the MCO complies with the requirements in this subpart. The State must provide documentation of compliance with requirements in this subpart to the general public and post this information on the State Medicaid Web site by October 2, 2017. Such documentation must be updated prior to any change in MCO, PIHP, PAHP or FFS State plan benefits.

(2) The State must ensure that all services are delivered to the enrollees of the MCO in compliance with this subpart.

(c) *Scope.* This subpart does not—

(1) Require a MCO, PIHP, or PAHP to provide any mental health benefits or substance use disorder benefits beyond what is specified in its contract, and the provision of benefits by a MCO, PIHP, or PAHP for one or more mental health conditions or substance use disorders does not require the MCO, PIHP or PAHP to provide benefits for any other mental health condition or substance use disorder;

(2) Require a MCO, PIHP, or PAHP that provides coverage for mental health or substance use disorder benefits only to the extent required under 1905(a)(4)(D) of the Act to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(3) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the Medicaid MCO, PIHP, or PAHP contract except as specifically provided in §§ 438.905 and 438.910.

§ 438.930 Compliance dates.

In general, contracts with MCOs, PIHPs, and PAHPs offering Medicaid State plan services to enrollees, and those entities, must comply with the requirements of this subpart no later than October 2, 2017.

PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

Sec.

Subpart B—Requirements and Limits Applicable to All Services

Subpart C—Benchmark Benefit and Benchmark-Equivalent Coverage

AUTHORITY: 42 U.S.C. 1302.

SOURCE: 43 FR 45224, Sept. 29, 1978, unless otherwise noted.

Subpart A—Definitions

§ 440.1 Basis and purpose.

This subpart interprets and implements the following sections of the Act:

1902(a)(70), State option to establish a non-emergency medical transportation program.

1905(a) Services included in the term ''medical assistance.''

1905 (c), (d), (f) through (i), (l), and (m) Definitions of institutions and services that are included in the term ''medical assistance.''

1913 ''Swing-bed'' services. (See §§ 447.280 and 482.58 of this chapter for related provisions on ''swing-bed'' services.)

1915(c) Home and community-based services listed as ''medical assistance'' and furnished under waivers under that section to individuals who would otherwise require the level of care furnished in a hospital, NF, or ICF/IID.

1915(d) Home and community-based services listed as ''medical assistance'' and furnished under waivers under that section to individuals age 65 or older who would otherwise require the level of care furnished in a NF.

1915(i) Home and community-based services furnished under a State plan to elderly and disabled individuals.

[57 FR 29155, June 30, 1992, as amended at 61 FR 38398, July 24, 1996; 73 FR 77530, Dec. 19, 2008; 79 FR 3029, Jan. 16, 2014; 79 FR 27153, May 12, 2014]

§ 440.2 Specific definitions; definitions of services for FFP purposes.

(a) *Specific definitions.*

Inpatient means a patient who has been admitted to a medical institution as an inpatient on recommendation of a physician or dentist and who—

(1) Receives room, board and professional services in the institution for a 24 hour period or longer, or

(2) Is expected by the institution to receive room, board and professional services in the institution for a 24 hour period or longer even though it later develops that the patient dies, is discharged or is transferred to another facility and does not actually stay in the institution for 24 hours.

Outpatient means a patient of an organized medical facility, or distinct part of that facility who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used, or whether or not the patient remains in the facility past midnight.

Patient means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward the maintenance, improvement, or protection of health, or lessening of illness, disability, or pain. (See also § 435.1010 of this chapter for definitions relating to institutional care.)

(b) *Definitions of services for FFP purposes.* Except as limited in part 441, FFP is available in expenditures under the State plan for medical or remedial

care and services as defined in this subpart.

[43 FR 45224, Sept. 29, 1978, as amended at 52 FR 47934, Dec. 17, 1987; 71 FR 39229, July 12, 2006]

§ 440.10 Inpatient hospital services, other than services in an institution for mental diseases.

(a) *Inpatient hospital services* means services that—

(1) Are ordinarily furnished in a hospital for the care and treatment of inpatients;

(2) Are furnished under the direction of a physician or dentist; and

(3) Are furnished in an institution that—

(i) Is maintained primarily for the care and treatment of patients with disorders other than mental diseases;

(ii) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting;

(iii) Meets the requirements for participation in Medicare as a hospital; and

(iv) Has in effect a utilization review plan, applicable to all Medicaid patients, that meets the requirements of § 482.30 of this chapter, unless a waiver has been granted by the Secretary.

(b) Inpatient hospital services do not include SNF and ICF services furnished by a hospital with a swing-bed approval.

[47 FR 21050, May 17, 1982, as amended at 47 FR 31532, July 20, 1982; 51 FR 22041, June 17, 1986, 52 FR 47934, Dec. 17, 1987; 60 FR 61486, Nov. 30, 1995]

§ 440.20 Outpatient hospital services and rural health clinic services.

(a) *Outpatient hospital services* means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that—

(1) Are furnished to outpatients;

(2) Are furnished by or under the direction of a physician or dentist; and

(3) Are furnished by an institution that—

(i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and

(ii) Meets the requirements for participation in Medicare as a hospital; and

(4) May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of ''outpatient hospital services'' those types of items and services that are not generally furnished by most hospitals in the State.

(b) *Rural health clinic services.* If nurse practitioners or physician assistants (as defined in § 491.2 of this chapter) are not prohibited by State law from furnishing primary health care, ''rural health clinic services'' means the following services when furnished by a rural health clinic that has been certified in accordance with part 491 of this chapter.

(1) Services furnished by a physician within the scope of practice of his profession under State law, if the physician performs the services in the clinic or the services are furnished away from the clinic and the physician has an agreement with the clinic providing that he will be paid by it for such services.

(2) Services furnished by a physician assistant, nurse practitioner, nurse midwife or other specialized nurse practitioner (as defined in §§ 405.2401 and 491.2 of this chapter) if the services are furnished in accordance with the requirements specified in § 405.2414(a) of this chapter.

(3) Services and supplies that are furnished as an incident to professional services furnished by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner. (See §§ 405.2413 and 405.2415 of this chapter for the criteria for determining whether services and supplies are included under this paragraph.)

(4) Part-time or intermittent visiting nurse care and related medical supplies (other than drugs and biologicals) if:

(i) The clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies (see § 405.2417 of this chapter):

(ii) The services are furnished by a registered nurse or licensed practical nurse or a licensed vocational nurse employed by, or otherwise compensated for the services by, the clinic;

(iii) The services are furnished under a written plan of treatment that is established and reviewed at least every 60 days by a supervising physician of the clinic or that is established by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner and reviewed and approved at least every 60 days by a supervising physician of the clinic; and

(iv) The services are furnished to a homebound beneficiary. For purposes of visiting nurse care, a ''homebound'' beneficiary means one who is permanently or temporarily confined to his place of residence because of a medical or health condition. He may be considered homebound if he leaves the place of residence infrequently. For this purpose, ''place of residence'' does not include a hospital or a skilled nursing facility.

(c) *Other ambulatory services furnished by a rural health clinic.* If the State plan covers rural health clinic services, other ambulatory services means ambulatory services other than rural health clinic services, as defined in paragraph (b) of this section, that are otherwise included in the plan and meet specific State plan requirements for furnishing those services. Other ambulatory services furnishd by a rural health clinic are not subject to the physician supervision requirements specified in §491.8(b) of this chapter, unless required by State law or the State plan.

[43 FR 45224, Sept. 29, 1978, as amended at 47 FR 21050, May 17, 1982; 52 FR 47934, Dec. 17, 1987; 60 FR 61486, Nov. 30, 1995; 73 FR 66198, Nov. 7, 2008; 74 FR 31195, June 30, 2009; 85 FR 72909, Nov. 16, 2020]

§ 440.30 Other laboratory and X-ray services.

Other laboratory and X-ray services means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practioner of the healing arts within the scope of his practice as defined by State law or ordered by a physician but provided by referral laboratory;

(b) Provided in an office or similar facility other than a hospital outpatient department or clinic; and

(c) Furnished by a laboratory that meets the requirements of part 493 of this chapter.

(d) During the Public Health Emergency defined in 42 CFR 400.200 or any future Public Health Emergency resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance (as defined in this paragraph), Medicaid coverage is available for laboratory tests and X-ray services that do not meet conditions specified in paragraph (a) or (b) of this section, if the purpose of such laboratory and X-ray services is to diagnose or detect SARS–CoV–2, antibodies to SARS–CoV–2, COVID–19, or the communicable disease named in the Public Health Emergency or its causes, and if the deviation from the conditions specified in paragraph (a) or (b) of this section is intended to avoid transmission of the communicable disease. For purposes of this paragraph, a period of active surveillance is defined as an outbreak of communicable disease during which no approved treatment or vaccine is widely available, and it ends on the date the Secretary terminates it, or the date that is two incubation periods after the last known case of the communicable disease, whichever is sooner. Additionally, during the Public Health Emergency defined in 42 CFR 400.200 or any future Public Health Emergency resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance (as defined in this paragraph), Medicaid coverage is available for laboratory processing of self-collected laboratory test systems that are authorized by the FDA for home use, if available to diagnose or detect SARS–CoV–2, antibodies to SARS–CoV–2, COVID–19, or the communicable disease named in the Public Health Emergency or its causes, even if those self-collected tests would not otherwise meet the requirements of paragraph (a) or (b) of this section, provided that the self-collection of the test is intended to avoid transmission of the communicable disease. If, pursuant to this paragraph, a laboratory processes a self-collected test system that is authorized by the FDA for home use, and the test system does not meet the conditions in paragraph (a) of this

section, the laboratory must notify the patient and the patient's physician or other licensed non-physician practitioner (if known by the laboratory), of the results.

[46 FR 42672, Aug. 24, 1981, as amended at 57 FR 7135, Feb. 28, 1992; 85 FR 27626, May 8, 2020]

§ 440.40 Nursing facility services for individuals age 21 or older (other than services in an institution for mental disease), EPSDT, and family planning services and supplies.

(a) *Nursing facility services.* (1) ''Nursing facility services for individuals age 21 or older, other than services in an institution for mental diseases'', means services that are—

(i) Needed on a daily basis and required to be provided on an inpatient basis under §§ 409.31 through 409.35 of this chapter.

(ii) Provided by—

(A) A facility or distinct part (as defined in § 483.5(b) of this chapter) that meets the requirements for participation under subpart B of part 483 of this chapter, as evidenced by a valid agreement between the Medicaid agency and the facility for providing nursing facility services and making payments for services under the plan; or

(B) If specified in the State plan, a swing-bed hospital that has an approval from CMS to furnish skilled nursing facility services in the Medicare program; and

(iii) Ordered by and provided under the direction of a physician.

(2) Nursing facility services include services provided by any facility located on an Indian reservation and certified by the Secretary as meeting the requirements of subpart B of part 483 of this chapter.

(b) *EPSDT.* ''Early and periodic screening and diagnosis and treatment'' means—

(1) Screening and diagnostic services to determine physical or mental defects in beneficiaries under age 21; and

(2) Health care, treatment, and other measures to correct or ameliorate any defects and chronic conditions discovered. (See subpart B of part 441 of this chapter.)

