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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

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AUTHORITY: 42 U.S.C. 1302.

SOURCE: 43 FR 45229, Sept. 29, 1978, unless otherwise noted.

§ 441.1 Purpose.

This part sets forth State plan requirements and limits on FFP for specific services defined in part 440 of this subchapter. Standards for payments for services provided in intermediate care facilities and skilled nursing facilities are set forth in part 442 of this subchapter.

Subpart A—General Provisions

§ 441.10 Basis.

This subpart is based on the following sections of the Act which state requirements and limits on the services specified or provide Secretarial authority to prescribe regulations relating to services:

(a) Section 1102 for end-stage renal disease (§ 441.40).

(b) Section 1138(b) for organ procurement organization services (§ 441.13(c)).

(c) Sections 1902(a)(10)(A) and 1905(a)(21) for nurse practitioner services (§ 441.22).

(d) Sections 1902(a)(10)(D) and 1905(a)(7) for home health services (§ 441.15).

(e) Section 1903(i)(1) for organ transplant procedures (§ 441.35).

(f) Section 1903(i)(5) for certain prescribed drugs (§ 441.25).

(g) Section 1903(i)(6) for prohibition (except in emergency situations) of FFP in expenditures for inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner (§ 441.12).

(h) Section 1903(i)(18) for the requirement that each home health agency provide the Medicaid agency with a surety bond (§ 441.16).

(i) Section 1905(a)(4)(C) for family planning (§ 441.20).

(j) Sections 1905 (a)(12) and (e) for optometric services (§ 441.30).

(k) Section 1905(a)(17) for nurse-midwife services (§ 441.21).

(l) Section 1905(a) (following (a)(24)) for prohibition of FFP in expenditures for certain services (§ 441.13).

(m) Section 1905(a)(19) and 1915(g) of the Act for case management services as set forth in § 441.18 and section 8435 of the Technical and Miscellaneous Revenue Act of 1988.

[60 FR 19862, Apr. 21, 1995, as amended at 63 FR 310, Jan. 5, 1998; 72 FR 68092, Dec. 4, 2007]

§ 441.11 Continuation of FFP for institutional services.

(a) *Basic conditions for continuation of FFP.* FFP may be continued for up to 30 days after the effective date of termination or expiration of a provider agreement, if the following conditions are met:

(1) The Medicaid payments are for beneficiaries admitted to the facility before the effective date of termination or expiration.

(2) The State agency is making reasonable efforts to transfer those beneficiaries to other facilities or to alternate care.

(b) *When the 30-day period begins.* The 30-day period begins on one of the following:

(1) The effective date of termination of the facility's provider agreement by CMS;

(2) The effective date of termination of the facility's Medicaid provider agreement by the Medicaid agency on its own volition; or

(3) In the case of an ICF/IID, the later of—

(i) The effective date of termination or nonrenewal of the facility's provider agreement by the Medicaid agency on its own volition; or

(ii) The date of issuance of an administrative hearing decision that upholds the agency's termination or nonrenewal action.

(c) *Services for which FFP may be continued.* FFP may be continued for any of the following services, as defined in subpart A of part 440 of this chapter:

(1) Inpatient hospital services.

(2) Inpatient hospital services for individuals age 65 or older in an institution for mental diseases.

(3) Nursing facility services for individuals age 21 or older.

(4) Nursing facility services for individuals age 65 or older in an institution for mental diseases.

(5) Inpatient psychiatric services for individuals under age 21.

(6) Nursing facility services for individuals under 21.

(7) Intermediate care facility services for individuals with intellectual disabilities.

[59 FR 56234, Nov. 10, 1994]

§ 441.12 Inpatient hospital tests.

Except in an emergency situation (see § 440.170(e)(1) of this chapter for definition), FFP is not available in expenditures for inpatient hospital tests unless the tests are specifically ordered by the attending physician or other licensed practitioner, acting within the scope of practice as defined under State law, who is responsible for the diagnosis or treatment of a particular patient's condition.

[46 FR 48554, Oct. 1, 1981]

§ 441.13 Prohibitions on FFP: Institutionalized individuals.

(a) FFP is not available in expenditures for services for—

(1) Any individual who is in a public institution, as defined in § 435.1010 of this chapter; or

(2) Any individual who is under age 65 and is in an institution for mental diseases, except an individual who is under age 22 and receiving inpatient psychiatric services under subpart D of this part.

(b) With the exception of active treatment services (as defined in § 483.440(a) of this chapter for residents of ICFs/IID and in § 441.154 for individuals under age 21 receiving inpatient psychiatric services), payments to institutions for Individuals with Intellectual Disabilities or persons with related conditions and to psychiatric facilities or programs providing inpatient psychiatric services to individuals under age 21 may not include reimbursement for formal educational services or for vocational services. Formal educational services relate to training in traditional academic subjects. Subject matter rather than setting, time of day, or class size determines whether a service is educational. Traditional academic subjects include, but are not limited to, science, history, literature, foreign languages, and mathematics. Vocational services relate to organized programs that are directly related to the preparation of individuals for paid or unpaid employment. An example of vocational services is time-limited vocational training provided as a part of a regularly scheduled class available to the general public.

(c) FFP is not available in expenditures for services furnished by an organ procurement organization on or after April 1, 1988, that does not meet the requirements of part 486 subpart G of this chapter.

[43 FR 45229, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986; 53 FR 6549, Mar. 1, 1988; 57 FR 54709, Nov. 20, 1992; 71 FR 31046, May 31, 2006; 71 FR 39229, July 12, 2006]

§ 441.15 Home health services.

With respect to the services defined in § 440.70 of this subchapter, a State plan must provide that—

(a) Home health services include, as a minimum—

(1) Nursing services;

(2) Home health aide services; and

(3) Medical supplies, equipment, and appliances.

(b) The agency provides home health services to—

(1) Categorically needy beneficiaries age 21 or over;

(2) Categorically needy beneficiaries under age 21, if the plan provides skilled nursing facility services for them; individuals; and

(3) Medically needy beneficiaries to whom skilled nursing facility services are provided under the plan.

(c) The eligibility of a beneficiary to receive home health services does not depend on his need for or discharge from institutional care.

(d) The agency providing home health services meets the capitalization requirements included in § 489.28 of this chapter.

[43 FR 45229, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 63 FR 310, Jan. 5, 1998]

§ 441.16 Home health agency requirements for surety bonds; Prohibition on FFP.

(a) *Definitions.* As used in this section, unless the context indicates otherwise—

Assets includes but is not limited to any listing that identifies Medicaid beneficiaries to whom home health services were furnished by a participating or formerly participating HHA.

Participating home health agency means a ''home health agency'' (HHA) as that term is defined at § 440.70(d) of this subchapter.

Surety bond means one or more bonds issued by one or more surety companies under 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225, provided the bond otherwise meets the requirements of this section.

Uncollected overpayment means an ''overpayment,'' as that term is defined under § 433.304 of this subchapter, plus accrued interest, for which the HHA is responsible, that has not been recouped by the Medicaid agency within a time period determined by the Medicaid agency.

(b) *Prohibition.* FFP is not available in expenditures for home health services under § 440.70 of this subchapter unless the home health agency furnishing these services meets the surety bond requirements of paragraphs (c) through (l) of this section.

(c) *Basic requirement.* Except as provided in paragraph (d) of this section, each HHA that is a Medicaid participating HHA or that seeks to become a Medicaid participating HHA must—

(1) Obtain a surety bond that meets the requirements of this section and instructions issued by the Medicaid agency; and

(2) Furnish a copy of the surety bond to the Medicaid agency.

(d) *Requirement waived for Government-operated HHAs.* An HHA operated by a Federal, State, local, or tribal government agency is deemed to have provided the Medicaid agency with a comparable surety bond under State law, and is therefore exempt from the requirements of this section if, during the preceding 5 years, the HHA has not had any uncollected overpayments.

(e) *Parties to the bond.* The surety bond must name the HHA as Principal, the Medicaid agency as Obligee, and the surety company (and its heirs, executors, administrators, successors and assignees, jointly and severally) as Surety.

(f) *Authorized Surety and exclusion of surety companies.* An HHA may obtain a surety bond required under this section only from an authorized Surety.

(1) An authorized Surety is a surety company that—

(i) Has been issued a Certificate of Authority by the U.S. Department of the Treasury in accordance with 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225 as an acceptable surety on Federal bonds and the Certificate has neither expired nor been revoked;

(ii) Has not been determined by the Medicaid agency to be an unauthorized Surety for the purpose of an HHA obtaining a surety bond under this section; and

(iii) Meets other conditions, as specified by the Medicaid agency.

(2) The Medicaid agency may determine that a surety company is an unauthorized Surety under this section—

(i) If, upon request by the Medicaid agency, the surety company fails to furnish timely confirmation of the issuance of, and the validity and accuracy of information appearing on, a surety bond that an HHA presents to the Medicaid agency that shows the surety company as Surety on the bond;

(ii) If, upon presentation by the Medicaid agency to the surety company of a request for payment on a surety bond and of sufficient evidence to establish the surety company's liability on the bond, the surety company fails to timely pay the Medicaid agency in full the amount requested up to the face amount of the bond; or

(iii) For other good cause.

(3) The Medicaid agency must specify the manner by which public notification of a determination under paragraph (f)(2) of this section is given and the effective date of the determination.

(4) A determination by the Medicaid agency that a surety company is an unauthorized Surety under paragraph (f)(2) of this section—

(i) Has effect only within the State; and

(ii) Is not a debarment, suspension, or exclusion for the purposes of Executive Order No. 12549 (3 CFR 1986 Comp., p. 189).

(g) *Amount of the bond*—(1) *Basic rule.* The amount of the surety bond must be $50,000 or 15 percent of the annual Medicaid payments made to the HHA by the Medicaid agency for home health services furnished under this subchapter for which FFP is available, whichever is greater.

(2) *Computation of the 15 percent: Participating HHA.* The 15 percent is computed by the Medicaid agency on the basis of Medicaid payments made to the HHA for the most recent annual period for which information is available as specified by the Medicaid agency.

(3) *Computation of 15 percent: An HHA that seeks to become a participating HHA by obtaining assets or ownership interest.* For an HHA that seeks to become a participating HHA by purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent is computed on the basis of Medicaid payments made by the Medicaid agency to the participating or formerly participating HHA for the most recent annual period as specified by the Medicaid agency.

(4) *Computation of 15 percent: Change of ownership.* For an HHA that undergoes a change of ownership (as ''change of ownership'' is defined by the State Medicaid agency) the 15 percent is computed on the basis of Medicaid payments made by the Medicaid agency to the HHA for the most recent annual period as specified by the Medicaid agency.

(5) *An HHA that seeks to become a participating HHA without obtaining assets or ownership interest.* For an HHA that seeks to become a participating HHA without purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent computation does not apply.

(6) *Exception to the basic rule.* If an HHA's overpayment in the most recent annual period exceeds 15 percent, the State Medicaid agency may require the HHA to secure a bond in an amount up to or equal to the amount of the overpayment, provided the amount of the bond is not less than $50,000.

(7) *Expiration of the 15 percent provision.* For an annual surety bond, or for a rider on a continuous surety bond, that is required to be submitted on or after June 1, 2005, notwithstanding any reference in this section to 15 percent as a basis for determining the amount of the bond, the amount of the bond or rider, as applicable, must be $50,000 or such amount as the Medicaid agency specifies in accordance with paragraph (g)(6) of this section, whichever amount is greater.

(h) *Additional requirements of the surety bond.* The surety bond that an HHA obtains under this section must meet the following additional requirements:

(1) The bond must guarantee that, upon written demand by the Medicaid agency to the Surety for payment under the bond and the Medicaid agency furnishing to the Surety sufficient evidence to establish the Surety's liability under the bond, the Surety will timely pay the Medicaid agency the amount so demanded, up to the stated amount of the bond.

(2) The bond must provide that the Surety is liable for uncollected overpayments, as defined in paragraph (a), provided such uncollected overpayments are determined during the term of the bond and regardless of when the overpayments took place. Further, the bond must provide that the Surety remains liable if the HHA fails to furnish a subsequent annual bond that meets the requirements of this subpart or fails to furnish a rider for a year for which a rider is required to be submitted, or if the HHA's provider agreement terminates and that the Surety's liability shall be based on the last bond or rider in effect for the HHA, which shall then remain in effect for an additional 2-year period.

(3) The bond must provide that the Surety's liability to the Medicaid agency is not extinguished by any of the following:

(i) Any action by the HHA or the Surety to terminate or limit the scope or term of the bond. The Surety's liability may be extinguished, however, when—

(A) The Surety furnishes the Medicaid agency with notice of such action not later than 10 days after receiving notice from the HHA of action by the HHA to terminate or limit the scope of the bond, or not later than 60 days before the effective date of such action by the Surety; or

(B) The HHA furnishes the Medicaid agency with a new bond that meets the requirements of both this section and the Medicaid agency.

(ii) The Surety's failure to continue to meet the requirements of paragraph (f)(1) of this section or the Medicaid agency's determination that the surety company is an unauthorized surety under paragraph (f)(2) of this section.

(iii) Termination of the HHA's provider agreement described under § 431.107 of this subchapter.

(iv) Any action by the Medicaid agency to suspend, offset, or otherwise recover payments to the HHA.

(v) Any action by the HHA to—

(A) Cease operation;

(B) Sell or transfer any assets or ownership interest;

(C) File for bankruptcy; or

(D) Fail to pay the Surety.

(vi) Any fraud, misrepresentation, or negligence by the HHA in obtaining the surety bond or by the Surety (or by the Surety's agent, if any) in issuing the surety bond, except that any fraud, misrepresentation, or negligence by the HHA in identifying to the Surety (or to the Surety's agent) the amount of Medicaid payments upon which the amount of the surety bond is determined shall not cause the Surety's liability to the Medicaid agency to exceed the amount of the bond.

(vii) The HHA's failure to exercise available appeal rights under Medicaid or to assign such rights to the Surety (provided the Medicaid agency permits such rights to be assigned).

