

(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.

**PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS**

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AUTHORITY: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

SOURCE: 51 FR 41339, Nov. 14, 1986, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 410 appear at 62 FR 46037, Aug. 29, 1997.

### Subpart A—General Provisions

#### § 410.1 Basis and scope.

(a) *Statutory basis.* This part is based on the indicated provisions of the following sections of the Act:

(1) Section 1832—Scope of benefits furnished under the Medicare Part B supplementary medical insurance (SMI) program.

(2) Section 1833 through 1835 and 1862—Amounts of payment for SMI services, the conditions for payment, and the exclusions from coverage.

(3) Section 1861(qq)—Definition of the kinds of services that may be covered.

(4) Section 1865(b)—Permission for CMS to approve and recognize a national accreditation organization for the purpose of deeming entities accredited by the organization to meet program requirements.

(5) Section 1881—Medicare coverage for end-stage renal disease beneficiaries.

(6) Section 1842(o)—Payment for drugs and biologicals not paid on a cost or prospective payment basis.

(b) *Scope of part.* This part sets forth the benefits available under Medicare Part B, the conditions for payment and the limitations on services, the percentage of incurred expenses that Medicare Part B pays, and the deductible and copayment amounts for which the beneficiary is responsible. (Exclusions applicable to these services are set forth in subpart C of part 405 of this chapter. General conditions for Medicare payment are set forth in part 424 of this chapter.)

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 55 FR 53521, Dec. 31, 1990; 59 FR 63462, Dec. 8, 1994; 63 FR 58905, Nov. 2, 1998; 65 FR 83148, Dec. 29, 2000; 69 FR 66420, Nov. 15, 2004]

#### § 410.2 Definitions.

As used in this part—  
*Community mental health center (CMHC)* means an entity that—

(1) Provides outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of its mental health service

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area who have been discharged from inpatient treatment at a mental health facility;

(2) Provides 24-hour-a-day emergency care services;

(3) Provides day treatment or other partial hospitalization services, or psychosocial rehabilitation services;

(4) Provides screening for patients being considered for admission to State mental health facilities to determine the appropriateness of this admission;

(5) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located; and

(6) Provides at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Social Security Act.

*Encounter* means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

*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.

*Outpatient* means a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.

*Partial hospitalization services* means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in §410.43.

*Participating* refers to a hospital, CAH, SNF, HHA, CORF, or hospice that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has a provider agreement to participate in Medicare but only for purposes of providing outpatient physical therapy, occupational therapy, or

speech pathology services; or a CMHC that has in effect a similar agreement but only for purposes of providing partial hospitalization services, and *non-participating* refers to a hospital, CAH, SNF, HHA, CORF, hospice, clinic, rehabilitation agency, public health agency, or CMHC that does not have in effect a provider agreement to participate in Medicare.

*Preventive services* means all of the following:

(1) The specific services listed in section 1861(w)(2) of the Act, with the explicit exclusion of electrocardiograms;

(2) The Initial Preventive Physical Examination (IPPE) (as specified by section 1861(w)(1) of the Act); and

(3) Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS) (as specified by section 1861(h)(1) of the Act).

[59 FR 6577, Feb. 11, 1994, as amended at 62 FR 46025, Aug. 29, 1997; 65 FR 18536, Apr. 7, 2000; 75 FR 72259, Nov. 24, 2010; 75 FR 73613, Nov. 29, 2010]

### §410.3 Scope of benefits.

(a) *Covered services.* The SMI program helps pay for the following:

(1) Medical and other health services such as physicians' services, outpatient services furnished by a hospital or a CAH, diagnostic tests, outpatient physical therapy and speech pathology services, rural health clinic services, Federally qualified health center services, IHS, Indian tribe, or tribal organization facility services, and outpatient renal dialysis services.

(2) Services furnished by ambulatory surgical centers (ASCs), home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and partial hospitalization services provided by community mental health centers (CMHCs).

(3) Other medical services, equipment, and supplies that are not covered under Medicare Part A hospital insurance.

(b) *Limitations on amount of payment.*  
(1) Medicare Part B does not pay the full reasonable costs or charges for all covered services. The beneficiary is responsible for an annual deductible and a blood deductible and, after the annual deductible has been satisfied, for

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coinsurance amounts specified for most of the services.

(2) Specific rules on payment are set forth in subpart I of this part.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993; 59 FR 6577, Feb. 11, 1994; 66 FR 55328, Nov. 1, 2001; 75 FR 73613, Nov. 29, 2010]

### § 410.5 Other applicable rules.

The following other rules of this chapter set forth additional policies and procedures applicable to four of the kinds of services covered under the SMI program:

(a) Part 494: End-Stage Renal Disease Facilities.

(b) Part 405, Subpart X: Rural Health Clinic and Federally Qualified Health Center services.

(c) Part 416: Ambulatory Surgical Center services.

(d) Part 493: Laboratory Services.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 7134, Feb. 28, 1992; 57 FR 24981, June 12, 1992; 73 FR 20474, Apr. 15, 2008]

### Subpart B—Medical and Other Health Services

#### § 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, “medical and other health services” includes the following services:

(a) Physicians’ services.

(b) Services and supplies furnished incident to a physician’s professional services, of kinds that are commonly furnished in physicians’ offices and are commonly either furnished without charge or included in the physicians’ bills.

(c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or a CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for

coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment; on or after July 1, 1991, epoetin (EPO) for home dialysis patients, and, on or after January 1, 1994, for dialysis patients, competent to use the drug; self-care home dialysis support services; and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

(p) Hepatitis B vaccine.

(q) Blood clotting factors for hemophilia patients competent to use these factors without medical or other supervision.

(r) Screening mammography services.

(s) Federally qualified health center services.

(t) Services of a certified registered nurse anesthetist or an anesthesiologist’s assistant.

(u) Prescription drugs used in immunosuppressive therapy.

(v) Clinical psychologist services and services and supplies furnished as an incident to the services of a clinical psychologist, as provided in § 410.71.

(w) Clinical social worker services, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

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(y) Intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases.

[51 FR 41339, Nov. 14, 1986, as amended at 52 FR 27765, July 23, 1987; 55 FR 22790, June 4, 1990; 55 FR 53522, Dec. 31, 1990; 56 FR 8841, Mar. 1, 1991; 56 FR 43709, Sept. 4, 1991; 57 FR 24981, June 12, 1992; 57 FR 33896, July 31, 1992; 58 FR 30668, May 26, 1993; 59 FR 26959, May 25, 1994; 59 FR 49833, Sept. 30, 1994; 60 FR 8955, Feb. 16, 1995; 63 FR 20128, Apr. 23, 1998; 66 FR 55328, Nov. 1, 2001; 69 FR 66420, Nov. 15, 2004]

### § 410.12 Medical and other health services: Basic conditions and limitations.

(a) *Basic conditions.* The medical and other health services specified in § 410.10 are covered by Medicare Part B only if they are not excluded under subpart A of part 411 of this chapter, and if they meet the following conditions:

(1) *When the services must be furnished.* The services must be furnished while the individual is in a period of entitlement. (The rules on entitlement are set forth in part 406 of this chapter.)

(2) *By whom the services must be furnished.* The services must be furnished by a facility or other entity as specified in §§ 410.14 through 410.69.

(3) *Physician certification and recertification requirements.* If the services are subject to physician certification requirements, they must be certified as being medically necessary, and as meeting other applicable requirements, in accordance with subpart B of part 424 of this chapter.

(b) *Limitations on payment.* Payment for medical and other health services is subject to limitations on the amounts of payment as specified in §§ 410.152 and 410.155 and to the annual and blood deductibles as set forth in §§ 410.160 and 410.161.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 33896, July 31, 1992]

### § 410.14 Special requirements for services furnished outside the United States.

Medicare part B pays for physicians' services and ambulance services furnished outside the United States if the services meet the applicable conditions of § 410.12 and are furnished in connec-

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tion with covered inpatient hospital services that meet the specific requirements and conditions set forth in subpart H of part 424 of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

### § 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) *Definitions.* For purposes of this section—

*Detection of any cognitive impairment* means assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers or others.

*Eligible beneficiary* means an individual who is no longer within 12 months after the effective date of his or her first Medicare Part B coverage period and who has not received either an initial preventive physical examination or an annual wellness visit providing a personalized prevention plan within the past 12 months.

*Establishment of, or an update to the individual's medical and family history* means, at minimum, the collection and documentation of the following:

(i) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries and treatments.

(ii) Use or exposure to medications and supplements, including calcium and vitamins.

(iii) Medical events in the beneficiary's parents and any siblings and children, including diseases that may be hereditary or place the individual at increased risk.

*First annual wellness visit providing personalized prevention plan services* means the following services furnished to an eligible beneficiary by a health professional that include, and take into account the results of, a health risk assessment, as those terms are defined in this section:

(i) Review (and administration if needed) of a health risk assessment (as defined in this section).

(ii) Establishment of an individual's medical and family history.

(iii) Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.

(iv) Measurement of an individual's height, weight, body-mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history.

(v) Detection of any cognitive impairment that the individual may have, as that term is defined in this section.

(vi) Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.

(vii) Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in this section may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

(viii) Establishment of the following:

(A) A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in this section), health status, screening history, and age-appropriate preventive services covered by Medicare.

(B) A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical

examination (as described under § 410.16 of this subpart), and a list of treatment options and their associated risks and benefits.

(ix) Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

(x) At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

(xi) Any other element determined appropriate through the national coverage determination process.

*Health professional* means—

(i) A physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act); or

(ii) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act); or

(iii) A medical professional (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision (as defined in § 410.32(b)(3)(ii)) of a physician as defined in paragraph (i) of this definition.

*Health risk assessment* means, for the purposes of this section, an evaluation tool that meets the following criteria:

(i) Collects self-reported information about the beneficiary.

(ii) Can be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter.

(iii) Is appropriately tailored to and takes into account the communication needs of underserved populations, persons with limited English proficiency, and persons with health literacy needs.

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(iv) Takes no more than 20 minutes to complete.

(v) Addresses, at a minimum, the following topics:

(A) Demographic data, including but not limited to age, gender, race, and ethnicity.

(B) Self assessment of health status, frailty, and physical functioning.

(C) Psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue.

(D) Behavioral risks, including but not limited to, tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual health, motor vehicle safety (seat belt use), and home safety.

(E) Activities of daily living (ADLs), including but not limited to, dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.

(F) Instrumental activities of daily living (IADLs), including but not limited to, shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

*Review of the individual's functional ability and level of safety* means, at minimum, assessment of the following topics:

(i) Hearing impairment.

(ii) Ability to successfully perform activities of daily living.

(iii) Fall risk.

(iv) Home safety.

*Subsequent annual wellness visit providing personalized prevention plan services* means the following services furnished to an eligible beneficiary by a health professional that include, and take into account the results of an updated health risk assessment, as those terms are defined in this section:

(i) Review (and administration, if needed) of an updated health risk assessment (as defined in this section).

(ii) An update of the individual's medical and family history.

(iii) An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first annual wellness visit providing personalized prevention

plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

(iv) Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.

(v) Detection of any cognitive impairment that the individual may have, as that term is defined in this section.

(vi) An update to the following:

(A) The written screening schedule for the individual as that schedule is defined in paragraph (a) of this section for the first annual wellness visit providing personalized prevention plan services.

(B) The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

(vii) Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of this section.

(viii) At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

(ix) Any other element determined appropriate through the national coverage determination process.

(b) *Conditions for coverage of annual wellness visits providing personalized prevention plan services.* Medicare Part B pays for first and subsequent annual wellness visits providing personalized prevention plan services that are furnished to an eligible beneficiary, as described in this section, if they are furnished by a health professional, as defined in this section.



(c) *Limitations on coverage of an annual wellness visit providing personalized prevention plan services.* Payment may not be made for either a first or a subsequent annual wellness visit providing personalized prevention plan services that is performed for an individual who is—

(1) Not an eligible beneficiary as described in this section.

(2) An eligible beneficiary as described in this section and who has had either an initial preventive physical examination as specified in § 410.16 of this subpart or either a first or a subsequent annual wellness visit providing personalized prevention plan services performed within the past 12 months.

(d) *Effective date.* Coverage for an annual wellness visit providing personalized prevention plan services is effective for services furnished on or after January 1, 2011.

[75 FR 73613, Nov. 29, 2010, as amended at 76 FR 1367, Jan. 10, 2011; 76 FR 73470, Nov. 28, 2011; 80 FR 71372, Nov. 16, 2015]

**§ 410.16 Initial preventive physical examination: Conditions for and limitations on coverage.**

(a) *Definitions.* As used in this section, the following definitions apply:

*Eligible beneficiary* means, for the purposes of this section, an individual who receives his or her initial preventive examination not more than 1 year after the effective date of his or her first Medicare Part B coverage period.

*End-of-life planning* means, for purposes of this section, verbal or written information regarding the following areas:

(1) An individual's ability to prepare an advance directive in the case where an injury or illness causes the individual to be unable to make health care decisions.

(2) Whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

*Initial preventive physical examination* means all of the following services furnished to an eligible beneficiary by a physician or other qualified nonphysician practitioner with the goal of health promotion and disease detection:

(1) Review of the beneficiary's medical and social history with attention

to modifiable risk factors for disease, as those terms are defined in this section.

(2) Review of the beneficiary's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.

(3) Review of the beneficiary's functional ability, and level of safety as those terms are defined in this section, as described in paragraph (4) of this definition, based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified nonphysician practitioner may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

(4) An examination to include measurement of the beneficiary's height, weight, body mass index, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.

(5) End-of-life planning as that term is defined in this section upon agreement with the individual.

(6) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(7) Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo), (pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

*Medical history* is defined to include, at a minimum, the following:

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(1) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.

(2) Current medications and supplements, including calcium and vitamins.

(3) Family history, including a review of medical events in the beneficiary's family, including diseases that may be hereditary or place the individual at risk.

A *physician* for purposes of this section means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

A *qualified nonphysician practitioner* for purposes of this section means a physician assistant, nurse practitioner, or clinical nurse specialist (as authorized under section 1861(s)(2)(K)(i) and section 1861(s)(2)(K)(ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76).

*Review of the beneficiary's functional ability and level of safety* must include, at a minimum, a review of the following areas:

- (1) Hearing impairment.
- (2) Activities of daily living.
- (3) Falls risk.
- (4) Home safety

*Social history* is defined to include, at a minimum, the following:

- (1) History of alcohol, tobacco, and illicit drug use.
- (2) Diet.
- (3) Physical activities.

(b) *Condition for coverage of an initial preventive physical examination.* Medicare Part B pays for an initial preventive physical examination provided to an eligible beneficiary, as described in this section, if it is furnished by a physician or other qualified nonphysician practitioner, as defined in this section.

(c) *Limitations on coverage of initial preventive physical examinations.* Payment may not be made for an initial preventive physical preventive examination that is performed for an individual who is not an eligible beneficiary as described in this section.

[69 FR 66420, Nov. 15, 2004, as amended at 71 FR 69783, Dec. 1, 2006; 73 FR 69932, Nov. 19, 2008]

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### § 410.17 Cardiovascular disease screening tests.

(a) *Definition.* For purposes of this subpart, the following definition apply: *Cardiovascular screening blood test* means:

(1) A lipid panel consisting of a total cholesterol, HDL cholesterol, and triglyceride. The test is performed after a 12-hour fasting period.

(2) Other blood tests, previously recommended by the U.S. Preventive Services Task Force (USPSTF), as determined by the Secretary through a national coverage determination process.

(3) Other non-invasive tests, for indications that have a blood test recommended by the USPSTF, as determined by the Secretary through a national coverage determination process.

(b) *General conditions of coverage.* Medicare Part B covers cardiovascular disease screening tests when ordered by the physician who is treating the beneficiary (see § 410.32(a)) for the purpose of early detection of cardiovascular disease in individuals without apparent signs or symptoms of cardiovascular disease.

(c) *Limitation on coverage of cardiovascular screening tests.* Payment may be made for cardiovascular screening tests performed for an asymptomatic individual only if the individual has not had the screening tests paid for by Medicare during the preceding 59 months following the month in which the last cardiovascular screening tests were performed.

[69 FR 66421, Nov. 15, 2004]

### § 410.18 Diabetes screening tests.

(a) *Definitions.* For purposes of this section, the following definitions apply:

*Diabetes* means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on two different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

*Pre-diabetes* means a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting glucose level of 100–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL. The term pre-diabetes includes the following conditions:

- (1) Impaired fasting glucose.
- (2) Impaired glucose tolerance.

(b) *General conditions of coverage.* Medicare Part B covers diabetes screening tests after a referral from a physician or qualified nonphysician practitioner to an individual at risk for diabetes for the purpose of early detection of diabetes.

(c) *Types of tests covered.* The following tests are covered if all other conditions of this subpart are met:

- (1) Fasting blood glucose test.
- (2) Post-glucose challenges including, but not limited to, an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, a 2-hour post glucose challenge test alone.
- (3) Other tests as determined by the Secretary through a national coverage determination.

(d) *Amount of testing covered.* Medicare covers the following for individuals:

- (1) Diagnosed with pre-diabetes, two screening tests per calendar year.
- (2) Previously tested who were not diagnosed with pre-diabetes, or who were never tested before, one screening test per year.

(e) *Eligible risk factors.* Individuals with the following risk factors are eligible to receive the benefit:

- (1) Hypertension.
- (2) Dyslipidemia.
- (3) Obesity, defined as a body mass index greater than or equal to 30 kg/m<sup>2</sup>.
- (4) Prior identification of impaired fasting glucose or glucose intolerance.
- (5) Any two of the following characteristics:
  - (i) Overweight, defined as body mass index greater than 25, but less than 30 kg/m<sup>2</sup>.
  - (ii) A family history of diabetes.
  - (iii) 65 years of age or older.
  - (iv) A history of gestational diabetes mellitus or delivery of a baby weighing more than 9 pounds.

[69 FR 66421, Nov. 15, 2004]

**§ 410.19 Ultrasound screening for abdominal aortic aneurysms: Condition for and limitation on coverage.**

(a) *Definitions:* As used in this section, the following definitions apply:

*Eligible beneficiary* means an individual who—

(1) Has not been previously furnished an ultrasound screening for an abdominal aortic aneurysm under Medicare program; and

(2) Is included in at least one of the following risk categories:

(i) Has a family history of an abdominal aortic aneurysm.

(ii) Is a man age 65 to 75 who has smoked at least 100 cigarettes in his lifetime.

(iii) Is an individual who manifests other risk factors in a beneficiary category recommended for screening by the United States Preventive Services Task Force regarding abdominal aortic aneurysms, as specified by the Secretary through a national coverage determination process.

*Ultrasound screening for abdominal aortic aneurysms* means the following services furnished to an asymptomatic individual for the early detection of an abdominal aortic aneurysm:

(1) A procedure using soundwaves (or other procedures using alternative technologies of commensurate accuracy and cost, as specified by the Secretary through a national coverage determination process) provided for the early detection of abdominal aortic aneurysms.

(2) Includes a physician's interpretation of the results of the procedure.

(b) *Conditions for coverage of an ultrasound screening for abdominal aortic aneurysms.* Medicare Part B pays for one ultrasound screening for an abdominal aortic aneurysm provided to eligible beneficiaries, as described in this section, after a referral from a physician or a qualified nonphysician practitioner as defined in § 410.16(a), when the test is performed by a provider or supplier that is authorized to provide covered ultrasound diagnostic services.

(c) *Limitation on coverage of ultrasound screening for abdominal aortic aneurysms.* Payment may not be made for an ultrasound screening for an abdominal aortic aneurysm that is performed for an individual that does not

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meet the definition of “eligible beneficiary” specified in this section.

[71 FR 69783, Dec. 1, 2006, as amended at 78 FR 74810, Dec. 10, 2013]

### § 410.20 Physicians’ services.

(a) *Included services.* Medicare Part B pays for physicians’ services, including diagnosis, therapy, surgery, consultations, and home, office, and institutional calls.

(b) *By whom services must be furnished.* Medicare Part B pays for the services specified in paragraph (a) of this section if they are furnished by one of the following professionals who is legally authorized to practice by the State in which he or she performs the functions or actions, and who is acting within the scope of his or her license.

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized in section 1101(a)(7) of the Act.

(2) A doctor of dental surgery or dental medicine.

(3) A doctor of podiatric medicine.

(4) A doctor of optometry.

(5) A chiropractor who meets the qualifications specified in § 410.22

(c) *Limitations on services.* The Services specified in paragraph (a) of this section may be covered under Medicare Part B if they are furnished within the limitations specified in §§ 410.22 through 410.25.

(d) *Prior determination of medical necessity for physicians’ services—(1) Definitions.* (i) A “Prior Determination of Medical Necessity” means an individual decision by a Medicare contractor, before a physician’s service is furnished, as to whether or not the physician’s service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity.

(ii) An “eligible requester” includes the following:

(A) A participating physician (or a physician that accepts assignment), but only with respect to physicians’ services to be furnished to an individual who is entitled to receive benefits under this part and who has consented to the physician making the request under this section for those physicians’ services.

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(B) An individual entitled to benefits under this part, but only with respect to physicians’ services for which the individual receives, from a physician, an advance beneficiary notice under section 1879(a) of the Act.

(2) *General rule.* Each Medicare contractor will, through the procedures established in CMS manual instructions, allow requests for prior determinations of medical necessity from eligible requesters under its respective jurisdiction for those services identified by CMS (updated annually in conjunction with the update to the MPFS and posted on that specific Medicare contractor’s Web site by the Healthcare Common Procedure Coding System procedure code and code description). Only those services listed on that Medicare contractor’s Web site on the date the request for a prior determination is made are subject to prior determination. Each contractor’s list will consist of the following:

(i) The national list, provided by CMS, of the most expensive physicians’ services (as defined in section 1848(j)(3) of the Act) included in the MPFS which are performed at least 50 times annually.

(ii) The national list, provided by CMS, of plastic and dental surgeries that may be covered by Medicare and that have an amount of at least \$1,000 on the MPFS (not including the adjustment for location by the GPCI).

(3) *Services with local coverage determinations (LCDs) or national coverage determinations (NCDs).* In instances where an LCD or an NCD exists that has sufficiently specific reasonable and necessary criteria addressing the particular clinical indication for the procedure for which the prior determination is requested, the contractor will send a copy of the LCD or NCD to the requestor along with an explanation that the LCD or NCD serves as the prior determination and that no further determination will be made.

(4) *Identification of eligible services.* CMS will identify the number of services that are eligible for a prior determination through manual instructions consistent with the criteria established in the regulation.

(5) *Statutory procedures.* Under sections 1869(h)(3) through (h)(6) of the Act, the following procedures apply:

(i) *Request for prior determination—(A) In general.* An eligible requester may submit to the contractor a request for a determination, before the furnishing of a physician's service, as to whether the physician's service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) of the Act (relating to medical necessity).

(B) *Accompanying documentation.* CMS may require that the request be accompanied by a description of the physician's service, supporting documentation relating to the medical necessity of the physician's service, and other appropriate documentation. In the case of a request submitted by an eligible requester who is described in section 1869(h)(1)(B)(ii) of the Act, the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(ii) *Response to request—(A) General rule.* The contractor will provide the eligible requester with written notice of a determination as to whether—

(1) The physician's service is covered (the physician's service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity); or

(2) The physician's service is not covered (the physician's service is not covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity); or

(3) The contractor lacks sufficient information to make a coverage determination with respect to the physician's service.

(B) *Contents of notice for certain determinations—(1) Coverage.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(1) of this section, the contractor will indicate in the prior determination notice that the physician service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity.

(2) *Noncoverage.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(2) of this section, the contractor will include in the notice a brief explanation of the basis

for the determination, including on what national or local coverage or non-coverage determination (if any) the determination is based, and a description of any applicable rights under section 1869(a) of the Act.

(3) *Insufficient information.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(3) of this section, the contractor will include in the notice a description of the additional information required to make the coverage determination.

(C) *Deadline to respond.* The notice described in paragraphs (d)(5)(ii)(A)(1) through (d)(5)(ii)(A)(3) of this section will be provided by the contractor within 45 days of the date the request for a prior determination is received by the contractor.

