNF care, including SNF-type care furnished in a hospital or CAH that has a swing-bed approval, is covered only if the beneficiary meets the requirements of this section and only for days when he or she needs and receives care of the level described in § 409.31. A beneficiary in an SNF is also considered to meet the level of care requirements of § 409.31 up to and including the assessment reference date for the initial Medicare assessment prescribed in § 413.343(b) of this chapter, when correctly assigned one of the case-mix classifiers that CMS designates for this purpose as representing the required level of care. For the purposes of this section, the assessment reference date is defined in accordance with § 483.315(d) of this chapter, and must be set for no later than the eighth day of posthospital SNF care.

(a) *Pre-admission requirements.* The beneficiary must—

(1) Have been hospitalized in a participating or qualified hospital or participating CAH, for medically necessary inpatient hospital or inpatient CAH care, for at least 3 consecutive calendar days, not counting the date of discharge; and

(2) Have been discharged from the hospital or CAH in or after the month he or she attained age 65, or in a month for which he or she was entitled to hospital insurance benefits on the basis of disability or end-stage renal disease, in accordance with part 406 of this chapter.

(b) *Date of admission requirements.*[1] (1) Except as specified in paragraph (b)(2) of this section, the beneficiary must be in need of posthospital SNF care, be

[1] Before December 5, 1980, the law required that admission and receipt of care be within 14 days after discharge from the hospital or CAH and permitted admission up to 28 days after discharge if a SNF bed was not available in the geographic area in which the patient lived, or at the time it would be medically appropriate to begin an active course of treatment, if SNF care would not be medically appropriate within 14 days after discharge.

admitted to the facility, and receive the needed care within 30 calendar days after the date of discharge from a hospital or CAH.

(2) The following exceptions apply—

(i) A beneficiary for whom posthospital SNF care would not be medically appropriate within 30 days after discharge from the hospital or CAH, or a beneficiary enrolled in a Medicare + Choice (M + C) plan, may be admitted at the time it would be medically appropriate to begin an active course of treatment.

(ii) If, upon admission to the SNF, the beneficiary was enrolled in an M + C plan, as defined in § 422.4 of this chapter, offering the benefits described in § 422.101(c) of this chapter, the beneficiary will be considered to have met the requirements described in paragraphs (a) and (b) of this section, and also in § 409.31(b)(2), for the duration of the SNF stay.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41338, Nov. 14, 1986; 58 FR 30666, 30667, May 26, 1993; 62 FR 46025, Aug. 29, 1997; 63 FR 26307, May 12, 1998; 64 FR 41681, July 30, 1999; 68 FR 50584, Aug. 22, 2003; 72 FR 43436, Aug. 3, 2007; 82 FR 36633, Aug. 4, 2017; 84 FR 38832, Aug. 7, 2019]

§ 409.31 Level of care requirement.

(a) *Definition.* As used in this section, *skilled nursing and skilled rehabilitation services* means services that:

(1) Are ordered by a physician;

(2) Require the skills of technical or professional personnel such as registered nurses, licensed practical (vocational) nurses, physical therapists, occupational therapists, and speech pathologists or audiologists; and

(3) Are furnished directly by, or under the supervision of, such personnel.

(b) *Specific conditions for meeting level of care requirements.* (1) The beneficiary must require skilled nursing or skilled rehabilitation services, or both, on a daily basis.

(2) Those services must be furnished for a condition—

(i) For which the beneficiary received inpatient hospital or inpatient CAH services; or

(ii) Which arose while the beneficiary was receiving care in a SNF or swing-bed hospital for a condition for which he or she received inpatient hospital or inpatient CAH services; or

(iii) For which, for an M + C enrollee described in § 409.20(c)(4), a physician has determined that a direct admission to a SNF without an inpatient hospital or inpatient CAH stay would be medically appropriate.

(3) The daily skilled services must be ones that, as a practical matter, can only be provided in a SNF, on an inpatient basis.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993; 68 FR 50854, Aug. 22, 2003; 70 FR 45055, Aug. 4, 2005]

§ 409.32 Criteria for skilled services and the need for skilled services.

(a) To be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel.

(b) A condition that does not ordinarily require skilled services may require them because of special medical complications. Under those circumstances, a service that is usually nonskilled (such as those listed in § 409.33(d)) may be considered skilled because it must be performed or supervised by skilled nursing or rehabilitation personnel. For example, a plaster cast on a leg does not usually require skilled care. However, if the patient has a preexisting acute skin condition or needs traction, skilled personnel may be needed to adjust traction or watch for complications. In situations of this type, the complications, and the skilled services they require, must be documented by physicians' orders and nursing or therapy notes.