(4) The bond must provide that actions under the bond may be brought by the Medicaid agency or by an agent that the Medicaid agency designates.

(i) *Term and type of bond*—(1) *Initial term:* Each participating HHA that is not exempted by paragraph (d) of this section must submit to the State Medicaid agency a surety bond for a term beginning January 1, 1998. If an annual bond is submitted for the initial term it must be effective for an annual period specified by the State Medicaid agency.

(2) *Type of bond.* The type of bond required to be submitted by an HHA, under this section, may be either—

(i) An annual bond (that is, a bond that specifies an effective annual period that corresponds to an annual period specified by the Medicaid agency); or

(ii) A continuous bond (that is, a bond that remains in full force and effect from term to term unless it is terminated or canceled as provided for in the bond or as otherwise provided by law) that is updated by the Surety for a particular period, via the issuance of a ''rider,'' when the bond amount changes. For the purposes of this section, ''Rider'' means a notice issued by a Surety that a change to a bond has occurred or will occur. If the HHA has submitted a continuous bond and there is no increase or decrease in the bond amount, no action is necessary by the HHA to submit a rider as long as the continuous bond remains in full force and effect.

(3) *HHA that seeks to become a participating HHA.* (i) An HHA that seeks to become a participating HHA must submit a surety bond before a provider agreement described under § 431.107 of this subchapter can be entered into.

(ii) An HHA that seeks to become a participating HHA through the purchase or transfer of assets or ownership interest of a participating or formerly participating HHA must also ensure that the surety bond is effective from the date of such purchase or transfer.

(4) *Change of ownership.* An HHA that undergoes a change of ownership (as ''change of ownership'' is defined by the State Medicaid agency) must submit the surety bond to the State Medicaid agency by such time and for such term as is specified in the instructions of the State Medicaid agency.

(5) *Government-operated HHA that loses its waiver.* A government-operated HHA that, as of January 1, 1998, meets the criteria for waiver of the requirements of this section but thereafter is determined by the Medicaid agency to not meet such criteria, must submit a surety bond to the Medicaid agency within 60 days after it receives notice from the Medicaid agency that it does not meet the criteria for waiver.

(6) *Change of Surety.* An HHA that obtains a replacement surety bond from a different Surety to cover the remaining term of a previously obtained bond must submit the new surety bond to the Medicaid agency within 60 days (or such earlier date as the Medicaid agency may specify) of obtaining the bond from the new Surety for a term specified by the Medicaid agency.

(j) *Effect of failure to obtain, maintain, and timely file a surety bond.* (1) The Medicaid agency must terminate the HHA's provider agreement if the HHA fails to obtain, file timely, and maintain a surety bond in accordance with

this section and the Medicaid agency's instructions.

(2) The Medicaid agency must refuse to enter into a provider agreement with an HHA if an HHA seeking to become a participating HHA fails to obtain and file timely a surety bond in accordance with this section and instructions issued by the State Medicaid agency.

(k) *Evidence of compliance.* (1) The Medicaid agency may at any time require an HHA to make a specific showing of being in compliance with the requirements of this section and may require the HHA to submit such additional evidence as the Medicaid agency considers sufficient to demonstrate the HHA's compliance.

(2) The Medicaid agency may terminate the HHA's provider agreement or refuse to enter into a provider agreement if an HHA fails to timely furnish sufficient evidence at the Medicaid agency's request to demonstrate compliance with the requirements of this section.

(l) *Surety's standing to appeal Medicaid determinations.* The Medicaid agency must establish procedures for granting appeal rights to Sureties.

(m) *Effect of conditions of payment.* If a Surety has paid the Medicaid agency an amount on the basis of liability incurred under a bond obtained by an HHA under this section, and the Medicaid agency subsequently collects from the HHA, in whole or in part, on such overpayment that was the basis for the Surety's liability, the Medicaid agency must reimburse the Surety such amount as the Medicaid agency collected from the HHA, up to the amount paid by the Surety to the Medicaid agency, provided the Surety has no other liability under the bond.

[63 FR 310, Jan. 5, 1998, as amended at 63 FR 10731, Mar. 4, 1998; 63 FR 29654, June 1, 1998; 63 FR 41170, July 31, 1998]

§ 441.17 Laboratory services.

(a) The plan must provide for payment of laboratory services as defined in § 440.30 of this subchapter if provided by—

(1) An independent laboratory that meets the requirements for participation in the Medicare program found in part 491 of this chapter;

(2) A hospital-based laboratory that meets the requirements for participation in the Medicare program found in § 482.27 of this chapter;

(3) A rural health clinic, as defined in § 491.9 of this chapter; or

(4) A skilled nursing facility—based clinical laboratory, as defined in part 491 of this chapter.

(b) Except as provided under paragraph (c), if a laboratory or other entity is requesting payment under Medicaid for testing for the presence of the human immunodeficiency virus (HIV) antibody or for the isolation and identification of the HIV causative agent as described in part 491 of this chapter, the laboratory records must contain the name and other identification of the person from whom the specimen was taken.

(c) An agency may choose to approve the use of alternative identifiers, in place of the requirement for patient's name, in paragraph (b) of this section for HIV antibody or causative agent testing of Medicaid beneficiaries.

[54 FR 48647, Dec. 2, 1988. Redesignated at 63 FR 310, Jan. 5, 1998, as amended at 85 FR 72909, Nov. 16, 2020]

§ 441.18 Case management services.

(a) If a State plan provides for case management services (including targeted case management services), as defined in § 440.169 of this chapter, the State must meet the following requirements:

(1) Allow individuals the free choice of any qualified Medicaid provider within the specified geographic area identified in the plan when obtaining case management services, in accordance with § 431.51 of this chapter, except as specified in paragraph (b) of this section.

(2) Not use case management (including targeted case management) services to restrict an individual's access to other services under the plan.

(3) Not compel an individual to receive case management services, condition receipt of case management (or targeted case management) services on the receipt of other Medicaid services, or condition receipt of other Medicaid services on receipt of case management (or targeted case management) services.

(4) Indicate in the plan that case management services provided in accordance with section 1915(g) of the Act will not duplicate payments made to public agencies or private entities under the State plan and other program authorities;

(5) [Reserved]

(6) Prohibit providers of case management services from exercising the agency's authority to authorize or deny the provision of other services under the plan.

(7) Require providers to maintain case records that document for all individuals receiving case management as follows:

(i) The name of the individual.

(ii) The dates of the case management services.

(iii) The name of the provider agency (if relevant) and the person providing the case management service.

(iv) The nature, content, units of the case management services received and whether goals specified in the care plan have been achieved.

(v) Whether the individual has declined services in the care plan.

(vi) The need for, and occurrences of, coordination with other case managers.

(vii) A timeline for obtaining needed services.

(viii) A timeline for reevaluation of the plan.

(8) Include a separate plan amendment for each group receiving case management services that includes the following:

(i) Defines the group (and any subgroups within the group) eligible to receive the case management services.

(ii) Identifies the geographic area to be served.

(iii) Describes the case management services furnished, including the types of monitoring.

(iv) Specifies the frequency of assessments and monitoring and provides a justification for those frequencies.

(v) Specifies provider qualifications that are reasonably related to the population being served and the case management services furnished.

(vi) [Reserved]

(vii) Specifies if case management services are being provided to Medicaid-eligible individuals who are in institutions (except individuals between ages 22 and 64 who are served in IMDs or individuals who are inmates of public institutions).

(9) Include a separate plan amendment for each subgroup within a group if any of the following differs among the subgroups:

(i) The case management services to be furnished;

(ii) The qualifications of case management providers; or

(iii) The methodology under which case management providers will be paid.

(b) If the State limits qualified providers of case management services for target groups of individuals with developmental disability or chronic mental illness, in accordance with § 431.51(a)(4) of this chapter, the plan must identify any limitations to be imposed on the providers and specify how these limitations enable providers to ensure that individuals within the target groups receive needed services.

(c) Case management does not include, and FFP is not available in expenditures for, services defined in § 440.169 of this chapter when the case management activities constitute the direct delivery of underlying medical, educational, social, or other services to which an eligible individual has been referred, including for foster care programs, services such as, but not limited to, the following:

(1) Research gathering and completion of documentation required by the foster care program.

(2) Assessing adoption placements.

(3) Recruiting or interviewing potential foster care parents.

(4) Serving legal papers.

(5) Home investigations.

(6) Providing transportation.

(7) Administering foster care subsidies.

(8) Making placement arrangements.

(d) After the State assesses whether the activities are within the scope of the case management benefit (applying the limitations described above), in determining the allowable costs for case management (or targeted case management) services that are also furnished by another federally-funded program, the State must use cost allocation methodologies, consistent with OMB Circular A–87, CMS policies, or any

subsequent guidance and reflected in an approved cost allocation plan.

[72 FR 68092, Dec. 4, 2007, as amended at 74 FR 31196, June 30, 2009; 85 FR 72909, Nov. 16, 2020]

§ 441.20 Family planning services.

For beneficiaries eligible under the plan for family planning services, the plan must provide that each beneficiary is free from coercion or mental pressure and free to choose the method of family planning to be used.

§ 441.21 Nurse-midwife services.

If a State plan, under § 440.210 or 440.220 of this subchapter, provides for nurse-midwife services, as defined in § 440.165, the plan must provide that the nurse-midwife may enter into an independent provider agreement, without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

[47 FR 21051, May 17, 1982]

§ 441.22 Nurse practitioner services.

With respect to nurse practitioner services that meet the definition of § 440.166(a) and the requirements of either § 440.166(b) or § 440.166(c), the State plan must meet the following requirements:

(a) Provide that nurse practitioner services are furnished to the categorically needy.

(b) Specify whether those services are furnished to the medically needy.

(c) Provide that services furnished by a nurse practitioner, regardless of whether the nurse practitioner is under the supervision of, or associated with, a physician or other health care provider, may—

(1) Be reimbursed by the State Medicaid agency through an independent provider agreement between the State and the nurse practitioner; or

(2) Be paid through the employing provider.

[60 FR 19862, Apr. 21, 1995]

§ 441.25 Prohibition on FFP for certain prescribed drugs.

(a) FFP is not available in expenditures for the purchase or administration of any drug product that meets all of the following conditions:

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

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

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

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(b) FFP is not available in expenditures for the purchase or administration of any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (a) of this section.

[46 FR 48554, Oct. 1, 1981]

§ 441.30 Optometric services.

The plan must provide for payment of optometric services as physician services, whether furnished by an optometrist or a physician, if—

(a) The plan does not provide for payment for services provided by an optometrist, except for eligibility determinations under §§ 435.531 and 436.531 of this subchapter, but did provide for those services at an earlier period; and

(b) The plan specifically provides that physicians' services include services an optometrist is legally authorized to perform.

§ 441.35 Organ transplants.

(a) FFP is available in expenditures for services furnished in connection with organ transplant procedures only if the State plan includes written standards for the coverage of those procedures, and those standards provide that—

(1) Similarly situated individuals are treated alike; and

(2) Any restriction on the practitioners or facilities that may provide organ transplant procedures is consistent with the accessibility of high quality care to individuals eligible for the procedures under the plan.

(b) Nothing in paragraph (a) permits a State to provide, under its plan, services that are not reasonable in amount, duration, and scope to achieve their purpose.

[56 FR 8851, Mar. 1, 1991]

§ 441.40 End-stage renal disease.

FFP in expenditures for services described in subpart A of part 440 is available for facility treatment of end-stage renal disease only if the facility has been approved by the Secretary to furnish those services under Medicare. This requirement for approval of the facility does not apply under emergency conditions permitted under Medicare (see § 482.2 of this chapter).

[43 FR 45229, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986]

Subpart B—Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21

SOURCE: 49 FR 43666, Oct. 31, 1984, unless otherwise noted.

§ 441.50 Basis and purpose.

This subpart implements sections 1902(a)(43) and 1905(a)(4)(B) of the Social Security Act, by prescribing State plan requirements for providing early and periodic screening and diagnosis of eligible Medicaid beneficiaries under age 21 to ascertain physical and mental defects, and providing treatment to correct or ameliorate defects and chronic conditions found.

§ 441.55 State plan requirements.

A State plan must provide that the Medicaid agency meets the requirements of §§ 441.56–441.62, with respect to EPSDT services, as defined in § 440.40(b) of this subchapter.

§ 441.56 Required activities.

(a) *Informing.* The agency must—

(1) Provide for a combination of written and oral methods designed to inform effectively all EPSDT eligible individuals (or their families) about the EPSDT program.

(2) Using clear and nontechnical language, provide information about the following—

(i) The benefits of preventive health care;

(ii) The services available under the EPSDT program and where and how to obtain those services;

(iii) That the services provided under the EPSDT program are without cost to eligible individuals under 18 years of age, and if the agency chooses, to those 18 or older, up to age 21, except for any enrollment fee, premium, or similar charge that may be imposed on medically needy beneficiaries; and

(iv) That necessary transportation and scheduling assistance described in § 441.62 of this subpart is available to the EPSDT eligible individual upon request.

(3) Effectively inform those individuals who are blind or deaf, or who cannot read or understand the English language.

(4) Provide assurance to CMS that processes are in place to effectively inform individuals as required under this paragraph, generally, within 60 days of the individual's initial Medicaid eligibility determination and in the case of families which have not utilized EPSDT services, annually thereafter.

(b) *Screening.* (1) The agency must provide to eligible EPSDT beneficiaries who request it, screening (periodic comprehensive child health assessments); that is, regularly scheduled examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children, and youth. (See paragraph (c)(3) of this section for requirements relating to provision of immunization at the time of screening.) As a minimum, these screenings must include, but are not limited to:

(i) Comprehensive health and developmental history.

(ii) Comprehensive unclothed physical examination.

(iii) Appropriate vision testing.

(iv) Appropriate hearing testing.

(v) Appropriate laboratory tests.

(vi) Dental screening services furnished by direct referral to a dentist for children beginning at 3 years of age. An agency may request from CMS an exception from this age requirement (within an outer limit of age 5) for a two year period and may request additional two year exceptions. If an agency requests an exception, it must demonstrate to CMS's satisfaction that there is a shortage of dentists that prevents the agency from meeting the age 3 requirement.