(c) *Family planning services and supplies for individuals of child-bearing age.* [Reserved]

[59 FR 56233, Nov. 10, 1994; 60 FR 50117, Sept. 28, 1995, as amended at 61 FR 59198, Nov. 21, 1996; 68 FR 46071, Aug. 4, 2003]

§ 440.50 Physicians' services and medical and surgical services of a dentist.

(a) ''Physicians' services,'' whether furnished in the office, the beneficiary's home, a hospital, a skilled nursing facility, or elsewhere, means services furnished by a physician—

(1) Within the scope of practice of medicine or osteopathy as defined by State law; and

(2) By or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy.

(b) ''Medical and surgical services of a dentist'' means medical and surgical services furnished, on or after January 1, 1988, by a doctor of dental medicine or dental surgery if the services are services that—

(1) If furnished by a physician, would be considered physician's services.

(2) Under the law of the State where they are furnished, may be furnished either by a physician or by a doctor of dental medicine or dental surgery; and

(3) Are furnished by a doctor of dental medicine or dental surgery who is authorized to furnish those services in the State in which he or she furnished the services.

[56 FR 8851, Mar. 1, 1991]

§ 440.60 Medical or other remedial care provided by licensed practitioners.

(a) ''Medical care or any other type remedial care provided by licensed practitioners'' means any medical or remedial care or services, other than physicians' services, provided by licensed practitioners within the scope of practice as defined under State law.

(b) Chiropractors' services include only services that—

(1) Are provided by a chiropractor who is licensed by the State and meets standards issued by the Secretary under § 405.232(b) of this chapter; and

(2) Consists of treatment by means of manual manipulation of the spine that

the chiropractor is legally authorized by the State to perform.

§ 440.70 Home health services.

(a) ''Home health services'' means the services in paragraph (b) of this section that are provided to a beneficiary—

(1) At his place of residence, as specified in paragraph (c) of this section; and

(2) On orders written by a physician, nurse practitioner, clinical nurse specialist or physician assistant, working in accordance with State law, as part of a written plan of care that the ordering practitioner reviews every 60 days for services described in (b)(1), (2), and (4) of this section; and

(3) On his or her physician's orders or orders written by a licensed practitioner of the healing arts acting within the scope of practice authorized under State law, as part of a written plan of care for services described in paragraph (b)(3) of this section. The plan of care must be reviewed by the ordering practitioner as specified in paragraph (b)(3)(iii) of this section.

(b) Home health services include the following services and items. Paragraphs (b)(1), (2) and (3) of this section are required services and items that must be covered according to the home health coverage parameters. Services in paragraph (b)(4) of this section are optional. Coverage of home health services cannot be contingent upon the beneficiary needing nursing or therapy services.

(1) Nursing service, as defined in the State Nurse Practice Act, that is provided on a part-time or intermittent basis by a home health agency as defined in paragraph (d) of this section, or if there is no agency in the area, a registered nurse who—

(i) Is currently licensed to practice in the State;

(ii) Receives written orders from the patient's practitioner as defined in (a)(2) of this section;

(iii) Documents the care and services provided; and

(iv) Has had orientation to acceptable clinical and administrative recordkeeping from a health department nurse.

(2) Home health aide service provided by a home health agency,

(3) Medical supplies, equipment, and appliances suitable for use in any setting in which normal life activities take place, as defined at § 440.70(c)(1).

(i) Supplies are health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual, that are required to address an individual medical disability, illness or injury.

(ii) Equipment and appliances are items that are primarily and customarily used to serve a medical purpose, generally are not useful to an individual in the absence of a disability, illness or injury, can withstand repeated use, and can be reusable or removable. State Medicaid coverage of equipment and appliances is not restricted to the items covered as durable medical equipment in the Medicare program.

(iii) A beneficiary's need for medical supplies, equipment, and appliances must be reviewed by a physician or, as defined in § 400.200 of this chapter, an other licensed practitioner of the healing arts acting within the scope of practice authorized under State law, annually.

(iv) Frequency of further physician or, as defined in § 400.200 of this chapter, an other licensed practitioner review of a beneficiary's continuing need for the items is determined on a case-by-case basis based on the nature of the item prescribed.

(v) States can have a list of preapproved medical equipment supplies and appliances for administrative ease but States are prohibited from having absolute exclusions of coverage on medical equipment, supplies, or appliances. States must have processes and criteria for requesting medical equipment that is made available to individuals to request items not on the State's list. The procedure must use reasonable and specific criteria to assess items for coverage. When denying a request, a State must inform the beneficiary of the right to a fair hearing.

(4) Physical therapy, occupational therapy, or speech pathology and audiology services, provided by a home health agency or by a facility licensed

by the State to provide medical rehabilitation services. (See § 441.15 of this subchapter.)

(c) A beneficiary's place of residence, for home health services, does not include a hospital, nursing facility, or intermediate care facility for individuals with intellectual disabilities, except for home health services in an intermediate care facility for Individuals with Intellectual Disabilities that are not required to be provided by the facility under subpart I of part 483. For example, a registered nurse may provide short-term care for a beneficiary in an intermediate care facility for Individuals with Intellectual Disabilities during an acute illness to avoid the beneficiary's transfer to a nursing facility.

(1) Nothing in this section should be read to prohibit a beneficiary from receiving home health services in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Home health services cannot be limited to services furnished to beneficiaries who are homebound.

(2) Additional services or service hours may, at the State's option, be authorized to account for medical needs that arise in the settings home health services are provided.

(d) ''Home health agency'' means a public or private agency or organization, or part of an agency or organization, that meets requirements for participation in Medicare, including the capitalization requirements under § 489.28 of this chapter.

(e) A ''facility licensed by the State to provide medical rehabilitation services'' means a facility that—

(1) Provides therapy services for the primary purpose of assisting in the rehabilitation of disabled individuals through an integrated program of—

(i) Medical evaluation and services; and

(ii) Psychological, social, or vocational evaluation and services; and

(2) Is operated under competent medical supervision either—

(i) In connection with a hospital; or

(ii) As a facility in which all medical and related health services are prescribed by or under the direction of individuals licensed to practice medicine or surgery in the State.

(f) No payment may be made for services referenced in paragraphs (b)(1) through (4) of this section, unless a practitioner referenced in paragraph (a)(2) of this section or for medical equipment, a practitioner described in paragraph (a)(3) of this section documents that there was a face-to-face encounter with the beneficiary that meets the following requirements.

(1) For the initiation of home health services, the face-to-face encounter must be related to the primary reason the beneficiary requires home health services and must occur within the 90 days before or within the 30 days after the start of the services.

(2) For the initiation of medical equipment, the face-to-face encounter must be related to the primary reason the beneficiary requires medical equipment and must occur no more than 6 months prior to the start of services.

(3) The face-to-face encounter may be conducted by one of the following practitioners:

(i) A physician;

(ii) A nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, in accordance with State law;

(iii) A certified nurse midwife, as defined in section 1861(gg) of the Act, as authorized by State law;

(iv) A physician assistant, as defined in section 1861(aa)(5) of the Act, in accordance with State law; or

(v) For beneficiaries admitted to home health immediately after an acute or post-acute stay, the attending acute or post-acute physician.

(vi) For medical equipment, supplies, or appliances, a licensed practitioner of the healing arts acting within the scope of practice authorized under state law.

(4) If State law does not allow the non-physician practitioner, as described in paragraphs (f)(3)(ii) through (vi) of this section, to perform the face-to-face encounter independently, the non-physician practitioner must communicate the clinical findings of that

face-to-face encounter to the ordering physician. Those clinical findings must be incorporated into a written or electronic document included in the beneficiary's medical record.

(5) To assure clinical correlation between the face-to-face encounter and the associated home health services, the practitioner responsible for ordering the services must:

(i) Document the face-to-face encounter which is related to the primary reason the patient requires home health services, occurred within the required timeframes prior to the start of home health services.

(ii) Must indicate the practitioner who conducted the encounter, and the date of the encounter.

(6) The face-to-face encounter may occur through telehealth, as implemented by the State.

(g)(1) No payment may be made for medical equipment, supplies, or appliances referenced in paragraph (b)(3) of this section to the extent that a face-to-face encounter requirement would apply as durable medical equipment (DME) under the Medicare program, unless a practitioner referenced in paragraph (a)(3) of this section documents a face-to-face encounter with the beneficiary consistent with the requirements of paragraph (f) of this section except as indicated in paragraph (g)(2) of this section.

(2) The face-to-face encounter may be performed by any of the practitioners described in paragraph (f)(3) of this section, with the exception of certified nurse-midwives, as described in paragraph (f)(3)(iii) of this section.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980; 62 FR 47902, Sept. 11, 1997; 63 FR 310, Jan. 5, 1998; 81 FR 5566, Feb. 2, 2016; 85 FR 19291, Apr. 6, 2020; 85 FR 27626, May 8, 2020]

§ 440.80 Private duty nursing services.

Private duty nursing services means nursing services for beneficiaries who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of the hospital or skilled nursing facility. These services are provided—

(a) By a registered nurse or a licensed practical nurse;

(b) Under the direction of the beneficiary's physician; and

(c) To a beneficiary in one or more of the following locations at the option of the State—

(1) His or her own home;

(2) A hospital; or

(3) A skilled nursing facility.

[52 FR 47934, Dec. 17, 1987]

§ 440.90 Clinic services.

Clinic services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients:

(a) Services furnished at the clinic by or under the direction of a physician or dentist.

(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

[56 FR 8851, Mar. 1, 1991, as amended at 60 FR 61486, Nov. 30, 1995]

§ 440.100 Dental services.

(a) ''Dental services'' means diagnostic, preventive, or corrective procedures provided by or under the supervision of a dentist in the practice of his profession, including treatment of—

(1) The teeth and associated structures of the oral cavity; and

(2) Disease, injury, or impairment that may affect the oral or general health of the beneficiary.

(b) ''Dentist'' means an individual licensed to practice dentistry or dental surgery.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980]

§ 440.110 Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.

(a) *Physical therapy*—(1) *Physical therapy* means services prescribed by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law and provided to a beneficiary by or

under the direction of a qualified physical therapist. It includes any necessary supplies and equipment.

(2) A ''qualified physical therapist'' is an individual who meets personnel qualifications for a physical therapist at § 484.115.

(b) *Occupational therapy*—(1) *Occupational therapy* means services prescribed by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law and provided to a beneficiary by or under the direction of a qualified occupational therapist. It includes any necessary supplies and equipment.

(2) A ''qualified occupational therapist'' is an individual who meets personnel qualifications for an occupational therapist at § 484.115.

(c) *Services for individuals with speech, hearing, and language disorders*—(1) *Services for individuals with speech, hearing, and language disorders* means diagnostic, screening, preventive, or corrective services provided by or under the direction of a speech pathologist or audiologist, for which a patient is referred by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law. It includes any necessary supplies and equipment.

(2) A ''speech pathologist'' is an individual who meets one of the following conditions:

(i) Has a certificate of clinical competence from the American Speech and Hearing Association.

(ii) Has completed the equivalent educational requirements and work experience necessary for the certificate.

(iii) Has completed the academic program and is acquiring supervised work experience to qualify for the certificate.

(3) A ''qualified audiologist'' means an individual with a master's or doctoral degree in audiology that maintains documentation to demonstrate that he or she meets one of the following conditions:

(i) The State in which the individual furnishes audiology services meets or exceeds State licensure requirements in paragraph (c)(3)(ii)(A) or (c)(3)(ii)(B) of this section, and the individual is licensed by the State as an audiologist to furnish audiology services.