(D) *Informing beneficiary in case of physician request.* In the case of a request by a participating physician or a physician accepting assignment, the process will provide that the individual to whom the physician's service is to be furnished will be informed of any determination described in paragraph (d)(5)(ii)(A)(2) of this section (relating to a determination of non-coverage). The beneficiary will also be notified that, notwithstanding the determination of non-coverage, the beneficiary has the right to obtain the physician's service in question and have a claim submitted for the physician's service.

(iii) *Binding nature of positive determination.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(1) of this section, that determination will be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(iv) *Limitation on further review—(A) General rule.* Contractor determinations described in paragraph (d)(5)(ii)(A)(2) of this section or paragraph (d)(5)(ii)(A)(3) of this section (relating to pre-service claims) are not subject to administrative appeal or judicial review.

(B) *Decision not to seek prior determination or negative determination does not impact the right to obtain services, seek reimbursement, or appeal rights.* Nothing in this paragraph will be construed as affecting the right of an individual who—

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(1) Decides not to seek a prior determination under this paragraph with respect to physicians' services; or

(2) Seeks such a determination and has received a determination described in paragraph (d)(5)(ii)(A)(2) of this section, from receiving (and submitting a claim for) those physicians' services and from obtaining administrative or judicial review respecting that claim under the other applicable provisions of this part 405 subpart I of this chapter. Failure to seek a prior determination under this paragraph with respect to physicians' services will not be taken into account in that administrative or judicial review.

(C) *No prior determination after receipt of services.* Once an individual is provided physicians' services, there will be no prior determination under this paragraph with respect to those physicians' services.

(e) *Medical record documentation.* The physician may review and verify (sign/date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team including, as applicable, notes documenting the physician's presence and participation in the services.

[51 FR 41339, Nov. 14, 1986, as amended at 73 FR 9678, Feb. 22, 2008; 84 FR 63187, Nov. 15, 2019]

### §410.21 Limitations on services of a chiropractor.

(a) *Qualifications for chiropractors.* (1) A chiropractor licensed or authorized to practice before July 1, 1974, and an individual who began studies in a chiropractic college before that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Graduated from a college of chiropractic approved by the State's chiropractic examiners after completing a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance and covering adequate courses of study in the subjects of anatomy, physiology, symptomatology

and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing and adjusting; and

(iii) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(1)(ii) of this section.

(2) A chiropractor first licensed or authorized to practice after June 30, 1974, and an individual who begins studies in a chiropractic college after that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Satisfactorily completed 2 years of pre-chiropractic study at the college level;

(iii) Satisfactorily completed a 4-year course of 8 months each year offered by a college or school of chiropractic approved by the State's chiropractic examiners and including at least 4,000 hours in courses in anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, principles and practice of chiropractic, and clinical instruction in vertebral palpation, nerve tracing and adjusting, plus courses in the use and effect of X-ray and chiropractic analysis;

(iv) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(2)(iii) of this section; and

(v) Attained 21 years of age.

(b) *Limitations on services.* (1) Medicare Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if the subluxation has resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment.

(2) Medicare Part B does not pay for X-rays or other diagnostic or therapeutic services furnished or ordered by a chiropractor.

[51 FR 41339, Nov. 14, 1986, as amended at 64 FR 59439, Nov. 2, 1999. Redesignated at 66 FR 55328, Nov. 1, 2001]

**§ 410.22 Limitations on services of an optometrist.**

Medicare Part B pays for the services of a doctor of optometry, which he or she is legally authorized to perform in the State in which he or she performs them, if the services are among those described in section 1861(s) of the Act and § 410.10 of this part.

[64 FR 59439, Nov. 2, 1999. Redesignated at 66 FR 55328, Nov. 1, 2001]

**§ 410.23 Screening for glaucoma: Conditions for and limitations on coverage.**

(a) *Definitions*: As used in this section, the following definitions apply:

(1) *Direct supervision in the office setting* means the optometrist or the ophthalmologist must be present in the office suite and be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean the physician must be present in the room when the procedure is performed.

(2) *Eligible beneficiary* means individuals in the following high risk categories:

- (i) Individual with diabetes mellitus.
- (ii) Individual with a family history of glaucoma.
- (iii) African-Americans age 50 and over.
- (iv) Hispanic-Americans age 65 and over.

(3) *Screening for glaucoma* means the following procedures furnished to an individual for the early detection of glaucoma:

- (i) A dilated eye examination with an intraocular pressure measurement.
- (ii) A direct ophthalmoscopy examination, or a slit-lamp biomicroscopic examination.

(b) *Condition for coverage of screening for glaucoma*. Medicare Part B pays for glaucoma screening examinations provided to eligible beneficiaries as described in paragraph (a)(2) of this section if they are furnished by or under the direct supervision in the office setting of an optometrist or ophthalmologist who is legally authorized to perform these services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished

by a physician or incident to a physician's professional service.

(c) *Limitations on coverage of glaucoma screening examinations*. (1) Payment may not be made for a glaucoma screening examination that is performed for an individual who is not an eligible beneficiary as described in paragraph (a)(2) of this section.

(2) Payment may be made for a glaucoma screening examination that is performed on an individual who is an eligible beneficiary as described in paragraph (a)(2) of this section, after at least 11 months have passed following the month in which the last glaucoma screening examination was performed.

[66 FR 55328, Nov. 1, 2001, as amended at 70 FR 70330, Nov. 21, 2005]

**§ 410.24 Limitations on services of a doctor of dental surgery or dental medicine.**

Medicare Part B pays for services furnished by a doctor of dental surgery or dental medicine within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.<sup>1</sup>

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8852, Mar. 1, 1991]

**§ 410.25 Limitations on services of a podiatrist.**

Medicare Part B pays for the services of a doctor of podiatric medicine, acting within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.

**§ 410.26 Services and supplies incident to a physician's professional services: Conditions.**

(a) *Definitions*. For purposes of this section, the following definitions apply:

<sup>1</sup>For services furnished before July 1, 1981, Medicare Part B paid only for the following services of a doctor of dental surgery or dental medicine;

Surgery on the jaw or any adjoining structure; and

Reduction of a fracture of the jaw or other facial bone.

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(1) *Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

(2) *Direct supervision* means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(i).

(3) *General supervision* means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service.

(4) *Independent contractor* means an individual (or an entity that has hired such an individual) who performs part-time or full-time work for which the individual (or the entity that has hired such an individual) receives an IRS-1099 form.

(5) *Leased employment* means an employment relationship that is recognized by applicable State law and that is established by two employers by a contract such that one employer hires the services of an employee of the other employer.

(6) *Noninstitutional setting* means all settings other than a hospital or skilled nursing facility.

(7) *Practitioner* means a non-physician practitioner who is authorized by the Act to receive payment for services incident to his or her own services.

(8) *Services and supplies* means any services or supplies (including drugs or biologicals that are not usually self-administered) that are included in section 1861(s)(2)(A) of the Act and are not specifically listed in the Act as a separate benefit included in the Medicare program.

(b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

(6) Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

(7) Services and supplies must be furnished in accordance with applicable State law.

(8) A physician (or other practitioner) may be an employee or an independent contractor.

(9) Claims for drugs payable administered by a physician as defined in section 1861(r) of the Social Security Act to refill an implanted item of DME may only be paid under Part B to the physician as a drug incident to a physician's service under section 1861(s)(2)(A). These drugs are not payable to a pharmacy/supplier as DME under section 1861(s)(6) of the Act.

(c) *Limitations.* (1) Drugs and biologicals are also subject to the limitations specified in § 410.29.



(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in §§ 410.59(a)(3)(iii), 410.60(a)(3)(iii), and 410.62(a)(3)(ii).

[51 FR 41339, Nov. 14, 1986, as amended at 66 FR 55328, Nov. 1, 2001; 67 FR 20684, Apr. 26, 2002; 69 FR 66421, Nov. 15, 2004; 77 FR 69361, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 80 FR 14870, Mar. 20, 2015; 80 FR 71372, Nov. 16, 2015; 81 FR 80552, Nov. 15, 2016]

**§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or non-physician practitioner's service: Conditions.**

(a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by the participating hospital or CAH, except in the case of a SNF resident as provided in § 411.15(p) of this subchapter;

(ii) As an integral although incidental part of a physician's or nonphysician practitioner's services;

(iii) In the hospital or CAH or in a department of the hospital or CAH, as defined in § 413.65 of this subchapter;

(iv) Under the general supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this chapter, general supervision means the definition specified at § 410.32(b)(3)(i).

(B) Certain therapeutic services and supplies may be assigned either direct

supervision or personal supervision. For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. Personal supervision means the definition specified at § 410.32(b)(3)(iii);

(C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77;

(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively. For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. During a Public Health Emergency, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider; and

(E) For nonsurgical extended duration therapeutic services (extended duration services), which are hospital or CAH outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature, Medicare requires a minimum of direct supervision during the initiation of the service

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which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. Initiation means the beginning portion of the nonsurgical extended duration therapeutic service which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision. During a Public Health Emergency, as defined in § 400.200 of this chapter, Medicare requires a minimum level of general supervision for the entire service; and

(v) In accordance with applicable State law.

(2) In the case of partial hospitalization services, also meet the conditions of paragraph (e) of this section.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.129.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in subpart G of Part 424 of this chapter.

(d) Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter.

(e) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

(f) Services furnished by an entity other than the hospital are subject to the limitations specified in § 410.42(a).

(g) For purposes of this section, “nonphysician practitioner” means a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

[76 FR 74580, Nov. 30, 2011, as amended at 78 FR 75196, Dec. 10, 2013; 84 FR 61490, Nov. 12, 2019; 85 FR 8476, Feb. 14, 2020; 85 FR 19285, Apr. 6, 2020]

**§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.**

(a) Medicare Part B pays for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

(1) They are furnished by or under arrangements made by a participating hospital or participating CAH, except in the case of an SNF resident as provided in § 411.15(p) of this chapter.

(2) They are ordinarily furnished by, or under arrangements made by, the hospital or CAH to its outpatients for the purpose of diagnostic study.

(3) They would be covered as inpatient hospital services if furnished to an inpatient.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29(b) and (c).

(c) Diagnostic services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § 410.42(a).

(d) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished by or under arrangements made by the participating hospital only when the diagnostic services are furnished under the appropriate level of physician supervision specified by CMS in accordance with the definitions in this paragraph and in § 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility. In addition—

(1) For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65 of this chapter, “direct supervision” means that the physician must be immediately available

to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where the procedure is performed. During a Public Health Emergency, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

(2) For services furnished under arrangement in nonhospital locations, “direct supervision” means the definition specified in § 410.32(b)(3)(ii).

(f) The rules for clinical diagnostic laboratory tests set forth in §§ 410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.

[51 FR 41339, Nov. 14, 1986, as amended at 58 FR 30668, May 26, 1993; 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000; 66 FR 58809, Nov. 23, 2001; 74 FR 60680, Nov. 20, 2009; 75 FR 72259, Nov. 24, 2010; 85 FR 19286, Apr. 6, 2020]

#### § 410.29 Limitations on drugs and biologicals.

Medicare part B does not pay for the following:

(a) Except as provided in § 410.28(a) for outpatient diagnostic services and § 410.63(b) for blood clotting factors, and except for EPO, any drug or biological which is usually self-administered by the patient.

(b) Any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program, that there is a compelling jus-

tification of the drug product’s medical need. (21 CFR 310.6 contains an explanation of the efficacy review program.)

(c) Any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (b) of this section.

[51 FR 41339, Nov. 14, 1986, as amended at 55 FR 22790, June 4, 1990; 56 FR 43709, Sept. 4, 1991; 80 FR 70602, Nov. 13, 2015]

#### § 410.30 Prescription drugs used in immunosuppressive therapy.

(a) *Scope.* Payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the FDA and that meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a carrier (in accordance with part 421, subpart C of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient’s transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient’s transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(b) *Eligibility.* For drugs furnished on or after December 21, 2000, coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, provided the individual is eligible to receive Medicare Part B benefits.

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(c) *Coverage.* Drugs are covered under this provision irrespective of whether they can be self-administered.

[60 FR 8955, Feb. 16, 1995. Redesignated at 63 FR 34327, June 24, 1998; 74 FR 62002, Nov. 25, 2009]

### §410.31 Bone mass measurement: Conditions for coverage and frequency standards.

(a) *Definition.* As used in this section unless specified otherwise, the following definition applies:

*Bone mass measurement* means a radiologic, radioisotopic, or other procedure that meets the following conditions:

(1) Is performed for the purpose of identifying bone mass, detecting bone loss, or determining bone quality.

(2) Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or with a bone sonometer system that has been cleared for marketing for this use by the FDA under 21 CFR part 807, or approved for marketing by the FDA for this use under 21 CFR part 814.

(3) Includes a physician's interpretation of the results of the procedure.

(b) *Conditions for coverage.* (1) Medicare covers a medically necessary bone mass measurement if the following conditions are met:

(i) Following an evaluation of the beneficiary's need for the measurement, including a determination as to the medically appropriate procedure to be used for the beneficiary, it is ordered by the physician or a qualified nonphysician practitioner (as these terms are defined in §410.32(a)) treating the beneficiary.

(ii) It is performed under the appropriate level of supervision of a physician (as set forth in §410.32(b)).

(iii) It is reasonable and necessary for diagnosing and treating the Condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(2) Medicare covers a medically necessary bone mass measurement for an individual defined under paragraph (d)(5) of this section if the conditions under paragraph (b)(1) of this section are met and the monitoring is performed by the use of a dual energy x-

ray absorptiometry system (axial skeleton).

(3) Medicare covers a medically necessary confirmatory baseline bone mass measurement for an individual defined under paragraph (d) of this section, if the conditions under paragraph (b)(1) of this section are met and the confirmatory baseline bone mass measurement is performed by a dual energy x-ray absorptiometry system (axial skeleton) and the initial measurement was not performed by a dual energy x-ray absorptiometry system (axial skeleton).

(c) *Standards on frequency of coverage—*(1) *General rule.* Except as allowed under paragraph (c)(2) of this section, Medicare may cover a bone mass measurement for a beneficiary if at least 23 months have passed since the month the last bone mass measurement was performed.

(2) *Exception.* If medically necessary, Medicare may cover a bone mass measurement for a beneficiary more frequently than allowed under paragraph (c)(1) of this section. Examples of situations where more frequent bone mass measurement procedures may be medically necessary include, but are not limited to the following medical circumstances:

(i) Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.

(ii) Allowing for a confirmatory baseline measurement to permit monitoring of beneficiaries in the future if the requirements of paragraph (b)(3) of this section are met.

(d) *Beneficiaries who may be covered.* The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average

of 5.0 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

(e) *Denial as not reasonable and necessary.* If CMS determines that a bone mass measurement does not meet the conditions for coverage in paragraphs (b) or (d) of this section, or the standards on frequency of coverage in paragraph (c) of this section, it is excluded from Medicare coverage as not “reasonable” and “necessary” under section 1862(a)(1)(A) of the Act and § 411.15(k) of this chapter.

(f) *Use of the National Coverage Determination Process.* For the purposes of paragraphs (b)(2) and (b)(3) of this section, CMS may determine through the National Coverage Determination process that additional bone mass measurement systems are reasonable and necessary under section 1862(a)(1) of the Act for monitoring and confirming baseline bone mass measurements.

[71 FR 69783, Dec. 1, 2006]

**§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.**

(a) *Ordering diagnostic tests.* Except as otherwise provided in this section, all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(1) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(2) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

(3) *Public Health Emergency exceptions.* During the Public Health Emergency for COVID-19, as defined in § 400.200 of this chapter, the order of a physician or other applicable practitioner is not required for one otherwise covered diagnostic laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis when performed in conjunction with COVID-19 diagnostic laboratory test in order to rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID-19 and related tests described in the previous sentence are reasonable and necessary when ordered by a physician or nonphysician practitioner in accordance with this paragraph (a), or when ordered by a pharmacist or other healthcare professional who is authorized under applicable state law to order diagnostic laboratory tests. FDA-authorized COVID-19 serology tests are included as covered tests subject to the same order requirements during the Public Health Emergency for COVID-19, as defined in § 400.20 of this chapter, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection.

(b) *Diagnostic x-ray and other diagnostic tests—*(1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of

supervision by a physician as defined in section 1861(r) of the Act or, during the Public Health Emergency as defined in §400.200 of this chapter, for the COVID–19 pandemic, by a nurse practitioner, clinical nurse specialist, physician assistant or a certified nurse-midwife to the extent that they are authorized to do so under applicable state law. Services furnished without the required level of supervision are not reasonable and necessary (see §411.15(k)(1) of this chapter).

(2) *Exceptions.* The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(11)(3) of the Act.

(iii) Diagnostic psychological and neuropsychological testing services when—

(A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or

(B) Furnished under the general supervision of a physician, clinical psychologist, or during the Public Health Emergency, as defined in §400.200 of this chapter, for the COVID–19 pandemic, by a nurse practitioner, clinical nurse specialist, physician assistant or a certified nurse-midwife, to the extent that they are authorized to perform the tests under applicable State law.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

(vi) Pathology and laboratory procedures listed in the 80000 series of the Current Procedural Terminology published by the American Medical Association.

(vii) Diagnostic tests performed by a certified nurse-midwife authorized to perform the tests under applicable State laws.

(viii) During the COVID–19 Public Health Emergency as defined in §400.200 of this chapter, diagnostic tests performed by a physician assistant authorized to perform the tests under applicable State law.

(3) *Levels of supervision.* Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraph (b)(3)(ii) or (iii) of this section, respectively. When direct or personal supervision is required, supervision at the specified level is required throughout the performance of the test.

(i) *General supervision* means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

(ii) *Direct supervision* in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. During a PHE, as defined in §400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

(iii) *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

(4) *Supervision requirement for RRA or RPA.* Diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (b)(3) of this section, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

(c) *Portable x-ray services.* Portable x-ray services furnished in a place of residence used as the patient's home are covered if the following conditions are met:

(1) These services are furnished under the general supervision of a physician, as defined in paragraph (b)(3)(i) of this section.

(2) These services are ordered by a physician as provided in paragraph (a) or by a nonphysician practitioner as provided in paragraph (a)(2) of this section.

(3) The supplier of these services meets the requirements set forth in part 486, subpart C of this chapter, concerning conditions for coverage for portable x-ray services.

(4) The procedures are limited to—

(i) Skeletal films involving the extremities, pelvis, vertebral column, or skull;

(ii) Chest or abdominal films that do not involve the use of contrast media; and

(iii) Diagnostic mammograms if the approved portable x-ray supplier, as defined in subpart C of part 486 of this chapter, meets the certification requirements of section 354 of the Public Health Service Act, as implemented by 21 CFR part 900, subpart B.

(d) *Diagnostic laboratory tests—(1) Who may furnish services.* Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:

(i) A participating hospital or participating RPCH.

(ii) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in subpart

G of part 424 of this chapter and the laboratory requirements specified in part 493 of this chapter.

(iii) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine.

(iv) An RHC.

(v) A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in subpart G of part 424 of this chapter.

(vi) An FQHC.

(vii) An SNF to its resident under § 411.15(p) of this chapter, either directly (in accordance with § 483.75(k)(1)(i) of this chapter) or under an arrangement (as defined in § 409.3 of this chapter) with another entity described in this paragraph.

(2) *Documentation and recordkeeping requirements—*

(i) *Ordering the service.* Except for tests described in paragraph (a)(3) of this section, the physician (or qualified nonphysician practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* Except for tests described in paragraph (a)(3) of this section, the entity submitting the claim must maintain the following documentation:

(A) The documentation that it receives from the ordering physician or nonphysician practitioner.

(B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.

(iii) *Requesting additional information.* The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

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#### (3) *Claims review.*

(i) *Documentation requirements.* Except for tests described in paragraph (a)(3) introductory text, upon request by CMS, the entity submitting the claim must provide the following information:

(A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).

(B) Documentation showing accurate processing of the order and submission of the claim.

(C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

(ii) *Services that are not reasonable and necessary.* If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

(A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.

(B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.

(C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review.* (i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization param-

eters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

(e) *Diagnostic laboratory tests furnished in hospitals and CAHs.* The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001; 69 FR 66421, Nov. 15, 2004; 72 FR 66398, Nov. 27, 2007; 75 FR 73615, Nov. 29, 2010; 77 FR 69361, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 54871, Sept. 2, 2020]

#### § 410.33 **Independent diagnostic testing facility.**

(a) *General rule.* (1) Effective for diagnostic procedures performed on or after March 15, 1999, carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or a clinical nurse specialist when he or she performs a test he or she is authorized by the State to perform, or an independent diagnostic testing facility (IDTF). An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is independent of a physician's office or hospital; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician's office.

(2) *Exceptions.* The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) and (g) and (h) of this section.



(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(11)(3) of the Act.

(iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(b) *Supervising physician.* (1) Each supervising physician must be limited to providing general supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

(2) The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. In the case of a procedure requiring the direct or personal supervision of a physician as set forth in § 410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.

(c) *Nonphysician personnel.* Any non-physician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department.

In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(d) *Ordering of tests.* All procedures performed by the IDTF must be specifically ordered in writing by the physician who is treating the beneficiary, that is, the physician who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. (Nonphysician practitioners may order tests as set forth in § 410.32(a)(3).) The order must specify the diagnosis or other basis for the testing. The supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the IDTF's supervising physician is in fact the beneficiary's treating physician. That is, the physician in question had a relationship with the beneficiary prior to the performance of the testing and is treating the beneficiary for a specific medical problem. The IDTF may not add any procedures based on internal protocols without a written order from the treating physician.

(e) *Multi-State entities.* (1) An IDTF that operates across State boundaries must—

(i) Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it operates; and

(ii) Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

(2) The point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary's location, the beneficiary's location is the place of service. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the place of service.

(f) *Applicability of State law.* An IDTF must comply with the applicable laws of any State in which it operates.

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(g) *Application certification standards.* The IDTF must certify in its enrollment application that it meets the following standards and related requirements:

(1) Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.

(2) Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

(3) Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not considered an appropriate site.

(i) The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.

(ii) IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

(4) Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—

(i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;

(ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request.

(iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers and provide this information to the

designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

(5) Maintain a primary business phone under the name of the designated business. The IDTF must have its—

(i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.

(ii) Telephone or toll free telephone numbers available in a local directory and through directory assistance.

(6) Have a comprehensive liability insurance policy of at least \$300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must—

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least \$300,000 per incident; and

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations.

(7) Agree not to directly solicit patients, which include, but is not limited to, a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician, who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Nonphysician practitioners may order tests as set forth in § 410.32(a)(3).

(8) Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(9) Openly post these standards for review by patients and the public.

(10) Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.

(11) Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

(12) Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

(13) Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days.

(14) Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must—

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours.

(15) With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization;

(ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test

with another Medicare-enrolled individual or organization.

(16) Enrolls for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

(17) Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act.

(h) *Failure to meet standards.* If an IDTF fails to meet one or more of the standards in paragraph (g) of this section at the time of enrollment, its enrollment will be denied. CMS will revoke a supplier's billing privileges if and IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section.

(i) *Effective date of billing privileges.* The filing date of the Medicare enrollment application is the date that the Medicare contractor receives a signed provider enrollment application that it is able to process to approval. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by a Medicare fee-for-service contractor; or

(2) The date the IDTF first started furnishing services at its new practice location.

[62 FR 59099, Oct. 31, 1997, as amended at 64 FR 59440, Nov. 2, 1999; 71 FR 69784, Dec. 1, 2006; 72 FR 18914, Apr. 16, 2007; 72 FR 66398, Nov. 27, 2007; 73 FR 2432, Jan. 15, 2008; 73 FR 69933, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008]

**§ 410.34 Mammography services: Conditions for and limitations on coverage.**

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Diagnostic mammography* means a radiologic procedure furnished to a man or woman with signs or symptoms of breast disease, or a personal history of breast cancer, or a personal history of biopsy-proven benign breast disease, and includes a physician's interpretation of the results of the procedure.

