

Centers for Medicare & Medicaid Services, HHS

§ 410.10

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, critical access hospital (CAH), skilled nursing facility (SNF), home health agencies (HHA), comprehensive outpatient rehabilitation facility (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 intensive outpatient services, and nonparticipating 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(hhh)(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; 88 FR 77874, Nov. 13, 2023; 88 FR 82177, Nov. 22, 2023]

§ 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), HHAs, CORFs, and partial hospitalization services and intensive outpatient services provided by 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 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; 88 FR 82177, Nov. 22, 2023]

§ 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

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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 and intensive outpatient 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, influenza, and COVID-19 vaccines (or monoclonal antibodies used for preexposure prophylaxis of COVID-19) and their administration.

(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 and its administration, as defined in § 410.63(a) of this subchapter.

(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.

(y) Intravenous immune globulin, including items and services, administered in the home for the treatment of primary immune deficiency diseases.

(z) Marriage and Family Therapist services, as provided in § 410.53.

(aa) Mental Health Counselor services, as provided in § 410.54.

[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; 87 FR 70223, Nov. 18, 2022; 88 FR 77874, Nov. 13, 2023; 88 FR 79525, Nov. 16, 2023; 88 FR 82177, Nov. 22, 2023]

§ 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 connection 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—

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

- (i) A review of the potential risk factors to the individual for opioid use disorder;
- (ii) An evaluation of the individual's severity of pain and current treatment plan;
- (iii) The provision of information on non-opioid treatment options; and
- (iv) A referral to a specialist, as appropriate.

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 re-

port, 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) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(xii) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xiii) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

(xiv) 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 AWW 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.

(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) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(x) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xi) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk

Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

(xii) 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; 85 FR 85025, Dec. 28, 2020; 88 FR 79525, Nov. 16, 2023]

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

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

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

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) A review of any current opioid prescriptions as defined in this section.

(7) Screening for potential substance use disorders to include a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(8) 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.

(9) 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:

(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 os-

teopathy (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; 85 FR 85025, Dec. 28, 2020]

§ 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.

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(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.

(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) Hemoglobin A1C test.

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

(d) *Amount of testing covered.* Medicare covers two tests within the 12-month period following the date of the most recent diabetes screening test of that individual.

(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/m².

(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/m².

(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, as amended at 88 FR 79525, Nov. 16, 2023]

§ 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 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.

(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—

(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;

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(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.¹

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

¹For services furnished before July 1, 1981, Medicare Part B paid only for the following

§ 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:

(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)(ii).

(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.

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.

(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). Behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary

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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; 87 FR 70223, Nov. 18, 2022]

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician 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, except for mental health services furnished to beneficiaries in their homes through the use of communication technology;

(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 subchapter, or through the use of communication technology for mental health services, general supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure.

(B) Certain therapeutic services and supplies may be assigned either direct supervision or personal supervision.

(I) 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. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished as specified in §§ 410.47 and 410.49, respectively. Through December 31, 2024, the presence of the physician or nonphysician

practitioner for the purpose of the supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

(2) Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure.

(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; and

(v) In accordance with applicable State law.

(2) In the case of partial hospitalization services or intensive outpatient 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 and intensive outpatient 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, *non-physician practitioner* means a clinical psychologist, licensed clinical social worker, marriage and family therapist, mental health counselor, 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; 85 FR 86299, Dec. 29, 2020; 87 FR 72284, Nov. 23, 2022; 88 FR 82177, Nov. 22, 2023]

§ 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 one of the three levels of supervision (as defined in paragraphs (e)(1) through (3) of this section) specified by CMS for the particular service by a physician or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a non-physician practitioner (physician assistant, nurse practitioner, clinical

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nurse specialist, certified nurse-midwife or certified registered nurse anesthetist).

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

(2) *Direct supervision.* (i) 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 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 where the procedure is performed.

(ii) For services furnished under arrangement in nonhospital locations, "direct supervision" means the physician or nonphysician practitioner 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 or nonphysician practitioner must be present in the room when the procedure is performed.

(iii) Through December 31, 2024, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).

(3) *Personal supervision.* Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure.

(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; 87 FR 72285, Nov. 23, 2022; 88 FR 82177, Nov. 22, 2023]

§ 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 justification 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, including, beginning January 1, 2023, an individual who meets the requirements specified in § 407.55 of this subchapter.