(c) The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities. For example, a terminal cancer patient may need some of the skilled services described in § 409.33.

[48 FR 12541, Mar. 25, 1983, as amended at 59 FR 65493, Dec. 20, 1994]

§ 409.33 Examples of skilled nursing and rehabilitation services.

(a) *Services that could qualify as either skilled nursing or skilled rehabilitation services*—(1) *Overall management and evaluation of care plan.* (i) When overall management and evaluation of care plan *constitute skilled services.* The development, management, and evaluation of a patient care plan based on the physician's orders constitute skilled services when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs, promote recovery, and ensure medical safety. Those activities include the management of a plan involving a variety of personal care services only when, in light of the patient's condition, the aggregate of those services requires the involvement of technical or professional personnel.

(ii) *Example.* An aged patient with a history of diabetes mellitus and angina pectoris who is recovering from an open reduction of a fracture of the neck of the femur requires, among other services, careful skin care, appropriate oral medications, a diabetic diet, an exercise program to preserve muscle tone and body condition, and observation to detect signs of deterioration in his or her condition or complications resulting from restricted, but increasing, mobility. Although any of the required services could be performed by a properly instructed person, such a person would not have the ability to understand the relationship between the services and evaluate the ultimate effect of one service on the other. Since the nature of the patient's condition, age, and immobility create a high potential for serious complications, such an understanding is essential to ensure the patient's recovery and safety. Under these circumstances, the management of the plan of care would require the skills of a nurse even though the individual services are not skilled. Skilled planning and management activities are not always specifically identified in the patient's clinical record. Therefore, if the patient's overall condition supports a finding that recovery and safety can be ensured only if the total care is planned, managed, and evaluated by technical or professional personnel, it is appropriate to infer that skilled services are being provided.

(2) *Observation and assessment of the patient's changing condition*—(i) *When observation and assessment constitute skilled services.* Observation and assessment constitute skilled services when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition is stabilized.

(ii) *Examples.* A patient with congestive heart failure may require continuous close observation to detect signs of decompensation, abnormal fluid balance, or adverse effects resulting from prescribed medication(s) that serve as indicators for adjusting therapeutic measures. Similarly, surgical patients transferred from a hospital to an SNF while in the complicated, unstabilized postoperative period, for example, after hip prosthesis or cataract surgery, may need continued close skilled monitoring for postoperative complications and adverse reaction. Patients who, in addition to their physical problems, exhibit acute psychological symptoms such as depression, anxiety, or agitation, may also require skilled observation and assessment by technical or professional personnel to ensure their safety or the safety of others, that is, to observe for indications of suicidal or hostile behavior. The need for services of this type must be documented by physicians' orders or nursing or therapy notes.

(3) *Patient education services*—(i) *When patient education services constitute skilled services.* Patient education services are skilled services if the use of technical or professional personnel is necessary to teach a patient self-maintenance.

(ii) *Examples.* A patient who has had a recent leg amputation needs skilled rehabilitation services provided by technical or professional personnel to provide gait training and to teach prosthesis care. Similarly, a patient newly

diagnosed with diabetes requires instruction from technical or professional personnel to learn the self-administration of insulin or foot-care precautions.

(b) *Services that qualify as skilled nursing services.* (1) Intravenous or intramuscular injections and intravenous feeding.

(2) Enteral feeding that comprises at least 26 per cent of daily calorie requirements and provides at least 501 milliliters of fluid per day.

(3) Nasopharyngeal and tracheostomy aspiration;

(4) Insertion and sterile irrigation and replacement of suprapubic catheters;

(5) Application of dressings involving prescription medications and aseptic techniques;

(6) Treatment of extensive decubitus ulcers or other widespread skin disorder;

(7) Heat treatments which have been specifically ordered by a physician as part of active treatment and which require observation by nurses to adequately evaluate the patient's progress;

(8) Initial phases of a regimen involving administration of medical gases;

(9) Rehabilitation nursing procedures, including the related teaching and adaptive aspects of nursing, that are part of active treatment, e.g., the institution and supervision of bowel and bladder training programs.