(2) *Screening mammography* means a radiologic procedure furnished to a

woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure.

(3) *Supplier of diagnostic mammography* means a facility that is certified and responsible for ensuring that all diagnostic mammography services furnished to Medicare beneficiaries meet the conditions for coverage of diagnostic mammography services as specified in paragraph (b) of this section.

(4) *Supplier of screening mammography* means a facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in paragraphs (c) and (d) of this section.

(5) *Certificate* means the certificate described in 21 CFR 900.2(b) that may be issued to, or renewed for, a facility that meets the requirements for conducting an examination or procedure involving mammography.

(6) *Provisional certificate* means the provisional certificate described in 21 CFR 900.2(m) that may be issued to a facility to enable the facility to qualify to meet the requirements for conducting an examination or procedure involving mammography.

(7) The term *meets the certification requirements of section 354 of the Public Health Service (PHS) Act* means that in order to qualify for coverage of its services under the Medicare program, a supplier of diagnostic or screening mammography services must meet the following requirements:

(i) Must have a valid provisional certificate, or a valid certificate, that has been issued by FDA indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(ii) Has not been issued a written notification by FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.

(iii) Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).

(b) *Conditions for coverage of diagnostic mammography services.* Medicare Part B pays for diagnostic mammography services if they meet the following conditions:

(1) They are ordered by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(2) They are furnished by a supplier of diagnostic mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(c) *Conditions for coverage of screening mammography services.* Medicare Part B pays for screening mammography services if they are furnished by a supplier of screening mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(d) *Limitations on coverage of screening mammography services.* The following limitations apply to coverage of screening mammography services as described in paragraphs (c) and (d) of this section:

(1) The service must be, at a minimum a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of each breast.

(2) Payment may not be made for screening mammography performed on a woman under age 35.

(3) Payment may be made for only 1 screening mammography performed on a woman over age 34, but under age 40.

(4) For an asymptomatic woman over 39 years of age, payment may be made for a screening mammography performed after at least 11 months have passed following the month in which

the last screening mammography was performed.

[59 FR 49833, Sept. 30, 1994, as amended at 60 FR 14224, Mar. 16, 1995; 60 FR 63176, Dec. 8, 1995; 62 FR 59100, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998]

**§ 410.35 X-ray therapy and other radiation therapy services: Scope.**

Medicare Part B pays for X-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

[51 FR 41339, Nov. 14, 1986. Redesignated at 55 FR 53522, Dec. 31, 1990]

**§ 410.36 Medical supplies, appliances, and devices: Scope.**

(a) Medicare Part B pays for the following medical supplies, appliances and devices:

(1) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(2) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including—

(i) Replacement of prosthetic devices; and

(ii) One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted.

(3) Leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the individual's physical condition.

(b) The conditions of payment described in § 410.38(d) also apply to medical supplies, appliances, and devices.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 36014, Aug. 12, 1992; 57 FR 57688, Dec. 7, 1992; 84 FR 60801, Nov. 8, 2019]

**§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.**

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Colorectal cancer screening tests* means any of the following procedures furnished to an individual for the pur-

pose of early detection of colorectal cancer:

(i) Screening fecal-occult blood tests.

(ii) Screening flexible sigmoidoscopies.

(iii) Screening colonoscopies, including anesthesia furnished in conjunction with the service.

(iv) Screening barium enemas.

(v) Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations

(2) *Screening fecal-occult blood test* means—

(i) A guaiac-based test for peroxidase activity, testing two samples from each of three consecutive stools, or,

(ii) Other tests as determined by the Secretary through a national coverage determination.

(3) An *individual at high risk for colorectal cancer* means an individual with—

(i) A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;

(ii) A family history of familial adenomatous polyposis;

(iii) A family history of hereditary nonpolyposis colorectal cancer;

(iv) A personal history of adenomatous polyps; or

(v) A personal history of colorectal cancer; or

(vi) Inflammatory bowel disease, including Crohn's Disease, and ulcerative colitis.

(4) *Screening barium enema* means—

(i) A screening double contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure); or

(ii) In the case of an individual whose attending physician decides that he or she cannot tolerate a screening double contrast barium enema, a screening single contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure).

(5) An *attending physician for purposes of this provision* is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's

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medical condition, and who would be responsible using the results of any examination performed in the overall management of the beneficiary's specific medical problem.

(b) *Condition for coverage of screening fecal-occult blood tests.* Medicare Part B pays for a screening fecal-occult blood test if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist.

(c) *Limitations on coverage of screening fecal-occult blood tests.* (1) Payment may not be made for a screening fecal-occult blood test performed for an individual under age 50.

(2) For an individual 50 years of age or over, payment may be made for a screening fecal-occult blood test performed after at least 11 months have passed following the month in which the last screening fecal-occult blood test was performed.

(d) *Condition for coverage of flexible sigmoidoscopy screening.* Medicare Part B pays for a flexible sigmoidoscopy screening service if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act), or by a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act and §§410.74, 410.75, and 410.76) who is authorized under State law to perform the examination.

(e) *Limitations on coverage of screening flexible sigmoidoscopies.* (1) Payment may not be made for a screening flexible sigmoidoscopy performed for an individual under age 50.

(2) For an individual 50 years of age or over, except as described in paragraph (e)(3) of this section, payment may be made for screening flexible sigmoidoscopy after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy or, as provided in paragraphs (h) and (i) of this section, the last screening barium enema was performed.

(3) In the case of an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section but who has had a screening colonoscopy performed, payment may be made for a screening flexible sigmoidoscopy only after at least 119

months have passed following the month in which the last screening colonoscopy was performed.

(f) *Condition for coverage of screening colonoscopies.* Medicare Part B pays for a screening colonoscopy if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(g) *Limitations on coverage of screening colonoscopies.* (1) Effective for services furnished on or after July 1, 2001, except as described in paragraph (g)(3) of this section, payment may be made for a screening colonoscopy performed for an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section, after at least 119 months have passed following the month in which the last screening colonoscopy was performed.

(2) Payment may be made for a screening colonoscopy performed for an individual who is at high risk for colorectal cancer as described in paragraph (a)(3) of this section, after at least 23 months have passed following the month in which the last screening colonoscopy was performed, or, as provided in paragraphs (h) and (i) of this section, the last screening barium enema was performed.

(3) In the case of an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section but who has had a screening flexible sigmoidoscopy performed, payment may be made for a screening colonoscopy only after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy was performed.

(h) *Conditions for coverage of screening barium enemas.* Medicare Part B pays for a screening barium enema if it is ordered in writing by the beneficiary's attending physician.

(i) *Limitations on coverage of screening barium enemas.* (1) In the case of an individual age 50 or over who is not at high risk of colorectal cancer, payment may be made for a screening barium enema examination performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed.

(2) In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed.

[62 FR 59100, Oct. 31, 1997, as amended at 66 FR 55329, Nov. 1, 2001; 67 FR 80040, Dec. 31, 2002; 77 FR 69362, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014]

**§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.**

(a) *General scope.* Medicare Part B pays for durable medical equipment, including ventilators, oxygen equipment, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) *Institutions that may not qualify as the patient's home.* An institution that is used as a home may not be a hospital or a CAH or a SNF as defined in sections 1861(e)(1), 1861(mm)(1) and 1819(a)(1) of the Act, respectively.

(c) *Definitions.* As used in this section:

(1) *Physician* has the same meaning as in section 1861(r)(1) of the Act.

(2) *Treating practitioner* means physician as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

(3) *DMEPOS supplier* means an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(4) *Written Order/Prescription* is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS.

(5) *Face-to-face encounter* is an in-person or telehealth encounter between the treating practitioner and the beneficiary.

(6) *Power mobility device (PMD)* means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control

direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

(7) *Master List of DMEPOS items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements, also referred to as "Master List,"* are items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list are specified in § 414.234 of this chapter. The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.

(8) *Required Face-to-Face Encounter and Written Order Prior to Delivery List* is a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery. The list of items is published in the FEDERAL REGISTER and posted on the CMS website. The list is effective no less than 60 days following its publication. When selecting items from the Master List, CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis.

(d) *Conditions of Payment.* The requirements described in this paragraph (d) are conditions of payment applicable to DMEPOS items.

(1) *Written Order/Prescription.* All DMEPOS items require a written order/prescription for Medicare payment. Medicare Contractors shall consider the totality of the medical records when reviewing for compliance with standardized written order/prescription elements.

(i) *Elements.* A written order/prescription must include the following elements:

(A) Beneficiary Name or Medicare Beneficiary Identifier (MBI).

(B) General Description of the item.

(C) Quantity to be dispensed, if applicable.

(D) Order Date.

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(E) Treating Practitioner Name or National Provider Identifier (NPI).

(F) Treating Practitioner Signature.

(ii) *Timing of the Written Order/Prescription.*

(A) For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery.

(B) For all other DMEPOS, the written order/prescription must be communicated to the supplier prior to claim submission.

(2) *Items Requiring a Face-to-Face Encounter.* For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription.

(i) The encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(ii) If it is a telehealth encounter, the requirements of §§ 410.78 and 414.65 of this chapter must be met.

(3) *Documentation:* A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.

(i) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the DMEPOS item.

(ii) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used

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for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(e) *Suspension of face-to-face encounter and written order prior to delivery requirements.* CMS may suspend face-to-face encounter and written order prior to delivery requirements generally or for a particular item or items at any time and without undertaking rule-making, except those items for which inclusion on the Master List was statutorily imposed.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 57688, Dec. 7, 1992; 58 FR 30668, May 26, 1993; 70 FR 50946, Aug. 26, 2005; 71 FR 17030, Apr. 5, 2006; 77 FR 69362, Nov. 16, 2012; 84 FR 60802, Nov. 8, 2019]

### § 410.39 Prostate cancer screening tests: Conditions for and limitations on coverage.

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Prostate cancer screening tests* means any of the following procedures furnished to an individual for the purpose of early detection of prostate cancer:

(i) A screening digital rectal examination.

(ii) A screening prostate-specific antigen blood test.

(iii) For years beginning after 2002, other procedures CMS finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and other factors CMS considers appropriate.

(2) *A screening digital rectal examination* means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate.

(3) *A screening prostate-specific antigen blood test* means a test that measures the level of prostate-specific antigen in an individual's blood.

(4) A physician for purposes of this provision means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(5) A physician assistant, nurse practitioner, clinical nurse specialist, or



certified nurse midwife for purposes of this provision means a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in sections 1861(aa) and 1861(gg) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(b) *Condition for coverage of screening digital rectal examinations.* Medicare Part B pays for a screening digital rectal examination if it is performed by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to perform this service under State law.

(c) *Limitation on coverage of screening digital rectal examinations.* (1) Payment may not be made for a screening digital rectal examination performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening digital rectal examination only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening digital rectal examination was performed.

(d) *Condition for coverage of screening prostate-specific antigen blood tests.* Medicare Part B pays for a screening prostate-specific antigen blood test if it is ordered by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to order this test under State law.

(e) *Limitation on coverage of screening prostate-specific antigen blood test.* (1) Payment may not be made for a screening prostate-specific antigen blood test performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening prostate-specific antigen blood test only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last

Medicare-covered screening prostate-specific antigen blood test was performed.

[64 FR 59440, Nov. 2, 1999, as amended at 65 FR 19331, Apr. 11, 2000]

**§ 410.40 Coverage of ambulance services.**

(a) *Definitions.* As used in this section, the following definitions apply:

*Non-physician certification statement* means a statement signed and dated by an individual which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met and who meets all of the criteria in paragraphs (i) through (iii) of this definition. The statement need not be a stand-alone document and no specific format or title is required.

(i) Has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished;

(ii) Who must be employed:

(A) By the beneficiary's attending physician; or

(B) By the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported;

(iii) Is among the following individuals, with respect to whom all Medicare regulations and all applicable State licensure laws apply:

(A) Physician assistant (PA).

(B) Nurse practitioner (NP).

(C) Clinical nurse specialist (CNS).

(D) Registered nurse (RN).

(E) Licensed practical nurse (LPN).

(F) Social worker.

(G) Case manager.

(H) Discharge planner.

*Physician certification statement* means a statement signed and dated by the beneficiary's attending physician which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met. The statement need not be a stand-alone document and no specific format or title is required.

(b) *Basic rules.* Medicare Part B covers ambulance services if the following conditions are met:

(1) The supplier meets the applicable vehicle, staff, and billing and reporting requirements of § 410.41 and the service meets the medical necessity and origin

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and destination requirements of paragraphs (e) and (f) of this section.

(2) Medicare Part A payment is not made directly or indirectly for the services.

(c) *Levels of service.* Medicare covers the following levels of ambulance service, which are defined in § 414.605 of this chapter:

(1) Basic life support (BLS) (emergency and nonemergency).

(2) Advanced life support, level 1 (ALS1) (emergency and non-emergency).

(3) Advanced life support, level 2 (ALS2).

(4) Paramedic ALS intercept (PI).

(5) Specialty care transport (SCT).

(6) Fixed wing transport (FW).

(7) Rotary wing transport (RW).

(d) *Paramedic ALS intercept services.* Paramedic ALS intercept services must meet the following requirements:

(1) Be furnished in an area that is designated as a rural area by any law or regulation of the State or that is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification). (The Goldsmith Modification is a methodology to identify small towns and rural areas within large metropolitan counties that are isolated from central areas by distance or other features.)

(2) Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:

(i) Are certified to furnish ambulance services as required under § 410.41.

(ii) Furnish services only at the BLS level.

(iii) Be prohibited by State law from billing for any service.

(3) Be furnished by a paramedic ALS intercept supplier that meets the following conditions:

(i) Is certified to furnish ALS services as required in § 410.41(b)(2).

(ii) Bills all the beneficiaries who receive ALS intercept services from the entity, regardless of whether or not those beneficiaries are Medicare beneficiaries.

(e) *Medical necessity requirements*—(1) *General rule.* Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if

they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary. Nonemergency transportation by ambulance is appropriate if either: the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation. It is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bed-confined, the following criteria must be met:

(i) The beneficiary is unable to get up from bed without assistance.

(ii) The beneficiary is unable to ambulate.

(iii) The beneficiary is unable to sit in a chair or wheelchair.

(2) *Special rule for nonemergency, scheduled, repetitive ambulance services.*

(i) Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a physician certification statement dated no earlier than 60 days before the date the service is furnished.

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the signed physician certification statement does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

(3) *Special rule for nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis.* Medicare covers medically necessary nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive

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basis under one of the following circumstances:

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a physician certification statement within 48 hours after the transport.

(ii) For a beneficiary residing at home or in a facility who is not under the direct care of a physician. A physician certification is not required.

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a non-physician certification statement must be obtained.

(iv) If the ambulance provider or supplier is unable to obtain the required physician or non-physician certification statement within 21 calendar days following the date of the service, the ambulance provider or supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (e)(3)(iii) of this section.

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the physician or non-physician certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

(f) *Origin and destination requirements.* Medicare covers the following ambulance transportation:

(1) From any point of origin to the nearest hospital, CAH, or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, or SNF to the beneficiary's home.

(3) From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip.

(4) For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

(5) During a Public Health Emergency, as defined in § 400.200 of this chapter, a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with any applicable state or local Emergency Medical Services protocol that governs the destination location. Such destinations include, but are not limited to, alternative sites determined to be part of a hospital, critical access hospital or skilled nursing facility, community mental health centers, federally qualified health centers, rural health clinics, physician offices, urgent care facilities, ambulatory surgical centers, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

(g) *Specific limits on coverage of ambulance services outside the United States.* If services are furnished outside the United States, Medicare Part B covers ambulance transportation to a foreign hospital only in conjunction with the beneficiary's admission for medically necessary inpatient services as specified in subpart H of part 424 of this chapter.

[64 FR 3648, Jan. 25, 1999, as amended at 65 FR 13914, Mar. 15, 2000; 67 FR 9132, Feb. 27, 2002; 77 FR 69362, Nov. 16, 2012; 84 FR 63187, Nov. 15, 2019; 85 FR 19286, Apr. 6, 2020]

### § 410.41 Requirements for ambulance providers and suppliers.

(a) *Vehicle.* A vehicle used as an ambulance must meet the following requirements:

(1) Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle.

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(2) Be equipped with emergency warning lights and sirens, as required by State or local laws.

(3) Be equipped with telecommunications equipment as required by State or local law to include, at a minimum, one two-way voice radio or wireless telephone.

(4) Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by State or local laws.

(b) *Vehicle staff.* A vehicle furnishing ambulance services must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished, and at least one of the staff members must, for:

(1) *BLS vehicles.* (i) Be certified at a minimum as an emergency medical technician-basic by the State or local authority where the services are furnished; and

(ii) Be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle;

(2) *ALS vehicles.* (i) Meet the requirements of paragraph (b)(1) of this section; and

(ii) Be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

(c) *Billing and reporting requirements.* An ambulance supplier must comply with the following requirements:

(1) Bill for ambulance services using CMS-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification statement or non-physician certification statement is on file, if required.

(2) Upon a carrier's request, complete and return the ambulance supplier form designated by CMS and provide the Medicare carrier with documentation of compliance with emergency vehicle and staff licensure and certification requirements in accordance with State and local laws.

(3) Upon a carrier's request, provide additional information and documentation as required.

[64 FR 3648, Jan. 25, 1999, as amended at 80 FR 71373, Nov. 16, 2015; 84 FR 63188, Nov. 15, 2019]

### § 410.42 Limitations on coverage of certain services furnished to hospital outpatients.

(a) *General rule.* Except as provided in paragraph (b) of this section, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient (as defined in § 410.2) during an encounter (as defined in § 410.2) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to its patients. As used in this paragraph, the term "hospital" includes a CAH.

(b) *Exception.* The limitations stated in paragraph (a) of this section do not apply to the following services:

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

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

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

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

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

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

(7) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

[65 FR 18536, Apr. 7, 2000]

### § 410.43 Partial hospitalization services: Conditions and exclusions.

(a) Partial hospitalization services are services that—

(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization;

(3) Are furnished in accordance with a physician certification and plan of care as specified under § 424.24(e) of this chapter; and

(4) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.

(ii) Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.

(iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

(v) Individualized activity therapies that are not primarily recreational or diversionary.

(vi) Family counseling, the primary purpose of which is treatment of the individual's condition.

(vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

(viii) Diagnostic services.

(b) The following services are separately covered and not paid as partial hospitalization services:

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

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

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

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

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

(c) Partial hospitalization programs are intended for patients who—

(1) Require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care;

(2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the partial hospitalization program.

[59 FR 6577, Feb. 11, 1994, as amended at 65 FR 18536, Apr. 7, 2000; 72 FR 66399, Nov. 27, 2007; 73 FR 68811, Nov. 18, 2008]

**§ 410.45 Rural health clinic services: Scope and conditions.**

(a) Medicare Part B pays for the following rural health clinic services, if they are furnished in accordance with the requirements and conditions specified in part 405, subpart X, and part 491 of this chapter:

(1) Physicians' services.

(2) Services and supplies furnished as an incident to physicians' professional services.

(3) Nurse practitioner and physician assistant services.

(4) Services and supplies furnished as an incident to nurse practitioners' or physician assistants' services.

(5) Visiting nurse services.

(b) Medicare pays for rural health clinic services when they are furnished at the clinic, at a hospital or other medical facility, or at the beneficiary's place of residence.

**§ 410.46 Physician and other practitioner services furnished in or at the direction of an IHS or Indian tribal hospital or clinic: Scope and conditions.**

(a) Medicare Part B pays, in accordance with the physician fee schedule, for services furnished in or at the direction of a hospital or outpatient clinic (provider-based or free-standing) that is operated by the Indian Health Service (IHS) or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act). These

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services are subject to the same situations, terms, and conditions that would apply if the services were furnished in or at the direction of a hospital or clinic that is not operated by IHS or by an Indian tribe or tribal organization. Payments include health professional shortage areas incentive payments when the requirements for these incentive payments in §414.42 of this chapter are met.

(b) Payment is not made under this section to the extent that Medicare otherwise pays for the same services under other provisions.

(c) Payment is made under these provisions for the following services:

(1) Services for which payment is made under the physician fee schedule in accordance with part 414 of this chapter.

(2) Services furnished by non-physician practitioners for which payment under Part B is made under the physician fee schedule.

(3) Services furnished by a physical therapist or occupational therapist, for which payment under Part B is made under the physician fee schedule.

(d) Payments under these provisions will be paid to the IHS or tribal hospital or clinic.

[66 FR 55329, Nov. 1, 2001]

### §410.47 Pulmonary rehabilitation program: Conditions for coverage.

(a) *Definitions.* As used in this section:

*Individualized treatment plan* means a written plan established, reviewed, and signed by a physician every 30 days, that describes all of the following:

(i) The individual's diagnosis.

(ii) The type, amount, frequency, and duration of the items and services under the plan.

(iii) The goals set for the individual under the plan.

*Medical director* means the physician who oversees or supervises the PR program.

*Outcomes assessment* means a written evaluation of the patient's progress as it relates to the individual's rehabilitation which includes the following:

(i) Beginning and end evaluations, based on patient-centered outcomes, which are conducted by the physician at the start and end of the program.

(ii) Objective clinical measures of effectiveness of the PR program for the individual patient, including exercise performance and self-reported measures of shortness of breath and behavior.

*Physician* means a doctor of medicine or osteopathy as defined in section 1861(r)(1) of the Act.

*Physician-prescribed exercise* means physical activity, including aerobic exercise, prescribed and supervised by a physician that improves or maintains an individual's pulmonary functional level.

*Psychosocial assessment* means a written evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation or respiratory condition.

*Pulmonary rehabilitation* means a physician-supervised program for COPD and certain other chronic respiratory diseases designed to optimize physical and social performance and autonomy.

*Supervising physician* means a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished under the PR program.

(b) *Beneficiaries who may be covered.*

(1) Medicare covers pulmonary rehabilitation for beneficiaries with moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease.

(2) Additional medical indications for coverage for pulmonary rehabilitation program services may be established through a national coverage determination (NCD).

(c) *Components.* Pulmonary rehabilitation includes all of the following components:

(1) *Physician-prescribed exercise.* This physical activity includes techniques such as exercise conditioning, breathing retraining, step, and strengthening exercises. Some aerobic exercise must be included in each pulmonary rehabilitation session.

(2) *Education or training.* (i) Education or training closely and clearly related to the individual's care and treatment which is tailored to the individual's needs.

(ii) Education includes information on respiratory problem management and, if appropriate, brief smoking cessation counseling.

(iii) Any education or training prescribed must assist in achievement of individual goals towards independence in activities of daily living, adaptation to limitations and improved quality of life.

(3) *Psychosocial assessment.* The psychosocial assessment must meet the criteria as defined in paragraph (a) of this section and includes:

(i) An assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment.

(ii) A psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

(4) *Outcomes assessment.* The outcomes assessment must meet the criteria as defined in paragraph (a) of this section.

(5) *Individualized treatment plan.* The individualized treatment plan must be established, reviewed, and signed by a physician, who is involved in the patient's care and has knowledge related to his or her condition, every 30 days.

(d) *Settings.* (1) Medicare Part B pays for a pulmonary rehabilitation in the following settings:

(i) Physician's offices.

(ii) Hospital outpatient settings.

(2) All settings must have the following available for immediate use and accessible at all times:

(i) The necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary (for example, oxygen, cardiopulmonary resuscitation equipment, and defibrillator) to treat chronic respiratory disease.

(ii) A physician must be immediately available and accessible for medical consultations and emergencies at all times when services are being provided under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services at § 410.26 of this subpart and for hospital outpatient services at § 410.27 of this subpart.

(e) *Physician standards.* Medicare Part B pays for pulmonary rehabilitation services for PR programs supervised by a physician who meets the following requirements—

(1) Is responsible and accountable for the pulmonary rehabilitation program, including oversight of the PR staff.

(2) Is involved substantially, in consultation with staff, in directing the progress of the individual in the program including direct patient contact related to the periodic review of his or her treatment plan.

(3) Has expertise in the management of individuals with respiratory pathophysiology, and cardiopulmonary training and/or certification including basic life support.