(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; 87 FR 66510, Nov. 3, 2022]

§ 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 stand-

ards 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, marriage and family therapists, mental health counselors, 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 non-physician 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.

(4) *Application to audiologists.* Except as otherwise provided in this paragraph, audiologists may personally furnish diagnostic audiology tests for a patient once per patient per 12-month period without an order from the physician or nonphysician practitioner treating the patient. Such diagnostic audiology tests can be for non-acute hearing conditions, but may not include audiology services that are related to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids that are outlined at § 411.15(d). Audiology services furnished without an order from the treating physician or practitioner are billed

using a modifier CMS designates for this purpose.

(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, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife. 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(l)(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 or clinical psychologist; or under the general supervision of a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist or certified nurse-midwife, to the extent they are authorized to perform the tests under their scope of practice and applicable State laws.

(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.

(ix) Diagnostic tests performed by a physician assistant authorized to perform the tests under their scope of practice and applicable State laws.

(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 (or other supervising practitioner) 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 (or other supervising

practitioner) must be present in the room when the procedure is performed. Through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

(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 informa-

tion 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.

(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 parameters 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; 85 FR 85026, Dec. 28, 2020; 87 FR 70223, Nov. 18, 2022; 88 FR 79525, Nov. 16, 2023]

§ 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.* (1) Except as otherwise stated in paragraph (c)(2) of this section, any nonphysician 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.

(2) For services that do not require direct or in-person beneficiary interaction, treatment, or testing, any nonphysician personnel used by the IDTF to perform the tests must meet all applicable State licensure requirements for doing so. If there are any applicable State licensure requirements, 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.

(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 (including additions and deletions of locations), 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) Except as otherwise stated in paragraph (g)(6)(ii) of this section, 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—

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

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

(ii) Paragraph (g)(6)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

(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) Except as otherwise stated in paragraph (g)(8)(ii) of this section, 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:

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

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

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

(ii) Paragraph (g)(8)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

(9) Openly post these standards for review by patients and the public. (This requirement does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.)

(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; 86 FR 65662, Nov. 19, 2021; 88 FR 79526, Nov. 16, 2023]

§ 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)(i) Leg, arm, back, and neck braces.

(A) A leg brace may include a shoe if it is an integral part of the brace (necessary for the leg brace to function properly) and its expense is included as part of the cost of the brace.

(ii) Artificial legs, arms, and eyes; and

(iii) Replacements for the devices specified in paragraphs (a)(3)(i) and (ii) if required because of a change in the individual's physical condition.

(4) Lymphedema compression treatment items, including the following:

(i) Standard and custom fitted gradient compression garments.

(ii) Gradient compression wraps with adjustable straps.

(iii) Compression bandaging systems.

(iv) Other items determined to be lymphedema compression treatment items under the process established under § 414.1670.

(v) For the purposes of paragraphs (i) and (ii) of this paragraph, the scope of the benefit for lymphedema compression treatment items includes accessories such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers that are necessary for the effective use of a gradient compression garment or wrap with adjustable straps.

(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; 88 FR 77874, Nov. 13, 2023]

§ 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 purpose 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 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 45.

(2) For an individual 45 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 45.

(2) For an individual 45 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 45 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.

(j) *Expansion of coverage of colorectal cancer screening tests.* Effective January 1, 2022, colorectal cancer screening tests include a planned screening flexible sigmoidoscopy or screening colonoscopy that involves the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(k) *A complete colorectal cancer screening.* Effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. The frequency limitations de-

scribed for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

[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; 86 FR 65662, Nov. 19, 2021; 87 FR 70223, Nov. 18, 2022]

§ 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.

(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 for diagnosing, treating, or managing a

clinical condition for which the DMEPOS is ordered.

(4) *Refills*—(i) *Definitions*. As used in this paragraph (d):

Date of service (for refilled items) means either—

(1) The date of delivery for the DMEPOS item; or

(2) For items rendered via delivery or shipping service, the shipping date.

Refills mean DMEPOS products that are provided on a recurring basis secondary to a medically necessary DMEPOS order.

Shipping date means—

(1) The date the delivery/shipping service label is created; or

(2) The date that the item is retrieved for delivery. These dates must not demonstrate significant variation.

