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

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

(3) Do not require 24-hour care;

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

(5) Have a mental health diagnosis;

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

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

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

§ 410.45 Rural health clinic services: Scope and conditions.

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

(1) Physicians' services.

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

(3) Nurse practitioner and physician assistant services.

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

(5) Visiting nurse services.

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

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

(a) Medicare Part B pays, in accordance with the physician fee schedule, for services furnished in or at the direction of a hospital or outpatient clinic (provider-based or free-standing) that is operated by the Indian Health Service (IHS) or by an Indian tribe or

tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act). These services are subject to the same situations, terms, and conditions that would apply if the services were furnished in or at the direction of a hospital or clinic that is not operated by IHS or by an Indian tribe or tribal organization. Payments include health professional shortage areas incentive payments when the requirements for these incentive payments in § 414.42 of this chapter are met.

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

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

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

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

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

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

[66 FR 55329, Nov. 1, 2001]

§ 410.47 Pulmonary rehabilitation program: Conditions for coverage.

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

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

(i) The individual's diagnosis.

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

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

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

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

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

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

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

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

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

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

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

(b) *Beneficiaries who may be covered.*

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

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

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

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

(2) *Education or training.* (i) Education or training closely and clearly related

to the individual's care and treatment which is tailored to the individual's needs.

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

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

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

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

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

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

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

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

(i) Physician's offices.

(ii) Hospital outpatient settings.

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

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

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

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this subpart and for hospital outpatient services at § 410.27 of this subpart.

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

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

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

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

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

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

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

[74 FR 62002, Nov. 25, 2009]

§ 410.48 Kidney disease education services.

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

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

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

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

(i) One of the following healthcare professionals who furnishes services for

which payment may be made under the physician fee schedule:

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

(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