(4) Is licensed to practice medicine in the State in which the pulmonary rehabilitation program is offered.

(f) *Limitations on coverage: Sessions.* Medicare Part B pays for services provided in connection with a pulmonary rehabilitation exercise program for up to 36 sessions, no more than two sessions per day. Up to an additional 36 sessions may be approved by the Medicare contractor, based on medical necessity in accordance with section 1862(a)(1)(A) of the Act.

(g) *Effective date.* Coverage for pulmonary rehabilitation program services is effective January 1, 2010.

[74 FR 62002, Nov. 25, 2009]

#### § 410.48 Kidney disease education services.

(a) *Definitions.* As used in this section:

*Kidney disease patient education services* means face-to-face educational services provided to patients with Stage IV chronic kidney disease.

*Physician* means a physician as defined in section 1861(r)(1) of the Act.

*Qualified person* means either of the following healthcare entities that meets the qualifications and requirements specified in this section to provide kidney disease patient education services—

(i) One of the following healthcare professionals who furnishes services for which payment may be made under the physician fee schedule:

(A) Physician (as defined in section 1861(r)(1) of the Act).

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(B) Physician assistant as defined in section 1861(aa)(5) of the Act and § 410.74 of this subpart).

(C) Nurse practitioner as defined in section 1861(aa)(5) of the Act and § 410.75 of this subpart).

(D) Clinical nurse specialist (as defined in section 1861(aa)(5) of the Act and § 410.76 of this subpart),

(ii)(A) A hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that is located in a rural area as defined in § 412.64(b)(ii)(C) of this chapter; or

(B) A hospital or critical access hospital that is treated as being rural under § 412.103 of this chapter.

*Renal dialysis facility* means a unit, which is approved to furnish dialysis service(s) directly to end-stage renal disease (ESRD) patients, as defined in § 405.2102 of this chapter.

*Stage IV chronic kidney disease* means kidney damage with a severe decrease in glomerular filtration rate (GFR) quantitatively defined by a GFR value of 15–29 ml/min/1.73m<sup>2</sup>, using the Modification of Diet in Renal Disease (MDRD) Study formula.

(b) *Covered beneficiaries.* Medicare Part B covers outpatient kidney disease patient education services if the beneficiary meets all of the conditions and requirements of this subpart, including all of the following:

(1) Is diagnosed with Stage IV chronic kidney disease.

(2) Obtains a referral from the physician (as defined in section 1861(r)(1) of the Act) managing the beneficiary's kidney condition.

(c) *Qualified person.* (1) Medicare Part B covers outpatient kidney disease patient education services provided by a qualified person as defined in paragraph (a) of this section and must be able to properly receive Medicare payment under part 424 of this chapter.

(2) A qualified person does not include either of the following:

(i) A hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency or hospice if kidney disease patient education services are provided outside of a rural area as defined in § 412.64(b)(ii)(C) of

this chapter unless the services are furnished in a hospital or critical access hospital that is treated as being in a rural area under § 412.103 of this chapter.

(ii) A renal dialysis facility, as defined in § 405.2102 of this chapter.

(d) *Standards for content of kidney disease patient education services.* The content of the kidney disease patient education services includes the following:

(1) The management of comorbidities including for the purpose of delaying the need for dialysis which includes, but not limited to, the following topics:

(i) Prevention and treatment of cardiovascular disease.

(ii) Prevention and treatment of diabetes.

(iii) Hypertension management.

(iv) Anemia management.

(v) Bone disease and disorders of calcium and phosphorus metabolism management.

(vi) Symptomatic neuropathy management.

(vii) Impairments in functioning and well-being.

(2) The prevention of uremic complications which includes, but not limited to, the following topics:

(i) Information on how the kidneys work and what happens when the kidneys fail.

(ii) Understanding if remaining kidney function can be protected, preventing disease progression, and realistic chances of survival.

(iii) Diet and fluid restrictions.

(iv) Medication review, including how each medication works, possible side effects and minimization of side effects, the importance of compliance, and informed decision-making if the patient decides not to take a specific drug.

(3) Therapeutic options, treatment modalities, and settings, including a discussion of the advantages and disadvantages of each treatment option and how the treatments replace the kidney, which includes, but not limited to, the following topics:

(i) Hemodialysis, both at home and in-facility.



(ii) Peritoneal dialysis (PD), including intermittent PD, continuous ambulatory PD, and continuous cycling PD, both at home and in-facility.

(iii) All dialysis access options for hemodialysis and peritoneal dialysis.

(iv) Transplantation.

(4) Opportunities for beneficiaries to actively participate in the choice of therapy and be tailored to meet the needs of the individual beneficiary involved which includes, but not limited to, the following topics:

(i) Physical symptoms.

(ii) Impact on family and social life.

(iii) Exercise.

(iv) The right to refuse treatment.

(v) Impact on work and finances.

(vi) The meaning of test results.

(vii) Psychological impact.

(5) Qualified persons must develop outcomes assessments designed to measure beneficiary knowledge about chronic kidney disease and its treatment.

(i) The outcomes assessments serve to assess program effectiveness of preparing the beneficiary to make informed decisions about their healthcare options related to chronic kidney disease.

(ii) The outcomes assessments serve to assess the program's effectiveness in meeting the communication needs of underserved populations, including persons with disabilities, persons with limited English proficiency, and persons with health literacy needs.

(iii) The assessment must be administered to the beneficiary during a kidney disease education session.

(iv) The outcomes assessments must be made available to CMS upon request.

(e) *Limitations for coverage of kidney disease education services.* (1) Medicare Part B makes payment for up to 6 sessions of kidney disease patient education services.

(2) A session is 1 hour long and may be provided individually or in group settings of 2 to 20 individuals who need not all be Medicare beneficiaries.

(f) *Effective date.* Medicare Part B covers kidney disease patient education services for dates of service on or after January 1, 2010.

[74 FR 62003, Nov. 25, 2009]

**§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.**

(a) *Definitions.* As used in this section:

*Cardiac rehabilitation (CR)* means a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

*Individualized treatment plan* means a written plan tailored to each individual patient that includes all of the following:

(i) A description of the individual's diagnosis.

(ii) The type, amount, frequency, and duration of the items and services furnished under the plan.

(iii) The goals set for the individual under the plan.

*Intensive cardiac rehabilitation (ICR) program* means a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in paragraph (c) of this section.

*Intensive cardiac rehabilitation site* means a hospital outpatient setting or physician's office that is providing intensive cardiac rehabilitation utilizing an approved ICR program.

*Medical director* means a physician that oversees or supervises the cardiac rehabilitation or intensive cardiac rehabilitation program at a particular site.

*Outcomes assessment* means an evaluation of progress as it relates to the individual's rehabilitation which includes all of the following:

(i) Minimally, assessments from the commencement and conclusion of cardiac rehabilitation and intensive cardiac rehabilitation, based on patient-centered outcomes which must be measured by the physician immediately at the beginning of the program and at the end of the program.

(ii) Objective clinical measures of exercise performance and self-reported measures of exertion and behavior.

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*Physician* means a doctor of medicine or osteopathy as defined in section 1861(r)(1) of the Act.

*Physician-prescribed exercise* means aerobic exercise combined with other types of exercise (that is, strengthening, stretching) as determined to be appropriate for individual patients by a physician.

*Psychosocial assessment* means an evaluation of an individual’s mental and emotional functioning as it relates to the individual’s rehabilitation which includes an assessment of those aspects of an individual’s family and home situation that affects the individual’s rehabilitation treatment, and psychosocial evaluation of the individual’s response to and rate of progress under the treatment plan.

*Supervising physician* means a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs.

(b) *General rule*—(1) *Covered beneficiary rehabilitation services.* Medicare part B covers cardiac rehabilitation and intensive cardiac rehabilitation program services for beneficiaries who have experienced one or more of the following:

- (i) An acute myocardial infarction within the preceding 12 months;
- (ii) A coronary artery bypass surgery;
- (iii) Current stable angina pectoris;
- (iv) Heart valve repair or replacement;
- (v) Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;
- (vi) A heart or heart-lung transplant.
- (vii) Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014 for cardiac rehabilitation and on or after February 9, 2018 for intensive cardiac rehabilitation; or
- (viii) Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process

may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

(2) *Components of a cardiac rehabilitation program and an intensive cardiac rehabilitation program.* Cardiac rehabilitation programs and intensive cardiac rehabilitation programs must include all of the following:

- (i) Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished.
- (ii) Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the patients’ individual needs.
- (iii) Psychosocial assessment.
- (iv) Outcomes assessment.
- (v) An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

(3) *Settings.* (i) Medicare Part B pays for cardiac rehabilitation and intensive cardiac rehabilitation in one of the following settings:

- (A) A physician’s office.
- (B) A hospital outpatient setting.

(ii) All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services, at §410.26 of this subpart; and for hospital outpatient services at §410.27 of this subpart.

(c) *Standards for an intensive cardiac rehabilitation program.* (1) To be approved as an intensive cardiac rehabilitation program, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients:

- (i) Positively affected the progression of coronary heart disease.
  - (ii) Reduced the need for coronary bypass surgery.
  - (iii) Reduced the need for percutaneous coronary interventions;
- (2) An intensive cardiac rehabilitation program must also demonstrate

through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

- (i) Low density lipoprotein.
- (ii) Triglycerides.
- (iii) Body mass index.
- (iv) Systolic blood pressure.
- (v) Diastolic blood pressure.
- (vi) The need for cholesterol, blood pressure, and diabetes medications.

(3) A list of approved intensive cardiac rehabilitation programs, identified through the national coverage determination process, will be posted to the CMS Web site and listed in the FEDERAL REGISTER.

(4) All prospective intensive cardiac rehabilitation sites must apply to enroll as an intensive cardiac rehabilitation program site using the designated forms as specified at § 424.510 of this chapter. For purposes of appealing an adverse determination concerning site approval, an intensive cardiac rehabilitation site is considered a supplier (or prospective supplier) as defined in § 498.2 of this chapter.

(d) *Standards for the physician responsible for cardiac rehabilitation program.* A physician responsible for a cardiac rehabilitation program or intensive cardiac rehabilitation programs is identified as the medical directors. The medical director, in consultation with staff, are involved in directing the progress of individuals in the program, must possess all of the following:

(1) Expertise in the management of individuals with cardiac pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the cardiac rehabilitation program is offered.

(e) *Standards for supervising-physicians.* Physicians acting as the supervising-physician must possess all of the following:

(1) Expertise in the management of individuals with cardiac pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the cardiac rehabilitation program is offered.

(f) *Limitations for coverage of cardiac rehabilitation programs.* (1) *Cardiac Rehabilitation:* The number of cardiac rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare contractor under section 1862(a)(1)(A) of the Act.

(2) *Intensive Cardiac Rehabilitation:* Intensive cardiac rehabilitation program sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

[74 FR 62003, Nov. 25, 2009, as amended at 84 FR 63188, Nov. 15, 2019]

#### § 410.50 Institutional dialysis services and supplies: Scope and conditions.

Medicare Part B pays for the following institutional dialysis services and supplies if they are furnished in approved ESRD facilities:

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary and the treatment of the patient for ESRD and, as of January 1, 2011, renal dialysis services as defined in § 413.171 of this chapter.

(b) Routine dialysis monitoring tests (i.e., hematocrit and clotting time) used by the facility to monitor the patients' fluids incident to each dialysis treatment, when performed by qualified staff of the facility under the direction of a physician, as provided in § 494.130 of this chapter, even if the facility does not meet the conditions for coverage of services of independent laboratories in part 494 of this chapter.

(c) Routine diagnostic tests.

(d) Epoetin (EPO) and its administration.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994; 73 FR 20474, Apr. 15, 2008; 75 FR 49197, Aug. 12, 2010]

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### § 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:

(1) Purchase or rental, installation, and maintenance of all dialysis equipment necessary for home dialysis, and reconditioning of this equipment. Dialysis equipment includes, but is not limited to, artificial kidney and automated peritoneal dialysis machines, and support equipment such as blood pumps, bubble detectors, and other alarm systems.

(2) Items and supplies required for dialysis, including (but not limited to) dialyzers, syringes and needles, forceps, scissors, scales, sphygmomanometer with cuff and stethoscope, alcohol wipes, sterile drapes, and rubber gloves.

(3) Home dialysis support services furnished by an approved ESRD facility, including periodic monitoring of the patient's home adaptation, emergency visits by qualified provider or facility personnel, any of the tests specified in paragraphs (b) through (d) of § 410.50, personnel costs associated with the installation and maintenance of dialysis equipment, testing and appropriate treatment of water, and ordering of supplies on an ongoing basis.

(4) On or after July 1, 1991, erythropoiesis-stimulating agents for use at home by a home dialysis patient and, on or after January 1, 1994, by a dialysis patient, if it has been determined, in accordance with § 494.90(a)(4) of this chapter, that the patient is competent to use the drug safely and effectively.

(b) Home dialysis support services specified in paragraph (a)(3) of this section must be furnished in accordance with a written treatment plan that is prepared and reviewed by a team consisting of the individual's physician and other qualified professionals. (Section 494.90 of this chapter contains details on patient plans of care).

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 26959, May 25, 1994; 73 FR 20474, Apr. 15, 2008]

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### § 410.55 Services related to kidney donations: Conditions.

Medicare Part B pays for medical and other health services covered under this subpart that are furnished in connection with a kidney donation—

(a) If the kidney is intended for an individual who has end-stage renal disease and is entitled to Medicare benefits; and

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

### § 410.56 Screening pelvic examinations.

(a) *Conditions for screening pelvic examinations.* Medicare Part B pays for a screening pelvic examination (including a clinical breast examination) if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act), or by a certified nurse midwife (as defined in section 1861(gg) of the Act), or a physician assistant, nurse practitioner, or clinic nurse specialist (as defined in section 1861(aa) of the Act) who is authorized under State law to perform the examination.

(b) *Limits on coverage of screening pelvic examinations.* The following limitations apply to coverage of screening pelvic examination services:

(1) *General rule.* Except as specified in paragraphs (b)(2) and (b)(3) of this section, payment may be made for a pelvic examination performed on an asymptomatic woman only if the individual has not had a pelvic examination paid for by Medicare during the preceding 23 months following the month in which her last Medicare-covered screening pelvic examination was performed.

(2) *More frequent screening based on high-risk factors.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner specified in paragraph (a) of this section, and there is evidence that the woman is at high risk (on the basis of her medical history or other findings) of developing cervical cancer or vaginal cancer, as determined in accordance with the following risk factors:

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(i) High risk factors for cervical cancer:

(A) Early onset of sexual activity (under 16 years of age).

(B) Multiple sexual partners (five or more in a lifetime).

(C) History of a sexually transmitted disease (including HIV infection).

(D) Absence of three negative or any Pap smears within the previous 7 years.

(ii) High risk factor for vaginal cancer: DES (diethylstilbestrol)-exposed daughters of women who took DES during pregnancy.

(3) *More frequent screening for women of childbearing age.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner as specified in paragraph (a) of this section for a woman of childbearing age who has had an examination that indicated the presence of cervical or vaginal cancer or other abnormality during any of the preceding 3 years. The term “woman of childbearing age” means a woman who is premenopausal, and has been determined by a physician, or a qualified practitioner, as specified in paragraph (a) of this section, to be of childbearing age, based on her medical history or other findings.

(4) *Limitation applicable to women at high risk and those of childbearing age.* Payment is not made for a screening pelvic examination for women considered to be at high risk (under any of the criteria described in paragraph (b)(2) of this section), or who qualify for coverage under the childbearing provision (under the criteria described in paragraph (b)(3) of this section) more frequently than once every 11 months after the month that the last screening pelvic examination covered by Medicare was performed.

[62 FR 59101, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998, as amended at 66 FR 55329, Nov. 1, 2001]

**§ 410.57 Pneumococcal vaccine and flu vaccine.**

(a) Medicare Part B pays for pneumococcal vaccine and its administration when reasonable and necessary for the

prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.

(b) Medicare Part B pays for the influenza virus vaccine and its administration.

[63 FR 35066, June 26, 1998]

**§ 410.58 Additional services to HMO and CMP enrollees.**

Services not usually covered under Medicare Part B may be covered as medical and other health services if they are furnished to an enrollee of an HMO or a CMP and the following conditions are met:

(a) The services are—

(1) Furnished by a physician assistant or nurse practitioner as defined in § 491.2 of this chapter, or are incident to services furnished by such a practitioner; or

(2) Furnished by a clinical psychologist as defined in § 417.416 of this chapter to an enrollee of an HMO or CMP that participates in Medicare under a risk-sharing contract, or are incident to those services.

(b) The services are services that would be covered under Medicare Part B if they were furnished by a physician or as incident to a physician’s professional services.

**§ 410.59 Outpatient occupational therapy services: Conditions.**

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient occupational therapy services only if they are furnished by an individual meeting the qualifications in part 484 of this chapter for an occupational therapist or an appropriately supervised occupational therapy assistant but only under the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.

(3) They are furnished—

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(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By, or under the direct supervision of, an occupational therapist in private practice as described in paragraph (c) of this section; or

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform occupational therapy services within the scope of State law. When an occupational therapy service is provided incident to the service of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to occupational therapy and occupational therapists, except that a license to practice occupational therapy in the State is not required.

(4) Effective for dates of service on and after January 1, 2020, for occupational therapy services described in paragraph (a)(3)(i) or (ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by an occupational therapy assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, “furnished in whole or in part” means when the occupational therapy assistant either:

(A) Furnishes all the minutes of a service exclusive of the occupational therapist; or

(B) Furnishes a portion of a service separately from the part furnished by the occupational therapist such that the minutes for that portion of a service furnished by the occupational therapy assistant exceed 10 percent of the total minutes for that service.

(b) *Conditions for coverage of outpatient therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient occupational therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by occupational therapists in private practice—*(1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient occupational therapy services, each individual occupational therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of occupational therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient’s home. A therapist’s private practice office space refers to the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient’s home does not include any institution that is a hospital, an CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of occupational therapy services.* Occupational therapy services are performed by, or under the direct supervision of, an occupational therapist in private practice. All services

not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services.

(d) *Excluded services.* No service is included as an outpatient occupational therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses.* (1) Amount of limitation. (i) In 1999, 2000, and 2001, no more than \$1,500 of allowable charges incurred in a calendar year for outpatient occupational therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation is determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

(iv) Outpatient occupational therapy services furnished by a CAH directly or under arrangements must be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is no longer applied as a limitation on incurred expenses for outpatient occupational therapy services, but, is instead applied as a threshold above which claims for occupational therapy services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient occupational therapy includes:

(i) Outpatient occupational therapy services furnished under this section;

(ii) Outpatient occupational therapy services furnished by a comprehensive outpatient rehabilitation facility;

(iii) Outpatient occupational therapy services furnished by a physician or incident to a physician's service;

(iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(v) Outpatient occupational therapy services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished under section 1834(k)(1)(B) of the Act.

(3) A process for medical review of claims for outpatient occupational therapy services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at or in excess of \$3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the \$3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the \$3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process applies when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, \$3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with \$3,000 in 2027) by the increase in the Medicare Economic Index for the current year.

[63 FR 58906, Nov. 2, 1998, as amended at 67 FR 80040, Dec. 31, 2002; 69 FR 66421, Nov. 15, 2004; 72 FR 66399, Nov. 27, 2007; 77 FR 69363, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 83 FR 60073, Nov. 23, 2018; 84 FR 63188, Nov. 15, 2019]

#### **§ 410.60 Outpatient physical therapy services: Conditions.**

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient physical therapy services only if they are furnished by an individual meeting the qualifications in part 484 of this

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chapter for a physical therapist or an appropriately supervised physical therapist assistant but only under the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.

(3) They are furnished—

(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By, or under the direct supervision of a physical therapist in private practice as described in paragraph (c) of this section; or

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform physical therapy services under State law. When a physical therapy service is provided incident to the service of a physician, physician's assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to physical therapy and physical therapists, except that a license to practice physical therapy in the State is not required.

(4) Effective for dates of service on and after January 1, 2020, for physical therapy services described in paragraphs (a)(3)(i) or (ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by a physical therapist assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, “furnished in whole or in part” means

when the physical therapist assistant either:

(A) Furnishes all the minutes of a service exclusive of the physical therapist; or

(B) Furnishes a portion of a service separately from the part furnished by the physical therapist such that the minutes for that portion of a service furnished by the physical therapist assistant exceed 10 percent of the total minutes for that service.

(b) *Condition for coverage of outpatient physical therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient physical therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise + ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by physical therapists in private practice—(1) Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient physical therapy services, each individual physical therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of physical therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of physical therapy on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any



institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of physical therapy services.* Physical therapy services are performed by, or under the direct supervision of, a physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services.

(d) *Excluded services.* No service is included as an outpatient physical therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses—(1) Amount of limitation.* (i) In 1999, 2000, and 2001, no more than \$1,500 of allowable charges incurred in a calendar year for outpatient physical therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation shall be determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

(iv) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements must be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is not applied as a limitation on incurred expenses for outpatient physical therapy and outpatient speech-language pathology services, but is instead applied as a threshold above which claims for physical therapy and speech-language pathology services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record; and

claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient physical therapy includes:

(i) Outpatient physical therapy services furnished under this section;

(ii) Outpatient speech-language pathology services furnished under § 410.62;

(iii) Outpatient physical therapy and speech-language pathology services furnished by a comprehensive outpatient rehabilitation facility;

(iv) Outpatient physical therapy and speech-language pathology services furnished by a physician or incident to a physician's service;

(v) Outpatient physical therapy and speech-language pathology services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(vi) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished and paid under section 1834(k)(1)(B) of the Act.

(3) A process for medical review of claims for physical therapy and speech-language pathology services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at or in excess of \$3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the \$3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the \$3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, \$3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the

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medical review threshold in effect for the previous year (starting with \$3,000 for 2017) by the increase in the Medicare Economic Index for the current year.

[63 FR 58906, Nov. 2, 1998, as amended at 67 FR 80041, Dec. 31, 2002; 69 FR 66422, Nov. 15, 2004; 72 FR 66399, Nov. 27, 2007; 77 FR 69363, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 83 FR 60073, Nov. 23, 2018; 84 FR 63188, Nov. 15, 2019]

### §410.61 Plan of treatment requirements for outpatient rehabilitation services.

(a) *Basic requirement.* Outpatient rehabilitation services (including services furnished by a qualified physical or occupational therapist in private practice), must be furnished under a written plan of treatment that meets the requirements of paragraphs (b) through (e) of this section.

(b) *Establishment of the plan.* The plan is established before treatment is begun by one of the following:

- (1) A physician.
- (2) A physical therapist who furnishes the physical therapy services.
- (3) A speech-language pathologist who furnishes the speech-language pathology services.
- (4) An occupational therapist who furnishes the occupational therapy services.
- (5) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(c) *Content of the plan.* The plan 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 indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan—

- (1) Are made in writing and signed by one of the following:
  - (i) The physician.
  - (ii) The physical therapist who furnishes the physical therapy services.
  - (iii) The occupational therapist that furnishes the occupational therapy services.
  - (iv) The speech-language pathologist who furnishes the speech-language pathology services.
  - (v) A registered professional nurse or a staff physician, in accordance with

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oral orders from the physician, physical therapist, occupational therapist, or speech-language pathologist who furnishes the services.

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

(2) The changes are incorporated in the plan immediately.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 54 FR 38680, Sept. 20, 1989; 54 FR 46614, Nov. 6, 1989. Redesignated at 56 FR 8854, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 63 FR 58907, Nov. 2, 1998; 67 FR 80040, Dec. 31, 2002; 72 FR 66399, Nov. 27, 2007; 77 FR 69363, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018]

### §410.62 Outpatient speech-language pathology services: Conditions and exclusions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(ii) of this section, Medicare Part B pays for outpatient speech-language pathology services only if they are furnished by an individual who meets the qualifications for a speech-language pathologist in §484.115 of this chapter and only under the following conditions:

- (1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine or osteopathy.
- (2) They are furnished under a written plan of treatment that meets the requirements of §410.61.
- (3) They are furnished by one of the following:

- (i) A provider as defined in §489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider.