(c) *Services which would qualify as skilled rehabilitation services.* (1) Ongoing assessment of rehabilitation needs and potential: Services concurrent with the management of a patient care plan, including tests and measurements of range of motion, strength, balance, coordination, endurance, functional ability, activities of daily living, perceptual deficits, speech and language or hearing disorders;

(2) Therapeutic exercises or activities: Therapeutic exercises or activities which, because of the type of exercises employed or the condition of the patient, must be performed by or under the supervision of a qualified physical therapist or occupational therapist to ensure the safety of the patient and the effectiveness of the treatment;

(3) Gait evaluation and training: Gait evaluation and training furnished to restore function in a patient whose ability to walk has been impaired by neurological, muscular, or skeletal abnormality;

(4) Range of motion exercises: Range of motion exercises which are part of the active treatment of a specific disease state which has resulted in a loss of, or restriction of, mobility (as evidenced by a therapist's notes showing the degree of motion lost and the degree to be restored);

(5) Maintenance therapy; Maintenance therapy, when the specialized knowledge and judgment of a qualified therapist is required to design and establish a maintenance program based on an initial evaluation and periodic reassessment of the patient's needs, and consistent with the patient's capacity and tolerance. For example, a patient with Parkinson's disease who has not been under a rehabilitation regimen may require the services of a qualified therapist to determine what type of exercises will contribute the most to the maintenance of his present level of functioning.

(6) Ultrasound, short-wave, and microwave therapy treatment by a qualified physical therapist;

(7) Hot pack, hydrocollator, infrared treatments, paraffin baths, and whirlpool; Hot pack hydrocollator, infrared treatments, paraffin baths, and whirlpool in particular cases where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fractures, or other complications, and the skills, knowledge, and judgment of a qualified physical therapist are required; and

(8) Services of a speech pathologist or audiologist when necessary for the restoration of function in speech or hearing.

(d) *Personal care services.* Personal care services which do not require the skills of qualified technical or professional personnel are not skilled services except under the circumstances specified in § 409.32(b). Personal care services include, but are not limited to, the following:

(1) Administration of routine oral medications, eye drops, and ointments;

(2) General maintenance care of colostomy and ileostomy;

(3) Routine services to maintain satisfactory functioning of indwelling bladder catheters;

(4) Changes of dressings for noninfected postoperative or chronic conditions;

(5) Prophylactic and palliative skin care, including bathing and application of creams, or treatment of minor skin problems;

(6) Routine care of the incontinent patient, including use of diapers and protective sheets;

(7) General maintenance care in connection with a plaster cast;

(8) Routine care in connection with braces and similar devices;

(9) Use of heat as a palliative and comfort measure, such as whirlpool and hydrocollator;

(10) Routine administration of medical gases after a regimen of therapy has been established;

(11) Assistance in dressing, eating, and going to the toilet;

(12) Periodic turning and positioning in bed; and

(13) General supervision of exercises which have been taught to the patient; including the actual carrying out of maintenance programs, i.e., the performance of the repetitive exercises required to maintain function do not require the skills of a therapist and would not constitute skilled rehabilitation services (see paragraph (c) of this section). Similarly, repetitious exercises to improve gait, maintain strength, or endurance; passive exercises to maintain range of motion in paralyzed extremities, which are not 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 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 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 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.

(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 4578, 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 dieticians 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 dietician 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 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-covered 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 the disposable Negative Pressure Wound Therapy (NPWT) device (as that term is defined in § 484.202 of this chapter).

[81 FR 76796, Nov. 3, 2016, as amended at 88 FR 77874, Nov. 13, 2023]

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;

(iv) A beneficiary's care did not meet the skilled level of care requirements if a Medicaid SNF claim was denied on the grounds that the services were not at the skilled level of care (even if paid under applicable Medicaid administratively necessary days provisions which result in payment for care not meeting the skilled level of care requirements);

(2) For purposes of determining whether a beneficiary was an inpatient of a SNF under paragraph (b)(2) of this section a beneficiary's care in a SNF is presumed—

(i) To have met the skilled level of care requirements during any period for which the beneficiary was assigned to one of the Resource Utilization Groups designated as representing the required level of care, as provided in § 409.30.

(ii) To have met the skilled level of care requirements if a Medicaid or Medicare claim was denied on grounds other than that the services were not at the skilled level of care;

(iii) Not to have met the skilled level of care requirements if a Medicare SNF claim was denied on the grounds that the services were not at the skilled level of care and payment was not made under § 411.400; or

(iv) Not to have met the skilled level of care requirements if no Medicare or Medicaid claim was submitted by the SNF.

(3) If information upon which to base a presumption is not readily available, the intermediary may, at its discretion review the beneficiary's medical records to determine whether he or she was an inpatient of a SNF as set forth under paragraph (b)(2) of this section.

(4) When the intermediary makes a benefit period determination based upon paragraph (c)(1) of this section, the beneficiary may seek to reverse the benefit period determination by timely appealing the prior Medicare SNF claim determination under part 405, subpart G of this chapter, or the prior Medicaid SNF claim under part 431, subpart E of this chapter.