(ii) *Documentation*. The DMEPOS supplier must document contact with the beneficiary or their representative to verify the refill is needed. This documentation must include both of the following:

(A) Evidence of the beneficiary or their representative's affirmative response of the need for supplies, which should be obtained as close to the expected end of the current supply as possible. Contact and affirmative response must be within 30 calendar days from the expected end of the current supply.

(B)(i) For shipped items, the beneficiary name, date of contact, the item requested, and an affirmative response from the beneficiary, indicative of the need for refill, prior to dispensing the product; or

(2) For items obtained in-person from a retail store, the delivery slip signed by the beneficiary or their representative or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

(iii) *Delivery of DMEPOS items provided on a recurring basis*. The date of service for DMEPOS items provided on a recurring basis must be no earlier than 10 calendar days before the expected end of the current supply.

(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; 88 FR 77875, Nov. 13, 2023]

§ 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 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 CMS. The ambulance service must meet all program coverage criteria including vehicle and staffing requirements. While a signed physician certification statement (PCS), does not alone demonstrate that transportation by ground ambulance was medically necessary, the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is medically necessary. The PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at § 410.41(a), that includes observation or other services rendered by qualified ambulance personnel, as described in § 410.41(b).

(3) *Special rule for nonemergency ambulance services that are either unscheduled*

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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 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, rural emergency hospital (REH), 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 or

REH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, REH, 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, REH (effective January 1, 2023), 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; 87 FR 70223, Nov. 18, 2022; 87 FR 72285, Nov. 23, 2022]

§ 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.

(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;

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(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 (including substance use disorder 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 (including patients with substance use disorder).

(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 or substance use disorder 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; 88 FR 82177, Nov. 22, 2023]

§ 410.44 Intensive outpatient services: Conditions and exclusions.

(a) Intensive outpatient 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(d) of this chapter; and

(4) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other mental health professionals (including substance use disorder 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 (including patients with substance use disorder).

(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 intensive outpatient 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) Intensive outpatient programs are intended for patients who—

(1) Require a minimum of 9 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 or substance use disorder 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 intensive outpatient program.

[88 FR 82177, Nov. 22, 2023]

§ 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 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

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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 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.

Medical director means the physician who oversees the pulmonary rehabilitation program at a particular site.

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

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

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

(ii) Objective clinical measures of 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 aerobic exercise combined with other

types of exercise (such as conditioning, breathing retraining, step, and strengthening) 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 or respiratory condition 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.

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

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

(b) *General rule—(1) Covered conditions.* Medicare Part B covers pulmonary rehabilitation for beneficiaries:

(i) With moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease;

(ii) Who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks;

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

(2) *Components.* Pulmonary rehabilitation must include all of the following:

(i) Physician-prescribed exercise during each pulmonary rehabilitation session.

(ii) Education or training that is closely and clearly related to the individual's care and treatment which is tailored to the individual's needs and

assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life. Education must include information on respiratory problem management and, if appropriate, brief smoking cessation counseling.

(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 pulmonary rehabilitation in the following settings:

(A) A physician's office.

(B) A hospital outpatient setting.

(ii) All settings must have the following:

(A) A physician or nonphysician practitioner 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 or nonphysician practitioner 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.

(B) 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.

(c) *Medical director standards.* The physician responsible for a pulmonary rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following:

(1) Expertise in the management of individuals with respiratory 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 pulmonary rehabilitation program is offered.

(d) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(e) *Limitations on coverage:* The number of pulmonary rehabilitation 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 Administrative Contractor.

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

[74 FR 62002, Nov. 25, 2009, as amended at 86 FR 65662, Nov. 19, 2021; 88 FR 79526, Nov. 16, 2023]

§ 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).

(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/1.73m², 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 or nonphysician practitioner 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 or nonphysician practitioner 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 the physician who oversees the cardiac rehabilitation or intensive cardiac rehabilitation program at a particular site.

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

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

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

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

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 (such as strengthening and 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 practitioner means a physician or nonphysician practitioner 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 conditions.* Medicare Part B covers cardiac rehabilitation and intensive cardiac rehabilitation 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.* Cardiac rehabilitation and intensive cardiac rehabilitation 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 individual's 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 the following settings:

- (A) A physician's office.
- (B) A hospital outpatient setting.
- (ii) All settings must have a physician or nonphysician practitioner 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 or nonphysician practitioner 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) *Medical director standards.* The physician responsible for a cardiac rehabilitation program or intensive cardiac rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and 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) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner 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.