- (ii) A speech-language pathologist in private practice as described in paragraph (c) of this section.

- (iii) Incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform speech-language pathology services under State law. When a speech-language pathology service is provided incident to the services of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that

apply to speech-language pathology and speech-language pathologists, except that a license to practice speech-language pathology services in the State is not required.

(b) *Condition for coverage of outpatient speech-language pathology services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient speech-language pathology services furnished to an inpatient of a hospital, CAH, or SNF who requires the services but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by speech-language pathologists in private practice—(1) Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient speech-language pathology services, each individual speech-language pathologist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of speech-language pathology by the State in which he or she practices, and practice only within the scope of his or her license and/or certification.

(ii) Engage in the private practice of speech-language pathology on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

(iii) Bill Medicare only for services furnished in one of the following:

(A) A speech-language pathologist's private practice office space that meets all of the following:

(1) The location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services and during the hours that the therapist engages in practice at that location.

(2) The space must be owned, leased, or rented by the practice, and used for the exclusive purpose of operating the practice.

(B) A patient's home not including any institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(d) *Excluded services.* No service is included as an outpatient speech-language pathology service if it is not included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 58 FR 30668, May 26, 1993; 63 FR 58907, Nov. 2, 1998; 69 FR 66422, Nov. 15, 2004; 73 FR 69933, Nov. 19, 2008; 76 FR 73470, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 79 FR 68002, Nov. 13, 2014; 82 FR 4578, Jan. 13, 2017; 83 FR 60073, Nov. 23, 2018]

#### § 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

Notwithstanding the exclusion from coverage of vaccines (see § 405.310 of this chapter) and self-administered drugs (see § 410.29), the following services are included as medical and other health services covered under § 410.10, subject to the specified conditions:

(a) *Hepatitis B vaccine: Conditions.* Effective September 1, 1984, hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals who are at high or intermediate risk of contracting hepatitis B as listed below:

(1) *High risk groups.* (i) End-Stage Renal Disease (ESRD) patients;

(ii) Hemophiliacs who receive Factor VIII or IX concentrates;

(iii) Clients of institutions for individuals with intellectual disabilities;

(iv) Persons who live in the same household as a hepatitis B carrier;

(v) Homosexual men;

(vi) Illicit injectable drug abusers;

(vii) Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii); and

(viii) Persons diagnosed with diabetes mellitus.

(2) *Intermediate risk groups.* (i) Staff in institutions for individuals with intellectual disabilities and classroom employees who work with individuals with intellectual disabilities;

(ii) Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work (including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions); and

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(iii) Heterosexually active persons with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years).

(3) *Exception.* Individuals described in paragraphs (a) (1) and (2) of this section are not considered at high or intermediate risk of contracting hepatitis B if they have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B.

(b) *Blood clotting factors: Conditions.* Effective July 18, 1984, blood clotting factors to control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

(c) *Blood clotting factors: Furnishing Fee.* (1) Effective January 1, 2005, a furnishing fee of \$0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay.

(2) The furnishing fee for blood clotting factors furnished in 2006 or a subsequent year is be equal to the furnishing fee paid the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

[55 FR 22790, June 4, 1990; 55 FR 31186, Aug. 1, 1990, as amended at 69 FR 66422, Nov. 15, 2004; 77 FR 69363, Nov. 16, 2012]

## §410.64 Additional preventive services.

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services”

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under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.

(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.

(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

[73 FR 69933, Nov. 19, 2008, as amended at 75 FR 73615, Nov. 29, 2010]

## §410.66 Emergency outpatient services furnished by a nonparticipating hospital and services furnished in a foreign country.

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 48136, Aug. 18, 2006]

## §410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

(a) *Basis and scope.* (1) *Basis.* This section implements sections 1861(jjj), 1861(s)(2)(HH), 1833(a)(1)(CC) and 1834(w) of the Act which provide for coverage of opioid use disorder treatment services furnished by an opioid treatment program and the payment of a bundled payment under Part B to an opioid treatment program for opioid use disorder treatment services that are furnished to a beneficiary during an episode of care beginning on or after January 1, 2020.

(2) *Scope.* This section sets forth the criteria for an opioid treatment program, the scope of opioid use disorder treatment services, and the methodology for determining the bundled payments to opioid treatment programs for furnishing opioid use disorder treatment services.

(b) *Definitions.* For purposes of this section, the following definitions apply:

*Episode of care* means a one-week (contiguous 7-day) period.

*Opioid treatment program* means an entity that is an opioid treatment program (as defined in § 8.2 of this title, or any successor regulation) that meets the requirements described in paragraph (c) of this section.

*Opioid use disorder treatment service* means one of the following items or services for the treatment of opioid use disorder that is furnished by an opioid treatment program that meets the requirements described in paragraph (c) of this section.

(1) Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug, and Cosmetic Act for use in treatment of opioid use disorder.

(2) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.

(3) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, where audio/video communication technology is not available to the beneficiary, the counseling services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(4) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate,

and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, where audio/video communication technology is not available to the beneficiary, the therapy services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(5) Toxicology testing.

(6) Intake activities, including initial medical examination services required under § 8.12(f)(2) of this title and initial assessment services required under § 8.12(f)(4) of this title.

(7) Periodic assessment services required under § 8.12(f)(4) of this title. During the Public Health Emergency for the COVID-19 pandemic, as defined in § 400.200 of this chapter, these periodic assessments can be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all other applicable requirements. In cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology if all other applicable requirements are met.

(c) *Requirements for opioid treatment programs.* To participate in the Medicare program and receive payment, an opioid treatment program must meet all of the following:

(1) Be enrolled in the Medicare program.

(2) Have in effect a certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the opioid treatment program.

(3) Be accredited by an accrediting body approved by the SAMHSA.

(4) Have in effect a provider agreement under part 489 of this title.

(d) *Bundled payments for opioid use disorder treatment services furnished by opioid treatment programs.*

(1) CMS will establish categories of bundled payments for opioid treatment programs for an episode of care as follows:

(i) Categories for each type of opioid agonist and antagonist treatment medication;

(ii) A category for medication not otherwise specified, which will be used for new FDA-approved opioid agonist or antagonist treatment medications for which CMS has not established a category; and

(iii) A category for episodes of care in which no medication is provided.

(2) The bundled payment for episodes of care in which a medication is provided consists of payment for a drug component, reflecting payment for the applicable FDA-approved opioid agonist or antagonist medication in the patient's treatment plan, and a non-drug component, reflecting payment for all other opioid use disorder treatment services reflected in the patient's treatment plan (including dispensing/administration of the medication, if applicable). The payments for the drug component and non-drug component are added together to create the bundled payment amount. The bundled payment for episodes of care in which no medication is provided consists of a single payment amount for all opioid use disorder treatment services reflected in the patient's treatment plan (excluding medication and dispensing/administration of medication).

(i) *Drug component.* The payment for the drug component for an episode of care will be determined as follows, using the most recent data available at time of ratesetting for the applicable calendar year:

(A) For implantable and injectable medications, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount shall be 100 percent of the ASP, if ASP is used.

(B) For oral medications, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in part 414, subpart 800 of this chapter and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate and for buprenorphine will be calculated using the National Average Drug Acquisition Cost.

(C) *Exception.* For the drug component of bundled payments in the medication not otherwise specified category

under paragraph (d)(1)(iii) of this section, the payment amount is based on the applicable methodology under paragraphs (d)(2)(i)(A) and (B) of this section (applying the most recent available data for such new medication), or invoice pricing until the necessary data become available.

(ii) *Non-drug component.* The payment for CY 2020 for the non-drug component of the bundled payment for an episode of care is the sum of:

(A) The CY 2019 Medicare physician fee schedule non-facility rates for the following items and services:

(1) Psychotherapy, 30 minutes with patient

(2) Group psychotherapy

(3) Alcohol and/or substance (other than tobacco) abuse structured assessment and brief intervention at the non-physician practitioner rate.

(4) For administration of an injectable medication, if applicable, drug administration (Therapeutic, prophylactic).

(5) For the insertion, removal, or insertion and removal of the implantable medication, if applicable, the applicable rate.

(B) For dispensing oral medication, if applicable, an approximation of the average dispensing fees under state Medicaid programs.

(C) One fourth of the sum of the CY 2019 Clinical Laboratory Fee Schedule rate for two drug tests, presumptive, capable of being read by direct optical observation only and for a drug test, definitive, 1–7 drug classes.

(iii) *No medication provided episodes of care.* The bundled payment amount for CY 2020 for an episode of care in which no medication is provided is based on the non-drug component rate for an episode of care in which a drug is dispensed or administered, not including any amounts reflecting the cost of dispensing or administration of a drug.

(3) At least one OUD treatment service described in paragraphs (b)(1) through (5) of this section must be furnished to bill for the bundled payment for an episode of care.

(4) Adjustments will be made to the bundled payment for the following:

(i) If the opioid treatment program furnishes:

(A) Counseling or therapy services in excess of the amount specified in the beneficiary's treatment plan and for which medical necessity is documented in the medical record, an adjustment will be made for each additional 30 minutes of counseling or individual therapy furnished during the episode of care.

(B) Intake activities described in paragraph (b)(6) of this section, an adjustment will be made when intake activities are furnished.

(C) Periodic assessments described in paragraph (b)(7) of this section, an adjustment will be made when this service is furnished.

(D) Additional take home supply of oral drugs of up to 21 days, in increments of 7 days, an adjustment will be made when oral medications are dispensed.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, and the adjustments for counseling or therapy, intake activities and periodic assessments will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this chapter.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, and the adjustments for counseling or therapy, intake activities and periodic assessments will be updated annually using the Medicare Economic Index described in § 405.504(d) of this chapter.

(5) Payment for medications delivered, administered or dispensed to a beneficiary as part of the bundled payment is considered a duplicative payment if a claim for delivery, administration or dispensing of the same medications for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. CMS will recoup the duplicative payment made to the opioid treatment program.

(e) *Beneficiary cost-sharing.* A beneficiary copayment amount of zero will apply.

[84 FR 63189, Nov. 15, 2019, as amended at 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020]

**§ 410.68 Antigens: Scope and conditions.**

Medicare Part B pays for—

(a) Antigens that are furnished as services incident to a physician's professional services; or

(b) A supply of antigen sufficient for not more than 12 months that is—

(1) Prepared for a patient by a doctor of medicine or osteopathy who has examined the patient and developed a plan of treatment including dosage levels; and

(2) Administered—

(i) In accord with the plan of treatment developed by the doctor of medicine or osteopathy who prepared the antigen; and

(ii) By a doctor of medicine or osteopathy or by a properly instructed person under the supervision of a doctor of medicine or osteopathy.

[54 FR 4026, Jan. 27, 1989, as amended at 65 FR 65440, Nov. 1, 2000]

**§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.**

(a) *Basic rule.* Medicare Part B pays for anesthesia services and related care furnished by a certified registered nurse anesthetist or an anesthesiologist's assistant who is legally authorized to perform the services by the State in which the services are furnished.

(b) *Definitions.* For purposes of this part—

*Anesthesia and related care* means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished.

*Anesthesiologist's assistant* means a person who—

(1) Works under the direction of an anesthesiologist;

(2) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthesiologists; and

(3) Is a graduate of a medical school-based anesthesiologist's assistant educational program that—

(A) Is accredited by the Committee on Allied Health Education and Accreditation; and

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(B) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

*Anesthetist* includes both an anesthesiologist's assistant and a certified registered nurse anesthetist.

*Certified registered nurse anesthetist* means a registered nurse who:

(1) Is licensed as a registered professional nurse by the State in which the nurse practices;

(2) Meets any licensure requirements the State imposes with respect to non-physician anesthetists;

(3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria:

(i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

(5) For certified registered nurse anesthetist services, the certified registered nurse anesthetist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the certified registered nurse anesthetist's presence and participation in the service.

[57 FR 33896, July 31, 1992, as amended at 77 FR 69363, Nov. 16, 2012; 84 FR 63190, Nov. 15, 2019]

**§410.71 Clinical psychologist services and services and supplies incident to clinical psychologist services.**

(a) *Included services.* (1) Medicare Part B covers services furnished by a clinical

psychologist, who meets the requirements specified in paragraph (d) of this section, that are within the scope of his or her State license, if the services would be covered if furnished by a physician or as an incident to a physician's services.

(2) Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of §410.26 are met.

(b) *Application of mental health treatment limitation.* The treatment services of a clinical psychologist and services and supplies furnished as an incident to those services are subject to the limitation on payment for outpatient mental health treatment services set forth in §410.155.

(c) *Payment for consultations.* A clinical psychologist or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph (e) of this section.

(d) *Qualifications.* For purposes of this subpart, a clinical psychologist is an individual who—

(1) Holds a doctoral degree in psychology; and

(2) Is licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

(e) *Agreement to consult.* A clinical psychologist who bills Medicare Part B must agree to meet the requirements of paragraphs (e)(1) through (e)(3) of this section. The clinical psychologist's signature on a Medicare provider/supplier enrollment form indicates his or her agreement.

(1) Unless the beneficiary's primary care or attending physician has referred the beneficiary to the clinical psychologist, to inform the beneficiary that it is desirable for the clinical psychologist to consult with the beneficiary's attending or primary care physician (if the beneficiary has such a physician) to consider any conditions contributing to the beneficiary's symptoms.



(2) If the beneficiary assents to the consultation, in accordance with accepted professional ethical norms and taking into consideration patient confidentiality—

(i) To attempt, within a reasonable time after receiving the consent, to consult with the physician; and

(ii) If attempts to consult directly with the physician are not successful, to notify the physician, within a reasonable time, that he or she is furnishing services to the beneficiary.

(3) Unless the primary care or attending physician referred the beneficiary to the clinical psychologist, to document, in the beneficiary's medical record, the date the patient consented or declined consent to consultation, the date of consultation, or, if attempts to consult did not succeed, the date and manner of notification to the physician.

[63 FR 20128, Apr. 23, 1998, as amended at 78 FR 74811, Dec. 10, 2013]

**§ 410.73 Clinical social worker services.**

(a) *Definition: clinical social worker.* For purposes of this part, a clinical social worker is defined as an individual who—

(1) Possesses a master's or doctor's degree in social work;

(2) After obtaining the degree, has performed at least 2 years of supervised clinical social work; and

(3) Either is licensed or certified as a clinical social worker by the State in which the services are performed or, in the case of an individual in a State that does not provide for licensure or certification as a clinical social worker—

(i) Is licensed or certified at the highest level of practice provided by the laws of the State in which the services are performed; and

(ii) Has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's degree level social worker in an appropriate setting such as a hospital, SNF, or clinic.

(b) *Covered clinical social worker services.* Medicare Part B covers clinical social worker services.

(1) *Definition.* "Clinical social worker services" means, except as specified in paragraph (b)(2) of this section, the services of a clinical social worker furnished for the diagnosis and treatment of mental illness that the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which the services are performed. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not clinical social worker services for purposes of billing Medicare Part B:

(i) Services furnished by a clinical social worker to an inpatient of a Medicare-participating hospital.

(ii) Services furnished by a clinical social worker to an inpatient of a Medicare-participating SNF.

(iii) Services furnished by a clinical social worker to a patient in a Medicare-participating dialysis facility if the services are those required by the conditions for coverage for ESRD facilities under § 405.2163 of this chapter.

(c) *Agreement to consult.* A clinical social worker must comply with the consultation requirements set forth at § 410.71(f) (reading "clinical psychologist" as "clinical social worker").

(d) *Prohibited billing.* (1) A clinical social worker may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A clinical social worker or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph (c) of this section.

[63 FR 20128, Apr. 23, 1998]

**§ 410.74 Physician assistants' services.**

(a) *Basic rule.* Medicare Part B covers physician assistants' services only if the following conditions are met:

(1) The services would be covered as physicians' services if furnished by a physician (a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act).

(2) The physician assistant—

(i) Meets the qualifications set forth in paragraph (c) of this section;

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(ii) Is legally authorized to perform the services in the State in which they are performed;

(iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion;

(iv) Performs the services in accordance with state law and state scope of practice rules for physician assistants in the state in which the physician assistant’s professional services are furnished. Any state laws and scope of practice rules that describe the required practice relationship between physicians and physician assistants, including explicit supervisory or collaborative practice requirements, describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Act. For states with no explicit state law and scope of practice rules regarding physician supervision of physician assistant’s services, physician supervision is a process in which a physician assistant has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the practice level the physician assistant’s scope of practice and the working relationships the physician assistant has with the supervising physician/s when furnishing professional services.

(v) Furnishes services that are billed by the employer of a physician assistant; and

(vi) Performs the services—

(A) In all settings in either rural and urban areas; or

(B) As an assistant at surgery.

(b) *Services and supplies furnished incident to a physician assistant’s services.* Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of §410.26 are met.

(c) *Qualifications.* For Medicare Part B coverage of his or her services, a physician assistant must meet all of the following conditions:

(1) Have graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(2) Have passed the national certification examination that is administered by the National Commission on

Certification of Physician Assistants; and

(3) Be licensed by the State to practice as a physician assistant.

(d) *Professional services.* Physician assistants can be paid for professional services only if the services have been professionally performed by them and no facility or other provider charges for the service or is paid any amount for the furnishing of those professional services.

(1) Supervision of other nonphysician staff by a physician assistant does not constitute personal performance of a professional service by the physician assistant.

(2) The services are provided on an assignment-related basis, and the physician assistant may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the physician assistant must make the appropriate refund to the beneficiary.

(e) *Medical record documentation.* For physician assistants’ services, the physician assistant may review and verify (sign and date), rather than re-document, notes in a patient’s medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the physician assistant’s presence and participation in the service.

[63 FR 58907, Nov. 2, 1998; 64 FR 25457, May 12, 1999, as amended at 78 FR 74811, Dec. 10, 2013; 84 FR 63190, Nov. 15, 2019]

§410.75 Nurse practitioners’ services.

(a) *Definition.* As used in this section, the term “physician” means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a nurse practitioner must be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law, and must meet one of the following:

(1) Obtained Medicare billing privileges as a nurse practitioner for the first time on or after January 1, 2003, and meets the following requirements:

(i) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

(ii) Possess a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

(2) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2003, and meets the standards in paragraph (b)(1)(i) of this section.

(3) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2001.

(c) *Services.* Medicare Part B covers nurse practitioners' services in all settings in both rural and urban areas, only if the services would be covered if furnished by a physician and the nurse practitioner—

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage because of one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a nurse practitioner has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by nurse practitioners documenting the nurse practitioners' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Nurse practitioners must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the nurse practitioner when the services are furnished or to make an independent eval-

uation of each patient who is seen by the nurse practitioner.

(d) *Services and supplies incident to a nurse practitioners' services.* Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of § 410.26 are met.

(e) *Professional services.* Nurse practitioners can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by a nurse practitioner does not constitute personal performance of a professional service by a nurse practitioner.

(2) The services are provided on an assignment-related basis, and a nurse practitioner may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the nurse practitioner must make the appropriate refund to the beneficiary.

(f) *Medical record documentation.* For nurse practitioners' services, the nurse practitioner may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the nurse practitioner's presence and participation in the service.

[63 FR 58908, Nov. 2, 1998; 64 FR 25457, May 12, 1999, as amended at 64 FR 59440, Nov. 2, 1999; 73 FR 69933, Nov. 19, 2008; 78 FR 74811, Dec. 10, 2013; 84 FR 63191, Nov. 15, 2019]

#### § 410.76 Clinical nurse specialists' services.

(a) *Definition.* As used in this section, the term "physician" means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a clinical nurse specialist must—

(1) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a

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clinical nurse specialist in accordance with State law;

(2) Have a master’s degree in a defined clinical area of nursing from an accredited educational institution or a Doctor of Nursing Practice (DNP) doctoral degree; and

(3) Be certified as a clinical nurse specialist by a national certifying body that has established standards for clinical nurse specialists and that is approved by the Secretary.

(c) *Services.* Medicare Part B covers clinical nurse specialists’ services in all settings in both rural and urban areas only if the services would be covered if furnished by a physician and the clinical nurse specialist—

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage by one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a clinical nurse specialist works with one or more physicians to deliver health care services within the scope of the practitioner’s expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a clinical nurse specialist has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by clinical nurse specialists documenting the clinical nurse specialists’ scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Clinical nurse specialists must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the clinical nurse specialist when the services are furnished, or to make an independent evaluation of each patient who is seen by the clinical nurse specialist.

(d) *Services and supplies furnished incident to clinical nurse specialists’ services.* Medicare Part B covers services and

supplies incident to the services of a clinical nurse specialist if the requirements of §410.26 are met.

(e) *Professional services.* Clinical nurse specialists can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by clinical nurse specialists does not constitute personal performance of a professional service by clinical nurse specialists.

(2) The services are provided on an assignment-related basis, and a clinical nurse specialist may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the clinical nurse specialist must make the appropriate refund to the beneficiary.

(f) *Medical record documentation.* For clinical nurse specialists’ services, the clinical nurse specialist may review and verify (sign and date), rather than re-document, notes in a patient’s medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the clinical nurse specialist’s presence and participation in the service.

[63 FR 58908, Nov. 2, 1998, as amended at 67 FR 80040, Dec. 31, 2002; 73 FR 69934, Nov. 19, 2008; 78 FR 74811, Dec. 10, 2013; 84 FR 63191, Nov. 15, 2019]

**§410.77 Certified nurse-midwives’ services: Qualifications and conditions.**

(a) *Qualifications.* For Medicare coverage of his or her services, a certified nurse-midwife must:

(1) Be a registered nurse who is legally authorized to practice as a nurse-midwife in the State where services are performed;

(2) Have successfully completed a program of study and clinical experience for nurse-midwives that is accredited by an accrediting body approved by the U.S. Department of Education; and

(3) Be certified as a nurse-midwife by the American College of Nurse-Midwives or the American College of Nurse-Midwives Certification Council.

(b) *Services.* A certified nurse-midwife's services are services furnished by a certified nurse-midwife and services and supplies furnished as an incident to the certified nurse-midwife's services that—

(1) Are within the scope of practice authorized by the law of the State in which they are furnished and would otherwise be covered if furnished by a physician or as an incident to a physician's service; and

(2) Unless required by State law, are provided without regard to whether the certified nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

(c) *Incident to services: Basic rule.* Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of § 410.26 are met.

(d) *Professional services.* A nurse-midwife can be paid for professional services only when the services have been performed personally by the nurse-midwife.

(1) Supervision of other nonphysician staff by a nurse-midwife does not constitute personal performance of a professional service by the nurse-midwife.

(2) The service is provided on an assignment-related basis, and a nurse-midwife may not charge a beneficiary for a service not payable under this provision. If the beneficiary has made payment for a service, the nurse-midwife must make the appropriate refund to the beneficiary.

(3) A nurse-midwife may provide services that he or she is legally authorized to perform under State law as a nurse-midwife, if the services would otherwise be covered by the Medicare program when furnished by a physician or incident to a physicians' professional services.

(e) *Medical record documentation.* For certified nurse-midwives' services, the certified nurse-midwife may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse

students; or other members of the medical team, including, as applicable, notes documenting the certified nurse-midwife's presence and participation in the service.

[63 FR 58909, Nov. 2, 1998, as amended at 78 FR 74811, Dec. 10, 2013; 84 FR 63191, Nov. 15, 2019]

#### § 410.78 Telehealth services.

(a) *Definitions.* For the purposes of this section the following definitions apply:

(1) *Asynchronous store and forward technologies* means the transmission of a patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs visualized by a telecommunications system must be specific to the patient's medical condition and adequate for furnishing or confirming a diagnosis and or treatment plan. Dermatological photographs, for example, a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this provision.

(2) *Distant site* means the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system.

(3) *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

(i) *Exception.* For the duration of the Public Health Emergency as defined in § 400.200 of this chapter, *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way,

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real-time interactive communication between the patient and distant site physician or practitioner.

(ii) [Reserved]

(4) *Originating site* means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous store and forward telecommunications technologies, the only originating sites are Federal telemedicine demonstration programs conducted in Alaska or Hawaii.