(5) When the intermediary makes a benefit period determination under paragraph (c)(2) of this section, the beneficiary will be notified of the basis for the determination, and of his or her right to present evidence to rebut the determination that the skilled level of care requirements specified in § 409.31 (b)(1) and (b)(3) were or were not met on reconsideration and appeal under 42 CFR, part 405, subpart G of this chapter.

(d) *Limitation on benefit period determinations.* When the intermediary considers the same prior SNF stay of a particular beneficiary in making benefit period determinations for more than one inpatient Medicare claim—

(1) Medicare will recognize only the initial level of care characterization for that prior SNF stay (or if appealed under 42 CFR part 405, subpart G of this chapter, the level of care determined under appeal); or

(2) If part of a prior SNF stay has one level of care characterization and another part has another level of care characterization, Medicare will recognize only the initial level of care characterization for a particular part of a prior SNF stay (or if appealed under 42 CFR part 405, subpart G of this chapter, the level of care determined under appeal).

(e) *Relation of benefit period to benefit limitations.* The limitations specified in §§ 409.61 and 409.64, and the deductible and coinsurance requirements set forth in subpart G of this part apply for each benefit period. The limitations of § 409.63 apply only to the initial benefit period.

[52 FR 22645, June 15, 1987; 52 FR 28824, Aug. 4, 1987, as amended at 58 FR 30667, May 26, 1993; 63 FR 26307, May 12, 1998; 70 FR 45055, Aug. 4, 2005]

§ 409.61 General limitations on amount of benefits.

(a) *Inpatient hospital or inpatient CAH services*—(1) *Regular benefit days.* Up to 90 days are available in each benefit period, subject to the limitations on days for psychiatric hospital services set forth in §§ 409.62 and 409.63.

(i) For the first 60 days (referred to in this subpart as *full benefit days*), Medicare pays the hospital or CAH for all covered services furnished the beneficiary, except for a deductible which is the beneficiary's responsibility. (Section 409.82 specifies the requirements for the inpatient hospital deductible.)

(ii) For the next 30 days (referred to in this subpart as *coinsurance days*), Medicare pays for all covered services except for a daily coinsurance amount, which is the beneficiary's responsibility. (Section 409.83 specifies the inpatient hospital coinsurance amounts.)

(2) *Lifetime reserve days.* Each beneficiary has a non-renewable lifetime reserve of 60 days of inpatient hospital or inpatient CAH services that he may draw upon whenever he is hospitalized for more than 90 days in a benefit period. Upon exhaustion of the regular benefit days, the reserve days will be used unless the beneficiary elects not to use them, as provided in § 409.65. For lifetime reserve days, Medicare pays for all covered services except for a daily coinsurance amount that is the beneficiary's responsibility. (See § 409.83.)

(3) *Order of payment for inpatient hospital or inpatient CAH services.* Medicare pays for inpatient hospital services in the following order.

(i) The 60 full benefit days;

(ii) The 30 coinsurance days;

(iii) The remaining lifetime reserve days.

(b) *Posthospital SNF care furnished by a SNF, or by a hospital or a CAH with a swing-bed approval.* Up to 100 days are available in each benefit period after discharge from a hospital or CAH. For the first 20 days, Medicare pays for all covered services. For the 21st through 100th day, Medicare pays for all covered services except for a daily coinsurance amount that is the beneficiary's responsibility.

(c) *Renewal of inpatient benefits.* The beneficiary's full entitlement to the 90 inpatient hospital or inpatient CAH regular benefit days, and the 100 SNF benefit days, is renewed each time he or she begins a benefit period. However, once lifetime reserve days are used, they can never be renewed.

(d) *Home health services.* Medicare Part A pays for all covered home health services[1] with no deductible, and subject to the following limitations on payment for durable medical equipment (DME):

(1) For DME furnished by an HHA that is a nominal charge provider, Medicare Part A pays 80 percent of fair compensation.

(2) For DME furnished by an HHA that is not a nominal charge provider,

[1] Before July 1, 1981, Medicare Part A paid for not more than 100 home health visits during one year following the beneficiary's most recent discharge from a hospital or a SNF.

Medicare Part A pays the lesser of the following:

(i) 80 percent of the reasonable cost of the service.

(ii) The reasonable cost of, or the customary charge for, the service, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41339, Nov. 14, 1986; 54 FR 4027, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.62 Lifetime maximum on inpatient psychiatric care.

There is a lifetime maximum of 190 days on inpatient psychiatric hospital services available to any beneficiary. Therefore, once an individual receives benefits for 190 days of care in a psychiatric hospital, no further benefits of that type are available to that individual.