(f) *Limitations on coverage—(1) Cardiac rehabilitation.* The number of cardiac

rehabilitation 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 Administrative Contractor.

(2) *Intensive cardiac rehabilitation.* Intensive cardiac rehabilitation 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; 86 FR 65663, Nov. 19, 2021; 88 FR 79526, Nov. 16, 2023]

§ 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]

§ 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

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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]

§ 410.53 Marriage and family therapist services.

(a) *Definition: marriage and family therapist.* For purposes of this part, a marriage and family therapist is defined as an individual who -

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual fur-

nishes the services defined as marriage and family therapist services;

(2) After obtaining such degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

(b) *Covered marriage and family therapist services.* Medicare Part B covers marriage and family therapist services.

(1) *Definition: marriage and family therapist services* means services furnished by a marriage and family therapist (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. 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 marriage and family therapist services for purposes of billing Medicare Part B under the MFT and MHC statutory benefit category:

(i) Services furnished by a marriage and family therapist to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A marriage and family therapist may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A marriage and family therapist or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

[88 FR 79526, Nov. 16, 2023]

§ 410.54 Mental health counselor services.

(a) *Definition: mental health counselor.* For purposes of this part, a mental

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health counselor is defined as an individual who—

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, professional counselor under the State law of the State in which such individual furnishes the services defined as mental health counselor services;

(2) After obtaining such a degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a mental health counselor, clinical professional counselor, professional counselor by the State in which the services are performed.

(b) *Covered mental health counselor services.* Medicare Part B covers mental health counselor services.

(1) *Definition: Mental health counselor services* means services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. 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 mental health counselor services for purposes of billing Medicare Part B:

(i) Services furnished by a mental health counselor to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A mental health counselor may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A mental health counselor or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is re-

quired under paragraph(b)(2) of this section.

[88 FR 79527, Nov. 16, 2023]

§ 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)

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of developing cervical cancer or vaginal cancer, as determined in accordance with the following risk factors:

(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]

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§ 410.57 Preventive vaccines.

(a) Medicare Part B pays for the pneumococcal vaccine and its administration.

(b) Medicare Part B pays for the influenza virus vaccine and its administration.

(c) Medicare Part B pays for the COVID-19 vaccine (or monoclonal antibodies used for pre-exposure prophylaxis of COVID-19) and its administration.

(d) Medicare Part B pays for the Hepatitis B vaccine and its administration, as defined in § 410.63(a).

[63 FR 35066, June 26, 1998, as amended at 85 FR 71197, Nov. 6, 2020; 87 FR 70223, Nov. 18, 2022; 88 FR 79527, Nov. 16, 2023]

§ 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:

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(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 (or as specified otherwise) 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) Except as provided in paragraph (a)(4)(iv) of this section, furnishes a portion of a service, or in the case of a 15-minute (or other time interval) timed code, a portion of a unit of service separately from the part furnished by the occupational therapist such that the minutes for that portion of a service (or unit of a service) furnished by the occupational therapist assistant exceed 10 percent of the total minutes for that service (or unit of a service).

(iv) Paragraph (a)(4)(iii)(B) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day when the occupational therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the occupational therapy assistant.

(v) Where there are two remaining 15-minute units to bill of the same service, and the occupational therapist and occupational therapy assistant each provided between 9 and 14 minutes of the service with a total time of at least 23 minutes and no more than 28 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the occupational therapy assistant and one unit is billed without the prescribed modifier for the service provided by the occupational therapist.

(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.* Except as otherwise provided in this paragraph, 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. Remote therapeutic monitoring services may be performed by an occupational therapy assistant under the general supervision of the occupational therapist in private practice; services performed by an unenrolled occupational therapist must be under the direct supervision of the occupational therapist.

(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; 86 FR 65664, Nov. 19, 2021; 88 FR 79527, Nov. 16, 2023]

§ 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 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 (or as specified otherwise) 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) Except as provided in paragraph (a)(4)(iv) of this section, furnishes a portion of a service, or in the case of a

15-minute (or other time interval) timed code, a portion of a unit of service separately from the part furnished by the physical therapist such that the minutes for that portion of a service (or unit of a service) furnished by the physical therapist assistant exceed 10 percent of the total minutes for that service (or unit of a service).

(iv) Paragraph (a)(4)(iii)(B) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day, when the physical therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the physical therapist assistant.