(b) *General rule.* Medicare Part B pays for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system if the following conditions are met, except that for the duration of the Public Health Emergency as defined in §400.200 of this chapter, Medicare Part B pays for office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, pharmacologic management and end stage renal disease related services included in the monthly capitation payment furnished by an interactive telecommunications system if the following conditions are met:

(1) The physician or practitioner at the distant site must be licensed to furnish the service under State law. The physician or practitioner at the distant site who is licensed under State law to furnish a covered telehealth service described in this section may bill, and receive payment for, the service when it is delivered via a telecommunications system.

(2) The practitioner at the distant site is one of the following:

(i) A physician as described in §410.20.

(ii) A physician assistant as described §410.74.

(iii) A nurse practitioner as described in §410.75.

(iv) A clinical nurse specialist as described in §410.76.

(v) A nurse-midwife as described in §410.77.

(vi) A clinical psychologist as described in §410.71.

(vii) A clinical social worker as described in §410.73.

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(viii) A registered dietitian or nutrition professional as described in §410.134.

(ix) A certified registered nurse anesthetist as described in §410.69.

(3) The services are furnished to a beneficiary at an originating site, which is one of the following:

(i) The office of a physician or practitioner.

(ii) A critical access hospital (as described in section 1861(mm)(1) of the Act).

(iii) A rural health clinic (as described in section 1861(aa)(2) of the Act).

(iv) A Federally qualified health center (as defined in section 1861(aa)(4) of the Act).

(v) A hospital (as defined in section 1861(e) of the Act).

(vi) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(vii) A skilled nursing facility (as defined in section 1819(a) of the Act).

(viii) A community mental health center (as defined in section 1861(ff)(3)(B) of the Act).

(ix) A renal dialysis facility (only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act);

(x) The home of an individual (only for purposes of the home dialysis ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act).

(xi) A mobile stroke unit (only for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke provided in accordance with section 1834(m)(6) of the Act).

(xii) The home of an individual (only for purposes of treatment of a substance use disorder or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a substance use disorder diagnosis.

(4) Except as provided in paragraph (b)(4)(iv) of this section, originating sites must be:

(i) Located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a

rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or

(ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or

(iii) An entity participating in a Federal telemedicine demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000, regardless of its geographic location.

(iv) The geographic requirements specified in paragraph (b)(4) of this section do not apply to the following telehealth services:

(A) Home dialysis monthly ESRD-related clinical assessment services furnished on or after January 1, 2019, at an originating site described in paragraphs (b)(3)(vi), (ix) or (x) of this section, in accordance with section 1881(b)(3)(B) of the Act; and

(B) Services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

(C) Services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis, for purposes of treatment of a substance use disorder or a co-occurring mental health disorder.

(5) The medical examination of the patient is under the control of the physician or practitioner at the distant site.

(c) *Telepresenter not required.* A telepresenter is not required as a condition of payment unless a telepresenter is medically necessary as determined by the physician or practitioner at the distant site.

(d) *Exception to the interactive telecommunications system requirement.* For Federal telemedicine demonstration programs conducted in Alaska or Hawaii only, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system.

(e) *Limitations.* (1) A clinical psychologist and a clinical social worker may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

(2) The physician visits required under § 483.40(c) of this title may not be furnished as telehealth services.

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph, changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. During the Public Health Emergency for the COVID-19 pandemic, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list during the Public Health Emergency taking into consideration infection control, patient safety, and other public health concerns resulting from the emergency. A list of the services covered as telehealth services under this section is available on the CMS website.

[66 FR 55330, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2002; 69 FR 66423, Nov. 15, 2004; 70 FR 70330, Nov. 21, 2005; 72 FR 66399, Nov. 27, 2007; 73 FR 69934, Nov. 19, 2008; 74 FR 62005, Nov. 25, 2009; 75 FR 73615, Nov. 29, 2010; 76 FR 73470, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 80 FR 71373, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27621, May 8, 2020]

**§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.**

(a) Medicare Diabetes Prevention Program (MDPP) services will be available beginning on April 1, 2018.

(b) *Definitions.* For purposes of this section, the following definitions apply:

*Baseline weight* means the MDPP beneficiary's body weight recorded during that beneficiary's first core session.

*CDC-approved DPP curriculum* refers to the content of the core sessions, core maintenance sessions, and ongoing maintenance sessions. The curriculum may be either the CDC-preferred curriculum as designated by the CDC DPRP Standards or an alternative

curriculum approved for use in DPP by the CDC.

*Core maintenance session* means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

*Core maintenance session interval* means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month.

*Core session* means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for core sessions.

*Diabetes Prevention Recognition Program (DPRP)* refers to a program administered by the Centers for Disease Control and Prevention (CDC) that recognizes organizations that are able to furnish diabetes prevention program (DPP) services, follow a CDC-approved DPP curriculum, and meet CDC's performance standards and reporting requirements.

*Full CDC DPRP recognition* refers to the designation from the CDC that an organization has consistently furnished CDC-approved DPP sessions, met CDC-performance standards and met CDC reporting requirements for at least 24–36 months following the organization's application to participate in the DPRP.

*Make-up session* means a core session, a core maintenance session, or an ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session.

*MDPP beneficiary* means a Medicare beneficiary who meets the criteria specified in paragraph (c)(1)(i) of this section, who has initiated the MDPP

services period by attending the first core session, and for whom the MDPP services period has not ended as specified in paragraph (c)(3) of this section.

*MDPP services* means structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

*MDPP services period* means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph (c)(2)(i) and, subject to paragraph (c)(3) of this section, one or more ongoing maintenance session intervals during the ongoing services period described in paragraph (c)(2)(ii) of this section.

*MDPP session* means a core session, a core maintenance session, or an ongoing maintenance session.

*MDPP supplier* means an entity that is enrolled in Medicare to furnish MDPP services as provided in §424.205 of this chapter.

*Medicare Diabetes Prevention Program (MDPP)* refers to a model test expanded under section 1115A(c) of the Act that makes MDPP services available to MDPP beneficiaries.

*National Diabetes Prevention Program (National DPP)* refers to an evidence-based intervention targeted to individuals with pre-diabetes that is furnished in community and health care settings and administered by the Centers for Disease Control and Prevention (CDC).

*Ongoing maintenance session* means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during an ongoing maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.



*Ongoing maintenance session interval* means one of the up to four consecutive 3-month time periods during the ongoing services period described in paragraph (c)(2)(ii) of this section, during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

*Required minimum weight loss* refers to the percentage by which the beneficiary's updated weight is less than the baseline weight. The required minimum weight loss percentage is 5 percent.

*Set of MDPP services* means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and subject to paragraph (c)(3) of this section, ongoing maintenance sessions, offered over the course of the MDPP services period.

*Virtual make-up session* means a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions.

(c) Coverage for MDPP services—(1) *Beneficiary eligibility.* (i) A Medicare beneficiary is eligible for MDPP services offered during the core services period described in paragraph (c)(2)(i) of this section if the beneficiary meets all of the following criteria:

(A) Is enrolled under Medicare Part B;

(B) Attended the first core session within the most recent 12-month time period and, prior to attending this first core session, had not previously received the set of MDPP services in his or her lifetime;

(C) Has, on the date of attendance at the first core session, a body mass index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian;

(D) Has received, within the 12-month time period prior to the date of attendance at the first core session, a hemoglobin A1c test with a value of between 5.7 and 6.4 percent, a fasting plasma glucose test with a value of between 110 and 125 mg/dL, or a 2-hour plasma glucose test (oral glucose tolerance test) with a value of between 140 and 199 mg/dL;

(E) Has, as of the date of attendance at the first core session, no previous di-

agnosis of diabetes, other than gestational diabetes; and

(F) Does not have end-stage renal disease (ESRD).

(ii) An MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary:

(A) Attends at least one in-person core maintenance session during the final core maintenance session interval; and

(B) Achieves or maintains the required minimum weight loss at a minimum of one in-person core maintenance session during the final core maintenance session interval.

(iii) An MDPP beneficiary is eligible for a subsequent ongoing maintenance session interval only if the beneficiary:

(A) Attends at least two ongoing maintenance sessions during the previous ongoing maintenance session interval, including at least one in-person ongoing maintenance session; and

(B) Maintains the required minimum weight loss at a minimum of one in-person ongoing maintenance session furnished during the previous ongoing maintenance session interval.

(iv) Weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session.

(2) *MDPP services period.* An MDPP beneficiary's MDPP services period is composed of the following periods and intervals:

(i) The core services period, which is the first 12 months of the MDPP services period, and consists of:

(A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and

(B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period.

(ii) Subject to paragraph (c)(3) of this section, the ongoing services period, which consists of up to four 3-month ongoing maintenance session intervals offered during months 13 through 24 of the MDPP services period.

(3) *Limitations on the MDPP services period.* (i) The MDPP services period

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ends upon completion of the core services period described in paragraph (c)(2)(i) of this section, unless the MDPP beneficiary qualifies for the first ongoing maintenance session interval, in accordance with paragraph (c)(1)(ii) of this section.

(ii) If the MDPP beneficiary qualifies for the first ongoing maintenance session interval as described in paragraph (c)(3)(i) of this section, the MDPP services period ends upon completion of this first ongoing maintenance session interval or any subsequent ongoing maintenance session interval, unless the beneficiary meets the eligibility requirements under paragraph (c)(1)(iii) of this section.

(iii) Unless sooner ended in accordance with this paragraph (c)(3), the MDPP services period ends automatically upon the completion of the fourth ongoing maintenance session interval.

(d) *Make-up sessions.* (1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. If an MDPP supplier offers one or more make-up sessions to an MDPP beneficiary, each such session must be furnished in accordance with the following requirements:

(i) The curriculum furnished during the make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session that the beneficiary missed;

(ii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session; and

(iii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week.

(2) An MDPP supplier may offer virtual make-up sessions only if consistent with the requirements in paragraph (d)(1) of this section. Virtual make-up sessions are also subject to the following requirements:

(i) Virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(ii) An MDPP supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request; and

(iii) An MDPP supplier may offer to an MDPP beneficiary:

(A) No more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions are core maintenance sessions; and

(B) No more than 3 virtual make-up sessions that are ongoing maintenance sessions.

(3) Make-up sessions furnished in accordance with paragraph (d)(1) of this section that an MDPP beneficiary attends in person are counted toward meeting the attendance requirements described in paragraph (c)(1) of this section and toward achieving the performance goals described in §414.84(b) of this chapter as if the MDPP beneficiary attended a regularly scheduled session. Virtual make-up sessions furnished in accordance with paragraph (d)(2) of this section are also counted toward such attendance requirements and performance goals, subject to the following limitations:

(i) The MDPP beneficiary receives no more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and

(ii) The MDPP beneficiary receives no more than 3 virtual make-up sessions that are ongoing maintenance sessions.

(e) *MDPP expanded model emergency policy.* (1) Notwithstanding paragraphs (a) through (d) of this section, the policies described in this paragraph (e) apply during the Public Health Emergency (PHE), as defined in §400.200 of this chapter.

(2) MDPP requirement changes described in paragraph (e)(1) of this section are applicable to:

(i) Organizations that are enrolled as an MDPP supplier as defined in paragraph (b) of this section, as of March 1, 2020; and

(ii) MDPP beneficiaries as defined in paragraph (b) of this section, who are receiving the MDPP set of services as of March 1, 2020.

(3) The following changes apply under this paragraph (e):

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A), (c)(1)(iii)(A), and (c)(3)(ii) of this section are waived. MDPP suppliers shall not start new cohorts with MDPP beneficiaries who are unable to attend the first core session in-person;

(ii) The limit described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section to the number of virtual make-up sessions is waived for MDPP suppliers with capabilities to provide services virtually so long as the provision of virtual services complies with the following:

(A) The curriculum furnished during the virtual make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session;

(B) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one session on the same day as a regularly scheduled session;

(C) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session per week;

(D) Virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(E) Virtual make-up sessions can only be furnished to achieve attendance goals and cannot be furnished to achieve weight-loss goals;

(F) An MDPP supplier can only offer virtual make-up sessions upon an individual MDPP beneficiary's request; and

(G) An MDPP supplier can offer to an MDPP beneficiary:

(1) No more than 15 virtual make-up sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(2) No more than 6 virtual make-up sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period; and

(3) No more than 12 virtual make-up sessions offered monthly during the ongoing maintenance session interval periods, months 13 through 24;

(iii) The once per lifetime requirement as described in paragraph (c)(1)(i)(B) of this section is waived to permit MDPP beneficiaries whose sessions were paused or cancelled due to the PHE to obtain the set of MDPP

services more than once per lifetime by electing to restart the MDPP set of services or resume with the most recent attendance session of record;

(iv) The minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in paragraphs (c)(1)(ii)(B) and (c)(1)(iii)(B) of this section are waived; and

(v) MDPP suppliers may pause or delay the delivery of the MDPP set of services and subsequently resume services on a delayed schedule. The time periods and intervals must be consistent with the MDPP requirements as described in paragraphs (c)(1)(i)(B), (c)(1)(ii)(A), (c)(1)(iii)(A), (c)(2)(i)(A) and (B), and (c)(3)(i) and (ii) of this section.

[81 FR 80552, Nov. 15, 2016; 81 FR 81698, Nov. 18, 2016, as amended at 82 FR 53358, Nov. 15, 2017; 85 FR 19287, Apr. 6, 2020]

### Subpart C—Home Health Services Under SMI

#### § 410.80 Applicable rules.

Home health services furnished under Medicare Part B are subject to the rules set forth in subpart E of part 409 of this chapter.

### Subpart D—Comprehensive Outpatient Rehabilitation Facility (CORF) Services

#### § 410.100 Included services.

Subject to the conditions and limitations set forth in §§ 410.102 and 410.105, CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in § 485.70 of this chapter. Payment for CORF services are made in accordance with § 414.1105.

(a) *Physician's services.* CORF facility physician services are administrative in nature and include consultation with and medical supervision of non-physician staff, participation in plan of treatment reviews and patient care review conferences, and other medical and facility administration activities. Diagnostic and therapeutic services furnished to an individual CORF patient by a physician in a CORF facility

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are not CORF physician services. These services, if covered, are physician services under §410.20 with payment for these services made to the physician in accordance with part 414 subpart B.

(b) *Physical therapy services.* (1) These services include—

(i) Testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular and respiratory systems; and.

(ii) Assessment and treatment related to dysfunction caused by illness or injury, and aimed at preventing or reducing disability or pain and restoring lost function.

(2) The establishment of a maintenance therapy program for an individual whose restoration potential has been reached is a physical therapy service; however, maintenance therapy itself is not covered as part of these services.

(c) *Occupational therapy services.* These services include—

(1) Teaching of compensatory techniques to permit an individual with a physical impairment or limitation to engage in daily activities.

(2) Evaluation of an individual's level of independent functioning.

(3) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; and

(4) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(d) *Speech-language pathology services.* These are services for the diagnosis and treatment of speech and language disorders that create difficulties in communication.

(e) *Respiratory therapy services.* (1) Respiratory therapy services are for the assessment, treatment, and monitoring of patients with deficiencies or abnormalities of cardiopulmonary function.

(2) Respiratory therapy services include the following:

(i) Application of techniques for support of oxygenation and ventilation of the patient.

(ii) Therapeutic use and monitoring of gases, mists, and aerosols and related equipment.

(iii) Bronchial hygiene therapy.

(iv) Pulmonary rehabilitation techniques to develop strength and endurance of respiratory muscles and other techniques to increase respiratory function, such as graded activity services; these services include physiologic monitoring and patient education.

(f) *Prosthetic device services.* These services include—

(1) Prosthetic devices (excluding dental devices and renal dialysis machines), that replace all or part of an internal body organ or external body member (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning external body member or internal body organ; and

(2) Services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct the patient in its use.

(g) *Orthotic device services.* These services include—

(1) Orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning; and

(2) Services necessary to design the device, select the materials and components, measure, fit, and align the device, and instruct the patient in its use.

(h) *Social and psychological services.* Social and psychological services include the assessment and treatment of an individual's mental and emotional functioning and the response to and rate of progress as it relates to the individual's rehabilitation plan of treatment, including physical therapy services, occupational therapy services, speech-language pathology services and respiratory therapy services.

(i) *Nursing care services.* Nursing care services include nursing services provided by a registered nurse that are prescribed by a physician and are specified in or directly related to the rehabilitation treatment plan and necessary for the attainment of the rehabilitation goals of the physical therapy, occupational therapy, speech-language pathology, or respiratory therapy plan of treatment.

(j) *Drugs and biologicals.* These are drugs and biologicals that are the following:

(1) Prescribed by a physician and administered by or under the supervision of a physician or by a registered professional nurse; and

(2) Not excluded from Medicare Part B payment for reasons specified in § 410.29.

(k) *Supplies and durable medical equipment.* Supplies and durable medical equipment include the following:

(1) Disposable supplies.

(2) Durable medical equipment of the type specified in § 410.38 (except for renal dialysis systems) for a patient's use outside the CORF, whether purchased or rented.

(1) *Home environment evaluation.* A home environment evaluation—

(1) Is a single home visit to evaluate the potential impact of the home situation on the patient's rehabilitation goals.

(2) Requires the presence of the patient and the physical therapist, occupational therapist, or speech-language pathologist, as appropriate.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987, as amended at 72 FR 66399, Nov. 27, 2007]

#### § 410.102 Excluded services.

None of the services specified in § 410.100 is covered as a CORF service if the service—

(a) Would not be covered as an inpatient hospital service if furnished to a hospital inpatient;

(b) Is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. An example would be services furnished as part of a maintenance program involving repetitive activities that do not require the skilled services of nurses or therapists.

#### § 410.105 Requirements for coverage of CORF services.

Services specified in § 410.100 and not excluded under § 410.102 are covered as CORF services if they are furnished by a participating CORF (that is, a CORF that meets the conditions of subpart B of part 485 of this chapter, and has in effect a provider agreement under part 489 of this chapter) and if the following requirements are met:

(a) *Referral and medical history.* The services must be furnished to an indi-

vidual who is referred by a physician who certifies that the individual needs skilled rehabilitation services, and makes the following information available to the CORF before or at the time treatment is begun:

(1) The individual's significant medical history.

(2) Current medical findings.

(3) Diagnosis(es) and contraindications to any treatment modality.

(4) Rehabilitation goals, if determined.

(b) *When and where services are furnished.* (1) All services must be furnished while the individual is under the care of a physician.

(2) Except as provided in paragraph (b)(3) of this section, the services must be furnished on the premises of the CORF.

(3) *Exceptions.* (i) Physical therapy, occupational therapy, and speech-language pathology services may be furnished away from the premises of the CORF including the individual's home when payment is not otherwise made under Title XVIII of the Act.

(ii) The single home environment evaluation visit specified in § 410.100(m) is also covered.

(c) *Plan of treatment.* (1) The service must be furnished under a written plan of treatment that—

(i) Is established and signed by a physician before treatment is begun; and

(ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals.

(2) The plan must be reviewed at least every 60 days for respiratory therapy services and every 90 days for physical therapy, occupational therapy and speech-language pathology services by a facility physician or the referring physician who, when appropriate, consults with the professional personnel providing the services.

(3) The reviewing physician must certify or recertify that the plan is being followed, the patient is making progress in attaining the rehabilitation goals, and the treatment is having no harmful effects on the patient.

(d) *Claims.* Effective for dates of service on and after January 1, 2020 physical therapy or occupational therapy

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services covered as part of a rehabilitation plan of treatment described in paragraph (c) of this section, as applicable—

(1) Claims for such services furnished in whole or in part by a physical therapist assistant or an occupational therapy assistant must be identified with the inclusion of the respective prescribed modifier; and

(2) Effective for dates of service on and after January 1, 2022, such claims are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service as defined at section 1834(k) of the Act.

(3) For purposes of this paragraph, “furnished in whole or in part” means when the physical therapist assistant or occupational therapy assistant either—

(i) Furnishes all the minutes of a service exclusive of the respective physical therapist or occupational therapist; or

(ii) Furnishes a portion of a service separately from the part furnished by the physical or occupational therapist such that the minutes for that portion of a service exceed 10 percent of the total time for that service.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8841, Mar. 1, 1991; 72 FR 66400, Nov. 27, 2007; 77 FR 69363, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 84 FR 63191, Nov. 15, 2019]

## Subpart E—Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services

### § 410.110 Requirements for coverage of partial hospitalization services by CMHCs.

Medicare part B covers partial hospitalization services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in § 410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are—

(a) Prescribed by a physician and furnished under the general supervision of a physician;

(b) Subject to certification by a physician in accordance with § 424.24(e)(1) of this subchapter; and

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(c) Furnished under a plan of treatment that meets the requirements of § 424.24(e)(2) of this subchapter.

[59 FR 6577, Feb. 11, 1994]

## Subpart F [Reserved]

## Subpart G—Medical Nutrition Therapy

SOURCE: 66 FR 55331, Nov. 1, 2001, unless otherwise noted.

### § 410.130 Definitions.

For the purposes of this subpart, the following definitions apply:

*Chronic renal insufficiency* means the stage of renal disease associated with a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate [GFR] 13–50 ml/min/1.73m<sup>2</sup>).

*Diabetes* means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

*Episode of care* means services covered in a 12-month time period when coordinated with initial diabetes self-management training (DSMT) and one calendar year for each year thereafter, starting with the assessment and including all covered interventions based on referral(s) from a physician as specified in § 410.132(c). The time period covered for gestational diabetes extends only until the pregnancy ends.

*Medical nutrition therapy services* means nutritional diagnostic, therapeutic, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing diabetes or a renal disease.

*Physician* means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs such function or action (including a physician within the meaning of section of 1101(a)(7) of the Act).

*Renal disease* means chronic renal insufficiency, end-stage renal disease when dialysis is not received, or the medical condition of a beneficiary for 36 months after kidney transplant.

*Treating physician* means the primary care physician or specialist coordinating care for the beneficiary with diabetes or renal disease.

[66 FR 55331, Nov. 1, 2001, as amended at 68 FR 63261, Nov. 7, 2003]

#### § 410.132 Medical nutrition therapy.

(a) *Conditions for coverage of MNT services.* Medicare Part B pays for MNT services provided by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by the treating physician. Except as provided at § 410.78, services covered consist of face-to-face nutritional assessments and interventions in accordance with nationally-accepted dietary or nutritional protocols.

(b) *Limitations on coverage of MNT services.* (1) MNT services based on a diagnosis of renal disease as described in this subpart are not covered for beneficiaries receiving maintenance dialysis for which payment is made under section 1881 of the Act.

(2) A beneficiary may only receive the maximum number of hours covered under the DSMT benefit for both DSMT and MNT during the initial DSMT training period unless additional hours are determined to be medically necessary under the national coverage determination process.

(3) In years when the beneficiary is eligible for MNT and follow-up DSMT, the beneficiary may only receive the maximum number of hours covered under MNT unless additional hours are determined to be medically necessary under the national coverage determination process.

(4) If a beneficiary has both diabetes and renal disease, the beneficiary may only receive the maximum number of hours covered under the renal MNT benefit in one episode of care unless he or she is receiving initial DSMT services, in which case the beneficiary would receive whichever is greater.

(5) An exception to the maximum number of hours in (b)(2), (3), and (4) of this section may be made when the

treating physician determines that there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.

(c) *Referrals.* Referral may only be made by the treating physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in this subpart with documentation maintained by the referring physician in the beneficiary's medical record. Referrals must be made for each episode of care and any additional assessments or interventions required by a change of diagnosis, medical condition, or treatment regimen during an episode of care.

[66 FR 55331, Nov. 1, 2001, as amended at 72 FR 66400, Nov. 27, 2007]

#### § 410.134 Provider qualifications.

For Medicare Part B coverage of MNT, only a registered dietitian or nutrition professional may provide the services. "Registered dietitian or nutrition professional" means an individual who, on or after December 22, 2000:

(a) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(b) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(c) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian" by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a) and (b) of this section.