(2) Screening services in paragraph (b)(1) of this section must be provided in accordance with reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care.

(c) *Diagnosis and treatment.* In addition to any diagnostic and treatment services included in the plan, the agency must provide to eligible EPSDT beneficiaries, the following services, the need for which is indicated by screening, even if the services are not included in the plan—

(1) Diagnosis of and treatment for defects in vision and hearing, including eyeglasses and hearing aids;

(2) Dental care, at as early an age as necessary, needed for relief of pain and infections, restoration of teeth and maintenance of dental health; and

(3) Appropriate immunizations. (If it is determined at the time of screening that immunization is needed and appropriate to provide at the time of screening, then immunization treatment must be provided at that time.)

(d) *Accountability.* The agency must maintain as required by §§ 431.17 and 431.18—

(1) Records and program manuals;

(2) A description of its screening package under paragraph (b) of this section; and

(3) Copies of rules and policies describing the methods used to assure that the informing requirement of paragraph (a)(1) of this section is met.

(e) *Timeliness.* With the exception of the informing requirements specified in paragraph (a) of this section, the agency must set standards for the timely provision of EPSDT services which meet reasonable standards of medical and dental practice, as determined by the agency after consultation with recognized medical and dental organizations involved in child health care, and must employ processes to ensure timely initiation of treatment, if required, generally within an outer limit of 6 months after the request for screening services.

[49 FR 43666, Oct. 31, 1984; 49 FR 45431, Nov. 16, 1984]

§ 441.57 Discretionary services.

Under the EPSDT program, the agency may provide for any other medical or remedial care specified in part 440 of this subchapter, even if the agency does not otherwise provide for these services to other beneficiaries or provides for them in a lesser amount, duration, or scope.

§ 441.58 Periodicity schedule.

The agency must implement a periodicity schedule for screening services that—

(a) Meets reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care;

(b) Specifies screening services applicable at each stage of the beneficiary's life, beginning with a neonatal examination, up to the age at which an individual is no longer eligible for EPSDT services; and

(c) At the agency's option, provides for needed screening services as determined by the agency, in addition to the otherwise applicable screening services specified under paragraph (b) of this section.

§ 441.59 Treatment of requests for EPSDT screening services.

(a) The agency must provide the screening services described in § 441.56(b) upon the request of an eligible beneficiary.

(b) To avoid duplicate screening services, the agency need not provide requested screening services to an EPSDT eligible if written verification exists that the most recent age-appropriate screening services, due under the agency's periodicity schedule, have already been provided to the eligible.

§ 441.60 Continuing care.

(a) *Continuing care provider.* For purposes of this subpart, a continuing care provider means a provider who has an agreement with the Medicaid agency to provide reports as required under paragraph (b) of this section and to provide at least the following services to eligible EPSDT beneficiaries formally enrolled with the provider:

(1) With the exception of dental services required under § 441.56, screening, diagnosis, treatment, and referral for follow-up services as required under this subpart.

(2) Maintenance of the beneficiary's consolidated health history, including information received from other providers.

(3) Physicians' services as needed by the beneficiary for acute, episodic or chronic illnesses or conditions.

(4) At the provider's option, provision of dental services required under § 441.56 or direct referral to a dentist to provide dental services required under § 441.56(b)(1)(vi). The provider must specify in the agreement whether dental services or referral for dental services are provided. If the provider does not choose to provide either service, then the provider must refer beneficiaries to the agency to obtain those dental services required under § 441.56.

(5) At the provider's option, provision of all or part of the transportation and scheduling assistance as required under § 441.62. The provider must specify in the agreement the transportation and scheduling assistance to be furnished. If the provider does not choose to provide some or all of the assistance, then the provider must refer beneficiaries to the agency to obtain the transportation and scheduling assistance required under § 441.62.

(b) *Reports.* A continuing care provider must provide to the agency any reports that the agency may reasonably require.

(c) *State monitoring.* If the State plan provides for agreements with continuing care providers, the agency must employ methods described in the State plan to assure the providers' compliance with their agreements.

(d) *Effect of agreement with continuing care providers.* Subject to the requirements of paragraphs (a), (b), and (c) of this section, CMS will deem the agency to meet the requirements of this subpart with respect to all EPSDT eligible beneficiaries formally enrolled with the continuing care provider. To be formally enrolled, a beneficiary or beneficiary's family agrees to use one continuing care provider to be a regular source of the described set of services for a stated period of time. Both the beneficiary and the provider must sign statements that reflect their obligations under the continuing care arrangement.

(e) If the agreement in paragraph (a) of this section does not provide for all or part of the transportation and scheduling assistance required under § 441.62, or for dental service under § 441.56, the agency must provide for those services to the extent they are not provided for in the agreement.

§ 441.61 Utilization of providers and coordination with related programs.

(a) The agency must provide referral assistance for treatment not covered by the plan, but found to be needed as a result of conditions disclosed during screening and diagnosis. This referral assistance must include giving the family or beneficiary the names, addresses, and telephone numbers of providers who have expressed a willingness to furnish uncovered services at little or no expense to the family.

(b) The agency must make available a variety of individual and group providers qualified and willing to provide EPSDT services.

(c) The agency must make appropriate use of State health agencies, State vocational rehabilitation agencies, and Title V grantees (Maternal and Child Health/Crippled Children's Services). Further, the agency should make use of other public health, mental health, and education programs and related programs, such as Head Start, Title XX (Social Services) programs, and the Special Supplemental Food Program for Women, Infants and Children (WIC), to ensure an effective child health program.

§ 441.62 Transportation and scheduling assistance.

The agency must offer to the family or beneficiary, and provide if the beneficiary requests—

(a) Necessary assistance with transportation as required under § 431.53 of this chapter; and

(b) Necessary assistance with scheduling appointments for services.

Subpart C—Medicaid for Individuals Age 65 or Over in Institutions for Mental Diseases

SOURCE: 44 FR 17940, Mar. 23, 1979, unless otherwise noted.

§ 441.100 Basis and purpose.

This subpart implements section 1905(a)(14) of the Act, which authorizes State plans to provide for inpatient hospital services, skilled nursing services, and intermediate care facility services for individuals age 65 or older in an institution for mental diseases, and sections 1902(a)(20)(B) and (C) and 1902(a)(21), which prescribe the conditions a State must meet to offer these services. (See § 431.620 of this subchapter for regulations implementing section 1902(a)(20)(A), which prescribe interagency requirements related to these services.)

§ 441.101 State plan requirements.

A State plan that includes Medicaid for individuals age 65 or older in institutions for mental diseases must provide that the requirements of this subpart are met.

§ 441.102 Plan of care for institutionalized beneficiaries.

(a) The Medicaid agency must provide for a recorded individual plan of treatment and care to ensure that institutional care maintains the beneficiary at, or restores him to, the greatest possible degree of health and independent functioning.

(b) The plan must include—

(1) An initial review of the beneficiary's medical, psychiatric, and social needs—

(i) Within 90 days after approval of the State plan provision for services in institutions for mental disease; and

(ii) After that period, within 30 days after the date payments are initiated for services provided a beneficiary.

(2) Periodic review of the beneficiary's medical, psychiatric, and social needs;

(3) A determination, at least quarterly, of the beneficiary's need for continued institutional care and for alternative care arrangements;

(4) Appropriate medical treatment in the institution; and

(5) Appropriate social services.

§ 441.103 Alternate plans of care.

(a) The agency must develop alternate plans of care for each beneficiary age 65 or older who would otherwise need care in an institution for mental diseases.

(b) These alternate plans of care must—

(1) Make maximum use of available resources to meet the beneficiary's medical, social, and financial needs; and

(2) In Guam, Puerto Rico, and the Virgin Islands, make available appropriate social services authorized under sections 3(a)(4) (i) and (ii) or 1603(a)(4)(A) (i) and (ii) of the Act.

§ 441.105 Methods of administration.

The agency must have methods of administration to ensure that its responsibilities under this subpart are met.

§ 441.106 Comprehensive mental health program.

(a) If the plan includes services in public institutions for mental diseases, the agency must show that the State is making satisfactory progress in developing and implementing a comprehensive mental health program.

(b) The program must—

(1) Cover all ages;

(2) Use mental health and public welfare resources; including—

(i) Community mental health centers;

(ii) Nursing homes; and

(iii) Other alternatives to public institutional care; and

(3) Include joint planning with State authorities.

(c) The agency must submit annual progress reports within 3 months after the end of each fiscal year in which

Medicaid is provided under this subpart.

Subpart D—Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs

§441.150 Basis and purpose.

This subpart specifies requirements applicable if a State provides inpatient psychiatric services to individuals under age 21, as defined in §440.160 of this subchapter and authorized under section 1905 (a)(16) and (h) of the Act.

§441.151 General requirements.

(a) Inpatient psychiatric services for individuals under age 21 must be:

(1) Provided under the direction of a physician;

(2) Provided by—

(i) 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.

(ii) A psychiatric facility that is not a hospital and is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children, or by any other accrediting organization with comparable standards that is recognized by the State.

(3) Provided before the individual reaches age 21, or, if the individual was receiving the services immediately before he or she reached age 21, before the earlier of the following—

(i) The date the individual no longer requires the services; or

(ii) The date the individual reaches 22; and

(4) Certified in writing to be necessary in the setting in which the services will be provided (or are being provided in emergency circumstances) in accordance with §441.152.

(b) Inpatient psychiatric services furnished in a psychiatric residential treatment facility as defined in §483.352 of this chapter, must satisfy all requirements in subpart G of part 483 of this chapter governing the use of restraint and seclusion.

(c) *COVID–19 Vaccination of facility staff*. The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the center setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID–19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

[66 FR 7160, Jan. 22, 2001, as amended at 75 FR 50418, Aug. 16, 2010; 86 FR 61617, Nov. 5, 2021]

§ 441.152 Certification of need for services.

(a) A team specified in § 441.154 must certify that—

(1) Ambulatory care resources available in the community do not meet the treatment needs of the beneficiary;

(2) Proper treatment of the beneficiary's psychiatric condition requires services on an inpatient basis under the direction of a physician; and

(3) The services can reasonably be expected to improve the beneficiary's condition or prevent further regression

so that the services will no longer be needed.

(b) The certification specified in this section and in §441.153 satisfies the utilization control requirement for physician certification in §§456.60, 456.160, and 456.360 of this subchapter.

[43 FR 45229, Sept. 29, 1978, as amended at 61 FR 38398, July 24, 1996]

§441.153 Team certifying need for services.

Certification under §441.152 must be made by terms specified as follows:

(a) For an individual who is a beneficiary when admitted to a facility or program, certification must be made by an independent team that—

(1) Includes a physician;

(2) Has competence in diagnosis and treatment of mental illness, preferably in child psychiatry; and

(3) Has knowledge of the individual's situation.

(b) For an individual who applies for Medicaid while in the facility of program, the certification must be—

(1) Made by the team responsible for the plan of care as specified in §441.156; and

(2) Cover any period before application for which claims are made.

(c) For emergency admissions, the certification must be made by the team responsible for the plan of care (§441.156) within 14 days after admission.

§441.154 Active treatment.

Inpatient psychiatric services must involve ''active treatment'', which means implementation of a professionally developed and supervised individual plan of care, described in §441.155 that is—

(a) Developed and implemented no later than 14 days after admission; and

(b) Designed to achieve the beneficiary's discharge from inpatient status at the earliest possible time.

§441.155 Individual plan of care.

(a) ''Individual plan of care'' means a written plan developed for each beneficiary in accordance with §§456.180 and 456.181 of this chapter, to improve his condition to the extent that inpatient care is no longer necessary.

(b) The plan of care must—

(1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral and developmental aspects of the beneficiary's situation and reflects the need for inpatient psychiatric care;

(2) Be developed by a team of professionals specified under §441.156 in consultation with the beneficiary; and his parents, legal guardians, or others in whose care he will be released after discharge;

(3) State treatment objectives;

(4) Prescribe an integrated program of therapies, activities, and experiences designed to meet the objectives; and

(5) Include, at an appropriate time, post-discharge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the beneficiary's family, school, and community upon discharge.

(c) The plan must be reviewed every 30 days by the team specified in §441.156 to—

(1) Determine that services being provided are or were required on an inpatient basis, and

(2) Recommend changes in the plan as indicated by the beneficiary's overall adjustment as an inpatient.

(d) The development and review of the plan of care as specified in this section satisfies the utilization control requirements for—

(1) Recertification under §§456.60(b), 456.160(b), and 456.360(b) of this subchapter; and

(2) Establishment and periodic review of the plan of care under §§456.80, 456.180, and 456.380 of this subchapter.

[43 FR 45229, Sept. 29, 1978, as amended at 46 FR 48560, Oct. 1, 1981; 61 FR 38398, July 24, 1996]

§441.156 Team developing individual plan of care.

(a) The individual plan of care under §441.155 must be developed by an interdisciplinary team of physicians and other personnel who are employed by, or provide services to patients in, the facility.

(b) Based on education and experience, preferably including competence in child psychiatry, the team must be capable of—

(1) Assessing the beneficiary's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;

(2) Assessing the potential resources of the beneficiary's family;

(3) Setting treatment objectives; and

(4) Prescribing therapeutic modalities to achieve the plan's objectives.

(c) The team must include, as a minimum, either—

(1) A Board-eligible or Board-certified psychiatrist;

(2) A clinical psychologist who has a doctoral degree and a physician licensed to practice medicine or osteopathy; or

(3) A physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases, and a psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

(d) The team must also include one of the following:

(1) A psychiatric social worker.

(2) A registered nurse with specialized training or one year's experience in treating mentally ill individuals.

(3) An occupational therapist who is licensed, if required by the State, and who has specialized training or one year of experience in treating mentally ill individuals.

(4) A psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

§ 441.180 Maintenance of effort: General rule.

FFP is available only if the State maintains fiscal effort as prescribed under this subpart.

§ 441.181 Maintenance of effort: Explanation of terms and requirements.