§ 409.63 Reduction of inpatient psychiatric benefit days available in the initial benefit period.

(a) *Reduction rule.* (1) If the individual was an inpatient in a psychiatric hospital on the first day of Medicare entitlement and for any of the 150 days immediately before that first day of entitlement, those days are subtracted from the 150 days (90 regular days plus 60 lifetime reserve days) which would otherwise be available in the initial benefit period for inpatient psychiatric services in a psychiatric or general hospital.

(2) Reduction is required only if the hospital was participating in Medicare as a psychiatric hospital on the individual's first day of entitlement.

(3) The reduction applies only to the beneficiary's first benefit period. For subsequent benefit periods, the 90 benefit days, plus any remaining lifetime reserve days, subject to the 190 day lifetime limit on psychiatric hospital care, are available.

(b) *Application to general hospital days.* (1) Days spent in a general hospital before entitlement are not subtracted under paragraph (a) of this section even if the stay was for diagnosis or treatment of mental illness.

(2) After entitlement, all psychiatric care days, whether in a general or a psychiatric hospital, are counted toward the number of days available in the initial benefit period.

(c) *Examples:* (1) The individual was an inpatient of a participating psychiatric hospital for 20 days before the first day of entitlement and remained there for another 6 months. Therefore, 130 days of benefits (150 minus 20) are payable. Payment could be made for: 60 full benefit days, 30 coinsurance days, and 40 lifetime reserve days.

(2) During the 150-day period preceding Medicare entitlement, an individual had been a patient of a general hospital for 60 days of inpatient psychiatric care and had spent 90 days in a psychiatric hospital, ending with the first day of entitlement. During the initial benefit period, the beneficiary spent 90 days in a general hospital and received psychiatric care there. The 60 days spent in the general hospital for psychiatric treatment before entitlement do not reduce the benefits available in the first benefit period. Only the 90 days spent in the psychiatric hospital before entitlement reduce such benefits, leaving a total of 60 available psychiatric days. However, after entitlement, the reduction applies not only to days spent in a psychiatric hospital, but also to days of psychiatric treatment in a general hospital. Thus, Medicare payment could be made only for 60 of the 90 days spent in the general hospital.

(3) An individual was admitted to a general hospital for a mental condition and, after 10 days, transferred to a participating psychiatric hospital. The individual remained in the psychiatric hospital for 78 days before becoming entitled to hospital insurance benefits and for 130 days after entitlement. The beneficiary was then transferred to a general hospital and received treatment of a medical condition for 20 days. The 10 days spent in the general hospital during the 150-day pre-entitlement period have no effect on the inpatient hospital benefit days available to the individual for psychiatric care in the first benefit period, even though the general hospital stay was for a mental condition. Only the 78 days spent in the psychiatric hospital during the pre-entitlement period are subtracted from the 150 benefit days. Accordingly, the individual has 72 days of

psychiatric care (150 days less 78 days) available in the first benefit period. Benefits could be paid for the individual's hospitalization during the first benefit period in the following manner. For the 130-day psychiatric hospital stay, 72 days (60 full benefit days and 12 coinsurance days), and for the general hospital stay, 20 days (18 coinsurance and 2 lifetime reserve days).

§ 409.64 Services that are counted toward allowable amounts.

(a) Except as provided in paragraph (b) of this section for lifetime reserve days, all covered inpatient days and home health visits are counted toward the allowable amounts specified in §§ 409.61 through 409.63 if—

(1) They are paid for by Medicare; or

(2) They would be paid for by Medicare if the following requirements had been met:

(i) A proper and timely request for payment had been filed; and

(ii) The hospital, CAH, SNF, or home health agency had submitted all necessary evidence, including physician or allowed practitioner certification of need for services when such certification was required;

(3) They could not be paid for because the total payment due was equal to, or less than, the applicable deductible and coinsurance amounts.

(b) *Exception.* Even though the requirements of paragraph (a)(2) of this section are met, lifetime reserve days are not counted toward the allowable amounts if the beneficiary elected or is deemed to have elected not to use them as set forth in § 409.65.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30667, May 26, 1993; 85 FR 70354, Nov. 4, 2020]

§ 409.65 Lifetime reserve days.

(a) *Election not to use lifetime reserve days.* (1) Whenever a beneficiary has exhausted the 90 regular benefit days, the hospital or CAH may bill Medicare for lifetime reserve days unless the beneficiary elects not to use them or, in accordance with paragraph (b) of this section, is deemed to have elected not to use them.

(2) It may be advantageous to elect not to use lifetime reserve days if the beneficiary has private insurance coverage that begins after the first 90 inpatient days in a benefit period, or if the daily charge is only slightly higher than the lifetime reserve days coinsurance amount. In such cases, the beneficiary may want to save the lifetime reserve days for future care that may be more expensive.