(ii) In the case of an individual who furnishes audiology services in a State that does not license audiologists, or an individual exempted from State licensure based on practice in a specific institution or setting, the individual must meet one of the following conditions:

(A) Have a Certificate of Clinical Competence in Audiology granted by the American Speech-Language-Hearing Association.

(B) Have successfully completed a minimum of 350 clock-hours of supervised clinical practicum (or is in the process of accumulating that supervised clinical experience under the supervision of a qualified master or doctoral-level audiologist); performed at least 9 months of full-time audiology services under the supervision of a qualified master or doctoral-level audiologist after obtaining a master's or doctoral degree in audiology, or a related field; and successfully completed a national examination in audiology approved by the Secretary.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980; 56 FR 8854, Mar. 1, 1991; 60 FR 19861, Apr. 21, 1995; 69 FR 30587, May 28, 2004; 77 FR 29031, May 16, 2012; 82 FR 4578, Jan. 13, 2017]

§ 440.120 Prescribed drugs, dentures, prosthetic devices, and eyeglasses.

(a) ''Prescribed drugs'' means simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are—

(1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law;

(2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and

(3) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records.

(b) ''Dentures'' are artificial structures made by or under the direction of a dentist to replace a full or partial set of teeth.

(c) ''Prosthetic devices'' means replacement, corrective, or supportive devices prescribed by a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law to—

(1) Artificially replace a missing portion of the body;

(2) Prevent or correct physical deformity or malfunction; or

(3) Support a weak or deformed portion of the body.

(d) ''Eyeglasses'' means lenses, including frames, and other aids to vision prescribed by a physician skilled in diseases of the eye or an optometrist.

§ 440.130 Diagnostic, screening, preventive, and rehabilitative services.

(a) ''Diagnostic services,'' except as otherwise provided under this subpart, includes any medical procedures or supplies recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, to enable him to identify the existence, nature, or extent of illness, injury, or other health deviation in a beneficiary.

(b) ''Screening services'' means the use of standardized tests given under medical direction in the mass examination of a designated population to detect the existence of one or more particular diseases or health deviations or to identify for more definitive studies individuals suspected of having certain diseases.

(c) ''Preventive services'' means services recommended by a physician or other licensed practitioner of the healing arts acting within the scope of authorized practice under State law to—

(1) Prevent disease, disability, and other health conditions or their progression;

(2) Prolong life; and

(3) Promote physical and mental health and efficiency.

(d) ''Rehabilitative services,'' except as otherwise provided under this subpart, includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a beneficiary to his best possible functional level.

[43 FR 45224, Sept. 29, 1978, as amended at 78 FR 42306, July 15, 2013]

§ 440.140 Inpatient hospital services, nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for mental diseases.

(a) *Inpatient hospital services.* ''Inpatient hospital services for individuals age 65 or older in institutions for mental diseases'' means services provided under the direction of a physician for the care and treatment of beneficiaries in an institution for mental diseases that meets the requirements specified in § 482.60(b), (c), and (e) of this chapter and—

(1) Meets the requirements for utilization review in § 482.30(a), (b), (d), and (e) of this chapter; or

(2) Has been granted a waiver of those utilization review requirements under section 1903(i)(4) of the Act and subpart H of part 456 of this chapter.

(b) *Nursing facility services.* ''Nursing facility services for individuals age 65 or older in institutions for mental diseases'' means nursing facility services as defined in § 440.40 and in subpart B of part 483 of this chapter that are provided in institutions for mental diseases, as defined in § 435.1010 of this chapter.

[59 FR 56234, Nov. 10, 1994, as amended at 71 FR 39229, July 12, 2006]

§ 440.150 Intermediate care facility (ICF/IID) services.

(a) ''ICF/IID services'' means those items and services furnished in an intermediate care facility for Individuals with Intellectual Disabilities if the following conditions are met:

(1) The facility fully meets the requirements for a State license to provide services that are above the level of room and board;

(2) The primary purpose of the ICF/IID is to furnish health or rehabilitative services to persons with Intellectual Disability or persons with related conditions;

(3) The ICF/IID meets the standards specified in subpart I of part 483 of this chapter.

(4) The beneficiary with Intellectual Disability for whom payment is requested is receiving active treatment, as specified in § 483.440 of this chapter.

(5) The ICF/IID has been certified to meet the requirements of subpart C of part 442 of this chapter, as evidenced by a valid agreement between the Medicaid agency and the facility for furnishing ICF/IID services and making payments for these services under the plan.

(b) ICF/IID services may be furnished in a distinct part of a facility other than an ICF/IID if the distinct part—

(1) Meets all requirements for an ICF/IID, as specified in subpart I of part 483 of this chapter;

(2) Is clearly an identifiable living unit, such as an entire ward, wing, floor or building;

(3) Consists of all beds and related services in the unit;

(4) Houses all beneficiaries for whom payment is being made for ICF/IID services; and

(5) Is approved in writing by the survey agency.

[59 FR 56234, Nov. 10, 1994]

§ 440.155 Nursing facility services, other than in institutions for mental diseases.

(a) ''Nursing facility services, other than in an institution for mental diseases'' means services provided in a facility that—

(1) Fully meets the requirements for a State license to provide, on a regular basis, health-related services to individuals who do not require hospital care, but whose mental or physical condition requires services that—

(i) Are above the level of room and board; and

(ii) Can be made available only through institutional facilities;

(2) Has been certified to meet the requirements of subpart C of part 442 of this chapter as evidenced by a valid agreement between the Medicaid agency and the facility for providing nursing facility services and making payments for services under the plan; and

(b) ''Nursing facility services'' include services—

(1) Considered appropriate by the State and provided by a religious nonmedical institution as defined in § 440.170(b); or

(2) Provided by a facility located on an Indian reservation that—

(i) Furnishes, on a regular basis, health-related services; and

(ii) Is certified by the Secretary to meet the standards in subpart E of part 442 of this chapter.

(c) ''Nursing facility services'' may include services provided in a distinct part (as defined in § 483.5(b) of this chapter) of a facility other than a nursing facility if the distinct part (as defined in § 483.5(b) of this chapter)—

(1) Meets all requirements for a nursing facility;

(2) Is an identifiable unit, such as an entire ward or contiguous ward, a wing, floor, or building;

(3) Consists of all beds and related facilities in the unit;

(4) Houses all beneficiaries for whom payment is being made for nursing facility services, except as provided in paragraph (d) of this section;

(5) Is clearly identified; and

(6) Is approved in writing by the survey agency.

(d) If a State includes as nursing facility services those services provided by a distinct part of a facility other than a nursing facility, it may not require transfer of a beneficiary within or between facilities if, in the opinion of the attending physician, it might be harmful to the physical or mental health of the beneficiary.

(e) Nursing facility services may include services provided in a swing-bed hospital that has an approval to furnish nursing facility services.

[59 FR 56234, Nov. 10, 1994, as amended at 64 FR 67052, Nov. 30, 1999; 68 FR 46071, Aug. 4, 2003]

§ 440.160 Inpatient psychiatric services for individuals under age 21.

''Inpatient psychiatric services for individuals under age 21'' means services that—

(a) Are provided under the direction of a physician;

(b) Are provided by—

(1) A psychiatric hospital that undergoes a State survey to determine

whether the hospital meets the requirements for participation in Medicare as a psychiatric hospital as specified in § 482.60 of this chapter, or is accredited by a national organization whose psychiatric hospital accrediting program has been approved by CMS; or a hospital with an inpatient psychiatric program that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a hospital, as specified in part 482 of this chapter, or is accredited by a national accrediting organization whose hospital accrediting program has been approved by CMS.

(2) A psychiatric facility which is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Council on Accreditation of Services for Families and Children, the Commission on Accreditation of Rehabilitation Facilities, or by any other accrediting organization, with comparable standards, that is recognized by the State.

(c) Meet the requirements in § 441.151 of this subchapter.

[63 FR 64198, Nov. 19, 1998, as amended at 75 FR 50418, Aug. 16, 2010]

§ 440.165 Nurse-midwife service.

(a) ''Nurse-midwife services'' means services that—

(1) Are furnished by a nurse-midwife within the scope of practice authorized by State law or regulation and, in the case of inpatient or outpatient hospital services or clinic services, are furnished by or under the direction of a nurse-midwife to the extent permitted by the facility; and

(2) Unless required by State law or regulations or a facility, are reimbursed without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider. (See § 441.21 of this chapter for provisions on independent provider agreements for nurse-midwives.)

(b) ''Nurse-midwife'' means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(4) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives (ACNM or by the ACNM Certification Council, Inc. (ACC).

(ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives (ACNM) or by the ACNM Certification Council, Inc. (ACC).

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

[47 FR 21050, May 17, 1982; 47 FR 23448, May 28, 1982, as amended at 55 FR 48611, Nov. 21, 1990; 61 FR 61486, Nov. 30, 1996]

§ 440.166 Nurse practitioner services.

(a) *Definition of nurse practitioner services.* Nurse practitioner services means services that are furnished by a registered professional nurse who meets a State's advanced educational and clinical practice requirements, if any, beyond the 2 to 4 years of basic nursing education required of all registered nurses.

(b) *Requirements for certified pediatric nurse practitioner.* The practitioner must be a registered professional nurse who meets the requirements specified in either paragraphs (b)(1) or (b)(2) of this section.

(1) If the State specifies qualifications for pediatric nurse practitioners, the practitioner must—

(i) Be currently licensed to practice in the State as a registered professional nurse; and

(ii) Meet the State requirements for qualification of pediatric nurse practitioners in the State in which he or she furnishes the services.

(2) If the State does not specify, by specialty, qualifications for pediatric nurse practitioners, but the State does define qualifications for nurses in advanced practice or general nurse practitioners, the practitioner must—

(i) Meet qualifications for nurses in advanced practice or general nurse practitioners as defined by the State; and

(ii) Have a pediatric nurse practice limited to providing primary health care to persons less than 21 years of age.

(c) *Requirements for certified family nurse practitioner.* The practitioner must be a registered professional nurse who meets the requirements specified in either paragraph (c)(1) or (c)(2) of this section.

(1) If the State specifies qualifications for family nurse practitioners, the practitioner must—

(i) Be currently licensed to practice in the State as a registered professional nurse; and

(ii) Meet the State requirements for qualification of family nurse practitioners in the State in which he or she furnishes the services.

(2) If the State does not specify, by specialty, qualifications for family nurse practitioners, but the State does define qualifications for nurses in advanced practice or general nurse practitioners, the practitioner must—

(i) Meet qualifications for nurses in advanced practice or general nurse practitioners as defined by the State; and

(ii) Have a family nurse practice limited to providing primary health care to individuals and families.

(d) *Payment for nurse practitioner services.* The Medicaid agency must reimburse nurse practitioners for their services in accordance with § 441.22(c) of this subchapter.

[60 FR 19861, Apr. 21, 1995]

§ 440.167 Personal care services.

Unless defined differently by a State agency for purposes of a waiver granted under part 441, subpart G of this chapter—

(a) *Personal care services* means services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for individuals with intellectual disabilities, or institution for mental disease that are—

(1) Authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State;

(2) Provided by an individual who is qualified to provide such services and who is not a member of the individual's family; and

(3) Furnished in a home, and at the State's option, in another location.

(b) For purposes of this section, *family member* means a legally responsible relative.