(a) For purposes of § 441.182:

(1) The base year is the 4-quarter period ending December 31, 1971.

(2) Quarterly per capita non-Federal expenditures are expenditures for inpatient psychiatric services determined by reimbursement principles under Medicare. (See part 405, subpart D.)

(3) The number of individuals receiving inpatient psychiatric services in the current quarter means—

(i) The number of individuals receiving services for the full quarter; plus

(ii) The full quarter composite number of individuals receiving services for less than a full quarter.

(4) In determining the per capita expenditures for the base year, the Medicaid agency must compute the number of individuals receiving services in a manner similar to that in paragraph (a)(3) of this section.

(5) Non-Federal expenditures means the total amount of funds expended by the State and its political subdivisions, excluding Federal funds received directly or indirectly from any source.

(6) Expenditures for the current calendar quarter exclude Federal funds received directly or indirectly from any source.

(b) As a basis for determining the correct amount of Federal payments, each State must submit estimated and actual cost data and other information necessary for this purpose in the form and at the times specified in this subchapter and by CMS guidelines.

(c) The agency must have on file adequate records to substantiate compliance with the requirements of § 441.182 and to ensure that all necessary adjustments have been made.

(d) Facilities that did not meet the requirements of §§ 441.151–441.156 in the base year, but are providing inpatient psychiatric services under those sections in the current quarter, must be included in the maintenance of effort computation if, during the base year, they were—

(1) Providing inpatient psychiatric services for individuals under age 21; and

(2) Receiving State aid.

§ 441.182 Maintenance of effort: Computation.

(a) For expenditures for inpatient psychiatric services for individuals under age 21, in any calendar quarter, FFP is available only to the extent

that the total State Medicaid expenditures in the current quarter for inpatient psychiatric services and outpatient psychiatric treatment for individuals under age 21 exceed the sum of the following:

(1) The total number of individuals receiving inpatient psychiatric services in the current quarter times the average quarterly per capita non-Federal expenditures for the base year; and

(2) The average non-Federal quarterly expenditures for the base year for outpatient psychiatric services for individuals under age 21.

(b) FFP is available for 100 percent of the increase in expenditures over the base year period, but may not exceed the Federal medical assistance percentage times the expenditures under this subpart for inpatient psychiatric services for individuals under age 21.

§441.184 Emergency preparedness.

The Psychiatric Residential Treatment Facility (PRTF) must comply with all applicable Federal, State, and local emergency preparedness requirements. The PRTF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The PRTF must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the PRTF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The PRTF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered residents in the PRTF's care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the PRTF must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the PRTF, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and

role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other PRTFs and other providers to receive residents in the event of limitations or cessation of operations to maintain the continuity of services to PRTF residents.

(8) The role of the PRTF under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The PRTF must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other PRTFs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the PRTF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the PRTF's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PRTF's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The PRTF must develop and maintain an emergency preparedness training program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program.* The PRTF must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) After initial training, provide emergency preparedness training every 2 years.

(iii) Demonstrate staff knowledge of emergency procedures.

(iv) Maintain documentation of all emergency preparedness training.

(v) If the emergency preparedness policies and procedures are significantly updated, the PRTF must conduct training on the updated policies and procedures.

(2) *Testing.* The PRTF must conduct exercises to test the emergency plan twice per year. The PRTF must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or

(B) If the PRTF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PRTF is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, a facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PRTF's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PRTF's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a PRTF is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the PRTF may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64025, Sept. 16, 2016, as amended at 84 FR 51816, Sept. 30, 2019]

Subpart E—Abortions

§ 441.200 Basis and purpose.

This subpart implements section 402 of Pub. L. 97–12, and subsequent laws that appropriate funds for the Medicaid program, including section 204 of Pub. L. 98–619. All of these laws prohibit the use of Federal funds to pay for abortions except when continuation of the pregnancy would endanger the mother's life.

[52 FR 47935, Dec. 17, 1987]

§ 441.201 Definition.

As used in this subpart, ''physician'' means a doctor of medicine or osteopathy who is licensed to practice in the State.

[52 FR 47935, Dec. 17, 1987]

§ 441.202 General rule.

FFP is not available in expenditures for an abortion unless the conditions specified in §§ 441.203 and 441.206 are met.

[52 FR 47935, Dec. 17, 1987]

§ 441.203 Life of the mother would be endangered.

FFP is available in expenditures for an abortion when a physician has found, and certified in writing to the Medicaid agency, that on the basis of his professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

§§ 441.204–441.205 [Reserved]

§ 441.206 Documentation needed by the Medicaid agency.

FFP is not available in any expenditures for abortions or other medical procedures otherwise provided for under § 441.203 if the Medicaid agency has paid without first having received

the certifications and documentation specified in that section.

[52 FR 47935, Dec. 17, 1987]

§ 441.207 Drugs and devices and termination of ectopic pregnancies.

FFP is available in expenditures for drugs or devices to prevent implantation of the fertilized ovum and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 441.208 Recordkeeping requirements.

Medicaid agencies must maintain copies of the certifications and documentation specified in § 441.203 for 3 years under the recordkeeping requirements at 45 CFR 75.361.

[52 FR 47935, Dec. 17, 1987, as amended at 81 FR 3011, Jan. 20, 2016]

Subpart F—Sterilizations

SOURCE: 43 FR 52171, Nov. 8, 1978, unless otherwise noted.

§ 441.250 Applicability.

This subpart applies to sterilizations and hysterectomies reimbursed under Medicaid.

§ 441.251 Definitions.

As used in this subpart:

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (a) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or (b) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

§ 441.252 State plan requirements.

A State plan must provide that the Medicaid agency will make payment under the plan for sterilization procedures and hysterectomies only if all the requirements of this subpart were met.

§ 441.253 Sterilization of a mentally competent individual aged 21 or older.

FFP is available in expenditures for the sterilization of an individual only if—

(a) The individual is at least 21 years old at the time consent is obtained;

(b) The individual is not a mentally incompetent individual;

(c) The individual has voluntarily given informed consent in accordance with all the requirements precribed in §§ 441.257 and 441.258; and

(d) At least 30 days, but not more than 180 days, have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery, if at least 72 hours have passed since he or she gave informed consent for the sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 441.254 Mentally incompetent or institutionalized individuals.

FFP is not available for the sterilization of a mentally incompetent or institutionalized individual.

§ 441.255 Sterilization by hysterectomy.

(a) FFP is not available in expenditures for a hysterectomy if—

(1) It was performed solely for the purpose of rendering an individual permanently incapable of reproducing; or

(2) If there was more than one purpose to the procedure, it would not have been performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) FFP is available in expenditures for a hysterectomy not covered by paragraph (a) of this section only under the conditions specified in paragraph (c), (d), or (e) of this section.

(c) FFP is available if—

(1) The person who secured authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make the individual permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(d) Effective on March 8, 1979 or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available if—

(1) The individual—

(i) Was already sterile before the hysterectomy; or

(ii) Requires a hysterectomy because of a life-threatening emergency situation in which the physician determines that prior acknowledgment is not possible; and

(2) The physician who performs the hysterectomy—

(i) Certifies in writing that the individual was already sterile at the time of the hysterectomy, and states the cause of the sterility; or

(ii) Certifies in writing that the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

(e) Effective March 8, 1979, or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available for hysterectomies performed during a period of an individual's retroactive Medicaid eligibility if the physician who performed the hysterectomy certifies in writing that—

(1) The individual was informed before the operation that the hysterectomy would make her permanently incapable of reproducing; or

(2) One of the conditions in paragraph (d)(1) of this section was met. The physician must supply the information specified in paragraph (d)(2) of this section.

[47 FR 33702, Aug. 4, 1982]

§441.256 Additional condition for Federal financial participation (FFP).

(a) FFP is not available in expenditures for any sterilization or hysterectomy unless the Medicaid agency, before making payment, obtained documentation showing that the requirements of this subpart were met. This documentation must include a consent from, an acknowledgement of receipt of hysterectomy information or a physician's certification under §441.255(d)(2), as applicable.

(b) With regard to the requirements of §441.255(d) for hysterectomies performed from March 8, 1979 through November 2, 1982, FFP is available in expenditures for those services if the documentation showing that the requirements of that paragraph were met is obtained by the Medicaid agency before submitting a claim for FFP for that procedure.

[47 FR 33702, Aug. 4, 1982]

§441.257 Informed consent.

(a) *Informing the individual.* For purposes of this subpart, an individual has given informed consent only if—

(1) The person who obtained consent for the sterilization procedure offered to answer any questions the individual to be sterilized may have concerning the procedure, provided a copy of the consent form and provided orally all of the following information or advice to the individual to be sterilized:

(i) Advice that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled.

(ii) A description of available alternative methods of family planning and birth control.

(iii) Advice that the sterilization procedure is considered to be irreversible.

(iv) A thorough explanation of the specific sterilization procedure to be performed.

(v) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used.

(vi) A full description of the benefits or advantages that may be expected as a result of the sterilization.

(vii) Advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in § 441.253(c).

(2) Suitable arrangements were made to insure that the information specified in paragraph (a)(1) of this section was effectively communicated to any individual who is blind, deaf, or otherwise handicapped;

(3) An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent;

(4) The individual to be sterilized was permitted to have a witness of his or her choice present when consent was obtained;

(5) The consent form requirements of § 441.258 were met; and

(6) Any additional requirement of State or local law for obtaining consent, except a requirement for spousal consent, was followed.

(b) *When informed consent may not be obtained.* Informed consent may not be obtained while the individual to be sterilized is—

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

§ 441.258 Consent form requirements.

(a) *Content of consent form.* The consent form must be a copy of the form appended to this subpart or another form approved by the Secretary.

(b) *Required signatures.* The consent form must be signed and dated by—

(1) The individual to be sterilized;

(2) The interpreter, if one was provided;

(3) The person who obtained the consent; and

(4) The physician who performed the sterilization procedure.

(c) *Required certifications.* (1) The person securing the consent must certify, by signing the consent form, that

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify, by signing the consent form, that:

(i) Shortly before the performance of sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual appeared mentally competent and knowingly and voluntarily consented to be sterilized.

Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed.

(3) In the case of premature delivery or emergency abdominal surgery performed within 30 days of consent, the physician must certify that the sterilization was performed less than 30 days, but not less than 72 hours after informed consent was obtained because of premature delivery or emergency abdominal surgery and—

(i) In the case of premature delivery, must state the expected date of delivery; or

(ii) In the case of abdominal surgery, must describe the emergency.

(4) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally and read the consent

form and explained its contents to the individual to be sterilized and that, to the best of the interpreter's knowledge and belief, the individual understood what the interpreter told him or her.

§ 441.259 Review of regulations.

The Secretary will request public comment on the operation of this subpart not later than 3 years after its effective date.

APPENDIX TO SUBPART F OF PART 441—REQUIRED CONSENT FORM

NOTICE: Your decision at any time not to be sterilized will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving Federal funds.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I understand that the sterilization must be considered permanent and not reversible. I have decided that I do not want to become pregnant, bear children or father children.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by Federally funded programs.

I am at least 21 years of age and was born on (Day) (Month) (Year).

I, _____, hereby consent of my own free will to be sterilized by _____ by a method called _____. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form. (Signature) (Date) (Month) (Day) (Year).

You are requested to supply the following information, but it is not required: (Race and ethnicity designation (please check)) Black (not of Hispanic origin); Hispanic; Asian or Pacific Islander; American Indian or Alaskan native; or White (not of Hispanic origin).

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation. (Interpreter) (Date).

STATEMENT OF PERSON OBTAINING CONSENT

Before (name of individual) signed the consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure. (Signature of person obtaining consent) (Date) (Facility) (Address).

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon (Name of individual to be sterilized) on (Date of sterilization) (operation), I explained to him/her the nature of the sterilization operation (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(*Instructions for use of alternative final paragraphs:* Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested): Premature delivery. Individual's expected date of delivery: _____

☐ Emergency abdominal surgery: (describe circumstances):_____ (Physician) (Date).

Subpart G—Home and Community-Based Services: Waiver Requirements

SOURCE: 46 FR 48541, Oct. 1, 1981, unless otherwise noted.

§ 441.300 Basis and purpose.

Section 1915(c) of the Act permits States to offer, under a waiver of statutory requirements, an array of home and community-based services that an individual needs to avoid institutionalization. Those services are defined in § 440.180 of this subchapter. This subpart describes what the Medicaid agency must do to obtain a waiver.

§ 441.301 Contents of request for a waiver.

(a) A request for a waiver under this section must consist of the following:

(1) The assurances required by § 441.302 and the supporting documentation required by § 441.303.

(2) When applicable, requests for waivers of the requirements of section 1902(a)(1), section 1902(a)(10)(B), or section 1902(a)(10)(C)(i)(III) of the Act, which concern respectively, statewide application of Medicaid, comparability of services, and income and resource rules applicable to medically needy individuals living in the community.

(3) A statement explaining whether the agency will refuse to offer home or community-based services to any beneficiary if the agency can reasonably expect that the cost of the services would exceed the cost of an equivalent level of care provided in—

(i) A hospital (as defined in § 440.10 of this chapter);

(ii) A NF (as defined in section 1919(a) of the Act); or

(iii) An ICF/IID (as defined in § 440.150 of this chapter), if applicable.

(b) If the agency furnishes home and community-based services, as defined in § 440.180 of this subchapter, under a waiver granted under this subpart, the waiver request must—

(1) Provide that the services are furnished—

(i) Under a written person-centered service plan (also called plan of care) that is based on a person-centered approach and is subject to approval by the Medicaid agency.

(ii) Only to beneficiaries who are not inpatients of a hospital, NF, or ICF/IID; and

(iii) Only to beneficiaries who the agency determines would, in the absence of these services, require the Medicaid covered level of care provided in—

(A) A hospital (as defined in § 440.10 of this chapter);

(B) A NF (as defined in section 1919(a) of the Act); or

(C) An ICF/IID (as defined in § 440.150 of this chapter);

(2) Describe the qualifications of the individual or individuals who will be responsible for developing the individual plan of care;

(3) Describe the group or groups of individuals to whom the services will be offered;

(4) Describe the services to be furnished so that each service is separately defined. Multiple services that are generally considered to be separate services may not be consolidated under a single definition. Commonly accepted terms must be used to describe the service and definitions may not be open ended in scope. CMS will, however, allow combined service definitions (bundling) when this will permit more efficient delivery of services and not compromise either a beneficiary's access to or free choice of providers.