(d) *Exceptions.* (i) A dietitian or nutritionist licensed or certified in a State as of December 21, 2000 is not required

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to meet the requirements of (a) and (b) of this section.

(ii) A “registered dietitian” in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of (a) and (b) of this section.

[66 FR 55331, Nov. 1, 2001; 67 FR 20684, Apr. 26, 2002]

## Subpart H—Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

SOURCE: 65 FR 83148, Dec. 29, 2000, unless otherwise noted.

### § 410.140 Definitions.

For purposes of this subpart, the following definitions apply:

*ADA* stands for the American Diabetes Association.

*Approved entity* means an individual, physician, or entity accredited by an approved organization as meeting one of the sets of quality standards described in § 410.144 and approved by CMS under § 410.141(e) to furnish training.

*Deemed entity* means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by CMS under § 410.145(b) to furnish training.

*Diabetes* means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

*NSDSMEP* stands for the National Standards for Diabetes Self Management Education Programs.

*Organization* means a national accreditation organization.

*Rural* means an area that meets one of the following conditions:

(1) Is not urbanized (as defined by the Bureau of the Census) and that is designated by the chief executive officer of the State, and certified by the Sec-

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retary, as an area with a shortage of personal health services.

(2) Is designated by the Secretary either as an area with a shortage of personal health services or as a health professional shortage area.

(3) Is designated by the Indian Health Service as a health service delivery area as defined in § 36.15 of this title.

*Training* means outpatient diabetes self-management training.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003; 76 FR 73471, Nov. 28, 2011]

### § 410.141 Outpatient diabetes self-management training.

(a) *General rule.* Medicare Part B covers training defined in § 410.140 if all of the conditions and requirements of this subpart are met.

(b) *Conditions for coverage.* The training must meet the following conditions:

(1) *Training orders.* Following an evaluation of the beneficiary’s need for the training, the training is ordered by the physician (or qualified nonphysician practitioner) (as defined in § 410.32(a)(2)) treating the beneficiary’s diabetes.

(2) *Plan of care.* It is included in a comprehensive plan of care established by the physician (or qualified nonphysician practitioner) treating the beneficiary for diabetes that meets the following requirements:

(i) Describes the content, number of sessions, frequency, and duration of the training as written by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(ii) Contains a statement specified by CMS and signed by the physician (or qualified nonphysician practitioner) managing the beneficiary’s diabetic condition. By signing this statement, the physician (or qualified nonphysician practitioner) certifies that he or she is managing the beneficiary’s diabetic condition and the training described in the plan of care is needed to ensure therapy compliance or to provide the beneficiary with the skills and knowledge to help manage the beneficiary’s diabetes. The physician’s (or qualified nonphysician practitioner’s) statement must identify the beneficiary’s specific medical conditions



(described in paragraph (d) of this section) that the training will address.

(iii) Provides that any changes to the plan of care are signed by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(iv) Is incorporated into the approved entity's medical record for the beneficiary and is made available, upon request, to CMS.

(3) *Reasonable and necessary.* It is reasonable and necessary for treating or monitoring the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(c) Types and frequency of training—

(1) Initial training—

*General rule.* (i) Medicare Part B covers initial training that meets the following conditions:

(A) Is furnished to a beneficiary who has not previously received initial training under this benefit.

(B) Is furnished within a continuous 12-month period.

(C) Does not exceed a total of 10 hours.

(D) Except as permitted under paragraph (c)(1)(ii) of this section, 9 hours of the training are furnished in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries.

(E) Is furnished in increments of no less than one-half hour.

(F) May include 1 hour of individual training for an assessment of the beneficiary's training needs.

(ii) *Exception.* Medicare covers training on an individual basis for a Medicare beneficiary who meets any of the following conditions:

(A) No group session is available within 2 months of the date the training is ordered.

(B) The beneficiary's physician (or qualified nonphysician practitioner) documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing, or language limitations that will hinder effective participation in a group training session.

(2) *Follow-up training.* After receiving the initial training described in paragraph (c)(1) of this section, Medicare covers follow-up training that meets the following conditions:

(i) Consists of no more than 2 hours individual or group training for a beneficiary each year.

(ii) Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries.

(iii) Is furnished any time in a calendar year following the year in which the beneficiary completes the initial training.

(iv) Is furnished in increments of no less than one-half hour.

(v) The physician (or qualified nonphysician practitioner) treating the beneficiary must document, in the referral for training and the beneficiary's medical record, the specific medical condition (described in paragraph (d) of this section) that the follow-up training must address.

(d) *Beneficiaries who may be covered.* Medicare Part B covers outpatient diabetes self-management training for a beneficiary who has been diagnosed with diabetes.

(e) *Who may furnish services.* Training may be furnished by a physician, individual, or entity that meets the following conditions:

(1) Furnishes other services for which direct Medicare payment may be made.

(2) May properly receive Medicare payment under § 424.73 or § 424.80 of this chapter, which set forth prohibitions on assignment and reassignment of benefits.

(3) Submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS under § 410.142 to meet one of the sets of quality standards described in § 410.144.

(4) Provides documentation to CMS, as requested, including diabetes outcome measurements set forth at § 410.146.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003; 76 FR 73471, Nov. 28, 2011]

**§ 410.142 CMS process for approving national accreditation organizations.**

(a) *General rule.* CMS may approve and recognize a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training.

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(b) *Required information and materials.* An organization requesting CMS's approval and recognition of its accreditation program must furnish to CMS the following information and materials:

(1) The requirements and quality standards that the organization uses to accredit entities to furnish training.

(2) If an organization does not use the CMS quality standards or the NSDSMEP quality standards described in §410.144(a) or (b), a detailed comparison including a crosswalk between the organization's standards and the CMS quality standards described in §410.144(a).

(3) Detailed information about the organization's accreditation process, including all of the following information:

(i) Frequency of accreditation.

(ii) Copies of accreditation forms, guidelines, and instructions to evaluators.

(iii) Descriptions of the following:

(A) The accreditation review process and the accreditation status decision making process.

(B) The procedures used to notify a deemed entity of deficiencies in its outpatient diabetes self-management training program and procedures to monitor the correction of those deficiencies.

(C) The procedures used to enforce compliance with the accreditation requirements and standards.

(4) Detailed information about the individuals who perform evaluations for the organization, including all of the following information:

(i) The education and experience requirements for the individuals who perform evaluations.

(ii) The content and frequency of continuing education furnished to the individuals who perform evaluations.

(iii) The process used to monitor the performance of individuals who perform evaluations.

(iv) The organization's policies and practices for participation in the accreditation process by an individual who is professionally or financially affiliated with the entity being evaluated.

(5) A description of the organization's data management and analysis system for its accreditation activities and de-

terminations, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

(7) A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.

(9) A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

(10) The name and address of each person with an ownership or control interest in the organization.

(11) Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.

(12) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.

(13) A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§410.142 through 410.146.

(14) Additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

(c) *Onsite visit.* CMS may visit the prospective organization's offices to verify information in the organization's application, including, but not limited to, review of documents, and interviews with the organization's staff.

(d) *Notice and comment—(1) Proposed notice.* CMS publishes a proposed notice in the FEDERAL REGISTER announcing its intention to approve an organization's request for CMS approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training. The notice includes the following information:

(i) The basis for approving the organization.

(ii) A description of how the organization's accreditation program applies and enforces quality standards that have been determined by CMS to meet or exceed the CMS quality standards described in § 410.144(a) or how the organization would use the NSDSMEP quality standards described in § 410.144(b).

(iii) An opportunity for public comment.

(2) *Final notice.* (i) After considering public comments CMS receives on the proposed notice, it publishes a final notice in the FEDERAL REGISTER indicating whether it has approved an organization's request for CMS approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training.

(ii) If CMS approves the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(e) *Criteria CMS uses to approve national accreditation organizations.* In deciding to approve and recognize an organization's accreditation program to accredit entities to furnish training, CMS considers the following criteria:

(1) The organization uses and enforces quality standards that CMS has determined meet or exceed the CMS quality standards described in § 410.144(a), or uses the NSDSMEP quality standards described in § 410.144(b).

(2) The organization meets the requirements for approved organizations in § 410.143.

(3) The organization is not owned or controlled by the entities it accredits, as defined in § 413.17(b)(2) or (b)(3), respectively, of this chapter.

(4) The organization does not accredit any entity it owns or controls.

(f) *Notice of CMS's decision.* CMS notifies the prospective organization in writing of its decision. The notice includes the following information:

(1) Statement of approval or denial.

(2) If approved, the expiration date of CMS's approval and recognition of the accreditation program.

(3) If denied, the rationale for the denial and the reconsideration and reapplication procedures.

(g) *Reconsideration of adverse decision.* An organization that has received CMS's notice of denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training may request reconsideration of CMS's decision in accordance with part 488 subpart D of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an organization that has received CMS's notice of denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training may submit a new request to CMS if it meets the following conditions:

(i) Has revised its accreditation program to correct the deficiencies CMS noted in its denial notice.

(ii) Demonstrates, through documentation, the use of one of the sets of quality standards described in § 410.144.

(iii) Resubmits the application in its entirety.

(2) For an organization that has requested reconsideration of CMS's denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training, CMS will not consider the organization's new request until all administrative proceedings on the previous request have been completed.

(i) *Withdrawal.* An organization requesting CMS approval and recognition of its accreditation program to accredit entities may withdraw its application at any time.

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(j) *Applying for continued CMS approval.* At least 6 months before the expiration of CMS's approval and recognition of the organization's program, an organization must request from CMS continued approval and recognition.

### § 410.143 Requirements for approved accreditation organizations.

(a) *Ongoing responsibilities of an approved accreditation organization.* An organization approved and recognized by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in writing, on a monthly basis, all of the following:

(i) Copies of all accreditation decisions and any accreditation-related information that CMS may require (including corrective action plans and summaries of unmet quality standards described in § 410.144).

(ii) Notice of all complaints related to approved entities.

(iii) Within 30 days of taking remedial or adverse action (including revocation, withdrawal, or revision of an approved entity's deemed status) against an approved entity, information describing the remedial or adverse action and the circumstances that led to taking the action.

(iv) Notice of any proposed changes in its accreditation standards and requirements or evaluation process. If an organization implements changes without CMS approval (other than changes to the NSDSMEP quality standards described in § 410.144(b)), CMS may withdraw its approval and recognition of the organization's accreditation program.

(2) If an organization does not use the NSDSMEP quality standards described in § 410.144(b), and wishes to change its quality standards that CMS previously approved, the organization must submit its plan to alter its quality standards and include a crosswalk between the set of quality standards described in § 410.144 and the organization's revised standards. If an organization implements changes in its quality standards without CMS approval, CMS may withdraw its approval and recognition of the organization's accreditation program.

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(3) If CMS notifies an organization that uses the CMS quality standards described in § 410.144(a) that it has changed the CMS quality standards, the organization must meet the following requirements:

(i) Submit to CMS, within 30 days of CMS's notification of a change in the quality standards, its organization's plan to alter its quality standards to conform to the revised quality standards described in § 410.144(a).

(ii) Implement the changes to its accreditation program by the implementation date specified in CMS's notification of the changes in the quality standards.

(b) *CMS oversight of approved national accreditation organizations.* CMS, or its agent, performs oversight activities to ensure that an approved organization and the entities the organization accredits continue to meet a set of quality standards described in § 410.144. CMS (or its agent) uses the following procedures:

(1) *Equivalency review.* CMS compares the organization's standards and its application and enforcement of its standards to a set of quality standards (described in § 410.144) and processes when any of the following conditions exist:

(i) CMS imposes new requirements or changes its process for approving and recognizing an organization.

(ii) Except for an organization that uses the NSDSMEP quality standards, the organization proposes to adopt new standards or changes its accreditation process.

(iii) The organization reapplies to CMS for continuation of its approval and recognition by CMS of its program to accredit entities to furnish training.

(2) *Validation reviews.* CMS validates an organization's accreditation process by conducting evaluations of approved entities accredited by the organization and comparing its results to the results of the organization's evaluation of the approved entities.

(3) *Onsite inspections.* CMS may conduct an onsite inspection of the organization's operations and offices to verify information and assess the organization's compliance with its own policies and procedures. The onsite inspection

may include, but is not limited to, reviewing documents, auditing documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Withdrawal of CMS approval and recognition.* (i) CMS gives an organization written notice of CMS's intent to withdraw its approval and recognition of the organization's program to accredit entities if CMS determines through an equivalency review, validation review, onsite inspection, or CMS's daily experience with the organization that any of the following conditions exist:

(A) Except for those accrediting organizations using quality standards in § 410.144(b), the quality standards that the organization applies and enforces do not meet or exceed the CMS quality standards described in § 410.144(a).

(B) The organization has failed to meet the requirements for accreditation in §§ 410.142 through 410.144.

(ii) *Request for reconsideration.* An organization may request a reconsideration of CMS's decision to withdraw its approval and recognition of the organization in accordance with part 488, subpart D of this chapter.

**§ 410.144 Quality standards for deemed entities.**

An organization approved and recognized by CMS may accredit an entity to meet one of the following sets of quality standards:

(a) *CMS quality standards.* Standards prescribed by CMS, which include the following:

(1) *Organizational structure.* (i) Provides the educational resources to support the programs offered and the beneficiaries served, including adequate space, personnel, budget, instructional materials, confidentiality, privacy, and operational support.

(ii) Defines clearly and documents the organizational relationships, lines of authority, staffing, job descriptions, and operational policies.

(iii) Maintains a written policy that affirms education as an integral component of diabetes care.

(iv) Includes in its operational policies, specific standards and procedures

identifying the amount of collaborative, interactive, skill-based training methods and didactic training methods furnished to the beneficiary.

(v) Assesses the service area to define the target population in order to appropriately allocate personnel and resources.

(vi) Identifies in its operational policies, the minimal amount that each team member must be involved in the following:

(A) Development of training materials.

(B) Instruction of beneficiaries.

(2) *Environment.* Maintains a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of all patients and that meets all applicable fire protection and life safety codes.

(3) *Program staff.* (i) Requires a program coordinator who is responsible for program planning, implementation, and evaluation.

(ii) Requires nonphysician professional staff to obtain 12 hours of continuing diabetes education concerning educational principles and behavior change strategies every 2 years.

(4) *Team approach.* (i) Except as provided in paragraph (a)(4)(ii) of this section for a rural area, furnishes services using a multidisciplinary instructional team that meets the following requirements:

(A) The team includes at least a registered dietitian, as recognized under State law, and a certified diabetes educator (CDE), certified by a qualified organization that has registered with CMS, who have didactic experience and knowledge of diabetes clinical and educational issues. (If the team includes a registered nurse, an approved entity may delay implementation of the requirement for a CDE until February 27, 2004.)

(B) The team is qualified to teach the training content areas required in paragraph (a)(5) of this section.

(C) All appropriate team members must be present during the portion of the training for which they are responsible and must directly furnish the training within the scope of their practices.

(ii) In a rural area, an individual who is qualified as a registered dietitian

and as a CDE that is currently certified by an organization approved by CMS (or until February 27, 2004 an individual who is qualified as a registered dietitian and as a registered nurse) may furnish training and is deemed to meet the multidisciplinary team requirement in paragraph (a)(4)(i) of this section.

(5) Training content. Offers training and is capable of meeting the needs of its patients on the following subjects:

(i) Diabetes overview/pathophysiology of diabetes.

(ii) Nutrition.

(iii) Exercise and activity.

(iv) Diabetes medications (including skills related to the self-administration of injectable drugs).

(v) Self-monitoring and use of the results.

(vi) Prevention, detection, and treatment of acute complications.

(vii) Prevention, detection, and treatment of chronic complications.

(viii) Foot, skin, and dental care.

(ix) Behavior change strategies, goal setting, risk factor reduction, and problem solving.

(x) Preconception care, pregnancy, and gestational diabetes.

(xi) Relationships among nutrition, exercise, medication, and blood glucose levels.

(xii) Stress and psychosocial adjustment.

(xiii) Family involvement and social support.

(xiv) Benefits, risks, and management options for improving glucose control.

(xv) Use of health care systems and community resources.

(6) *Training methods.* (i) Offers individual and group instruction for effective training.

(ii) Uses instructional methods and materials that are appropriate for the target population, and participants being served.

(iii) Uses primarily interactive, collaborative, skill-based training methods and maximizes the use of interactive training methods.

(7) *Review of plan of care and goals.* (i) Reviews each beneficiary's plan of care.

(ii) Develops and updates an individual assessment, in collaboration

with each beneficiary, that includes relevant medical history, present health status, health service or resource utilization, risk factors, diabetes knowledge and skills, cultural influences, health beliefs and attitudes, health behaviors and goals, support systems, barriers to learning, and socioeconomic factors.

(iii) Based on the assessment, develops, in collaboration with each beneficiary, an individual education plan. Includes in the education plan, the goals for education, the periodic updates, the specific amount of interactive, collaborative, skill-based training methods and didactic training methods that have been and will be furnished.

(iv) Documents the results, including assessment, intervention, evaluation and follow-up in the beneficiary's medical record.

(v) Forwards a copy of the documentation in paragraph (a)(7)(ii) through (iv) of this section to the referring physician (or qualified nonphysician practitioner).

(vi) Periodically updates the beneficiary's referring physician (or qualified nonphysician practitioner) about the beneficiary's educational status.

(8) Educational intervention. Offers appropriate and timely educational intervention based on referral from the beneficiary's physician (or qualified nonphysician practitioner) and based on periodic reassessments of health status, knowledge, skills, attitudes, goals, and self-care behaviors.

(9) *Performance measurement and quality improvement.* Establishes and maintains an effective internal performance measurement and quality improvement program that focuses on maximizing outcomes by improving patient safety and quality of care. The program must meet the following requirements:

(i) Stresses health outcomes (for example, improved beneficiary diabetes control, beneficiary understanding, or beneficiary compliance) and provides for the collection, analysis, and reporting of data that permits measurement of performance outcomes, or other quality indicators.

(ii) Requires an entity to take the following actions:

(A) Evaluate itself on an annual basis as to its effectiveness in using performance measures.

(B) Improve its performance on at least one outcome or quality indicator each year.

(10) *Quality improvement.* Has an agreement with a QIO to participate in quality improvement projects defined by the QIO, or if a program elects not to participate in a QIO project, it must be able to demonstrate a level of achievement through a project of its own design that is comparable to or better than the achievement to be expected from participation in the QIO quality improvement project.

(b) *The National Standards for Diabetes Self-Management Education Programs.* The set of quality standards contained in the NSDSMEP or any NSDSMEP standards subsequently revised.

(c) *Standards of a national accreditation organization that represents individuals with diabetes.* Standards that meet or exceed the CMS quality standards described in paragraph (a) of this section that have been developed by a national organization (and approved by CMS) that is either a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals, including health care professionals and Medicare beneficiaries, with diabetes.

#### § 410.145 Requirements for entities.

(a) *Deemed entities.* (1) Except as permitted in paragraph (a)(2) of this section, an entity may be deemed to meet a set of quality standards described in § 410.144 if the following conditions are met:

(i) The entity has submitted necessary documentation and is fully accredited (and periodically reaccredited) by an organization approved by CMS under § 410.142.

(ii) The entity is not accredited by an organization that owns or controls the entity.

(2) Before August 27, 2002 CMS may deem an entity to meet the NSDSMEP quality standards described in § 410.144(b), if the entity provides the Medicare contractor that will process its claims with a copy of a current certificate the entity received from the ADA that verifies the training program

it furnishes meets the NSDSMEP quality standards described in § 410.144(b).

(b) *Approved entities.* An entity may be approved to furnish training if the entity meets the following conditions:

(1) Before submitting a claim for Medicare payment, forwards a copy of its certificate or proof of accreditation from an organization approved by CMS under § 410.142 indicating that the entity meets a set of quality standards described in § 410.144, or before August 27, 2002, submits documentation of its current ADA recognition status.

(2) Agrees to submit to evaluation (including onsite inspections) by CMS (or its agent) to validate its approved organization's accreditation process.

(3) Authorizes its approved organization to release to CMS a copy of its most recent accreditation evaluation, and any accreditation-related information that CMS may require.

(4) At a minimum, allows the QIO (under a contract with CMS) access to beneficiary or group training records.

(c) *Effective dates—*(1) *Deemed to meet quality standards.* Except as permitted in paragraph (c)(2) of this section, the date on which an entity is deemed to meet a set of quality standards described in § 410.144 is the later of one of the following dates:

(i) The date CMS approves and recognizes the accreditation organization to accredit entities to furnish training.

(ii) The date an organization accredits the entity to meet a set of quality standards described in § 410.144.

(2) *Approved to furnish training.* CMS covers the training furnished by an entity beginning on the later of one of the following dates:

(i) The date CMS approves the deemed entity as meeting the conditions for coverage in § 410.141(e).

(ii) The date the entity is deemed to meet a set of quality standards described in § 410.144.

(d) *Removal of approved status—*(1) *General rule.* CMS removes an entity's approved status for any of the following reasons:

(i) CMS determines, on the basis of its own evaluation or the results of the accreditation evaluation, that the entity does not meet a set of quality standards described in § 410.144.

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(ii) CMS withdraws its approval of the organization that deemed the entity to meet a set of quality standards described in § 410.144.

(iii) The entity fails to meet the requirements of paragraphs (a) and (b) of this section.

(2) *Effective date.* The effective date of CMS's removal of an entity's approved status is 60 days after the date of CMS's notice to the entity.

### § 410.146 Diabetes outcome measurements.

(a) *Information collection.* An approved entity must collect and record in an organized systematic manner the following patient assessment information at least on a quarterly basis for a beneficiary who receives training under § 410.141:

(1) Medical information that includes the following:

- (i) Duration of the diabetic condition.
- (ii) Use of insulin or oral agents.
- (iii) Height and weight by date.
- (iv) Results and date of last lipid test.
- (v) Results and date of last HbA1C.
- (vi) Information on self-monitoring (frequency and results).
- (vii) Blood pressure with the corresponding dates.
- (viii) Date of the last eye exam.

(2) Other information that includes the following:

- (i) Educational goals.
- (ii) Assessment of educational needs.
- (iii) Training goals.
- (iv) Plan for a follow-up assessment of achievement of training goals between 6 months and 1 year after the beneficiary completes the training.
- (v) Documentation of the training goals assessment.

(b) *Follow-up assessment information.*

An approved entity may obtain information from the beneficiary's survey, primary care physician contact, and follow-up visits.

### Subpart I—Payment of SMI Benefits

SOURCE: 51 FR 41339, Nov. 14, 1986, unless otherwise noted. Redesignated at 59 FR 6577, Feb. 11, 1994.

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### § 410.150 To whom payment is made.

(a) *General rules.* (1) Any SMI enrollee is, subject to the conditions, limitations, and exclusions set forth in this part and in parts 405, 416 and 424 of this chapter, entitled to have payment made as specified in paragraph (b) of this section.

(2) The services specified in paragraphs (b)(5) through (b)(14) of this section must be furnished by a facility that has in effect a provider agreement or other appropriate agreement to participate in Medicare.

(b) *Specific rules.* Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

(1) To the individual, or to a physician or other supplier on the individual's behalf, for medical and other health services furnished by the physician or other supplier.

(2) To a nonparticipating hospital on the individual's behalf for emergency outpatient services furnished by the hospital, in accordance with subpart G of part 424 of this chapter.

(3) To the individual, for emergency outpatient services furnished by a nonparticipating hospital, in accordance with § 424.53 of this chapter.

(4) To the individual, for physicians' services and ambulance services furnished outside the United States in accordance with § 424.53 of this chapter.

(5) To a provider on the individual's behalf for medical and other health services furnished by the provider (or by others under arrangements made with them by the provider).

(6) To a home health agency on the individual's behalf for home health services furnished by the home health agency.

(7) To a clinic, rehabilitation agency, or public health agency on the individual's behalf for outpatient physical therapy or speech pathology services furnished by the clinic or agency (or by others under arrangements made with them by the clinic or agency).

(8) To a rural health clinic or Federally qualified health center on the individual's behalf for rural health clinic or Federally qualified health center services furnished by the rural health clinic or Federally qualified health center, respectively.