[42 FR 47902, Sept. 11, 1997]

§ 440.168 Primary care case management services.

(a) Primary care case management services means case management related services that—

(1) Include location, coordination, and monitoring of primary health care services; and

(2) Are provided under a contract between the State and either of the following:

(i) A PCCM who is a physician or may, at State option, be a physician assistant, nurse practitioner, or certified nurse-midwife.

(ii) A physician group practice, or an entity that employs or arranges with physicians to furnish the services.

(b) Primary care case management services may be offered by the State—

(1) As a voluntary option under the State plan; or

(2) On a mandatory basis under section 1932 (a)(1) of the Act or under section 1915(b) or section 1115 waiver authority.

[67 FR 41115, June 14, 2002]

§ 440.169 Case management services.

(a) *Case management services* means services furnished to assist individuals, eligible under the State plan who reside in a community setting or are transitioning to a community setting, in gaining access to needed medical, social, educational, and other services, in accordance with § 441.18 of this chapter.

(b) T*argeted case management services* means case management services furnished without regard to the requirements of § 431.50(b) of this chapter (related to statewide provision of services) and § 440.240 (related to comparability). Targeted case management services may be offered to individuals in any defined location of the State or to individuals within targeted groups specified in the State plan.

(c) [Reserved]

(d) The assistance that case managers provide in assisting eligible individuals obtain services includes—

(1) Comprehensive assessment and periodic reassessment of individual needs, to determine the need for any medical, educational, social, or other services. These assessment activities include the following:

(i) Taking client history.

(ii) Identifying the needs of the individual, and completing related documentation.

(iii) Gathering information from other sources, such as family members, medical providers, social workers, and educators (if necessary) to form a complete assessment of the eligible individual.

(2) Development (and periodic revision) of a specific care plan based on the information collected through the assessment, that includes the following:

(i) Specifies the goals and actions to address the medical, social, educational, and other services needed by the eligible individual.

(ii) Includes activities such as ensuring the active participation of the eligible individual and working with the individual (or the individual's authorized health care decision maker) and others to develop those goals.

(iii) Identifies a course of action to respond to the assessed needs of the eligible individual.

(3) Referral and related activities (such as scheduling appointments for the individual) to help the eligible individual obtain needed services, including activities that help link the individual with medical, social, and educational providers or other programs and services that are capable of providing needed services to address identified needs and achieve goals specified in the care plan.

(4) Monitoring and follow-up activities, including activities and contacts that are necessary to ensure that the care plan is effectively implemented and adequately addresses the needs of the eligible individual and which may be with the individual, family members, service providers, or other entities or individuals and conducted as frequently as necessary, and including at least one annual monitoring, to help determine whether the following conditions are met:

(i) Services are being furnished in accordance with the individual's care plan.

(ii) Services in the care plan are adequate.

(iii) There are changes in the needs or status of the eligible individual. Monitoring and follow-up activities include making necessary adjustments in the care plan and service arrangements with providers.

(e) Case management may include contacts with non-eligible individuals that are directly related to the identification of the eligible individual's needs and care, for the purposes of helping the eligible individual access services, identifying needs and supports to assist the eligible individual in obtaining services, providing case managers with useful feedback, and alerting case managers to changes in the eligible individual's needs.

[72 FR 68091, Dec. 4, 2007, as amended at 74 FR 31196, June 30, 2009]

§ 440.170 Any other medical care or remedial care recognized under State law and specified by the Secretary.

(a) *Transportation.* (1) ''Transportation'' includes expenses for transportation and other related travel expenses determined to be necessary by the agency to secure medical examinations and treatment for a beneficiary.

(2) Except as provided in paragraph (a)(4), transportation, as defined in this section, is furnished only by a provider to whom a direct vendor payment can appropriately be made by the agency.

(3) ''Travel expenses'' include—

(i) The cost of transportation for the beneficiary by ambulance, taxicab, common carrier, or other appropriate means;

(ii) The cost of meals and lodging en route to and from medical care, and while receiving medical care; and

(iii) The cost of an attendant to accompany the beneficiary, if necessary, and the cost of the attendant's transportation, meals, lodging, and, if the attendant is not a member of the beneficiary's family, salary.

(4) Non-emergency medical transportation brokerage program. At the option of the State, and notwithstanding §431.50 (statewide operation) and §431.51 (freedom of choice of providers) of this chapter and §440.240 (comparability of services for groups), a State plan may provide for the establishment of a non-emergency medical transportation brokerage program in order to more cost-effectively provide non-emergency medical transportation services for individuals eligible for medical assistance under the State plan who need access to medical care or services, and have no other means of transportation. These transportation services include wheelchair vans, taxis, stretcher cars, bus passes and tickets, secured transportation containing an occupant protection system that addresses safety needs of disabled or special needs individuals, and other forms of transportation otherwise covered under the state plan.

(i) Non-emergency medical transportation services may be provided under contract with individuals or entities that meet the following requirements:

(A) Is selected through a competitive bidding process that is consistent with 45 CFR 75.326 through 75.340 and is based on the State's evaluation of the broker's experience, performance, references, resources, qualifications, and costs.

(B) Has oversight procedures to monitor beneficiary access and complaints and ensure that transportation is timely and that transport personnel are licensed, qualified, competent, and courteous.

(C) Is subject to regular auditing and oversight by the State in order to ensure the quality and timeliness of the transportation services provided and the adequacy of beneficiary access to medical care and services.

(D) Is subject to a written contract that imposes the requirements related to prohibitions on referrals and conflicts of interest described at §440.170(a)(4)(ii), and provides for the broker to be liable for the full cost of services resulting from a prohibited referral or subcontract.

(ii) Federal financial participation is available at the medical assistance rate for the cost of a written brokerage contract that:

(A) Except as provided in paragraph (a)(4)(ii)(B) of this section, prohibits the broker (including contractors, owners, investors, Boards of Directors, corporate officers, and employees) from providing non-emergency medical transportation services or making a referral or subcontracting to a transportation service provider if:

(*1*) The broker has a financial relationship with the transportation provider as defined at §411.354(a) of this chapter with ''transportation broker'' substituted for ''physician'' and ''non-emergency transportation'' substituted for ''DHS''; or

(*2*) The broker has an immediate family member, as defined at §411.351 of this chapter, that has a direct or indirect financial relationship with the transportation provider, with the term ''transportation broker'' substituted for ''physician.''

(B) Exceptions: The prohibitions described at clause (A) of this paragraph do not apply if there is documentation to support the following:

(*1*) Transportation is provided in a rural area, as defined at §412.62(f), and there is no other available Medicaid participating provider or other provider determined by the State to be qualified except the non-governmental broker.

(*2*) Transportation is so specialized that there is no other available Medicaid participating provider or other provider determined by the State to be

qualified except the non-governmental broker.

(*3*) Except for the non-governmental broker, the availability of other Medicaid participating providers or other providers determined by the State to be qualified is insufficient to meet the need for transportation.

(*4*) The broker is a government entity and the individual service is provided by the broker, or is referred to or subcontracted with another government-owned or operated transportation provider generally available in the community, if the following conditions are met:

(*i*) The contract with the broker provides for payment that does not exceed the actual costs calculated as though the broker were a distinct unit, and excludes from these payments any personnel or other costs shared with or allocated from parent or related entities; and the governmental broker maintains an accounting system such that all funds allocated to the Medicaid brokerage program and all costs charged to the brokerage program will be completely separate from any other program;

(*ii*) The broker documents that, with respect to the individual's specific transportation needs, the government provider is the most appropriate and lowest cost alternative; and

(*iii*) The broker documents that the Medicaid program is paying no more for fixed route public transportation than the rate charged to the general public and no more for public paratransit services than the rate charged to other State human services agencies for comparable services.

(C) Transportation providers may not offer or make any payment or other form of remuneration, including any kickback, rebate, cash, gifts, or service in kind to the broker in order to influence referrals or subcontracting for non-emergency medical transportation provided to a Medicaid beneficiary.

(D) In referring or subcontracting for non-emergency medical transportation with transportation providers, a broker may not withhold necessary non-emergency medical transportation from a Medicaid beneficiary or provide non-emergency medical transportation that is not the most appropriate and a cost-effective means of transportation for that beneficiary for the purpose of financial gain, or for any other purpose.

(b) *Services furnished in a religious nonmedical health care institution.* Services furnished in a religious nonmedical health care institution are services furnished in an institution that:

(1) Is an institution that is described in (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under section 501(a) of that section.

(2) Is lawfully operated under all applicable Federal, State, and local laws and regulations.

(3) Furnishes only nonmedical nursing items and services to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs.

(4) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients.

(5) Furnishes these nonmedical items and services to inpatients on a 24-hour basis.

(6) Does not furnish, on the basis of its religious beliefs, through its personnel or otherwise, medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.

(7) Is not owned by, is not under common ownership with, or does not have an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest or 5 percent or more in a provider of medical treatment or services. Permissible affiliations are described in paragraph (c) of this section.

(8) Has in effect a utilization review plan that meets the following criteria:

(i) Provides for the review of admissions to the institution, duration of stays, cases of continuous extended duration, and items and services furnished by the institution.

(ii) Requires that the reviews be made by a committee of the institution

that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

(iii) Provides that records be maintained of the meetings, decisions, and actions of the utilization review committee.

(iv) Meets other requirements as CMS finds necessary to establish an effective utilization review plan.

(9) Provides information CMS may require to implement section 1821 of the Act, including information relating to quality of care and coverage determinations.

(10) Meets other requirements as CMS finds necessary in the interest of the health and safety of patients who receive services in the institution. These requirements are the conditions of participation found at part 403, subpart G of this chapter.

(c) *Affiliations.* An affiliation is permissible for purposes of paragraph (b)(7) of this section if it is between one of the following:

(1) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of an RNHCI and a provider of medical treatment or services.

(2) An individual who is a director, trustee, officer, employee, or staff member of an RNHCI and an another individual, with whom he or she has a family relationship, who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(3) The RNHCI and an individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and RNHCIs.

(d) *Skilled nursing facility services for individuals under age 21.* ''Skilled nursing facility services for individuals under 21'' means those services specified in § 440.40 that are provided to beneficiaries under 21 years of age.

(e) *Emergency hospital services.* ''Emergency hospital services'' means services that—

(1) Are necessary to prevent the death or serious impairment of the health of a beneficiary; and

(2) Because of the threat to the life or health of the beneficiary necessitate the use of the most accessible hospital available that is equipped to furnish the services, even if the hospital does not currently meet—

(i) The conditions for participation under Medicare; or

(ii) The definitions of inpatient or outpatient hospital services under §§ 440.10 and 440.20.

(f) [Reserved]

(g) *Critical access hospital (CAH).* (1) CAH services means services that (i) are furnished by a provider that meet the requirements for participation in Medicare as a CAH (see subpart F of part 485 of this chapter), and (ii) are of a type that would be paid for by Medicare when furnished to a Medicare beneficiary.

(2) Inpatient CAH services do not include nursing facility services furnished by a CAH with a swing-bed approval.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 46 FR 48540, Oct. 1, 1981; 58 FR 30671, May 26, 1993; 62 FR 46037, Aug. 29, 1997; 64 FR 67051, Nov. 30, 1999; 72 FR 73651, Dec. 28, 2007; 73 FR 77530, Dec. 19, 2008; 74 FR 31196, June 30, 2009; 81 FR 3011, Jan. 20, 2016]

§ 440.180 Home and community-based waiver services.