(5) Provide that the documentation requirements regarding individual evaluation, specified in §441.303(c), will be met; and

(6) Be limited to one or more of the following target groups or any subgroup thereof that the State may define:

(i) Aged or disabled, or both.

(ii) Individuals with Intellectual or Developmental Disabilities, or both.

(iii) Mentally ill.

(c) A waiver request under this subpart must include the following—

(1) *Person-centered planning process.* The individual will lead the person-centered planning process where possible. The individual's representative should have a participatory role, as needed and as defined by the individual, unless State law confers decision-making authority to the legal representative. All references to individuals include the role of the individual's representative. In addition to being led by the individual receiving services and supports, the person-centered planning process:

(i) Includes people chosen by the individual.

(ii) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.

(iii) Is timely and occurs at times and locations of convenience to the individual.

(iv) Reflects cultural considerations of the individual and is conducted by providing information in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with §435.905(b) of this chapter.

(v) Includes strategies for solving conflict or disagreement within the process, including clear conflict-of-interest guidelines for all planning participants.

(vi) Providers of HCBS for the individual, or those who have an interest in or are employed by a provider of HCBS for the individual must not provide case management or develop the person-centered service plan, except when the State demonstrates that the only willing and qualified entity to provide case management and/or develop person-centered service plans in a geographic area also provides HCBS. In these cases, the State must devise conflict of interest protections including separation of entity and provider functions within provider entities, which must be approved by CMS. Individuals must be provided with a clear and accessible alternative dispute resolution process.

(vii) Offers informed choices to the individual regarding the services and supports they receive and from whom.

(viii) Includes a method for the individual to request updates to the plan as needed.

(ix) Records the alternative home and community-based settings that were considered by the individual.

(2) *The Person-Centered Service Plan.* The person-centered service plan must reflect the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports. Commensurate with the level of need of the individual, and the scope of services and supports available under the State's 1915(c) HCBS waiver, the written plan must:

(i) Reflect that the setting in which the individual resides is chosen by the individual. The State must ensure that the setting chosen by the individual is integrated in, and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and

work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) Reflect the individual's strengths and preferences.

(iii) Reflect clinical and support needs as identified through an assessment of functional need.

(iv) Include individually identified goals and desired outcomes.

(v) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and the providers of those services and supports, including natural supports. Natural supports are unpaid supports that are provided voluntarily to the individual in lieu of 1915(c) HCBS waiver services and supports.

(vi) Reflect risk factors and measures in place to minimize them, including individualized back-up plans and strategies when needed.

(vii) Be understandable to the individual receiving services and supports, and the individuals important in supporting him or her. At a minimum, for the written plan to be understandable, it must be written in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with §435.905(b) of this chapter.

(viii) Identify the individual and/or entity responsible for monitoring the plan.

(ix) Be finalized and agreed to, with the informed consent of the individual in writing, and signed by all individuals and providers responsible for its implementation.

(x) Be distributed to the individual and other people involved in the plan.

(xi) Include those services, the purpose or control of which the individual elects to self-direct.

(xii) Prevent the provision of unnecessary or inappropriate services and supports.

(xiii) Document that any modification of the additional conditions, under paragraph (c)(4)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(A) Identify a specific and individualized assessed need.

(B) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(C) Document less intrusive methods of meeting the need that have been tried but did not work.

(D) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(E) Include a regular collection and review of data to measure the ongoing effectiveness of the modification.

(F) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(G) Include informed consent of the individual.

(H) Include an assurance that interventions and supports will cause no harm to the individual.

(3) *Review of the Person-Centered Service Plan.* The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required by §441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

(4) *Home and Community-Based Settings.* Home and community-based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options including non-disability specific settings and an option for a private unit

in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the qualities at §441.301(c)(4)(i) through (v), the following additional conditions must be met:

(A) The unit or dwelling is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord/tenant law of the State, county, city, or other designated entity. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS participant, and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

(B) Each individual has privacy in their sleeping or living unit:

(*1*) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors.

(*2*) Individuals sharing units have a choice of roommates in that setting.

(*3*) Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time.

(D) Individuals are able to have visitors of their choosing at any time.

(E) The setting is physically accessible to the individual.

(F) Any modification of the additional conditions, under §441.301(c)(4)(vi)(A) through (D), must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(*1*) Identify a specific and individualized assessed need.

(*2*) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(*3*) Document less intrusive methods of meeting the need that have been tried but did not work.

(*4*) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(*5*) Include regular collection and review of data to measure the ongoing effectiveness of the modification.

(*6*) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(*7*) Include the informed consent of the individual.

(*8*) Include an assurance that interventions and supports will cause no harm to the individual.

(5) *Settings that are not Home and Community-Based.* Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for individuals with intellectual disabilities;

(iv) A hospital; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. Any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of

individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(6) *Home and Community-Based Settings: Compliance and Transition:*

(i) States submitting new and initial waiver requests must provide assurances of compliance with the requirements of this section for home and community-based settings as of the effective date of the waiver.

(ii) CMS will require transition plans for existing section 1915(c) waivers and approved state plans providing home and community-based services under section 1915(i) to achieve compliance with this section, as follows:

(A) For each approved section 1915(c) HCBS waiver subject to renewal or submitted for amendment within one year after the effective date of this regulation, the State must submit a transition plan at the time of the waiver renewal or amendment request that sets forth the actions the State will take to bring the specific waiver into compliance with this section. The waiver approval will be contingent on the inclusion of the transition plan approved by CMS. The transition plan must include all elements required by the Secretary; and within one hundred and twenty days of the submission of the first waiver renewal or amendment request the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(B) For States that do not have a section 1915(c) HCBS waiver or a section 1915(i) State plan benefit due for renewal or proposed for amendments within one year of the effective date of this regulation, the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. This plan must be submitted no later than one year after the effective date of this regulation. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(iii) A State must provide at least a 30-day public notice and comment period regarding the transition plan(s) that the State intends to submit to CMS for review and consideration, as follows:

(A) The State must at a minimum provide two (2) statements of public notice and public input procedures.

(B) The State must ensure the full transition plan(s) is available to the public for public comment.

(C) The State must consider and modify the transition plan, as the State deems appropriate, to account for public comment.

(iv) A State must submit to CMS, with the proposed transition plan:

(A) Evidence of the public notice required.

(B) A summary of the comments received during the public notice period, reasons why comments were not adopted, and any modifications to the transition plan based upon those comments.

(v) Upon approval by CMS, the State will begin implementation of the transition plans. The State's failure to submit an approvable transition plan as required by this section and/or to comply with the terms of the approved transition plan may result in compliance actions, including but not limited to deferral/disallowance of Federal Financial Participation.

[46 FR 48541, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985; 59 FR 37717, July 25, 1994; 65 FR 60107, Oct. 10, 2000; 79 FR 3029, Jan. 16, 2014]

§ 441.302 State assurances.

Unless the Medicaid agency provides the following satisfactory assurances to CMS, CMS will not grant a waiver under this subpart and may terminate a waiver already granted:

(a) *Health and Welfare*—Assurance that necessary safeguards have been taken to protect the health and welfare

of the beneficiaries of the services. Those safeguards must include—

(1) Adequate standards for all types of providers that provide services under the waiver;

(2) Assurance that the standards of any State licensure or certification requirements are met for services or for individuals furnishing services that are provided under the waiver; and

(3) Assurance that all facilities covered by section 1616(e) of the Act, in which home and community-based services will be provided, are in compliance with applicable State standards that meet the requirements of 45 CFR part 1397 for board and care facilities.

(4) Assurance that the State is able to meet the unique service needs of the individuals when the State elects to serve more than one target group under a single waiver, as specified in § 441.301(b)(6).

(i) On an annual basis the State will include in the quality section of the CMS–372 form (or any successor form designated by CMS) data that indicates the State continues to serve multiple target groups in the single waiver and that a single target group is not being prioritized to the detriment of other groups.

(ii) [Reserved]

(5) Assurance that services are provided in home and community based settings, as specified in § 441.301(c)(4).

(b) *Financial accountability*— The agency will assure financial accountability for funds expended for home and community-based services, provide for an independent audit of its waiver program (except as CMS may otherwise specify for particular waivers), and it will maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services provided under the waiver, including reports of any independent audits conducted.

(c) *Evaluation of need.* Assurance that the agency will provide for the following:

(1) *Initial evaluation.* An evaluation of the need for the level of care provided in a hospital, a NF, or an ICF/IID when there is a reasonable indication that a beneficiary might need the services in the near future (that is, a month or less) unless he or she receives home or community-based services. For purposes of this section, ''evaluation'' means a review of an individual beneficiary's condition to determine—

(i) If the beneficiary requires the level of care provided in a hospital as defined in § 440.10 of this subchapter, a NF as defined in section 1919(a) of the Act, or an ICF/IID as defined by § 440.150 of this subchapter; and

(ii) That the beneficiary, but for the provision of waiver services, would otherwise be institutionalized in such a facility.

(2) *Periodic reevaluations.* Reevaluations, at least annually, of each beneficiary receiving home or community-based services to determine if the beneficiary continues to need the level of care provided and would, but for the provision of waiver services, otherwise be institutionalized in one of the following institutions:

(i) A hospital;

(ii) A NF; or

(iii) An ICF/IID.

(d) *Alternatives*—Assurance that when a beneficiary is determined to be likely to require the level of care provided in a hospital, NF, or ICF/IID, the beneficiary or his or her legal representative will be—

(1) Informed of any feasible alternatives available under the waiver; and

(2) Given the choice of either institutional or home and community-based services.

(e) *Average per capita expenditures.* Assurance that the average per capita fiscal year expenditures under the waiver will not exceed 100 percent of the average per capita expenditures that would have been made in the fiscal year for the level of care provided in a hospital, NF, or ICF/IID under the State plan had the waiver not been granted.

(1) These expenditures must be reasonably estimated and documented by the agency.

(2) The estimate must be on an annual basis and must cover each year of the waiver period.

(f) *Actual total expenditures.* Assurance that the agency's actual total expenditures for home and community-based and other Medicaid services under the waiver and its claim for FFP

in expenditures for the services provided to beneficiaries under the waiver will not, in any year of the waiver period, exceed 100 percent of the amount that would be incurred by the State's Medicaid program for these individuals, absent the waiver, in—

(1) A hospital;

(2) A NF; or

(3) An ICF/IID.

(g) *Institutionalization absent waiver.* Assurance that, absent the waiver, beneficiaries in the waiver would receive the appropriate type of Medicaid-funded institutional care (hospital, NF, or ICF/IID) that they require.

(h) *Reporting.* Assurance that annually, the agency will provide CMS with information on the waiver's impact. The information must be consistent with a data collection plan designed by CMS and must address the waiver's impact on—

(1) The type, amount, and cost of services provided under the State plan; and

(2) The health and welfare of beneficiaries.

(i) *Habilitation services.* Assurance that prevocational, educational, or supported employment services, or a combination of these services, if provided as habilitation services under the waiver, are—

(1) Not otherwise available to the individual through a local educational agency under section 602 (16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401 (16 and 17)) or as services under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730); and

(2) Furnished as part of expanded habilitation services, if the State has requested and received CMS's approval under a waiver or an amendment to a waiver.

(j) *Day treatment or partial hospitalization, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness.* Assurance that FFP will not be claimed in expenditures for waiver services including, but not limited to, day treatment or partial hospitalization, psychosocial rehabilitation services, and clinic services provided as home and community-based services to individuals with chronic mental illnesses if these individuals, in the absence of a waiver, would be placed in an IMD and are—

(1) Age 22 to 64;

(2) Age 65 and older and the State has not included the optional Medicaid benefit cited in § 440.140; or

(3) Age 21 and under and the State has not included the optional Medicaid benefit cited in § 440.160.

[50 FR 10026, Mar. 13, 1985, as amended at 59 FR 37717, July 25, 1994; 65 FR 60107, Oct. 10, 2000; 79 FR 3031, Jan. 16, 2014]

§ 441.303 Supporting documentation required.

The agency must furnish CMS with sufficient information to support the assurances required by § 441.302. Except as CMS may otherwise specify for particular waivers, the information must consist of the following:

(a) A description of the safeguards necessary to protect the health and welfare of beneficiaries. This information must include a copy of the standards established by the State for facilities that are covered by section 1616(e) of the Act.

(b) A description of the records and information that will be maintained to support financial accountability.

(c) A description of the agency's plan for the evaluation and reevaluation of beneficiaries, including—

(1) A description of who will make these evaluations and how they will be made;

(2) A copy of the evaluation form to be used; and if it differs from the form used in placing beneficiaries in hospitals, NFs, or ICFs/IID, a description of how and why it differs and an assurance that the outcome of the new evaluation form is reliable, valid, and fully comparable to the form used for hospital, NF, or ICF/IID placement;

(3) The agency's procedure to ensure the maintenance of written documentation on all evaluations and reevaluations; and

(4) The agency's procedure to ensure reevaluations of need at regular intervals.

(d) A description of the agency's plan for informing eligible beneficiaries of the feasible alternatives available under the waiver and allowing beneficiaries to choose either institutional

services or home and community-based services.

(e) An explanation of how the agency will apply the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services who are eligible under a special income level (included in §435.217 of this chapter).

(f) An explanation with supporting documentation satisfactory to CMS of how the agency estimated the average per capita expenditures for services.

(1) The annual average per capita expenditure estimate of the cost of home and community-based and other Medicaid services under the waiver must not exceed the estimated annual average per capita expenditures of the cost of services in the absence of a waiver. The estimates are to be based on the following equation:

$D + D' \leq G + G'$.

The symbol ''≤'' means that the result of the left side of the equation must be less than or *equal* to the result of the right side of the equation.