(3) If the beneficiary elects not to use lifetime reserve days for a particular hospital or CAH stay, they are still available for a later stay. However, once the beneficiary uses lifetime reserve days, they can never be renewed.

(4) If the beneficiary elects not to use lifetime reserve days, the hospital or CAH may require him or her to pay for any services furnished after the regular days are exhausted.

(b) *Deemed election.* A beneficiary will be deemed to have elected not to use lifetime reserve days if the average daily charges for such days is equal to or less than the applicable coinsurance amount specified in § 409.83. A beneficiary would get no benefit from using the days under those circumstances.

(c) *Who may file an election.* An election not to use reserve days may be filed by—

(1) The beneficiary; or

(2) If the beneficiary is physically or mentally unable to act, by the beneficiary's legal representative. In addition, if some other payment source is available, such as private insurance, any person authorized under § 405.1664 of this chapter to execute a request for payment for the beneficiary may file the election.

(d) *Filing the election.* (1) The beneficiary's election not to use lifetime reserve days must be filed in writing with the hospital or CAH.

(2) The election may be filed at the time of admission to the hospital or CAH or at any time thereafter up to 90 days after the beneficiary's discharge.

(3) A retroactive election (that is, one made after lifetime reserve days have been used because the regular days were exhausted), is not acceptable unless it is approved by the hospital or CAH.

(e) *Period covered by election*—(1) *General rule.* Except as provided in paragraph (e)(2) of this section, an election not to use lifetime reserve days may apply to an entire hospital or CAH stay

or to a single period of consecutive days in a stay, but cannot apply to selected days in a stay. For example, a beneficiary may restrict the election to the period covered by private insurance but cannot use individual lifetime reserve days within that period. If an election not to use reserve days is effective after the first day on which reserve days are available, it must remain in effect until the end of the stay, unless it is revoked in accordance with § 409.66.

(2) *Exception.* A beneficiary election not to use lifetime reserve days for an inpatient hospital or inpatient CAH stay for which payment may be made under the prospective payment system (part 412 of this chapter) is subject to the following rules:

(i) If the beneficiary has one or more regular benefit days (see § 409.61(a)(1) of this chapter) remaining in the benefit period upon entering the hospital or CAH, an election not to use lifetime reserve days will apply automatically to all days that are not outlier days. The beneficiary may also elect not to use lifetime reserve days for outlier days but this election must apply to all outlier days.

(ii) If the beneficiary has no regular benefit days (see § 409.61(a)(1) of this chapter) remaining in the benefit period upon entering the hospital or CAH, an election not to use lifetime reserve days must apply to the entire hospital or CAH stay.

[48 FR 12541, Mar. 25, 1983, as amended at 48 FR 39837, Sept. 1, 1983; 49 FR 323, Jan. 3, 1984; 58 FR 30666, 30667, May 26, 1993]

§ 409.66 Revocation of election not to use lifetime reserve days.

(a) Except as provided in paragraph (c) of this section, a beneficiary (or anyone authorized to execute a request for payment, if the beneficiary is incapacitated) may revoke an election not to use lifetime reserve days during hospitalization or within 90 days after discharge.

(b) The revocation must be submitted to the hospital or CAH in writing and identify the stay or stays to which it applies.

(c) *Exceptions.* A revocation of an election not to use lifetime reserve days may not be filed—

(1) After the beneficiary dies; or

(2) After the hospital or CAH has filed a claim under the supplementary medical insurance program (Medicare Part B), for medical and other health services furnished to the beneficiary on the days in question.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.68 Guarantee of payment for inpatient hospital or inpatient CAH services furnished before notification of exhaustion of benefits.

(a) *Conditions for payment.* Payment may be made for inpatient hospital or inpatient CAH services furnished a beneficiary after he or she has exhausted the available benefit days if the following conditions are met:

(1) The services were furnished before CMS or the intermediary notified the hospital or CAH that the beneficiary had exhausted the available benefit days and was not entitled to have payment made for those services.

(2) At the time the hospital or CAH furnished the services, it was unaware that the beneficiary had exhausted the available benefit days and could reasonably have assumed that he or she was entitled to have payment made for these services.

(3) Payment would be precluded solely because the beneficiary has no benefit days available for the particular hospital or CAH stay.

(4) The hospital or CAH claims reimbursement for the services and refunds any payments made for those services by the beneficiary or by another person on his or her behalf.