(v) Where there are two remaining 15-minute units to bill of the same service, and the physical therapist and physical therapist assistant each provided between 9 and 14 minutes of the service with a total time of at least 23 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the physical therapist assistant and one unit is billed without the prescribed modifier for the service provided by the physical therapist.

(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.* Except as otherwise provided in this paragraph, 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. Remote therapeutic monitoring services may be performed by a physical therapist assistant under the general supervision of the physical therapist in private practice; services performed by an unenrolled physical therapist must be under the direct supervision of the physical therapist.

(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 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; 86 FR 65664, Nov. 19, 2021; 88 FR 79527, Nov. 16, 2023]

§ 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.

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(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 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 § 411.15 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

(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

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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; 87 FR 70223, Nov. 18, 2022]

§ 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” 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

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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.

(i) 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.

(ii) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.

(iii) 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, or for services furnished after the end of such emergency, in cases 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.

(iv) 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, or for services furnished after the end of such emergency, in cases 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.

(v) Toxicology testing.

(vi) 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. Services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically

appropriate, and in compliance with all applicable requirements. In cases where audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine may be furnished using audio-only telephone calls if all other applicable requirements are met.

(vii) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency, as defined in § 400.200 of this chapter, and through the end of CY 2024, 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 if all other applicable requirements are met.

(viii) Opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication.

(ix) Opioid treatment program (OTP) intensive outpatient services, which means one or more services specified in § 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of opioid use disorder (OUD) and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician or non-physician practitioner (as defined in section 1842(b)(18)(C) of the Act) certification and plan of care, as permitted by State law and scope of practice requirements, in which a physician or

non-physician practitioner must certify that the individual has a need for a minimum of nine hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services. OTP intensive outpatient services do not include FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, or toxicology testing.

(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.

(5) OTPs that provide OTP intensive outpatient services must meet the requirements set forth in § 424.24(d)(1) through (3) of this chapter related to content of certification, plan of treatment, and recertification for the purposes of furnishing OTP intensive outpatient services, except that the recertification required under § 424.24(d)(3)(ii) of this chapter may occur any time during an episode of care and any reference to a physician requirement in § 424.24(d)(1) through (3) may also be performed by a non-physician practitioner (as defined in section 1842(b)(18)(C) of the Act, as permitted by state law and scope of practice requirements.

(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) *Implantable and injectable medications.* 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 must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the wholesale acquisition cost (WAC), if WAC is used.

(B) *For oral medications.* (1) Except as provided under paragraph (d)(2)(i)(B)(2) of this section, 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 J 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.

(2) For CY 2022, the payment amount for methadone is the payment amount determined under paragraph (d)(2)(i)(B)(I) of this section for methadone in CY 2021. For CY 2023 and subsequent years, the payment amount for methadone will be based on the payment amount determined under paragraph (d)(2)(i)(B)(I) of this section for methadone in CY 2021 and updated by the PPI for Pharmaceuticals for Human Use (Prescription).

(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.

(iv) *Increased level of psychotherapy.* For CY 2023 and subsequent years, the payment for the non-drug component of the bundled payment for an episode of care under paragraph (d)(2) of this section is adjusted to reflect the CY 2019 Medicare physician fee schedule non-facility rate for psychotherapy, 45 minutes with patient.

(3) At least one OUD treatment service described in paragraphs (i) through (v) of the definition of *opioid use disorder treatment service* in paragraph (b) 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.

(E) Take-home supply of opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication, an adjustment will be made when these medications are dispensed. This adjustment will be limited to once every 30 days, except

when a further take home supply of these medications is medically reasonable and necessary. The opioid treatment program must document in the medical record the reason(s) for the exception. The amount of the drug component of the adjustment will be determined using the methodology in paragraph (d)(2)(i) of this section. The amount of the non-drug component of the adjustment will be determined based on the CY 2020 Medicare payment rate for CPT code 96161.

(F) For OTP intensive outpatient services, an adjustment will be made when at least nine OTP intensive outpatient services described in paragraph (ix) of the definition of *opioid use disorder treatment service* in paragraph (b) of this section are furnished in a week. This adjustment will be based on the per diem payment rate for intensive outpatient services at hospital-based programs defined at § 410.44(c) and multiplied by a factor of three for a weekly payment adjustment.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the geographic adjustment factor described in § 414.26 of this chapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications 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 or an adjustment to the bundled payment under paragraph (d)(4)(i) of this section 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.