D = the estimated annual average per capita Medicaid cost for home and community-based services for individuals in the waiver program.

D′ = the estimated annual average per capita Medicaid cost for all other services provided to individuals in the waiver program.

G = the estimated annual average per capita Medicaid cost for hospital, NF, or ICF/IID care that would be incurred for individuals served in the waiver, were the waiver not granted.

G′ = the estimated annual average per capita Medicaid costs for all services other than those included in factor G for individuals served in the waiver, were the waiver not granted.

(2) For purposes of the equation, the prime factors include the average per capita cost for all State plan services and expanded EPSDT services provided that are not accounted for in other formula values.

(3) In making estimates of average per capita expenditures for a waiver that applies only to individuals with a particular illness (for example, acquired immune deficiency syndrome) or condition (for example, chronic mental illness) who are inpatients in or who would require the level of care provided in hospitals as defined by §440.10, NFs as defined in section 1919(a) of the Act, or ICFs/IID, the agency may determine the average per capita expenditures for these individuals absent the waiver without including expenditures for other individuals in the affected hospitals, NFs, or ICFs/IID.

(4) In making estimates of average per capita expenditures for a separate waiver program that applies only to individuals identified through the preadmission screening annual resident review (PASARR) process who are developmentally disabled, inpatients of a NF, and require the level of care provided in an ICF/IID as determined by the State on the basis of an evaluation under §441.303(c), the agency may determine the average per capita expenditures that would have been made in a fiscal year for those individuals based on the average per capita expenditures for inpatients in an ICF/IID. When submitting estimates of institutional costs without the waiver, the agency may use the average per capita costs of ICF/IID care even though the deinstitutionalized developmentally disabled were inpatients of NFs.

(5) For persons diverted rather than deinstitutionalized, the State's evaluation process required by §441.303(c) must provide for a more detailed description of their evaluation and screening procedures for beneficiaries to ensure that waiver services will be limited to persons who would otherwise receive the level of care provided in a hospital, NF, or ICF/IID, as applicable.

(6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver participants in a waiver amendment.

(7) In determining the average per capita expenditures that would have been made in a waiver year, for waiver estimates that apply to persons with Intellectual Disability or related conditions, the agency may include costs of Medicaid residents in ICFs/IID that have been terminated on or after November 5, 1990.

(8) In submitting estimates for waivers that include personal caregivers as a waiver service, the agency may include a portion of the rent and food attributed to the unrelated personal caregiver who resides in the home or residence of the beneficiary covered under the waiver. The agency must submit to CMS for review and approval the method it uses to apportion the costs of rent and food. The method must be explained fully to CMS. A personal caregiver provides a waiver service to meet the beneficiary's physical, social, or emotional needs (as opposed to services not directly related to the care of the beneficiary; that is, housekeeping or chore services). FFP for live-in caregivers is not available if the beneficiary lives in the caregiver's home or in a residence that is owned or leased by the caregiver.

(9) In submitting estimates for waivers that apply to individuals with Intellectual Disability or a related condition, the agency may adjust its estimate of average per capita expenditures to include increases in expenditures for ICF/IID care resulting from implementation of a PASARR program for making determinations for individuals with Intellectual Disability or related conditions on or after January 1, 1989.

(10) For a State that has CMS approval to bundle waiver services, the State must continue to compute separately the costs and utilization of the component services that make up the bundled service to support the final cost and utilization of the bundled service that will be used in the cost-neutrality formula.

(g) The State, at its option, may provide for an independent assessment of its waiver that evaluates the quality of care provided, access to care, and cost-neutrality. The results of the assessment should be submitted to CMS at least 90 days prior to the expiration date of the approved waiver-period and cover the first 24 or 48 months of the waiver. If a State chooses to provide for an independent assessment, FFP is available for the costs attributable to the independent assessment.

(h) For States offering habilitation services that include prevocational, educational, or supported employment services, or a combination of these services, consistent with the provisions of § 440.180(c) of this chapter, an explanation of why these services are not available as special education and related services under sections 602 (16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401 (16 and 17)) or as services under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. section 730);

(i) For States offering home and community-based services for individuals diagnosed as chronically mentally ill, an explanation of why these individuals would not be placed in an institution for mental diseases (IMD) absent the waiver, and the age group of these individuals.

[46 FR 48532, Oct. 1, 1981, as amended at 50 FR 10027, Mar. 13, 1985; 50 FR 25080, June 17, 1985; 59 FR 37718, July 25, 1994]

§ 441.304 Duration, extension, and amendment of a waiver.

(a) The effective date for a new waiver of Medicaid requirements to provide home and community-based services approved under this subpart is established by CMS prospectively on or after the date of approval and after consultation with the State agency. The initial approved waiver continues for a 3-year period from the effective date. If the agency requests it, the waiver may be extended for additional periods unless—

(1) CMS's review of the prior waiver period shows that the assurances required by § 441.302 were not met; and

(2) CMS is not satisfied with the assurances and documentation provided by the State in regard to the extension period.

(b) CMS will determine whether a request for extension of an existing waiver is actually an extension request or a request for a new waiver. If a State submits an extension request that would add a new group to the existing group of beneficiaries covered under the waiver (as defined under § 441.301(b)(6)), CMS will consider it to be two requests: One as an extension request for the existing group, and the other as a new waiver request for the new group. Waivers may be extended for additional 5-year periods.

(c) CMS *may* grant a State an extension of its existing waiver for up to 90 days to permit the State to document more fully the satisfaction of statutory and regulatory requirements needed to approve a new waiver request. CMS will consider this option when it requests additional information on a new waiver request submitted by a State to extend its existing waiver or when CMS disapproves a State's request for extension.

(d) The agency may request that waiver modifications be made effective retroactive to the first day of a waiver year, or another date after the first day of a waiver year, in which the amendment is submitted, unless the amendment involves substantive changes as determined by CMS.

(1) Substantive changes include, but are not limited to, revisions to services available under the waiver including elimination or reduction of services, or reduction in the scope, amount, and duration of any service, a change in the qualifications of service providers, changes in rate methodology or a constriction in the eligible population.

(2) A request for an amendment that involves a substantive change as determined by CMS, may only take effect on or after the date when the amendment is approved by CMS, and must be accompanied by information on how the State has assured smooth transitions and minimal effect on individuals adversely impacted by the change.

(e) The agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services in accordance with §447.205 of this chapter.

(f) The agency must establish and use a public input process, for any changes in the services or operations of the waiver.

(1) This process must be described fully in the State's waiver application and be sufficient in light of the scope of the changes proposed, to ensure meaningful opportunities for input for individuals served, or eligible to be served, in the waiver.

(2) This process must be completed at a minimum of 30 days prior to implementation of the proposed change or submission of the proposed change to CMS, whichever comes first.

(3) This process must be used for both existing waivers that have substantive changes proposed, either through the renewal or the amendment process, and new waivers.

(4) This process must include consultation with Federally-recognized Tribes, and in accordance with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), Indian health programs and Urban Indian Organizations.

(g)(1) If CMS finds that the Medicaid agency is not meeting one or more of the requirements for a waiver contained in this subpart, the agency is given a notice of CMS' findings and an opportunity for a hearing to rebut the findings.

(2) If CMS determines that the agency is substantively out of compliance with this subpart after the notice and any hearing, CMS may employ strategies to ensure compliance as described in paragraph (g)(3) of this section or terminate the waiver.

(3)(i) Strategies to ensure compliance may include the imposition of a moratorium on waiver enrollments, other corrective strategies as appropriate to ensure the health and welfare of waiver participants, or the withholding of a portion of Federal payment for waiver services until such time that compliance is achieved, or other actions as determined by the Secretary as necessary to address non-compliance with 1915(c) of the Act, or termination. When a waiver is terminated, the State must comport with §441.307.

(ii) CMS will provide states with a written notice of the impending strategies to ensure compliance for a waiver program. The notice of CMS' intent to utilize strategies to ensure compliance would include the nature of the noncompliance, the strategy to be employed, the effective date of the compliance strategy, the criteria for removing the compliance strategy and the opportunity for a hearing.

[50 FR 10028, Mar. 13, 1985; 50 FR 25080, June 17, 1985, as amended at 59 FR 37719, July 25, 1994; 79 FR 3032, Jan. 16, 2014]

§ 441.305 Replacement of beneficiaries in approved waiver programs.

(a) *Regular waivers.* A State's estimate of the number of individuals who may receive home and community-based services must include those who will replace beneficiaries who leave the program for any reason. A State may replace beneficiaries who leave the program due to death or loss of eligibility under the State plan without regard to any federally-imposed limit on utilization, but must maintain a record of beneficiaries replaced on this basis.

(b) *Model waivers.* (1) The number of individuals who may receive home and community-based services under a model waiver may not exceed 200 beneficiaries at any one time.

(2) The agency may replace any individuals who die or become ineligible for State plan services to maintain a count up to the number specified by the State and approved by CMS within the 200-maximum limit.

[59 FR 37719, July 25, 1994]

§ 441.306 Cooperative arrangements with the Maternal and Child Health program.

Whenever appropriate, the State agency administering the plan under Medicaid may enter into cooperative arrangements with the State agency responsible for administering a program for children with special health care needs under the Maternal and Child Health program (Title V of the Act) in order to ensure improved access to coordinated services to meet the children's needs.

[59 FR 37720, July 25, 1994]

§ 441.307 Notification of a waiver termination.

(a) If a State chooses to terminate its waiver before the initial 3-year period or 5-year renewal period expires, it must notify CMS in writing 30 days before terminating services to beneficiaries.

(b) If CMS or the State terminates the waiver, the State must notify beneficiaries of services under the waiver in accordance with § 431.210 of this subchapter and notify them 30 days before terminating services.

[46 FR 48541, Oct. 1, 1981. Redesignated at 59 FR 37719, July 25, 1994, as amended at 65 FR 60107, Oct. 10, 2000]

§ 441.308 Hearings procedures for waiver terminations.

The procedures specified in subpart D of part 430 of this chapter are applicable to State requests for hearings on terminations.

[50 FR 10028, Mar. 13, 1985. Redesignated at 59 FR 37720, July 25, 1994]

§ 441.310 Limits on Federal financial participation (FFP).

(a) FFP for home and community-based services listed in § 440.180 of this chapter is not available in expenditures for the following:

(1) Services provided in a facility subject to the health and welfare requirements described in § 441.302(a) during any period in which the facility is found not to be in compliance with the applicable State standards described in that section.

(2) The cost of room and board except when provided as—

(i) Part of respite care services in a facility approved by the State that is not a private residence; or

(ii) For waivers that allow personal caregivers as providers of approved waiver services, a portion of the rent and food that may be reasonably attributed to the unrelated caregiver who resides in the same household with the waiver beneficiary. FFP for a live-in caregiver is not available if the beneficiary lives in the caregiver's home or in a residence that is owned or leased by the provider of Medicaid services (the caregiver). For purposes of this provision, ''board'' means 3 meals a day or any other full nutritional regimen and does not include meals provided as part of a program of adult day health services as long as the meals provided do not constitute a ''full'' nutritional regimen.

(3) Prevocational, educational, or supported employment services, or any combination of these services, as part of habilitation services that are—

(i) Provided in approved waivers that include a definition of ''habilitation services'' but which have not included

prevocational, educational, and supported employment services in that definition; or

(ii) Otherwise available to the beneficiary under either special education and related services as defined in section 602(16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401(16) and (17)) or vocational rehabilitation services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

(4) For waiver applications and renewals approved on or after October 21, 1986, home and community-based services provided to individuals aged 22 through 64 diagnosed as chronically mentally ill who would be placed in an institution for mental diseases. FFP is also not available for such services provided to individuals aged 65 and over and 21 and under as an alternative to institutionalization in an IMD if the State does not include the appropriate optional Medicaid benefits specified at §§440.140 and 440.160 of this chapter in its State plan.

(b) FFP is available for expenditures for expanded habilitation services, as described in §440.180 of this chapter, if the services are included under a waiver or waiver amendment approved by CMS.

[59 FR 37720, July 25, 1994, as amended at 65 FR 60107, Oct. 10, 2000]

Subpart H—Home and Community-Based Services Waivers for Individuals Age 65 or Older: Waiver Requirements

SOURCE: 57 FR 29156, June 30, 1992, unless otherwise noted.

§441.350 Basis and purpose.

Section 1915(d) of the Act permits States to offer, under a waiver of statutory requirements, home and community-based services not otherwise available under Medicaid to individuals age 65 or older, in exchange for accepting an aggregate limit on the amount of expenditures for which they claim FFP for certain services furnished to these individuals. The home and community-based services that may be furnished are listed in §440.181 of this subchapter. This subpart describes the procedures the Medicaid agency must follow to request a waiver.

§441.351 Contents of a request for a waiver.

A request for a waiver under this section must meet the following requirements:

(a) *Required signatures.* The request must be signed by the Governor, the Director of the Medicaid agency or the Director of the larger State agency of which the Medicaid agency is a component or any official of the Medicaid agency to whom this authority has been delegated. A request from any other agency of State government will not be accepted.

(b) *Assurances and supporting documentation.* The request must provide the assurances required by §441.352 of this part and the supporting documentation required by §441.353.

(c) *Statement for sections of the Act.* The request must provide a statement as to whether waiver of section 1902(a)(1), 1902(a)(10)(B), or 1902(a)(10)(C)(i)(III) of the Act is requested. If the State requests a waiver of section 1902(a)(1) of the Act, the waiver must clearly specify the geographic areas or political subdivisions in which the services will be offered. The State must indicate whether it is requesting a waiver of one or all of these sections. The State may request a waiver of any one of the sections cited above.

(d) *Identification of services.* The request must identify all services available under the approved State plan, which are also included in the APEL and which are identified under §440.181, and any limitations that the State has imposed on the provision of any service. The request must also identify and describe each service specified in §440.181 of this subchapter to be furnished under the waiver, and any additional services to be furnished under the authority of §440.181(b)(7). Descriptions of additional services must explain how each additional service included under §440.181(b)(7) will contribute to the health and well-being of the beneficiaries and to their ability to reside in a community-based setting.