(a) *Description and requirements for services.* ''Home or community-based services'' means services, not otherwise furnished under the State's Medicaid plan, that are furnished under a waiver granted under the provisions of part 441, subpart G of this chapter.

(1) These services may consist of any or all of the services listed in paragraph (b) of this section, as those services are defined by the agency and approved by CMS.

(2) The services must meet the standards specified in § 441.302(a) of this chapter concerning health and welfare assurances.

(3) The services are subject to the limits on FFP described in § 441.310 of this chapter.

(b) *Included services.* Home or community-based services may include the following services, as they are defined by the agency and approved by CMS:

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Habilitation services.

(7) Respite care services.

(8) Day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services (whether or not furnished in a facility) for individuals with chronic mental illness, subject to the conditions specified in paragraph (d) of this section.

(9) Other services requested by the agency and approved by CMS as cost effective and necessary to avoid institutionalization.

(c) *Expanded habilitation services, effective October 1, 1997*—(1) *General rule.* Expanded habilitation services are those services specified in paragraph (c)(2) of this section.

(2) *Services included.* The agency may include as expanded habilitation services the following services:

(i) Prevocational services, which means services that prepare an individual for paid or unpaid employment and that are not job-task oriented but are, instead, aimed at a generalized result. These services may include, for example, teaching an individual such concepts as compliance, attendance, task completion, problem solving and safety. Prevocational services are distinguishable from noncovered vocational services by the following criteria:

(A) The services are provided to persons who are not expected to be able to join the general work force or participate in a transitional sheltered workshop within one year (excluding supported employment programs).

(B) If the beneficiaries are compensated, they are compensated at less than 50 percent of the minimum wage;

(C) The services include activities which are not primarily directed at teaching specific job skills but at underlying habilitative goals (for example, attention span, motor skills); and

(D) The services are reflected in a plan of care directed to habilitative rather than explicit employment objectives.

(ii) Educational services, which means special education and related services (as defined in sections 602(16) and (17) of the Education of the Handicapped Act) (20 U.S.C. 1401 (16 and 17)) to the extent they are not prohibited under paragraph (c)(3)(i) of this section.

(iii) Supported employment services, which facilitate paid employment, that are—

(A) Provided to persons for whom competitive employment at or above the minimum wage is unlikely and who, because of their disabilities, need intensive ongoing support to perform in a work setting;

(B) Conducted in a variety of settings, particularly worksites in which persons without disabilities are employed; and

(C) Defined as any combination of special supervisory services, training, transportation, and adaptive equipment that the State demonstrates are essential for persons to engage in paid employment and that are not normally required for nondisabled persons engaged in competitive employment.

(3) *Services not included.* The following services may not be included as habilitation services:

(i) Special education and related services (as defined in sections 602(16) and (17) of the Education of the Handicapped Act) (20 U.S.C. 1401 (16) and (17)) that are otherwise available to the individual through a local educational agency.

(ii) Vocational rehabilitation services that are otherwise available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

(d) *Services for the chronically mentally ill*—(1) *Services included.* Services listed in paragraph (b)(8) of this section include those provided to individuals who have been diagnosed as being chronically mentally ill, for which the agency has requested approval as part of either a new waiver request or a renewal and which have been approved by CMS on or after October 21, 1986.

(2) *Services not included.* Any home and community-based service, including those indicated in paragraph (b)(8) of this section, may not be included in home and community-based service waivers for the following individuals:

(i) For individuals aged 22 through 64 who, absent the waiver, would be institutionalized in an institution for mental diseases (IMD); and, therefore, subject to the limitation on IMDs specified in § 435.1009(a)(2) of this chapter.

(ii) For individuals, not meeting the age requirements described in paragraph (d)(2)(i) of this section, who, absent the waiver, would be placed in an IMD in those States that have not opted to include the benefits defined in § 440.140 or § 440.160.

[59 FR 37716, July 25, 1994, as amended at 65 FR 60107, Oct. 10, 2000; 71 FR 39229, July 12, 2006]

§ 440.181 Home and community-based services for individuals age 65 or older.

(a) *Description of services*— Home and community-based services for individuals age 65 or older means services, not otherwise furnished under the State's Medicaid plan, or services already furnished under the State's Medicaid plan but in expanded amount, duration, or scope, which are furnished to individuals age 65 or older under a waiver granted under the provisions of part 441, subpart H of this subchapter. Except as provided in § 441.310, the services may consist of any of the services listed in paragraph (b) of this section that are requested by the State, approved by CMS, and furnished to eligible beneficiaries. Service definitions for each service in paragraph (b) of this section must be approved by CMS.

(b) *Included services.* (1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Respite care services.

(7) Other medical and social services requested by the Medicaid agency and approved by CMS, which will contribute to the health and well-being of individuals and their ability to reside in a community-based care setting.

[57 FR 29156, June 30, 1992]

§ 440.182 State plan home and community-based services.

(a) *Definition.* State plan home and community-based services (HCBS) benefit means the services listed in paragraph (c) of this section when provided under the State's plan (rather than through an HCBS waiver program) for individuals described in paragraph (b) of this section.

(b) *State plan HCBS coverage.* State plan HCBS can be made available to individuals who—

(1) Are eligible under the State plan and have income, calculated using the otherwise applicable rules, including any less restrictive income disregards used by the State for that group under section 1902(r)(2) of the Act, that does not exceed 150 percent of the Federal Poverty Line (FPL); and

(2) In addition to the individuals described in paragraph (b)(1) of this section, to individuals based on the State's election of the eligibility groups described in § 435.219(b) or § 436.219(b) of this chapter.

(c) *Services.* The State plan HCBS benefit consists of one or more of the following services:

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Habilitation services, which include expanded habilitation services as specified in § 440.180(c).

(7) Respite care services.

(8) Subject to the conditions in § 440.180(d)(2), for individuals with chronic mental illness:

(i) Day treatment or other partial hospitalization services;

(ii) Psychosocial rehabilitation services;

(iii) Clinic services (whether or not furnished in a facility).

(9) Other services requested by the agency and approved by the Secretary as consistent with the purpose of the benefit.

(d) *Exclusion.* FFP is not available for the cost of room and board in State plan HCBS. The following HCBS costs are not considered room or board for purposes of this exclusion:

(1) The cost of temporary food and shelter provided as an integral part of respite care services in a facility approved by the State.

(2) Meals provided as an integral component of a program of adult day health services or another service and

consistent with standard procedures in the State for such a program.

(3) A portion of the rent and food costs that may be reasonably attributed to an unrelated caregiver providing State plan HCBS who is residing in the same household with the recipient, but not if the recipient is living in the home of the caregiver or in a residence that is owned or leased by the caregiver.

[79 FR 3029, Jan. 16, 2014]

§ 440.185 Respiratory care for ventilator-dependent individuals.

(a) ''Respiratory care for ventilator-dependent individuals'' means services that are not otherwise available under the State's Medicaid plan, provided on a part-time basis in the beneficiary's home by a respiratory therapist or other health care professional trained in respiratory therapy (as determined by the State) to an individual who—

(1) Is medically dependent on a ventilator for life support at least 6 hours per day;

(2) Has been so dependent for at least 30 consecutive days (or the maximum number of days authorized under the State plan, whichever is less) as an inpatient in one or more hospitals, NFs, or ICFs/IID;

(3) Except for the availability of respiratory care services, would require respiratory care as an inpatient in a hospital, NF, or ICF/IID and would be eligible to have payment made for inpatient care under the State plan;

(4) Has adequate social support services to be cared for at home;

(5) Wishes to be cared for at home; and

(6) Receives services under the direction of a physician who is familiar with the technical and medical components of home ventilator support, and who has medically determined that in-home care is safe and feasible for the individual.

(b) For purposes of paragraphs (a)(4) and (5) of this section, a beneficiary's home does not include a hospital, NF, ICF/IID or other institution as defined in § 435.1010 of this chapter.

[59 FR 37717, July 25, 1994, as amended at 71 FR 39229, July 12, 2006]

Subpart B—Requirements and Limits Applicable to All Services

§ 440.200 Basis, purpose, and scope.

(a) This subpart implements the following statutory requirements—

(1) Section 1902(a)(10), regarding comparability of services for groups of beneficiaries, and the amount, duration, and scope of services described in section 1905(a) of the Act that the State plan must provide for beneficiaries;

(2) Section 1902(a)(22)(D), which provides for standards and methods to assure quality of services;

(3) Section 1903(v)(1), which provides that no payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law;

(4) Section 1903(v)(2) which provides that FFP will be available for services necessary to treat an emergency medical condition of an alien not described in paragraph (a)(3) of this section if that alien otherwise meets the eligibility requirements of the State plan;

(5) Section 1907 on observance of religious beliefs;

(6) Section 1915 on exceptions to section 1902(a)(10) and waivers of other requirements of section 1902 of the Act; and

(7) Sections 245A(h), 210 and 210A of the Immigration and Nationality Act which provide that certain aliens who are legalized may be eligible for Medicaid.

(b) The requirements and limits of this subpart apply for all services defined in subpart A of this part.

[55 FR 36822, Sept. 7, 1990]

§ 440.210 Required services for the categorically needy.

(a) A State plan must specify that, at a minimum, categorically needy beneficiaries are furnished the following services:

(1) The services defined in §§ 440.10 through 440.50, 440.70, and (to the extent nurse-midwives and nurse practitioners are authorized to practice under State law or regulation) the

services defined in §§ 440.165 and 440.166, respectively.

(2) Pregnancy-related services and services for other conditions that might complicate the pregnancy.

(i) Pregnancy-related services are those services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of the woman having been pregnant. These include, but are not limited to, prenatal care, delivery, postpartum care, and family planning services.

(ii) Services for other conditions that might complicate the pregnancy include those for diagnoses, illnesses, or medical conditions which might threaten the carrying of the fetus to full term or the safe delivery of the fetus; and

(3) For women who, while pregnant, applied for, were eligible for, and received Medicaid services under the plan, all services under the plan that are pregnancy-related for an extended postpartum period. The postpartum period begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends.

(b) A State plan must specify that eligible aliens as defined in §§ 435.406(a) and 436.406(a) of this subchapter will receive at least the services provided in paragraph (a) of this section.

(c) A State plan must specify that aliens not defined in §§ 435.406(a) and 436.406(a) of this subchapter will only be provided the limited services specified in § 440.255.

[56 FR 24010, May 28, 1991, as amended at 60 FR 19862, Apr. 21, 1995]

§ 440.220 Required services for the medically needy.

(a) A State plan that includes the medically needy must specify that the medically needy are provided, as a minimum, the following services:

(1) Prenatal care and delivery services for pregnant women.

(2) Ambulatory services, as defined in the State plan, for:

(i) Individuals under age 18; and

(ii) Groups of individuals entitled to institutional services.

(3) Home health services (§ 440.70) to any individual entitled to skilled nursing facility services.

(4) If the State plan includes services in an institution for mental diseases (§ 440.140 or § 440.160) or in an intermediate care facility for Individuals with Intellectual Disabilities (§ 440.150(c)) for any group of medically needy, either of the following sets of services to each of the medically needy groups:

(i) The services contained in §§ 440.10 through 440.50 and (to the extent nurse-midwives are authorized to practice under State law or regulation) § 440.165; or

(ii) The services contained in any seven of the sections in §§ 440.10 through 440.165.