(b) *Limitations on payment.* (1) If all of the conditions in paragraph (a) of this section are met, Medicare payment may be made for the day of admission, and up to 6 weekdays thereafter, plus any intervening Saturdays, Sundays, and Federal holidays.

(2) Payment may not be made under this section for any day after the hospital or CAH is notified that the beneficiary has exhausted the available benefit days.

(c) *Recovery from the beneficiary.* Any payment made to a hospital or CAH under this section is considered an overpayment to the beneficiary and may be recovered from him or her

under the provisions set forth elsewhere in this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, May 26, 1993]

Subpart G—Hospital Insurance Deductibles and Coinsurance

§ 409.80 Inpatient deductible and coinsurance: General provisions.

(a) *What they are.* (1) The inpatient deductible and coinsurance amounts are portions of the cost of covered hospital or CAH or SNF services that Medicare does not pay.

(2) The hospital or CAH or SNF may charge these amounts to the beneficiary or someone on his or her behalf.

(b) *Changes in the inpatient deductible and coinsurance amounts.* (1) The law requires the Secretary to adjust the inpatient hospital deductible each year to reflect changes in the average cost of hospital care. In adjusting the deductible, the Secretary must use a formula specified in section 1813(b)(2) of the Act. Under that formula, the inpatient hospital deductible is increased each year by about the same percentage as the increase in the average Medicare daily hospital costs. The result of the deductible increase is that the beneficiary continues to pay about the same proportion of the hospital bill.

(2) Since the coinsurance amounts are, by statute, specific fractions of the deductible, they change when the deductible changes.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.82 Inpatient hospital deductible.

(a) *General provisions*—(1) The inpatient hospital deductible is a fixed amount chargeable to the beneficiary when he or she receives covered services in a hospital or a CAH for the first time in a benefit period.

(2) Although the beneficiary may be hospitalized several times during a benefit period, the deductible is charged only once during that period. If the beneficiary begins more than one benefit period in the same year, a deductible is charged for each of those periods.

(3) For services furnished before January 1, 1982, the applicable deductible is the one in effect when the benefit period began.

(4) For services furnished after December 31, 1981, the applicable deductible is the one in effect during the calendar year in which the services were furnished.

(b) *Specific deductible amounts.* The specific deductible amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exception to published amounts.* If the total hospital or CAH charge is less than the deductible amount applicable for the calendar year in which the services were furnished, the amount of the charge is the deductible for the year.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.83 Inpatient hospital coinsurance.

(a) *General provisions*—(1) Inpatient hospital coinsurance is the amount chargeable to a beneficiary for each day after the first 60 days of inpatient hospital care or inpatient CAH care or both in a benefit period.

(2) For each day from the 61st to the 90th day, the coinsurance amount is ¼ of the applicable deductible.

(3) For each day from the 91st to the 150th day (lifetime reserve days), the coinsurance amount is ½ of the applicable deductible.

(4) For coinsurance days before January 1, 1982, the coinsurance amount is based on the deductible applicable for the calendar year in which the benefit period began. The coinsurance amounts do not change during a beneficiary's benefit period even though the coinsurance days may fall in a subsequent year for which a higher deductible amount has been determined.

(5) For coinsurance days after December 31, 1981, the coinsurance amount is based on the deductible applicable for the calendar year in which the services were furnished. For example, if an individual starts a benefit period by being admitted to a hospital in 1981 and remains in the hospital long enough to use coinsurance days in 1982, the coinsurance amount charged for

those days is based on the 1982 inpatient hospital deductible.

(b) *Specific coinsurance amounts.* The specific coinsurance amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exceptions to published amounts.* (1) If the actual charge to the patient for the 61st through the 90th day of inpatient hospital or inpatient CAH services is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the actual charge per day is the daily coinsurance amount.

(2) If the actual charge to the patient for the 91st through the 150th day (lifetime reserve days) is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the beneficiary is deemed to have elected not to use the days because he or she would not benefit from using them.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.85 Skilled nursing facility (SNF) care coinsurance.

(a) *General provisions.* (1) SNF care coinsurance is the amount chargeable to a beneficiary after the first 20 days of SNF care in a benefit period.

(2) For each day from the 21st through the 100th day, the coinsurance is ⅛ of the applicable inpatient hospital deductible.

(3) For coinsurance days before January 1, 1982, the coinsurance amount is based on the deductible applicable for the year in which the benefit period began. The coinsurance amounts do not change during a beneficiary's benefit period even though the coinsurance days may fall in a subsequent year for which a higher deductible amount has been determined.

(4) For coinsurance days after December 31, 1981, the coinsurance amount is based on the deductible applicable for the calendar year in which the services were furnished.