(e) *Beneficiaries served.* The request must provide that the home and community-based services described in § 440.181 of this subchapter, are furnished only to individuals who—

(1) Are age 65 or older;

(2) Are not inpatients of a hospital, NF, or ICF/IID; and

(3) The agency determines would be likely to require the care furnished in a NF under Medicaid.

(f) *Plan of care.* The request must provide that the home and community-based services described in § 440.181 of this subchapter, are furnished under a written plan of care based on an assessment of the individual's health and welfare needs and developed by qualified individuals for each beneficiary under the waiver. The qualifications of the individual or individuals who will be responsible for developing the individual plan of care must be described. Each plan of care must contain, at a minimum, the medical and other services to be provided, their frequency, and the type of provider to furnish them. Plans of care must be subject to the approval of the Medicaid agency.

(g) *Medicaid agency review.* The request must assure that the State agency maintain and exercise its authority to review (at a minimum) a valid statistical sample of each month's plans of care. When the services in a plan do not comport with the stated disabilities and needs of the beneficiary, the agency must implement immediate corrective action procedures to ensure that the needs of the beneficiary are adequately addressed.

(h) *Groups served.* The request must describe the group or groups of individuals to whom the services will be offered.

(i) *Assurances regarding amount expended.* The request must assure that the total amount expended by the State under the plan for individuals age 65 or older during a waiver year for medical assistance with respect to NF, home health, private duty nursing, personal care, and home and community-based services described in §§ 440.180 and 440.181 of this subchapter and furnished as an alternative to NF care will not exceed the aggregate projected expenditure limit (APEL) defined in § 441.354.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.351 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.352 State assurances.

Unless the Medicaid agency provides the following satisfactory assurances to CMS, CMS will not grant a waiver under this subpart and may terminate a waiver already granted.

(a) *Health and welfare.* The agency must assure that necessary safeguards have been taken to protect the health and welfare of the beneficiaries of services by assuring that the following conditions are met:

(1) Adequate standards for all types of providers that furnish services under the waiver are met. (These standards must be reasonably related to the requirements of the waiver service to be furnished.)

(2) The standards of any State licensure or certification requirements are met for services or for individuals furnishing services under the waiver.

(3) All facilities covered by section 1616(e) of the Act, in which home and community-based services are furnished, are in compliance with applicable State standards that meet the requirements of 45 CFR part 1397 for board and care facilities.

(4) Physician reviews of prescribed psychotropic drugs (when prescribed for purposes of behavior control of waiver beneficiaries) occur at least every 30 days.

(b) *Financial accountability.* The agency must assure financial accountability for funds expended for home and community-based services. The State must provide for an independent audit f its waiver program. The performance of a single financial audit, in accordance with the Single Audit Act of 1984 (Pub. L. 98–502, enacted on October 19, 1984), is deemed to satisfy the requirement for an independent audit. The agency must maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services furnished to individuals age 65 or older under the waiver and the State plan, including reports of any independent audits conducted.

(c) *Evaluation of need.* The agency must provide for an initial evaluation (and periodic reevaluations) of the need for the level of care furnished in a NF when there is a reasonable indication that individuals age 65 or older might need those services in the near future, but for the availability of home and community-based services. The procedures used to assess level of care for a potential waiver beneficiary must be at least as stringent as any existing State procedures applicable to individuals entering a NF. The qualifications of individuals performing the waiver assessment must be as high as those of individuals assessing the need for NF care, and the assessment instrument itself must be the same as any assessment instrument used to establish level of care of prospective inpatients in NFs. A periodic reevaluation of the level of care must be performed. The period of reevaluation of level of care cannot extend beyond 1 year.

(d) *Expenditures.* The agency must assure that the total amount expended by the State for medical assistance with respect to NF, home health, private duty nursing, personal care services, home and community-based services furnished under a section 1915(c) waiver granted under Subpart G of this part to individuals age 65 or older, and the home and community-based services approved and furnished under a section 1915(d) waiver for individuals age 65 or older during a waiver year will not exceed the APEL, calculated in accordance with §441.354.

(e) *Reporting.* The agency must assure that it will provide CMS annually with information on the waiver's impact. The information must be consistent with a reasonable data collection plan designed by CMS and must address the waiver's impact on—

(1) The type, amount, and cost of services furnished under the State plan; and

(2) The health and welfare of beneficiaries of the services described in §440.181 of this chapter.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, §441.352 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§441.353 Supporting documentation required.

The agency must furnish CMS with sufficient information to support the assurances required under §441.352, in order to meet the requirement that the assurances are satisfactory. At a minimum, this information must consist of the following:

(a) *Safeguards.* A description of the safeguards necessary to protect the health and welfare of beneficiaries.

This information must include:

(1) A copy of the standards established by the State for facilities (in which services will be furnished) that are covered by section 1616(e) of the Act.

(2) The minimum educational or professional qualifications of the providers of the services.

(3) A description of the administrative oversight mechanisms established by the State to ensure quality of care.

(b) *Records.* A description of the records and information that are maintained by the agency and by providers of services to support financial accountability, information regarding how the State meets the requirement for financial accountability, and an explanation of how the State assures that there is an audit trail for State and Federal funds expended for section 1915(d) home and community-based waiver services. If the State has an approved Medicaid Management Information System (MMIS), this system must be used to process individual claims data and account for funds expended for services furnished under the waiver.

(c) *Evaluation and reevaluation of beneficiaries.* A description of the agency's plan for the evaluation and reevaluation of beneficiaries' level of care, including the following:

(1) A description of who makes these evaluations and how they are made.

(2) A copy of the evaluation instrument.

(3) The agency's procedure to assure the maintenance of written documentation on all evaluations and reevaluations and copies of the forms. In accordance with regulations at 45 CFR part 75, written documentation of all evaluations and reevaluations must be maintained for a minimum period of 3 years.

(4) The agency's procedure to assure reevaluations of need at regular intervals.

(5) The intervals at which reevaluations occur, which may be no less frequent than for institutionalized individuals at comparable levels of care.

(6) The procedures and criteria used for evaluation and reevaluation of waiver beneficiaries must be the same or more stringent than those used for individuals served in NFs.

(d) *Alternatives available.* A description of the agency's plan for informing eligible beneficiaries of the feasible alternatives available under the waiver and allowing beneficiaries to choose either institutional or home and community-based services must be submitted to CMS. A copy of the forms or documentation used by the agency to verify that this choice has been offered and that beneficiaries of waiver services, or their legal representatives, have been given the free choice of the providers of both waiver and State plan services must also be available for CMS review. The Medicaid agency must provide an opportunity for a fair hearing, under 42 CFR part 431, subpart E, to beneficiaries who are not given the choice of home or community-based services as an alternative to institutional care in a NF or who are denied the service(s) or the providers of their choice.

(e) *Post-eligibility of income.* An explanation of how the agency applies the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services who are eligible under a special income level (included in § 435.217 of this subchapter).

[57 FR 29156, June 30, 1992, as amended at 81 FR 3012, Jan. 20, 2016]

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.353 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.354 Aggregate projected expenditure limit (APEL).

(a) *Definitions.* For purposes of this section, the term *base year* means—

(1) Federal fiscal year (FFY) 1987 (that is, October 1, 1986 through September 30, 1987); or

(2) In the case of a State which did not report expenditures on the basis of age categories during FFY 1987, the base year means FFY 1989 (that is, October 1, 1988 through September 30, 1989).

(b) *General.* (1) The total amount expended by the State for medical assistance with respect to NF, home and community-based services under the waiver, home health services, personal care services, private duty nursing services, and services furnished under a waiver under subpart G of this part to individuals age 65 or older furnished as an alternative to care in an SNF or ICF (NF effective October 1, 1990), may not exceed the APEL calculated in accordance with paragraph (c) of this section.

(2) In applying for a waiver under this subpart, the agency must clearly identify the base year it intends to use.

(3) The State may make a preliminary calculation of the expenditure limit at the time of the waiver approval; however, CMS makes final calculations of the aggregate limit after base data have been verified and accepted.

(4) All base year and waiver year data are subject to final cost settlement within 2 years from the end of the base or waiver year involved.

(c) *Formula for calculating APEL.* Except as provided in paragraph (d) of this section, the formula for calculating the APEL follows:

$APEL = P \times (1 + Y) + V \times (1 + Z)$, where

P = The aggregate amount of the State's medical assistance under title XIX for SNF and ICF (NF effective October 1, 1990) services furnished to individuals who have reached age 65, defined as the total medical assistance payments (Federal and State) reported on line 6 of form CMS 64 (as adjusted) for SNF services, ICF-other services, and mental health facility services for the base year, multiplied by the ratio of expenditures for SNF and ICF-other services for the aged to total expenditures for these services as reported on form CMS 2082 for the base year.

Q = The market basket index for SNF and ICF (NF effective October 1, 1990) services for the waiver year involved, defined as the total SNF Input Price Index used

in the Medicare program, identified as the third quarter data available from CMS's Office of National Cost Estimates in August preceding the start of the fiscal year.

R = The SNF Input Price Index for the base year.

S = The number of residents in the State in the waiver year involved who have reached age 65, defined as the number of aged Medicare beneficiaries in the State, equal to the Mid-Period Enrollment in HI or SMI in that State on July 1 preceding the start of the fiscal year.

T = The number of aged Medicare beneficiaries in the State who are enrolled in either the HI or SMI programs in the base year, as defined in S, above.

U = The number of years beginning after the base year and ending on the last day of the waiver year involved.

V = The aggregate amount of the State's medical assistance under title XIX in the base year for home and community-based services for individuals who have reached age 65, defined as the total medical assistance payments (Federal and State) reported on line 6 of form CMS 64 (as adjusted) for home health, personal care, and home and community-based services waivers, which provide services as an alternative to care in a SNF or ICF (NF effective October 1, 1990), increased by an estimate (acceptable to CMS) of expenditures for private duty nursing services, multiplied by the ratio of expenditures for home health services for the aged to total expenditures for home health services, as reported on form CMS 2082, for the base year.

W = The market basket index for home and community-based services for the waiver year involved, defined as the Home Agency Input Price Index, used in the Medicare program identified as the third quarter data available from CMS's Office of National Cost Estimates in August preceding the start of the fiscal year.

X = The Home Health Agency Input Price Index for the base year.

Y = The greater of—
(U × .07), or (Q/R)-1 + (S/T)-1 + (U × .02).

Z = The greater of—
(U × .07), or (W/X)-1 + (S/T)-1 + + (U × .02).

(d) *Amendment of the APEL.* The State may request amendment of its APEL to reflect an increase in the aggregate amount of medical assistance for NF services and for services included in the calculation of the APEL as required by paragraph (c) of this section when the increase is directly attributable to legislation enacted on or after December 22, 1987, which amends title XIX of the Act. Costs attributable to laws enacted before December 22, 1987 will not be considered. Because the APEL for each year of the waiver is computed separately from the APEL for any other waiver year, a separate amendment must be submitted for each year in which the State chooses to raise its APEL. Documentation specific to the waiver year involved must be submitted to CMS.

§ 441.355 Duration, extension, and amendment of a waiver.

(a) *Effective dates and extension periods.* (1) The effective date for a waiver of Medicaid requirements to furnish home and community-based services to individuals age 65 or older under this subpart is established by CMS prospectively on the first day of the FFY following the date on which the waiver is approved.

(2) The initial waiver is approved for a 3-year period from the effective date. Subsequent renewals are approved for 5-year periods.

(3) If the agency requests it, the waiver may be extended for an additional 5-year period if CMS's review of the prior period shows that the assurances required by § 441.352 were met.

(4) The agency may request that waiver modifications be made effective retroactive to the first day of the waiver year in which the amendment is submitted, unless the amendment involves substantive change. Substantive changes may include, but are not limited to, addition of services under the waiver, a change in the qualifications of service providers, or a change in the eligible population.

(5) A request for an amendment that involves a substantive change is given a prospective effective date, but this date need not coincide with the start of the next FFY.

(b) *Extension or new waiver request.* CMS determines whether a request for extension of an existing waiver is actually an extension request, or a request for a new waiver. Generally, if a State's extension request proposes a substantive change in services furnished, eligible population, service area, statutory sections waived, or qualifications of service providers, CMS considers it a new waiver request.

(c) *Reconsideration of denial.* A determination of CMS to deny a request for a waiver (or for extension of a waiver) under this subpart may be reconsidered in accordance with § 441.357.

(d) *Existing waiver effectiveness after denial.* If CMS denies a request for an extension of an existing waiver under this subpart:

(1) The existing waiver remains in effect for a period of not less than 90 days after the date on which CMS denies the request, or, if the State seeks reconsideration in accordance with § 441.357, the date on which a final determination is made with respect to that review.

(2) CMS calculates an APEL for the period for which the waiver remains in effect, and this calculation is used to pro-rate the limit according to the number of days to which it applies.

§ 441.356 Waiver termination.

(a) *Termination by the State.* If a State chooses to terminate its waiver before an approved program is due to expire, the following conditions apply:

(1) The State must notify CMS in writing at least 30 days before terminating services to beneficiaries.

(2) The State must notify beneficiaries of services under the waiver at least 30 days before terminating services in accordance with § 431.210 of this chapter.

(3) CMS continues to apply the APEL described in § 441.354 through the end of the waiver year, but this limit is not applied in subsequent years.

(4) The State may not decrease the services available under the approved State plan to individuals age 65 or older by an amount that violates the comparability of service requirements set forth in § 440.240 of this chapter.

(b) *Termination by CMS.* (1) If CMS finds, during an approved waiver period, that an agency is not meeting one or more of the requirements for a waiver contained in this subpart, CMS notifies the agency in writing of its findings and grants an opportunity for a hearing in accordance with § 441.357. If CMS determines that the agency is not in compliance with this subpart after the notice and any hearing, CMS may terminate the waiver.

(2) If CMS terminates the waiver, the following conditions apply:

(i) The State must notify beneficiaries of services under the waiver at least 30 days before terminating services in accordance with § 431.210 of this chapter.