(5) For women who, while pregnant, applied for, were eligible as medically needy for, and received Medicaid services under the plan, services under the plan that are pregnancy-related (as defined in § 440.210(a)(2)(i) of this subpart) for an extended postpartum period. The postpartum period begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends.

(b) A State plan must specify that eligible aliens as defined in §§ 435.406(a) and 436.406(a) of this subchapter will receive at least the services provided in paragraphs (a)(4) (i) and (ii) of this section.

(c) A State plan must specify that aliens defined in §§ 435.406(b), 435.406(c), 436.406(b) and 436.406(c) of this subchapter will only be provided the limited services specified in § 440.255.

[56 FR 24011, May 28, 1991, as amended at 58 FR 4938, Jan. 19, 1993]

§ 440.225 Optional services.

Any of the services defined in subpart A of this part that are not required under §§ 440.210 and 440.220 may be furnished under the State plan at the State's option.

[60 FR 19862, Apr. 21, 1995]

§ 440.230 Sufficiency of amount, duration, and scope.

(a) The plan must specify the amount, duration, and scope of each service that it provides for—

(1) The categorically needy; and

(2) Each covered group of medically needy.

(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition.

(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.

(e) For prior authorization requests for items and services (excluding drugs, as defined in § 431.60(b)(6) of this chapter), the State Medicaid agency must—

(1) Beginning January 1, 2026, make prior authorization decisions within the following timeframes:

(i) For a standard determination, as expeditiously as a beneficiary's health condition requires, but in no case later than 7 calendar days after receiving the request, unless a shorter minimum timeframe is established under State law. The timeframe for standard authorization decisions can be extended by up to 14 calendar days if the beneficiary or provider requests an extension, or if the State agency determines that additional information from the provider is needed to make a decision.

(ii) For an expedited determination, as expeditiously as a beneficiary's health condition requires, but in no case later than 72 hours after receiving the request, unless a shorter minimum timeframe is established under State law.

(2) Provide the beneficiary with notice of the agency's prior authorization decision in accordance with § 435.917 of this chapter and provide fair hearing rights, including advance notice, in accordance with part 431, subpart E, of this chapter.

(3) Beginning in 2026, annually report prior authorization data, excluding data on drugs, as defined in § 431.60(b)(6) of this chapter, at the State level by March 31. The State must make the following data from the previous calendar year publicly accessible by posting them on its website:

(i) A list of all items and services that require prior authorization.

(ii) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(iii) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(iv) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(v) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(vi) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(vii) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(viii) The average and median time that elapsed between the submission of a request and a determination by the State Medicaid agency, for standard prior authorizations, aggregated for all items and services.

(ix) The average and median time that elapsed between the submission of a request and a decision by the State Medicaid agency for expedited prior authorizations, aggregated for all items and services.

[46 FR 47993, Sept. 30, 1981, as amended at 89 FR 8981, Feb. 8, 2024]

§ 440.240 Comparability of services for groups.

Except as limited in § 440.250—

(a) The plan must provide that the services available to any categorically needy beneficiary under the plan are not less in amount, duration, and scope than those services available to a medically needy beneficiary; and

(b) The plan must provide that the services available to any individual in the following groups are equal in

amount, duration, and scope for all beneficiaries within the group:

(1) The categorically needy.

(2) A covered medically needy group.

[46 FR 47993, Sept. 30, 1981]

§ 440.250 Limits on comparability of services.

(a) Skilled nursing facility services (§ 440.40(a)) may be limited to beneficiaries age 21 or older.

(b) Early and periodic screening, diagnosis, and treatment (§ 440.40(b)) must be limited to beneficiaries under age 21.

(c) Family planning services and supplies must be limited to beneficiaries of childbearing age, including minors who can be considered sexually active and who desire the services and supplies.

(d) If covered under the plan, services to beneficiaries in institutions for mental diseases (§ 440.140) must be limited to those age 65 or older.

(e) If covered under the plan, inpatient psychiatric services (§ 440.160) must be limited to beneficiaries under age 22 as specified in § 441.151(c) of this subchapter.

(f) If Medicare benefits under Part B of title XVIII are made available to beneficiaries through a buy-in agreement or payment of premiums, or part or all of the deductibles, cost sharing or similar charges, they may be limited to beneficiaries who are covered by the agreement or payment.

(g) If services in addition to those offered under the plan are made available under a contract between the agency or political subdivision and an organization providing comprehensive health services, those additional services may be limited to beneficiaries who reside in the geographic area served by the contracting organization and who elect to receive services from it.

(h) Ambulatory services for the medically needy (§ 440.220(a)(2)) may be limited to:

(1) Individuals under age 18; and

(2) Groups of individuals entitled to institutional services.

(i) Services provided under an exception to requirements allowed under § 431.54 may be limited as provided under that exception.

(j) If CMS has approved a waiver of Medicaid requirements under § 431.55, services may be limited as provided by the waiver.

(k) If the agency has been granted a waiver of the requirements of § 440.240 (Comparability of services) in order to provide for home or community-based services under § 440.180 or § 440.181, the services provided under the waiver need not be comparable for all individuals within a group.

(l) If the agency imposes cost sharing on beneficiaries in accordance with 447.53, the imposition of cost sharing on an individual who is not exempted by one of the conditions in section 447.53(b) shall not require the State to impose copayments on an individual who is eligible for such exemption.

(m) Eligible legalized aliens who are not in the exempt groups described in §§ 435.406(a) and 436.406(a), and considered categorically needy or medically needy must be furnished only emergency services (as defined in § 440.255), and services for pregnant women as defined in section 1916(a)(2)(B) of the Social Security Act for 5 years from the date the alien is granted lawful temporary resident status.

(n) Aliens who are not lawful permanent residents, permanently residing in the United States under color of law, or granted lawful status under section 245A, 210 or 210A of the Immigration and Nationality Act, who, otherwise meet the eligibility requirements of the State plan (except for receipt of AFDC, SSI or a State Supplementary payment) must be furnished only those services necessary to treat an emergency medical condition of the alien as defined in § 440.255(c).

(o) If the agency makes respiratory care services available under § 440.185, the services need not be made available in equal amount, duration, and scope to any individual not eligible for coverage under that section. However, the services must be made available in equal amount, duration, and scope to all individuals eligible for coverage under that section.

(p) A State may provide a greater amount, duration, or scope of services to pregnant women than it provides under its plan to other individuals who

are eligible for Medicaid, under the following conditions:

(1) These services must be pregnancy-related or related to any other condition which may complicate pregnancy, as defined in § 440.210(a)(2) of this subpart; and

(2) These services must be provided in equal amount, duration, and scope to all pregnant women covered under the State plan.

(q) [Reserved]

(r) If specified in the plan, targeted case management services may be limited to the following:

(1) Certain geographic areas within a State, without regard to the statewide requirements in § 431.50 of this chapter.

(2) Targeted groups specified by the State.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 46 FR 48541, Oct. 1, 1981; 48 FR 5735, Jan. 8, 1983; 51 FR 22041, June 17, 1986; 55 FR 36822, Sept. 7, 1990; 56 FR 24011, May 28, 1991; 57 FR 29156, June 30, 1992; 58 FR 4939, Jan. 19, 1993; 59 FR 37717, July 25, 1994; 72 FR 68092, Dec. 4, 2007]

§ 440.255 Limited services available to certain aliens.

(a) *FFP for services.* FFP is available for services provided to aliens described in this section which are necessary to treat an emergency medical condition as defined in paragraphs (b)(1) and (c) or services for pregnant women described in paragraph (b)(2).

(b) *Legalized aliens eligible only for emergency services and services for pregnant women.* Aliens granted lawful temporary resident status, or lawful permanent resident status under sections 245A, 210 or 210A of the Immigration and Nationality Act, who are not in one of the exempt groups described in §§ 435.406(a)(3) and 436.406(a)(3) and who meet all other requirements for Medicaid will be eligible for the following services—

(1) Emergency services required after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

(i) Placing the patient's health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part.

(2) Services for pregnant women which are included in the approved State plan. These services include routine prenatal care, labor and delivery, and routine post-partum care. States, at their option, may provide additional plan services for the treatment of conditions which may complicate the pregnancy or delivery.

(c) Effective January 1, 1987, aliens who are not lawfully admitted for permanent residence in the United States or permanently residing in the United States under the color of law must receive the services necessary to treat the condition defined in paragraph (1) of this section if—

(1) The alien has, after sudden onset, a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

(i) Placing the patient's health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part, and

(2) The alien otherwise meets the requirements in §§ 435.406(c) and 436.406(c) of this subpart.

[55 FR 36823, Sept. 7, 1990; 56 FR 10807, Mar. 14, 1991]

§ 440.260 Methods and standards to assure quality of services.

The plan must include a description of methods and standards used to assure that services are of high quality.

§ 440.262 Access and cultural conditions.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. These methods must ensure that beneficiaries

have access to covered services that are delivered in a manner that meets their individualized needs.

[89 FR 37692, May 6, 2024]

§ 440.270 Religious objections.

(a) Except as specified in paragraph (b) of this section, the agency may not require any individual to undergo any medical service, diagnosis, or treatment or to accept any other health service provided under the plan if the individual objects, or in the case of a child, a parent or guardian objects, on religious grounds.

(b) If a physical examination is necessary to establish eligibility based on disability or blindness, the agency may not find an individual eligible for Medicaid unless he undergoes the examination.

Subpart C—Benchmark Benefit and Benchmark-Equivalent Coverage

SOURCE: 75 FR 23101, Apr. 30, 2010, unless otherwise noted.

§ 440.300 Basis.

This subpart implements section 1937 of the Act, which authorizes States to provide for medical assistance to one or more groups of Medicaid-eligible individuals, specified by the State under an approved State plan amendment, through enrollment in coverage that provides benchmark or benchmark-equivalent health care benefit coverage.

§ 440.305 Scope.

(a) *General.* This subpart sets out requirements for States that elect to provide medical assistance to certain Medicaid eligible individuals within one or more groups of individuals specified by the State, through enrollment of the individuals in coverage, identified as ''benchmark'' or ''benchmark-equivalent.'' Groups must be identified by characteristics of individuals rather than the amount or level of FMAP.

(b) *Limitations.* A State may only apply the option in paragraph (a) of this section for an individual whose eligibility is based on an eligibility category under section 1905(a) of the Act that could have been covered under the State's plan on or before February 8, 2006, except that individuals who are eligible under section 1902(a)(10)(A)(i)(VIII) of the Act must enroll in an Alternative Benefit Plan to receive medical assistance.

(c) A State may not require but may offer enrollment in benchmark or benchmark-equivalent coverage to the Medicaid eligible individuals listed in § 440.315. States allowing individuals to voluntarily enroll must be in compliance with the rules specified at § 440.320.

[75 FR 23101, Apr. 30, 2010, as amended at 78 FR 42306, July 15, 2013]

§ 440.310 Applicability.

(a) *Enrollment.* The State may require ''full benefit eligible'' individuals not excluded in § 440.315 to enroll in benchmark or benchmark-equivalent coverage.

(b) *Full benefit eligible.* An individual is a full benefit eligible if determined by the State to be eligible to receive the standard full Medicaid benefit package under the approved State plan if not for the application of the option available under this subpart.