(b) *Specific coinsurance amounts.* The specific SNF coinsurance amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exception to published amounts.* If the actual charge to the patient is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the actual charge per day is the daily coinsurance.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989]

§ 409.87 Blood deductible.

(a) *General provisions.* (1) As used in this section, packed red cells means the red blood cells that remain after plasma is separated from whole blood.

(2) A unit of packed red cells is treated as the equivalent of a unit of whole blood.

(3) Medicare does not pay for the first 3 units of whole blood or units of packed red cells that a beneficiary receives, during a calendar year, as an inpatient of a hospital or CAH or SNF, or on an outpatient basis under Medicare Part B.

(4) The deductible does not apply to other blood components such as platelets, fibrinogen, plasma, gamma globulin, and serum albumin, or to the cost of processing, storing, and administering blood.

(5) The blood deductible is in addition to the inpatient hospital deductible and daily coinsurance.

(6) The Part A blood deductible is reduced to the extent that the Part B blood deductible has been applied. For example, if a beneficiary had received one unit under Medicare Part B, and later in the same benefit period received three units under Medicare Part A, Medicare Part A would pay for the third of the latter units. (As specified in § 410.161 of this chapter, the Part B blood deductible is reduced to the extent a blood deductible has been applied under Medicare Part A.)

(b) *Beneficiary's responsibility for the first 3 units of whole blood or packed red cells*—(1) *Basic rule.* Except as specified in paragraph (b)(2) of this section, the beneficiary is responsible for the first 3 units of whole blood or packed red cells. He or she has the option of paying the hospital's or CAH's charges for the blood or packed red cells or arranging for it to be replaced.

(2) *Exception.* The beneficiary is not responsible for the first 3 units of

whole blood or packed red cells if the provider obtained that blood or red cells at no charge other than a processing or service charge. In that case, the blood or red cells is deemed to have been replaced.

(c) *Provider's right to charge for the first 3 units of whole blood or packed red cells*—(1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, a provider may charge a beneficiary its customary charge for any of the first 3 units of whole blood or packed red cells.

(2) *Exception.* A provider may not charge the beneficiary for the first 3 units of whole blood or packed red cells in any of the following circumstances:

(i) The blood or packed red cells has been replaced.

(ii) The provider (or its blood supplier) receives, from an individual or a blood bank, a replacement offer that meets the criteria specified in paragraph (d) of this section. The provider is precluded from charging even if it or its blood supplier rejects the replacement offer.

(iii) The provider obtained the blood or packed red cells at no charge other than a processing or service charge and it is therefore deemed to have been replaced.

(d) *Criteria for replacement of blood.* A blood replacement offer made by a beneficiary, or an individual or a blood bank on behalf of a beneficiary, discharges the beneficiary's obligation to pay for deductible blood or packed red cells if the replacement blood meets the applicable criteria specified in Food and Drug Administration regulations under 21 CFR part 640, i.e.—

(1) The replacement blood would not endanger the health of a beneficiary; and

(2) The prospective donor's health would not be endangered by making a blood donation.

[48 FR 12541, Mar. 25, 1983, as amended at 56 FR 8840, Mar. 1, 1991; 57 FR 36014, Aug. 12, 1992; 58 FR 30666, 30667, May 26, 1993]

§ 409.89 Exemption of kidney donors from deductible and coinsurance requirements.

The deductible and coinsurance requirements set forth in this subpart do not apply to any services furnished to an individual in connection with the donation of a kidney for transplant surgery.

Subpart H—Payment of Hospital Insurance Benefits

SOURCE: 53 FR 6633, Mar. 2, 1988, unless otherwise noted.

§ 409.100 To whom payment is made.

(a) *Basic rule.* Except as provided in paragraph (b) of this section—

(1) Medicare pays hospital insurance benefits only to a participating provider.

(2) For home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA, payment is made to the HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

(b) *Exceptions.* Medicare may pay hospital insurance benefits as follows:

(1) For emergency services furnished by a nonparticipating hospital, to the hospital or to the beneficiary, under the conditions prescribed in subpart G of part 424 of this chapter.

(2) For services furnished by a Canadian or Mexican hospital, to the hospital or to the beneficiary, under the conditions prescribed in subpart H of part 424 of this chapter.

[53 FR 6633, Mar. 2, 1988, as amended at 65 FR 41211, July 3, 2000]

§ 409.102 Amounts of payment.

(a) The amounts Medicare pays for hospital insurance benefits are generally determined in accordance with part 412 or part 413 of this chapter.

(b) Except as provided in §§ 409.61(d) and 409.89, hospital insurance benefits are subject to the deductible and coinsurance requirements set forth in subpart G of this part.