(6) For purposes of the adjustment to the bundled payment under paragraph (d)(4)(i)(A) of this section, after the end of the Public Health Emergency as defined in § 400.200 of this chapter, when services are furnished using audio-only technology the practitioner must certify, in a form and manner specified by CMS, that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because audio/video communication technology was not available to the beneficiary.

(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; 85 FR 85026, Dec. 28, 2020; 86 FR 65664, 66036, Nov. 19, 2021; 87 FR 70224, Nov. 18, 2022; 88 FR 79528, Nov. 16, 2023; 88 FR 82178, Nov. 22, 2023]

§ 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 anesthetists; 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

(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 nonphysician 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

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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]

§ 410.72 Registered dietitians' and nutrition professionals' services.

(a) *Definition: Registered dietitians and nutrition professionals.* Meet the qualifications at § 410.134.

(b) *Covered registered dietitian and nutrition professional services.* Medicare Part B covers:

(1) *Coverage condition.* Medical nutrition therapy (MNT) services as defined at § 410.130 under the conditions of coverage at § 410.132.

(2) *Other services.* Registered dietitians and nutrition professionals may also provide diabetes self-management (DSMT) services if they are or represent an accredited DSMT entity and have an order from a physician or qualified nonphysician practitioner who is treating the patient's diabetic condition.

(3) *Limits on MNT and DSMT.* (i) DSMT and MNT cannot be furnished to a patient on the same date of service, and

(ii) MNT and DSMT services cannot be furnished incident to the professional services of a physician or nonphysician practitioner service.

(c) *Limitations.* The following services are not registered dietitian or nutrition professional services for purposes of billing Medicare Part B:

(1) Services furnished by a registered dietitian or nutrition professional to an inpatient of a Medicare-participating hospital.

(2) Services furnished by a registered dietitian or nutrition professional to an inpatient of a Medicare-participating SNF.

(3) Services furnished by a registered dietitian or nutrition professional to a patient in a Medicare-participating ESRD facility in accordance with the limitation on coverage of MNT service listed at § 410.132(b)(1).

(d) *Professional services.* Except for DSMT services furnished as, or on behalf of, an accredited DSMT entity,

registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

(e) *Telehealth services.* MNT and DSMT services may be provided as telehealth services (meeting the requirements in § 410.78) when registered dietitians or nutrition professionals act as distant site practitioners.

(f) *Restrictions.* The services of a registered dietitian or nutrition professional are provided on an assignment-related basis, and a registered dietitian or nutrition professional may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the registered dietitian or nutrition professional must refund the full amount of the impermissible charge to the beneficiary.

[86 FR 65665, Nov. 19, 2021, as amended at 88 FR 79528, Nov. 16, 2023]

§ 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) Prior to January 1, 2022, 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 of a physician assistant are provided on an assignment-related basis, and the physician assistant may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the physician assistant must refund the full amount of the impermissible charge 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; 86 FR 65665, Nov. 19, 2021]

§ 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 evaluation 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 of a nurse practitioner are provided on an assignment-related basis, and the nurse practitioner may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the nurse practitioner must refund the full amount of the impermissible charge 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; 86 FR 65665, Nov. 19, 2021]

§ 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.

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(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 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 of a clinical nurse specialist are provided on an assignment-related basis, and the clinical nurse specialist may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the clinical nurse specialist must refund the full amount of the impermissible charge 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; 86 FR 65665, Nov. 19, 2021]

§ 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-

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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 services of a certified nurse-midwife are provided on an assignment-related basis, and the certified nurse-midwife may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the certified nurse-midwife must refund the full amount of the impermissible charge 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; 86 FR 65665, Nov. 19, 2021]

§ 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, except as otherwise provided in this paragraph, multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-

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time interactive communication between the patient and distant site physician or practitioner. For services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, interactive telecommunications may include two-way, real-time audio-only communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology. A modifier designated by CMS must be appended to the claim for services described in this paragraph to verify that these conditions have been met.

(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.

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(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 in § 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.
- (viii) A registered dietitian or nutrition professional as described in § 410.134.
- (ix) A certified registered nurse anesthetist as described in § 410.69.
- (x) Any distant site practitioner who can appropriately bill for diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.
- (xi) A marriage and family therapist as described in 410.53.
- (xii) A mental health counselor as described in 410.54.