§ 440.315 Exempt individuals.

Individuals within one (or more) of the following categories are exempt from mandatory enrollment in an Alternative Benefit Plan, unless the individuals are eligible under section 1902(a)(10)(A)(i)(VIII) of the Act. Individuals in that eligibility group who meet the conditions for exemption must be given the option of an Alternative Benefit Plan that includes all benefits available under the approved State plan.

(a) The individual is a pregnant woman who is required to be covered under the State plan under section 1902(a)(10)(A)(i) of the Act.

(b) The individual qualifies for medical assistance under the State plan on the basis of being blind or disabled (or being treated as being blind or disabled) without regard to whether the individual is eligible for Supplemental Security Income benefits under title XVI on the basis of being blind or disabled and including an individual who

is eligible for medical assistance on the basis of section 1902(e)(3) of the Act.

(c) The individual is entitled to benefits under any part of Medicare.

(d) The individual is terminally ill and is receiving benefits for hospice care under title XIX.

(e) The individual is an inpatient in a hospital, nursing facility, intermediate care facility for individuals with intellectual disabilities, or other medical institution, and is required, as a condition of receiving services in that institution under the State plan, to spend for costs of medical care all but a minimal amount of the individual's income required for personal needs.

(f) The individual is medically frail or otherwise an individual with special medical needs. For these purposes, the State's definition of individuals who are medically frail or otherwise have special medical needs must at least include those individuals described in §438.50(d)(3) of this chapter, individuals with disabling mental disorders (including children with serious emotional disturbances and adults with serious mental illness), individuals with chronic substance use disorders, individuals with serious and complex medical conditions, individuals with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living, or individuals with a disability determination based on Social Security criteria or in States that apply more restrictive criteria than the Supplemental Security Income program, the State plan criteria.

(g) The individual qualifies based on medical condition for medical assistance for long-term care services described in section 1917(c)(1)(C) of the Act.

(h) The individual is eligible and enrolled for Medicaid under §435.145 of this chapter based on current eligibility for assistance under title IV–E of the Act or under §435.150 of this chapter based on current status as a former foster care child.

(i) The individual is a parent or caretaker relative whom the State is required to cover under section 1931 of the Act.

(j) The individual is a woman who is receiving medical assistance by virtue of the application of sections 1902(a)(10)(ii)(XVIII) and 1902(aa) of the Act.

(k) The individual qualifies for medical assistance on the basis of section 1902(a)(10)(A)(ii)(XII) of the Act.

(l) The individual is only covered by Medicaid for care and services necessary for the treatment of an emergency medical condition in accordance with section 1903(v) of the Act.

(m) The individual is determined eligible as medically needy or eligible because of a reduction of countable income based on costs incurred for medical or other remedial care under section 1902(f) of the Act or otherwise based on incurred medical costs.

[75 FR 23101, Apr. 30, 2010, as amended at 78 FR 42306, July 15, 2013]

§ 440.320 State plan requirements: Optional enrollment for exempt individuals.

(a) *General rule.* A State plan that offers exempt individuals as defined in §440.315 the option to enroll in benchmark or benchmark-equivalent coverage must identify in its State plan the exempt groups for which this coverage is available, and must comply with the following provisions:

(1) In any case in which the State offers an exempt individual the option to obtain coverage in a benchmark or benchmark-equivalent benefit package, the State must effectively inform the individual prior to enrollment that the enrollment is voluntary and that the individual may disenroll from the benchmark or benchmark-equivalent coverage at any time and regain immediate access to standard full Medicaid coverage under the State plan.

(2) Prior to any enrollment in benchmark or benchmark-equivalent coverage, the State must inform the exempt individual of the benefits available under the benchmark or benchmark-equivalent benefit package and the costs under such a package and provide a comparison of how they differ from the benefits and costs available under the standard full Medicaid program. The State must also inform exempt individuals that they may disenroll at any time and provide them with information about the process for disenrolling.

(3) The State must document in the exempt individual's eligibility file that the individual was informed in accordance with this section prior to enrollment, was given ample time to arrive at an informed choice, and voluntarily and affirmatively chose to enroll in the benchmark or benchmark-equivalent benefit package.

(4) For individuals who the State determines have become exempt individuals while enrolled in benchmark or benchmark-equivalent coverage, the State must comply with the requirements in paragraphs (a)(1) through (a)(3) of this section above within 30 days after such determination.

(b) *Disenrollment Process.* (1) The State must act upon requests promptly for exempt individuals who choose to disenroll from benchmark or benchmark-equivalent coverage.

(2) The State must have a process in place to ensure that exempt individuals have access to all standard State plan services while disenrollment requests are being processed.

(3) The State must maintain data that tracks the total number of beneficiaries that have voluntarily enrolled in a benchmark plan and the total number of individuals that have disenrolled from the benchmark plan.

§ 440.325 State plan requirements: Coverage and benefits.

Subject to requirements in §§ 440.345 and 440.365, States may elect to provide any of the following types of health benefits coverage:

(a) Benchmark coverage in accordance with § 440.330.

(b) Benchmark-equivalent coverage in accordance with § 440.335.

§ 440.330 Benchmark health benefits coverage.

Benchmark coverage is health benefits coverage that is equal to the coverage under one or more of the following benefit plans:

(a) *Federal Employees Health Benefit Plan Equivalent Coverage (FEHBP—Equivalent Health Insurance Coverage).* A benefit plan equivalent to the standard Blue Cross/Blue Shield preferred provider option service benefit plan that is described in and offered to Federal employees under 5 U.S.C. 8903(1).

(b) *State employee coverage.* Health benefits coverage that is offered and generally available to State employees in the State.

(c) *Health maintenance organization (HMO) plan.* A health insurance plan that is offered through an HMO, (as defined in section 2791(b)(3) of the Public Health Service Act) that has the largest insured commercial, non-Medicaid enrollment in the State.

(d) *Secretary-approved coverage.* Any other health benefits coverage that the Secretary determines, upon application by a State, provides appropriate coverage to meet the needs of the population provided that coverage. Secretarial coverage may include benefits of the type that are available under 1 or more of the standard benchmark coverage packages defined in paragraphs (a) through (c) of this section, State plan benefits described in section 1905(a), 1915(i), 1915(j), 1915(k) or section 1945 of the Act, any other Medicaid State plan benefits enacted under title XIX, or benefits available under base benchmark plans described in 45 CFR 156.100.

(1) States wishing to elect Secretary-approved coverage should submit a full description of the proposed coverage (including a benefit-by-benefit comparison of the proposed plan to one or more of the three other benchmark plans specified above or to the State's standard full Medicaid coverage package), and of the population to which coverage will be offered. In addition, the State should submit any other information that will be relevant to a determination that the proposed health benefits coverage will be appropriate for the proposed population.

(2) [Reserved]

[75 FR 23101, Apr. 30, 2010, as amended at 78 FR 42306, July 15, 2013]

§ 440.335 Benchmark-equivalent health benefits coverage.

(a) *Aggregate actuarial value.* Benchmark-equivalent coverage is health benefits coverage that has an aggregate actuarial value, as determined under § 440.340, that is at least actuarially equivalent to the coverage under one of the benchmark benefit packages described in § 440.330 for the identified

Medicaid population to which it will be offered.

(b) *Required coverage.* Benchmark-equivalent health benefits coverage must include coverage for the following categories of services:

(1) Inpatient and outpatient hospital services.

(2) Physicians' surgical and medical services.

(3) Laboratory and x-ray services.

(4) Well-baby and well-child care, including age-appropriate immunizations.

(5) Emergency services.

(6) Family planning services and supplies and other appropriate preventive services, as designated by the Secretary.

(7) Prescription drugs.

(8) Mental health benefits.

(c) *Additional coverage.* (1) In addition to the types of benefits of this section, benchmark-equivalent coverage may include coverage for any additional benefits of the type which are covered in 1 or more of the standard benchmark coverage packages described in § 440.330(a) through (c) or State plan benefits, described in section 1905(a), 1915(i), 1915(j), 1915(k) and 1945 of the Act, any other Medicaid State plan benefits enacted under title XIX, or benefits available under base-benchmark plans described in 45 CFR 156.100.

(2) If the benchmark coverage package used by the State for purposes of comparison in establishing the aggregate actuarial value of the benchmark-equivalent package includes any of the following four categories of services: Prescription drugs; mental health services; vision services; and hearing services; then the actuarial value of the coverage for each of these categories of service in the benchmark-equivalent coverage package must be at least 75 percent of the actuarial value of the coverage for that category of service in the benchmark plan used for comparison by the State.

[75 FR 23101, Apr. 30, 2010, as amended at 78 FR 42306, July 15, 2013]

§ 440.340 Actuarial report for benchmark-equivalent coverage.

(a) A State plan amendment that would provide for benchmark-equivalent health benefits coverage described in § 440.335, must include an actuarial report. The actuarial report must contain an actuarial opinion that the benchmark-equivalent health benefits coverage meets the actuarial requirements set forth in § 440.335. The report must also specify the benchmark coverage used for comparison.

(b) The actuarial report must state that it was prepared according to the following requirements:

(1) By an individual who is a member of the American Academy of Actuaries (AAA).

(2) Using generally accepted actuarial principles and methodologies of the AAA.

(3) Using a standardized set of utilization and price factors.

(4) Using a standardized population that is representative of the population involved.

(5) Applying the same principles and factors in comparing the value of different coverage (or categories of services).

(6) Without taking into account any differences in coverage based on the method of delivery or means of cost control or utilization used.

(7) Taking into account the ability of the State to reduce benefits by considering the increase in actuarial value of health benefits coverage offered under the State plan that results from the limitations on cost sharing (with the exception of premiums) under that coverage.

(c) The actuary preparing the opinion must select and specify the standardized set of factors and the standardized population to be used in paragraphs (b)(3) and (b)(4) of this section.

(d) The State must provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value or, if requested by CMS, to replicate the State's result.

§ 440.345 EPSDT and other required benefits.

(a) The State must assure access to early and periodic screening, diagnostic and treatment (EPSDT) services through benchmark or benchmark-equivalent plan benefits or as additional benefits provided by the State

for any child under 21 years of age eligible under the State plan in a category under section 1902(a)(10)(A) of the Act.

(1) Sufficiency. Any additional EPSDT benefits not provided by the benchmark or benchmark-equivalent plan must be sufficient so that, in combination with the benchmark or benchmark-equivalent benefits plan, these individuals have access to the full EPSDT benefit.

(2) State Plan requirement. The State must include a description of how the additional benefits will be provided, how access to additional benefits will be coordinated and how beneficiaries and providers will be informed of these processes in order to ensure that these individuals have access to the full EPSDT benefit.

(b) *Family planning.* Alternative Benefit Plans must include coverage for family planning services and supplies.

(c) *Mental health parity.* Alternative Benefit Plans that provide both medical and surgical benefits, and mental health or substance use disorder benefits, must comply with the Mental Health Parity and Addiction Equity Act.

(d) *Essential health benefits.* Alternative Benefit Plans must include at least the essential health benefits described in § 440.347, and include all updates or modifications made thereafter by the Secretary to the definition of essential health benefits.

(e) *Updating of benefits.* States are not required to update Alternative Benefit Plans that have been determined to include essential health benefits as of January 1, 2014, until December 31, 2015. States will adhere to future guidance for updating benefits beyond that date, as described by the Secretary.