(9) To an ambulatory surgical center (ASC) on the individual's behalf for covered ambulatory surgical center facility services that are furnished in connection with surgical procedures performed in an ASC, as provided in part 416 of this chapter.

(10) To a comprehensive outpatient rehabilitation facility (CORF) on the individual's behalf for comprehensive outpatient rehabilitation facility services furnished by the CORF.

(11) To a renal dialysis facility, on the individual's behalf, for institutional or home dialysis services, supplies, and equipment furnished by the facility.

(12) To a critical access hospital (CAH) on the individual's behalf for outpatient CAH services furnished by the CAH.

(13) To a community mental health center (CMHC) on the individual's behalf, for partial hospitalization services furnished by the CMHC (or by others under arrangements made with them by the CMHC).

(14) To an SNF for services (other than those described in § 411.15(p)(2) of this chapter) that it furnishes to a resident (as defined in § 411.15(p)(3) of this chapter) of the SNF who is not in a covered Part A stay.

(15) To the qualified employer of a physician assistant for professional services furnished by the physician assistant and for services and supplies furnished incident to his or her services. Payment is made to the employer of a physician assistant regardless of whether the physician assistant furnishes services under a W-2, employer-employee employment relationship, or whether the physician assistant is an independent contractor who receives a 1099 reflecting the relationship. Both types of relationships must conform to the appropriate guidelines provided by the Internal Revenue Service. A qualified employer is not a group of physician assistants that incorporate to bill for their services. Payment is made only if no facility or other provider charges or is paid any amount for services furnished by a physician assistant.

(16) To a nurse practitioner or clinical nurse specialist for professional services furnished by a nurse practitioner or clinical nurse specialist in all

settings in both rural and nonrural areas and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges, or is paid, any amount for the furnishing of the professional services of the nurse practitioner or clinical nurse specialist.

(17) To a clinical psychologist on the individual's behalf for clinical psychologist services and for services and supplies furnished as an incident to his or her services.

(18) To a clinical social worker on the individual's behalf for clinical social worker services.

(19) To a participating HHA, 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 (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).

(20) To a certified nurse-midwife for professional services furnished by the certified nurse-midwife in all settings and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges or is paid any amount for the furnishing of the professional services of the certified nurse-midwife.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993; 59 FR 6577, Feb. 11, 1994; 63 FR 20129, Apr. 23, 1998; 63 FR 26308, May 12, 1998; 63 FR 58909, Nov. 2, 1998; 65 FR 41211, July 3, 2000; 66 FR 39599, July 31, 2001; 75 FR 73615, Nov. 29, 2010]

#### § 410.152 Amounts of payment.

(a) *General provisions*—(1) *Exclusion from incurred expenses*. As used in this section, “incurred expenses” are expenses incurred by an individual, during his or her coverage period, for covered Part B services, excluding the following:

(i) Expenses incurred for services for which the beneficiary is entitled to have payment made under Medicare Part A or would be so entitled except

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for the application of the Part A deductible and coinsurance requirements.

(ii) Expenses incurred in meeting the Part B blood deductible (§410.161).

(iii) In the case of services payable under a formula that takes into account reasonable charges, reasonable costs, customary charges, customary (insofar as reasonable) charges, charges related to reasonable costs, fair compensation, a pre-treatment prospective payment rate, or a standard overhead amount, or any combination of two or more of these factors, expenses in excess of any factor taken into account under that formula.

(iv) Expenses in excess of the outpatient mental health treatment limitation described in §410.155.

(v) In the case of expenses incurred for outpatient physical therapy services including speech-language pathology services, the expenses excluded are from the incurred expenses under §410.60(e). In the case of expenses incurred for outpatient occupational therapy including speech-language pathology services, the expenses excluded are from the incurred expenses under §410.59(e).

(2) *Other applicable provisions.* Medicare Part B pays for incurred expenses the amounts specified in paragraphs (b) through (k) of this section, subject to the following:

(i) The principles and procedures for determining reasonable costs and reasonable charges and the conditions for Medicare payment, as set forth in parts 405 (subparts E and X), 413, and 424 of this chapter.

(ii) The Part B annual deductible (§410.160).

(iii) The special rules for payment to health maintenance organizations (HMOs), health care prepayment plans (HCPPs), and competitive medical plans (CMPs) that are set forth in part 417 of this chapter. (A prepayment organization that does not qualify as an HMO, CMP, or HCPP is paid in accordance with paragraph (b)(4) of this section.)

(b) *Basic rules for payment.* Except as specified in paragraphs (c) through (h) of this section, Medicare Part B pays the following amounts:

(1) For services furnished by, or under arrangements made by, a pro-

vider other than a nominal charge provider, whichever of the following is less:

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

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

(2) For services furnished by, or under arrangements made by, a nominal charge provider, 80 percent of fair compensation.

(3) For emergency outpatient hospital services furnished by a non-participating hospital that is eligible to receive payment for those services under subpart G of part 424 of this chapter, the amount specified in paragraph (b)(1) of this section.

(4) For services furnished by a person or an entity other than those specified in paragraphs (b)(1) through (b)(3) of this section, 80 percent of the reasonable charges or 80 percent of the payment amount computed on any other payment basis for the services.

(c) *Amount of payment: Home health services other than durable medical equipment (DME).* For home health services other than DME furnished by, or under arrangements made by, a participating HHA, Medicare Part B pays the following amounts:

(1) For services furnished by an HHA that is a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by an HHA that is not a nominal charge provider, the lesser of the reasonable cost of the services and the customary charges for the services.

(d) *Amount of payment: DME furnished as a home health service—(1) Basic rule.* Except as specified in paragraph (d)(2) of this section—

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

(ii) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays the lesser of the following:

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

(B) 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.

(2) *Exception.* If the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for new equipment—

(i) For used DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 100 percent of fair compensation.

(ii) For used DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays 100 percent of the reasonable cost of, or the customary charge for, the services, whichever is less.

(e) *Amount of payment: Renal dialysis services, supplies, and equipment.* Effective for services furnished on or after August 1, 1983, Medicare Part B pays for the institutional dialysis services specified in §409.250 and the home dialysis services, supplies, and equipment specified in §409.252, as follows:

(1) Except as provided in paragraph (d)(2) of this section, 80 percent of the per treatment prospective reimbursement rate established under §413.170 of this chapter, for outpatient maintenance dialysis furnished by ESRD facilities approved in accordance with part 494 of this chapter.

(2) *Exception.* If a home dialysis patient elects to obtain home dialysis supplies or equipment (or both) from a party other than an approved ESRD facility, payment is in accordance with paragraph (b)(4) of this section.

(f) *Amount of payment: Rural health clinic (RHC) and Federally qualified health center (FQHC) services.* Medicare Part B pays, for services by a participating RHC or FQHC that is authorized to bill under the reasonable cost system, 80 percent of the costs determined under subpart X of part 405 of this chapter, to the extent those costs are reasonable and related to the cost of furnishing RHC or FQHC services or reasonable on the basis of other tests specified by CMS.

(g) *Amount of payment: Used durable medical equipment furnished by other than an HHA.* Medicare Part B pays the following amounts for used DME purchased by or on behalf of the beneficiary at a price at least 25 percent

less than the reasonable charge for comparable new equipment:

(1) For used DME furnished by, or under arrangements made by, a nominal charge provider, 100 percent of fair compensation.

(2) For used DME furnished by or under arrangements made by a provider that is not a nominal charge provider, 100 percent of the reasonable cost of the service or the customary charge for the service, whichever is less.

(3) For used DME furnished by other than a provider, 100 percent of the reasonable charge.

(h) *Amount of payment: Pneumococcal vaccine.* Medicare Part B pays for pneumococcal vaccine and its administration as follows:

(1) For services furnished by a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by a provider that is not a nominal charge provider, the reasonable cost of the services or the customary charge for the service, whichever is less.

(3) For services furnished by other than a provider, a rural health clinic or a Federally qualified health center, 100 percent of the reasonable charge.

(4) For services furnished by a rural health clinic or a Federally qualified health center, 100 percent of the reasonable cost.

(i) *Amount of payment: ASC facility services.* (1) For ASC facility services furnished on or after July 1, 1987 and before January 1, 2008, in connection with the surgical procedures specified in part 416 of this chapter, Medicare Part B pays 80 percent of a standard overhead amount as specified in §416.120(c) of this chapter, except that, for screening flexible sigmoidoscopies and screening colonoscopies, Part B coinsurance is 25 percent of the standard overhead amount and Medicare Part B pays 75 percent of the standard overhead amount.

(2) For ASC services furnished on or after January 1, 2008, in connection with the covered surgical procedures specified in §416.166 of this subchapter, except as provided in paragraphs (i)(2)(i), (i)(2)(ii), and (1) of this section, Medicare Part B pays the lesser of 80

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percent of the actual charge or 80 percent of the prospective payment amount, geographically adjusted, if applicable, as determined under Subpart F of Part 416 of this subchapter. Part B coinsurance is 20 percent of the actual charge or 20 percent of the prospective payment amount, geographically adjusted, if applicable.

(i) If the limitation described in § 416.167(b)(3) of this subchapter applies, Medicare pays 80 percent of the amount determined under Subpart B of Part 414 of this subchapter and Part B coinsurance is 20 percent of the applicable payment amount, except as provided in paragraph (l) of this section.

(ii) Between January 1, 2008 and December 31, 2010, Medicare Part B pays 75 percent of the applicable payment amount for screening flexible sigmoidoscopies and screening colonoscopies, and Part B coinsurance is 25 percent of the applicable payment amount.

(j) *Amount of payment: services of Federally funded health facilities prior to October 1, 1991.* Medicare Part B pays 80 percent of charges related to the reasonable costs that a Federally funded health facility incurs in furnishing the services. See § 411.8(b)(6) of this chapter.

(k) *Amount of payment: Outpatient CAH services.* (1) Payment for CAH outpatient services is the reasonable cost of the CAH in providing these services, as determined in accordance with section 1861(v)(1)(A) of the Act, with § 413.70(b) and (c) of this chapter, and with the applicable principles of cost reimbursement in part 413 and in part 415 of this chapter.

(2) Payment for CAH outpatient services is subject to the applicable Medicare Part B deductible and coinsurance amounts, except as described in § 413.70(b)(2)(iii) of this chapter, with Part B coinsurance being calculated as 20 percent of the customary (insofar as reasonable) charges of the CAH for the services.

(l) *Amount of payment: Preventive services.* Medicare Part B pays 100 percent of the Medicare payment amount established under the applicable payment methodology for the service setting for providers and suppliers for the following preventive services:

(1) Pneumococcal (as specified in paragraph (h) of this section), influenza, and hepatitis B vaccine and administration.

(2) Screening mammography.

(3) Screening pap tests and screening pelvic exam.

(4) Prostate cancer screening tests (excluding digital rectal examinations).

(5) Colorectal cancer screening tests (excluding barium enemas).

(6) Bone mass measurement.

(7) Medical nutrition therapy (MNT) services.

(8) Cardiovascular screening blood tests.

(9) Diabetes screening tests.

(10) Ultrasound screening for abdominal aortic aneurysm (AAA).

(11) Additional preventive services identified for coverage through the national coverage determination (NCD) process.

(12) Initial Preventive Physical Examination (IPPE).

(13) Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS).

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 410.152, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.govinfo.gov](http://www.govinfo.gov).

### § 410.155 Outpatient mental health treatment limitation.

(a) *Limitation.* For services subject to the limitation as specified in paragraph (b) of this section, the percentage of the expenses incurred for such services during a calendar year that is considered incurred expenses under Medicare Part B when determining the amount of payment and deductible under § 410.152 and § 410.160 of this part, respectively, is as follows:

(1) For expenses incurred in years before 2010, 62½ percent.

(2) For expenses incurred in 2010 and 2011, 68¾ percent.

(3) For expenses incurred in 2012, 75 percent.

(4) For expenses incurred in 2013, 81¼ percent.

(5) For expenses incurred in CY 2014 and subsequent years, 100 percent.

(b) *Application of the limitation*—(1) *Services subject to the limitation.* Except as specified in paragraph (b)(2) of this section, services furnished by physicians and other practitioners, whether furnished directly or incident to those practitioners' services, are subject to the limitation if they are furnished in connection with the treatment of a mental, psychoneurotic, or personality disorder (that is, any condition identified by a diagnosis code within the range of 290 through 319) and are furnished to an individual who is not an inpatient of a hospital:

(i) Services furnished by physicians and other practitioners, whether furnished directly or as an incident to those practitioners' services.

(ii) Services provided by a CORF.

(2) *Services not subject to the limitation.* Services not subject to the limitation include the following:

(i) Services furnished to a hospital inpatient.

(ii) Brief office visits for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental, psychoneurotic, or personality disorders billed under HCPCS code M0064 (or its successor).

(iii) Partial hospitalization services not directly provided by a physician.

(iv) Psychiatric diagnostic services billed under CPT codes 90801 and 90802 (or successor codes) and diagnostic psychological and neuropsychological tests billed under CPT code range 96101 through 96125 (or successor codes) that are performed to establish a diagnosis.

(v) Medical management such as that furnished under CPT code 90862 (or its successor code), as opposed to psychotherapy, furnished to a patient diagnosed with Alzheimer's disease or a related disorder.

(3) *Payment amounts.* The Medicare payment amount and the patient liability amounts for outpatient mental health services subject to the limitation for each year during which the limitation is phased out are as follows:

Calendar year	Recognized incurred expenses	Patient pays	Medicare pays
CY 2009 and prior calendar years .....	62.50%	50%	50%
CYs 2010 and 2011 ..	68.75%	45%	55%
CY 2012 .....	75.00%	40%	60%
CY 2013 .....	81.25%	35%	65%

Calendar year	Recognized incurred expenses	Patient pays	Medicare pays
CY 2014 .....	100.00%	20%	80%

(c) *General formula.* A general formula for calculating the amount of Medicare payment and the patient liability for outpatient mental health services subject to the limitation is as follows:

(1) Multiply the Medicare approved amount by the percentage of incurred expenses that is recognized as incurred expenses for Medicare payment purposes for the year involved;

(2) Subtract from this amount the amount of any remaining Part B deductible for the patient and year involved; and,

(3) Multiply this amount by 0.80 (80 percent) to obtain the Medicare payment amount.

(4) Subtract the Medicare payment amount from the Medicare-approved amount to obtain the patient liability amount.

[63 FR 20129, Apr. 23, 1998, as amended at 73 FR 69934, Nov. 19, 2008; 74 FR 62005, Nov. 25, 2009]

**§ 410.160 Part B annual deductible.**

(a) *Basic rule.* Except as provided in paragraph (b) of this section, incurred expenses (as defined in § 410.152) are subject to, and count toward meeting the annual deductible.

(b) *Exceptions.* Expenses incurred for the following services are not subject to the Part B annual deductible and do not count toward meeting that deductible:

(1) Home health services.

(2) Pneumococcal, influenza, and hepatitis b vaccines and their administration.

(3) Federally qualified health center services.

(4) ASC facility services furnished before July 1987 and physician services furnished before April 1988 that met the requirements for payment of 100 percent of the reasonable charges.

(5) Screening mammography services as described in § 410.34 (c) and (d).

(6) Screening pelvic examinations as described in § 410.56.

(7) Beginning January 1, 2007, colorectal cancer screening tests as described in § 410.37.

(8) Beginning January 1, 2011, for a surgical service, and beginning January 1, 2015, for an anesthesia service, furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal cancer screening test. A surgical or anesthesia service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test means—a surgical or anesthesia service furnished on the same date as a planned colorectal cancer screening test as described in §410.37.

(9) Beginning January 1, 2009, initial preventive physical examinations as described in §410.16.

(10) Bone mass measurement.

(11) Medical nutrition therapy (MNT) services.

(12) Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS).

(13) Additional preventive services identified for coverage through the national coverage determination (NCD) process.

(c) *Application of the Part B annual deductible.* (1) Before payment is made under §410.152, an individual's incurred expenses for the calendar year are reduced by the Part B annual deductible.

(2) The Part B annual deductible is applied to incurred expenses in the order in which claims for those expenses are processed by the Medicare program.

(3) Only one Part B annual deductible may be imposed for any calendar year and it may be met by any combination of expenses incurred in that year.

(d) *Special rule for services reimbursable on a formula basis.* (1) In applying the formula that takes into account reasonable costs, customary charges, and customary (insofar as reasonable) charges, and is used to determine payment for services furnished by a provider that is not a nominal charge provider, the Medicare intermediary takes the following steps:

(i) Reduces the customary charges for the services by an amount equal to any unmet portion of the deductible for the calendar year, in accordance with paragraph (b) of this section. (The amount of this reduction is considered to be the amount of the deductible that

is met on the basis of the services to which it is applied.)

(ii) Determines 20 percent of any remaining portion of the customary (insofar as reasonable) charge.

(iii) Determines the lesser of the reasonable cost of the services and the customary charges for the services.

(iv) Reduces the amount determined under paragraph (c)(1)(iii) of this section by the sum of the reduction made under paragraph (c)(1)(i) of this section and the amount determined under paragraph (c)(1)(ii) of this section.

(v) Reduces the reasonable cost of the services by the amount of the reduction made under paragraph (c)(1)(i) of this section and multiplies the result by 80 percent.

(2) In accordance with §410.152(b)(1), the amount payable is the amount determined under paragraph (c)(1)(iv) of this section, or the amount determined under paragraph (c)(1)(v) of this section, whichever is less.

(e) *Special rule for services of an independent rural health clinic.* Application of the Part B annual deductible to rural health clinic services is in accordance with §405.2425(b)(2) of this chapter.

(f) *Amount of the Part B annual deductible.* (1) Beginning with expenses for services furnished during calendar year 2006, and for all succeeding years, the annual deductible is the previous year's deductible plus the annual percentage increase in the monthly actuarial rate for Medicare enrollees age 65 and over, rounded to the nearest dollar.

(2) For 2005, the deductible is \$110.

(3) From 1991 through 2004, the deductible was \$100.

(4) From 1982 through 1990, the deductible was \$75.

(5) From 1973 through 1981, the deductible was \$60.

(6) From 1966 through 1972, the deductible was \$50.

(g) *Carryover of Part B annual deductible.* For calendar years before 1982, the Part B annual deductible was reduced by the amount of expenses incurred during the last quarter of the preceding year that was applied to meet the deductible for that preceding year. *Example:* If \$20 of expenses incurred in November 1980 was used to meet the 1980

deductible, the 1981 deductible was reduced to \$40 (\$60–\$20).

(h) *Examples of application of the annual deductible.* (1) Mr. A submitted claims for the following expenses incurred during 1982: \$20 for services furnished in March by physician X; \$30 for services furnished in April by physician Y; \$50 for services furnished in June by physician Z, for a total of \$100. The carrier determined that the charges as submitted were the reasonable charges. The first \$75 of expenses for which claims were processed is applied to meet the \$75 deductible for that year. Medicare Part B pays 80 percent of the remaining \$25, or \$20.

(2) Mr. B submitted a claim that included a \$25 charge by a doctor for an examination to prescribe a hearing aid and an \$80 charge for office surgery. This was the first claim relating to Mr. B's medical expenses processed in the calendar year. The carrier disallowed the \$25 charge because the type of examination is not covered by Medicare. The carrier reduced the \$80 surgery charge to a reasonable charge of \$40. Only the \$40 reasonable charge for covered services will count toward meeting Mr. B's deductible. Since the remainder of the surgery charge constitutes and excess over the reasonable charge, it cannot be applied to satisfy Mr. B's deductible.

(3) Mr. C became entitled to Medicare Part B benefits on July 1, 1982. He incurred expenses of \$200 in July, August, and September. The carrier determined that the charges as submitted were reasonable. Even though Mr. C was entitled to benefits for only half the year, he must meet the full \$75 deductible. Thus, \$75 of this expense constitutes Mr. C's deductible. Medicare would pay \$100, which is 80 percent of the remaining \$125.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8842, 8852, Mar. 1, 1991; 57 FR 24981, June 12, 1992; 62 FR 59101, Oct. 31, 1997; 69 FR 66423, Nov. 15, 2004; 71 FR 69785, Dec. 1, 2006; 73 FR 69934, Nov. 19, 2008; 75 FR 73615, Nov. 29, 2010; 77 FR 69363, Nov. 16, 2012; 80 FR 71373, Nov. 16, 2015]

#### § 410.161 Part B blood deductible.

(a) *General rules.* (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 pint of whole blood, which in this section is referred to as 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 are furnished under Part A or Part B in a calendar year. The Part B blood deductible is reduced to the extent that a blood deductible has been applied under Part A.

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

(5) The blood deductible is in addition to the Part B annual deductible specified in § 410.160.

(b) *Beneficiary's responsibility for the first 3 units of blood.* (1) The beneficiary is responsible for the first three units of whole blood or packed red cells received during a calendar year.

(2) If the blood is furnished by a hospital or CAH, the rules set forth in § 409.87 (b), (c), and (d) of this chapter apply.

(3) If the blood is furnished by a physician, clinic, or other supplier that has accepted assignment of Medicare benefits, or claims payment under § 424.64 of this chapter because the beneficiary died without assigning benefits, the supplier may charge the beneficiary the reasonable charge for the first 3 units, to the extent that those units are not replaced.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 58 FR 30668, May 26, 1993]

#### § 410.163 Payment for services furnished to kidney donors.

Notwithstanding any other provisions of this chapter, there are no deductible or coinsurance requirements with respect to services furnished to an individual who donates a kidney for transplant surgery.

**§ 410.165**

**§ 410.165 Payment for rural health clinic services and ambulatory surgical center services: Conditions.**

(a) Medicare Part B pays for covered rural health clinic and Federally qualified health center services if—

(1) The services are furnished in accordance with the requirements of subpart X of part 405 of this chapter and subpart A of part 491 of this chapter; and

(2) The clinic or center files a written request for payment on the form and in the manner prescribed by CMS.

(b) Medicare Part B pays for covered ambulatory surgical center (ASC) services if—

(1) The services are furnished in accordance with the requirements of part 416 of this chapter; and

(2) The ASC files a written request for payment on the form and in the manner prescribed by CMS.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 24981, June 12, 1992]

**§ 410.170 Payment for home health services, for medical and other health services furnished by a provider or an approved ESRD facility, and for comprehensive outpatient rehabilitation facility (CORF) services: Conditions.**

Payment under Medicare Part B, for home health services, for medical and other health services, or for CORF services, may be made to the provider or facility only if the following conditions are met:

(a) *Request for payment.* A written request for payment is filed by or on behalf of the individual to whom the services were furnished.

(b) *Physician certification.* (1) For home health services, a physician provides certification and recertification in accordance with § 424.22 of this chapter.

(2) For medical and other health services, a physician provides certification and recertification in accordance with § 424.24 of this chapter.

(3) For CORF services, a physician provides certification and recertification in accordance with § 424.27 of this chapter.

(c) In the case of home dialysis support services described in § 410.52, the services are furnished in accordance

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with a written plan prepared and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition as required by § 494.90 of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 73 FR 20474, Apr. 15, 2008]

**§ 410.172 Payment for partial hospitalization services in CMHCs: Conditions.**

Medicare Part B pays for partial hospitalization services furnished in a CMHC on behalf of an individual only if the following conditions are met:

(a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and

(b) The services are furnished in accordance with the requirements described in § 410.110.

[59 FR 6578, Feb. 11, 1994]

**§ 410.175 Alien absent from the United States.**

(a) Medicare does not pay Part B benefits for services furnished to an individual who is not a citizen or a national of the United States if those services are furnished in any month for which the individual is not paid monthly social security cash benefits (or would not be paid if he or she were entitled to those benefits) because he or she has been outside the United States continuously for 6 full calendar months.

(b) Payment of benefits resumes with services furnished during the first full calendar month the alien is back in the United States.

[53 FR 6634, Mar. 2, 1988]

**PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT**

**Subpart A—General Exclusions and Exclusion of Particular Services**

Sec.

411.1 Basis and scope.

411.2 Conclusive effect of QIO determinations on payment of claims.

411.4 Services for which neither the beneficiary nor any other person is legally obligated to pay.