(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);

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(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).

(xiii) A rural emergency hospital (as defined in section 1861(kkk)(2) of the Act), for services furnished on or after January 1, 2023.

(xiv) The home of a beneficiary for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder for services that are furnished during the period beginning on the first day after the end of the emergency period as defined in our regulation at § 400.200 and ending on December 31, 2024 except as otherwise provided in this paragraph. Payment will not be made for a telehealth service furnished under this paragraph unless the following conditions are met:

(A) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service;

(B) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, at least once within 12 months of each subsequent telehealth service described in this paragraph, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens associated with an in-person service outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reason(s) for this decision in the patient's medical record.

(C) The requirements of paragraphs (b)(3)(xiv)(A) and (B) may be met by another physician or practitioner of

the same specialty and subspecialty in the same group as the physician or practitioner who furnishes the telehealth service, if the physician or practitioner who furnishes the telehealth service described under this paragraph is not available.

(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.

(D) Services furnished on or after January 1, 2025 for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder. Payment will

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not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service.

(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, a marriage and family therapist (MFT), and a mental health counselor (MHC) 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.

(3) The distant site practitioner who reports the DSMT services may bill and receive payment when a professional furnishes injection training for an insulin-dependent patient using interactive telecommunications technology when such training is included as part of the DSMT plan of care referenced at § 410.141(b)(2).

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph (f), changes to the list of Medicare telehealth services are

made through the annual physician fee schedule rulemaking process. During the Public Health Emergency, 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. CMS maintains the list of services that are Medicare telehealth services under this section, including the current HCPCS codes that describe the services 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; 85 FR 85027, Dec. 28, 2020; 86 FR 65666, Nov. 19, 2021; 87 FR 70224, Nov. 18, 2022; 88 FR 79528, Nov. 16, 2023]

§ 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.

Combination delivery. MDPP sessions that are delivered by trained Coaches and are furnished in a manner consistent with the DPRP Standards for distance learning and in-person sessions for each individual participant.

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 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.

Distance learning refers to an MDPP session that is delivered by trained Coaches via remote classroom and is furnished in a manner consistent with the DPRP Standards for distance learning sessions. The Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.

Extended flexibilities refer to the flexibilities as described in paragraphs (e)(3)(iii) and (iv) of this section.

Extended flexibilities period refers to the 4-year period (January 1, 2024 to December 31, 2027) for the Extended flexibilities to apply.

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.

Full-Plus CDC DPRP recognition refers to organizations that have met the Full CDC DPRP recognition, and at the time full recognition is achieved, has met the following retention criterion: Eligible participants in the evaluation cohort must have been retained at the

following percentages: A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions; A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.

Make-up session means a core session or a core maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session or core 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.

MDPP session means a core session or a core 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 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.

Online delivery refers to an MDPP session that is delivered online for all participants and is furnished in a manner consistent with the DPRP Standards for online sessions. The program is experienced through the internet via phone, tablet, laptop, in an asynchronous classroom where participants are experiencing the content on their own time without a live Coach teaching the content. However, live Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.

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.

Virtual session refers to an MDPP session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for distance learning sessions.

(c) Coverage for MDPP services—(1) *Beneficiary eligibility.* (i) A Medicare beneficiary is eligible for MDPP serv-

ices 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 diagnosis of diabetes, other than gestational diabetes; and

(F) Does not have end-stage renal disease (ESRD).

(ii) 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) Up to 16 core sessions offered at least 1 week apart during months 1 through 6 of the MDPP services period; and

(B) Up to 6 core maintenance sessions offered at least 1 month apart during months 7 through 12 of the MDPP services period.

(ii) [Reserved]

(3) *Limitations on the MDPP services period.*

(i) The MDPP services period ends upon completion of the core services

period described in paragraph (c)(2)(i) of this section.

(ii) [Reserved]

(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) [Reserved]

(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) [Reserved]

(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 and during any future 1135 waiver event that CMS determines may disrupt in-person MDPP services (an "applicable 1135 waiver event"). For purposes of this paragraph (e), "1135 waiver event" means an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized one or more waivers under section 1135 of the Act.

(2)(i) CMS determines that an 1135 waiver event may disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include, but are not limited to, the avoidance of transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries and MDPP coaches, as defined in §424.205(a) of this chapter, during an 1135 waiver event.