(f) *Covered outpatient drugs.* To the extent states pay for covered outpatient drugs under their Alternative Benefit Plan's prescription drug coverage, states must comply with the requirements under section 1927 of the Act.

[75 FR 23101, Apr. 30, 2010, as amended at 78 FR 42306, July 15, 2013]

§ 440.347 Essential health benefits.

(a) Alternative Benefit Plans must contain essential health benefits coverage, including benefits in each of the following ten categories, consistent with the applicable requirements set forth in 45 CFR part 156:

(1) Ambulatory patient services;

(2) Emergency services;

(3) Hospitalization;

(4) Maternity and newborn care;

(5) Mental health and substance use disorders, including behavioral health treatment;

(6) Prescription drugs;

(7) Rehabilitative and habilitative services and devices, except that such coverage shall be in accordance with § 440.347(d);

(8) Laboratory services;

(9) Preventive and wellness services and chronic disease management; and

(10) Pediatric services, including oral and vision care, in accordance with section 1905(r) of the Act.

(b) Alternative Benefit Plans must include essential health benefits in one of the state options for establishing essential health benefits described in 45 CFR 156.100, subject to supplementation under 45 CFR 156.110(b) and substitution as permitted under 45 CFR 156.115(b).

(c) States may select more than one base benchmark option for establishing essential health benefits in keeping with the flexibility for States to implement more than one Alternative Benefit Plan for targeted populations.

(d) To comply with paragraph (a) of this section, Alternative Benefit Plan coverage of habilitative services and devices will be based on the habilitative services and devices that are in the applicable base benchmark plan. If habilitative services and devices are not in the applicable base benchmark plan, the state will define habilitative services and devices required as essential health benefits using the methodology set forth in 45 CFR 156.115(a)(5).

(e) Essential health benefits cannot be based on a benefit design or implementation of a benefit design that discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health conditions.

[78 FR 42307, July 15, 2013]

§ 440.350 Employer-sponsored insurance health plans.

(a) A State may provide benchmark or benchmark-equivalent coverage by obtaining employer sponsored health plans (either alone or with additional services covered separately under Medicaid) for individuals with access to private health insurance.

(b) The State must assure that employer sponsored plans meet the requirements of benchmark or benchmark-equivalent coverage, including the economy and efficiency requirements at § 440.370.

(c) A State may provide benchmark or benchmark-equivalent coverage through a combination of employer sponsored health plans and additional benefit coverage provided by the State that wraps around the employer sponsored health plan which, in the aggregate, results in benchmark or benchmark-equivalent level of coverage for those individuals.

§ 440.355 Payment of premiums.

Payment of premiums by the State, net of beneficiary contributions, to obtain benchmark or benchmark-equivalent benefit coverage on behalf of beneficiaries under this section will be treated as medical assistance under section 1905(a) of the Act.

§ 440.360 State plan requirements for providing additional services.

In addition to the requirements of § 440.345, the State may elect to provide additional coverage to individuals enrolled in Alternative Benefit Plans, except that the coverage for individuals eligible only through section 1902(a)(10)(A)(i)(VIII) of the Act is limited to benchmark or benchmark-equivalent coverage. The State must describe the populations covered and the payment methodology for these benefits. Additional benefits must be benefits of the type, which are covered in 1 or more of the standard benchmark coverage packages described in § 440.330(a) through (c) or State plan benefits including those described in sections 1905(a), 1915(i), 1915(j), 1915(k) and 1945 of the Act and any other Medicaid State plan benefits enacted under title XIX, or benefits available under base benchmark plans described in 45 CFR 156.100.

[78 FR 42307, July 15, 2013]

§ 440.365 Coverage of rural health clinic and federally qualified health center (FQHC) services.

If a State provides benchmark or benchmark-equivalent coverage to individuals, it must assure that the individual has access, through that coverage or otherwise, to rural health clinic services and FQHC services as defined in subparagraphs (B) and (C) of section 1905(a)(2) of the Act. Payment for these services must be made in accordance with the payment provisions of section 1902(bb) of the Act.

§ 440.370 Economy and efficiency.

Benchmark and benchmark-equivalent coverage and any additional benefits must be provided in accordance with Federal upper payment limits, procurement requirements and other economy and efficiency principles that would otherwise be applicable to the services or delivery system through which the coverage and benefits are obtained.

§ 440.375 Comparability.

States have the option to amend their State plan to provide benchmark or benchmark-equivalent coverage to individuals without regard to comparability.

§ 440.380 Statewideness.

States have the option to amend their State plan to provide benchmark or benchmark-equivalent coverage to individuals without regard to statewideness.

§ 440.385 Delivery of benchmark and benchmark-equivalent coverage through managed care entities.

In implementing benchmark or benchmark-equivalent benefit packages, States must comply with the managed care provisions at section 1932 of the Act and part 438 of this chapter, if benchmark and benchmark-equivalent benefits are provided through a managed care entity.

§ 440.386 Public notice.

Prior to submitting to the Centers for Medicare and Medicaid Services for approval of a State plan amendment to establish an Alternative Benefit Plan or an amendment to substantially modify an existing Alternative Benefit Plan, a state must have provided the public with advance notice of the amendment and reasonable opportunity to comment for such amendment, and have included in the notice a description of the method for assuring compliance with § 440.345 related to full access to EPSDT services, and the method for complying with the provisions of section 5006(e) of the American Recovery and Reinvestment Act of 2009.

[78 FR 42307, July 15, 2013]

§ 440.390 Assurance of transportation.

If a benchmark or benchmark-equivalent plan does not include transportation to and from medically necessary covered Medicaid services, the State must nevertheless assure that emergency and non-emergency transportation is covered for beneficiaries enrolled in the benchmark or benchmark-equivalent plan, as required under § 431.53 of this chapter.

§ 440.395 Parity in mental health and substance use disorder benefits.

(a) *Meaning of terms.* For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under an ABP.

Alternative Benefit Plans (ABPs) mean benefit packages in one or more of the benchmark coverage packages described in §§ 440.330(a) through (c) and 440.335. Benefits may be delivered through managed care and non-managed care delivery systems. Consistent with the requirements of § 440.385, States must comply with the managed care provisions at section 1932 of the Act and part 438 of this chapter, if benchmark and benchmark-equivalent benefits are provided through a managed care entity.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under an ABP.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

EPSDT means benefits defined in section 1905(r) of the Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined by the State under the terms of the ABP and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the state as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines). Medical/surgical benefits include long term services.

Mental health benefits means benefits for items or services for mental health conditions, as defined by the State under the terms of the ABP and in accordance with applicable Federal and State law. Any condition defined by the State as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines. Mental health benefits include long term care services.

Substance use disorder benefits means benefits for items or services for substance use disorder, as defined by the State under the terms of the ABP and in accordance with applicable Federal and State law. Any disorder defined by the State as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines). Substance use disorder benefits include long term care services.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under an ABP. (*See* paragraph (b)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(b) *Parity requirements for financial requirements and treatment limitations*—(1) *Clarification of terms*—(i) *Classification of benefits.* When reference is made in this paragraph (b) to a classification of benefits, the term ''classification'' means a classification as described in paragraph (b)(2)(ii) of this section.

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (b) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. *See* paragraph (b)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) *Level of a type of financial requirement or treatment limitation.* When reference is made in this paragraph (b) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(2) *General parity requirement*—(i) *General rule.* A State may not apply within an ABP any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (b)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (b)(3) of this section; the application of the rules of this paragraph (b)(2) to nonquantitative treatment limitations is addressed in paragraph (b)(4) of this section.

(ii) *Classifications of benefits used for applying rules.* ABPs must include mental health or substance use disorder benefits in every classification of benefits described in this paragraph (b)(2)(ii) in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, the State must apply the same reasonable standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a State provides ABP benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (b) apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in

applying the rules of this paragraph (b):

(A) *Inpatient.* Benefits furnished on an inpatient basis.

(B) *Outpatient.* Benefits furnished on an outpatient basis. See special rules for office visits in paragraph (b)(3)(ii)(B)(*1*) of this section.

(C) *Emergency care.* Benefits for emergency care.

(D) *Prescription drugs.* Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (b)(3)(ii) of this section.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining ''substantially all'' and ''predominant''*—(A) *Substantially all.* For purposes of this paragraph (b), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) *Predominant*—(*1*) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (b)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(*2*) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the State may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a State may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) *Portion based on ABP payments.* For purposes of this paragraph (b), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all ABP payments for medical/surgical benefits in the classification expected to be paid under the ABP for the plan year (or for the portion of the plan year after a change in ABP benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of ABP payments includes all payments for claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of ABP payments includes all payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of payment changes.

(E) *Determining the dollar amount of ABP payments.* Subject to paragraph (b)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any

level of a financial requirement or quantitative treatment limitation).

(ii) *Special rules*—(A) *Multi-tiered prescription drug benefits.* If a State or plan administrator applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (b)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the ABP satisfies the parity requirements of this paragraph (b) for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(B) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (b), a State may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (b)(3)(ii)(B). After the sub-classifications are established, the State may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (b)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (b)(3)(ii)(B) are:

(*1*) Office visits (such as physician visits); and

(*2*) All other outpatient items and services (such as outpatient surgery, laboratory services, or other medical items).

(iii) *No separate cumulative financial requirements.* A State may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(iv) *Compliance with other cost-sharing rules.* States must meet the requirements of §§ 447.50 through 447.57 of this chapter when applying Medicaid cost-sharing.

(4) *Nonquantitative treatment limitations*—(i) *General rule.* A State may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the terms of the ABP as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(ii) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Methods for determining usual, customary, and reasonable charges;

(E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(F) Exclusions based on failure to complete a course of treatment; and

(G) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits or services provided under the ABP.

(c) *ABP providing EPSDT benefits.* An ABP that provides EPSDT benefits is deemed to be compliant with the parity

requirements for financial requirements and treatment limitations with respect to individuals entitled to such benefits. Annual or lifetime limits are not permissible in EPSDT benefits.

(d) *Availability of information*—(1) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations made by the State for beneficiaries served through the ABP for mental health or substance use disorder benefits must be made available by the State to any beneficiary or Medicaid provider upon request.

(2) *Reason for any denial.* The reason for any denial made by the State in the case of a beneficiary served through an ABP of reimbursement or payment for services for mental health or substance use disorder benefits must be made available by the State to the beneficiary.

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law.

(e) *Applicability*—(1) *ABPs.* The requirements of this section apply to States providing benefits through ABPs. For those States providing ABPs through an MCO, PIHP, or PAHP, the rules of 42 CFR part 438, subpart K also apply, and approved contracts will be viewed as evidence of compliance with the requirements of this section.

(2) *Scope.* This section does not—

(i) Require a State to provide any specific mental health benefits or substance use disorder benefits; however, in providing coverage through an ABP, the State must include EHBs, including the ten EHBs as required in §440.347, which include mental health and substance use disorder benefits; or

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the ABP except as specifically provided in paragraph (b) of this section.

(3) *State plan requirement.* If a State plan provides for an ABP, the State must provide sufficient information in ABP State plan amendment requests to assure compliance with the requirements of this subpart.

(4) *Compliance dates*—(i) *In general.* ABP coverage offered by States must comply with the requirements of this section no later than October 2, 2017.

(ii) [Reserved]

[81 FR 18439, Mar. 30, 2016]

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

Sec.