(ii) If CMS determines that an 1135 waiver event may disrupt in-person MDPP services, CMS will communicate such determination for purposes of the policies described in this paragraph (e), to all affected MDPP suppliers.

(3) The following changes apply under this paragraph (e), when CMS has determined that an 1135 waiver event may disrupt in-person MDPP services:

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A) and

(c)(1)(iii)(A) of this section do not apply.

(ii) MDPP suppliers may start new cohorts during the PHE as defined in § 400.200 of this chapter or an applicable 1135 waiver event only if a baseline weight measurement can be obtained as described in paragraph (e)(3)(iii) of this section.

(iii) MDPP suppliers can obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss based performance achievement goals in the following manner:

(A) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations;

(B) Via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or

(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, a date-stamped photo or video recording of the beneficiary's weight with the beneficiary visible on the scale, or a recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session.

(iv) The virtual session limits described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section do not apply, and MDPP suppliers may provide all MDPP sessions virtually, through distance learning or a combination of in-person or distance learning, during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. If the beneficiary began the MDPP services period virtually, or changed from in-person to virtual services during the Extended flexibilities period, a PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event, he/she may

continue to receive the Set of MDPP services virtually even after the PHE or 1135 waiver event has concluded, until the end of the beneficiary's MDPP services period, so long as the provision of virtual services complies with all of the following requirements:

(A) The curriculum furnished during the virtual session addresses 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 virtual make-up 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 sessions are furnished in a manner consistent with the DPRP standards for distance learning sessions.

(E) The MDPP supplier offers virtual sessions only upon an individual MDPP beneficiary's request or agreement to receive services virtually.

(F) The MDPP supplier offers to an MDPP beneficiary:

(1) Up to 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(2) Up to 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period.

(3) No more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24.

(v) MDPP suppliers may suspend the in-person delivery of the set of MDPP services, when necessary due to the applicable 1135 waiver event, and subsequently resume in-person services either upon the end date of the 1135 waiver event emergency period or an effective date specified by CMS. Upon resumption of the set of MDPP services on an in-person basis, the following paragraphs apply:

(A) Beneficiaries who were receiving MDPP services as of March 31, 2020 whose in-person sessions are suspended due to the PHE as defined in § 400.200 of this chapter may elect to restart the set of MDPP services at the beginning

or resume with the most recent attendance session of record.

(B) Beneficiaries who begin the set of MDPP services on or after January 1, 2021 who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may elect to restart the set of MDPP services at the beginning or may resume with the most recent attendance session of record.

(C) Beneficiaries who began the set of MDPP services between January 1, 2021 and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually can elect to attend ongoing maintenance sessions; and may restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or may resume with the most recent attendance session of record.

(D) Beneficiaries whose in-person sessions are suspended due to the applicable 1135 waiver event who elect to continue with MDPP services virtually, as described in paragraph (e)(2)(i) of this section, are not eligible to restart the set of MDPP services at a later date, but may elect to suspend the virtual set of MDPP services and resume the set of in-person MDPP services with the most recent attendance session of record.

(E) Beneficiaries may make an election as described in paragraph (e)(3)(v)(A), (B), (C), or (D) of this section, as applicable, only one time per applicable 1135 waiver event.

(F) Beneficiary eligibility, as described in paragraph (c)(1)(i) of this section, will not be impacted by any changes to the beneficiary's body mass index (BMI) or reduction in hemoglobin A1c, fasting plasma glucose, or 2-hour plasma glucose test values achieved during the set of MDPP services or any intervening time in which a beneficiary has suspended the set of MDPP services. MDPP suppliers will utilize

the following weight measurements as the baseline weight for purposes of determining all weight-loss achievements:

(1) For an MDPP beneficiary who began receiving the set of MDPP services before March 31, 2020, has suspended services during an applicable 1135 waiver event, and then elects to restart the set of MDPP services at the first core session, the MDPP supplier must record a new baseline weight on the date of first core session that restarts the set of MDPP services.

(2) For an MDPP beneficiary who began receiving the set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, and then resumes the set of MDPP services either at the most recent attendance session of record or restarts the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

(vi) 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 only for MDPP beneficiaries who were receiving the MDPP set of services prior to January 1, 2021.

[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; 85 FR 85027, Dec. 28, 2020; 86 FR 65666, Nov. 19, 2021; 88 FR 79528, Nov. 16, 2023]

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,