(ii) CMS continues to apply the APEL in § 441.354 of this subpart, but the limit is prorated according to the number of days in the fiscal year during which waiver services were offered. The limit expires concurrently with the termination of home and community-based services under the waiver.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.356 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.357 Hearing procedures for waiver denials.

The procedures specified in § 430.18 of this subchapter apply to State requests for hearings on denials, renewals, or amendments of waivers for home and community-based services for individuals age 65 or older.

§ 441.360 Limits on Federal financial participation (FFP).

FFP for home and community-based services listed in § 440.181 of this subchapter is not available in expenditures for the following:

(a) Services furnished in a facility subject to the health and welfare requirements described in § 441.352(a) during any period in which the facility is found not to be in compliance with the applicable State requirements described in that section.

(b) The cost of room and board except when furnished as part of respite care services in a facility, approved by the State, that is not a private residence. For purposes of this subpart, ''board'' means three meals a day or any other full nutritional regimen. ''Board'' does not include meals, which do not comprise a full nutritional regimen, furnished as part of adult day health services.

(c) The portion of the cost of room and board attributed to unrelated, live-in personal caregivers when the waiver beneficiary lives in the caregiver's

home or a residence owned or leased by the provider of the Medicaid services (the caregiver).

(d) Services that are not included in the approved State plan and not approved as waiver services by CMS.

(e) Services furnished to beneficiaries who are ineligible under the terms of the approved waiver.

(f) Services furnished by a provider when either the services or the provider do not meet the standards that are set by the State and included in the approved waiver.

(g) Services furnished to a beneficiary by his or her spouse.

§441.365 Periodic evaluation, assessment, and review.

(a) *Purpose.* This section prescribes requirements for periodic evaluation, assessment, and review of the care and services furnished to individuals receiving home and community-based waiver services under this subpart.

(b) *Evaluation and assessment review team.* (1) A review team, as described in paragraphs (b)(2) and (c) of this section, must periodically evaluate and assess the care and services furnished to beneficiaries under this subpart. The review team must be created by the State agency directly, or (through interagency agreement) by other departments of State government (such as the Department of Health or the Agency on Aging).

(2) Each review team must consist of at least one physician or registered nurse, and at least one other individual with health and social service credentials who the State believes is qualified to properly evaluate and assess the care and services provided under the waiver. If there is no physician on the review team, the Medicaid agency must ensure that a physician is available to provide consultation to the review team.

(3) For waiver services furnished to individuals who have been found to be likely to require the level of care furnished in a NF that is also an IMD, each review team must have a psychiatrist or physician and other appropriate mental health or social service personnel who are knowledgeable about geriatric mental illness.

(c) *Financial interests and employment of review team members.* (1) No member of a review team may have a financial interest in or be employed by any entity that furnishes care and services under the waiver to a beneficiary whose care is under review.

(2) No physician member of a review team may evaluate or assess the care of a beneficiary for whom he or she is the attending physician.

(3) No individual who serves as case manager, caseworker, benefit authorizer, or any similar position, may serve as member of a review team that evaluates and assesses care furnished to a beneficiary with whom he or she has had a professional relationship.

(d) *Number and location of review teams.* A sufficient number of teams must be located within the State so that onsite inspections can be made at appropriate intervals at sites where waiver beneficiaries receive care and services.

(e) *Frequency of periodic evaluations and assessments.* Periodic evaluations and assessments must be conducted at least annually for each beneficiary under the waiver. The review team and the agency have the option to determine the frequency of further periodic evaluations and assessments, based on the quality of services and access to care being furnished under the waiver and the condition of patients receiving care and services.

(f) *Notification before inspection.* No provider of care and services under the waiver may be notified in advance of a periodic evaluation, assessment, and review. However, when a beneficiary receives services in his own home or the home of a relative, notification must be provided to the residents of the household at least 48 hours in advance. The beneficiary must have an opportunity to decline access to the home. If the beneficiary declines access to his or her own home, or the home of a relative, the review is limited solely to the review of the provider's records. If the beneficiary is incompetent, the head of the household has the authority to decline access to the home.

(g) *Personal contact with and observation of beneficiaries and review of records.* (1) For beneficiaries of care and services under a waiver, the review team's

evaluation and assessment must include—

(i) A review of each beneficiary's medical record, the evaluation and reevaluation required by § 441.353(c), and the plan of care under which the waiver and other services are furnished; and

(ii) If the records described in paragraph (g)(1)(i) of this section are inadequate or incomplete, personal contact and observation of each beneficiary.

(2) The review team may personally contact and observe any beneficiary whose care the team evaluates and assesses.

(3) The review team may consult with both formal and informal caregivers when the beneficiary's records are inadequate or incomplete and when any apparent discrepancy exists between services required by the beneficiary and services furnished under the waiver.

(h) *Determinations by the review team.* The review team must determine in its evaluation and assessment whether—

(1) The services included in the plan of care are adequate to meet the health and welfare needs of each beneficiary;

(2) The services included in the plan of care have been furnished to the beneficiary as planned;

(3) It is necessary and in the interest of the beneficiary to continue receiving services through the waiver program; and

(4) It is feasible to meet the beneficiary's health and welfare needs through the waiver program.

(i) *Other information considered by review team.* When making determinations, under paragraph (h) of this section, for each beneficiary, the review team must consider the following information and may consider other information as it deems necessary:

(1) Whether the medical record, the determination of level of care, and the plan of care are consistent, and whether all ordered services have been furnished and properly recorded.

(2) Whether physician review of prescribed psychotropic medications (when required for behavior control) has occurred at least every 30 days.

(3) Whether tests or observations of each beneficiary indicated by his or her medical record are made at appropriate times and properly recorded.

(4) Whether progress notes entered in the record by formal and informal caregivers are made as required and appear to be consistent with the observed condition of the beneficiary.

(5) Whether reevaluations of the beneficiary's level of care have occurred at least as frequently as would be required if that individual were served in a NF.

(6) Whether the beneficiary receives adequate care and services, based, at a minimum, on the following when observations are necessary (the requirements for the necessity of observations are set forth in new § 441.365(g)(3)):

(i) Cleanliness.

(ii) Absence of bedsores.

(iii) Absence of signs of malnutrition or dehydration.

(7) Whether the beneficiary needs any service that is not included in the plan of care, or if included, is not being furnished by formal or informal caregivers under the waiver or through arrangements with another public or private source of assistance.

(8) Determination as to whether continued home and community-based services are required by the beneficiary to avoid the likelihood of placement in a NF.

(j) *Submission of review team's results.* The review team must submit to the Medicaid agency the results of its periodic evaluation, assessment and review of the care of the beneficiary:

(1) Within 1 month of the completion of the review.

(2) Immediately upon its determination that conditions exist that may constitute a threat to the life or health of a beneficiary.

(k) *Agency's action.* The Medicaid agency must establish and adhere to procedures for taking appropriate action in response to the findings reported by the review team. These procedures must provide for immediate response to any finding that the life or health of a beneficiary may be jeopardized.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.365 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

Subpart I—Community Supported Living Arrangements Services

SOURCE: 56 FR 48114, Sept. 24, 1991, unless otherwise noted.

§ 441.400 Basis and purpose.

This subpart implements section 1905(a)(24) of the Act, which adds community supported living arrangements services to the list of services that States may provide as medical assistance under title XIX (to the extent and as defined in section 1930 of the Act), and section 1930(h)(1)(B) of the Act, which specifies minimum protection requirements that a State which provides community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals must meet to ensure the health, safety and welfare of those individuals.

§ 441.402 State plan requirements.

If a State that is eligible to provide community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals provides such services, the State plan must specify that it complies with the minimum protection requirements in § 441.404.

§ 441.404 Minimum protection requirements.

To be eligible to provide community supported living arrangements services to developmentally disabled individuals, a State must assure, through methods other than reliance on State licensure processes or the State quality assurance programs described under section 1930(d) of the Act, that:

(a) Individuals receiving community supported living arrangements services are protected from neglect, physical and sexual abuse, and financial exploitation;

(b) Providers of community supported living arrangements services—

(1) Do not use individuals who have been convicted of child or client abuse, neglect, or mistreatment, or of a felony involving physical harm to an individual; and

(2) Take all reasonable steps to determine whether applicants for employment by the provider have histories indicating involvement in child or client abuse, neglect, or mistreatment, or a criminal record involving physical harm to an individual;

(c) Providers of community supported living arrangements services are not unjustly enriched as a result of abusive financial arrangements (such as owner lease-backs) with developmentally disabled clients; and

(d) Providers of community supported living arrangements services, or the relatives of such providers, are not named beneficiaries of life insurance policies purchased by or on behalf of developmentally disabled clients.

Subpart J—Optional Self-Directed Personal Assistance Services Program

SOURCE: 73 FR 57881, Oct. 3, 2008, unless otherwise noted.

§ 441.450 Basis, scope, and definitions.

(a) *Basis.* This subpart implements section 1915(j) of the Act concerning the self-directed personal assistance services (PAS) option through a State Plan.

(b) *Scope.* A self-directed PAS option is designed to allow individuals, or their representatives, if applicable, to exercise decision-making authority in identifying, accessing, managing and purchasing their PAS. This authority includes, at a minimum, all of the following:

(1) The purchase of PAS and supports for PAS.

(2) Recruiting workers.

(3) Hiring and discharging workers.

(4) Training workers and accessing training provided by or through the State if additional worker training is required or desired by the participant, or participant's representative, if applicable.

(5) Specifying worker qualifications.

(6) Determining worker duties.

(7) Scheduling workers.

(8) Supervising workers.

(9) Evaluating worker performance.

(10) Determining the amount paid for a service, support or item.

(11) Scheduling when services are provided.

(12) Identifying service workers.

(13) Reviewing and approving invoices.

(c) *Definitions.* As used in this part—

Assessment of need means an evaluation of the needs, strengths, and preferences of participants for services. This includes one or more processes to obtain information about an individual, including health condition, personal goals and preferences, functional limitation, age, school, employment, household, and other factors that are relevant to the authorization and provision of services. Assessment information supports the development of the service plan and the subsequent service budget.

Individualized backup plan means a written plan that meets all of the following:

(1) Is sufficiently individualized to address each participant's critical contingencies or incidents that would pose a risk of harm to the participant's health or welfare;

(2) Must demonstrate an interface with the risk management provision at § 441.476 which requires States to assess and identify the potential risks to the participant (such as any critical health needs), and ensure that the risks and how they will be managed are the result of discussion and negotiation among the persons involved in the service plan development;

(3) Must not include the 911 emergency system or other emergency system as the sole backup feature of the plan; and

(4) Must be incorporated into the participant's service plan.

Legally liable relatives means persons who have a duty under the provisions of State law to care for another person. Legally liable relatives may include any of the following:

(1) The parent (biological or adoptive) of a minor child or the guardian of a minor child who must provide care to the child.

(2) Legally-assigned caretaker relatives.

(3) A spouse.

Self-directed personal assistance services (PAS) means personal care and related services, or home and community-based services otherwise available under the State plan or a 1915(c) waiver program that are provided to an individual who has been determined eligible for the PAS option. Self-directed PAS also includes, at the State's option, items that increase the individual's independence or substitutes (such as a microwave oven or an accessibility ramp) for human assistance, to the extent the expenditures would otherwise be made for the human assistance.

Self-direction means the opportunity for participants or their representatives to exercise choice and control over the budget, planning, and purchase of self-directed PAS, including the amount, duration, scope, provider, and location of service provision.

Service budget means an amount of funds that is under the control and direction of a participant, or the participant's representative, if any, when the State has selected the State plan option for provision of self-directed PAS. It is developed using a person-centered and directed process and is individually tailored in accordance with the participant's needs and personal preferences as established in the service plan.

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to remain in the community. The service plan is developed based on the assessment of need using a person-centered and directed process. The service plan builds upon the participant's capacity to engage in activities that promote community life and respects the participant's preferences, choices, and abilities. The participant's representative, if any, families, friends and professionals, as desired or required by the participant, will be involved in the service-planning process.

Support system means information, counseling, training, and assistance that support the participant (or the participant's family or representative, as appropriate) in identifying, accessing, managing, and directing their PAS and supports and in purchasing their PAS identified in the service plan and budget.

Supports broker or consultant means an individual who supports participants in directing their PAS and service budgets. The supports broker or consultant is an agent of the participants and takes direction from the participants, or their representatives, if applicable, about what information, counseling, training or assistance is needed or desired. The supports broker or consultant is primarily responsible for facilitating participants' development of a service budget and effective management of the participants' PAS and budgets in a manner that comports with the participants' preferences. States must develop a protocol to ensure that supports brokers or consultants: are accessible to participants; have regularly scheduled phone and in-person contacts with participants; monitor whether participants' health status has changed and whether expenditure of funds are being made in accordance with service budgets. States must also develop the training requirements and qualifications for supports brokers or consultants that include, at a minimum, the following:

(1) An understanding of the philosophy of self-direction and person-centered and directed planning;

(2) The ability to facilitate participants' independence and participants' preferences in managing PAS and budgets, including any risks assumed by participants;

(3) The ability to develop service budgets and ensure appropriate documentation; and

(4) Knowledge of the PAS and resources available in the participant's community and how to access them.

The availability of a supports broker or consultant to each participant is a requirement of the support system.

§441.452 Self-direction: General.

(a) States must have in place, before electing the self-directed PAS option, personal care services through the State plan, or home and community-based services under a section 1915(c) waiver.

(b) The State must have both traditional service delivery and the self-directed PAS service delivery option available in the event that an individual voluntarily disenrolls or is involuntarily disenrolled, from the self-directed PAS service delivery option.

(c) The State's assessment of an individual's needs must form the basis of the level of services for which the individual is eligible.

(d) Nothing in this subpart will be construed as affecting an individual's Medicaid eligibility, including that of an individual whose Medicaid eligibility is attained through receipt of section 1915(c) waiver services.

§441.454 Use of cash.

(a) States have the option of disbursing cash prospectively to participants, or their representatives, as applicable, self-directing their PAS.

(b) States that choose to offer the cash option must ensure compliance with all applicable requirements of the Internal Revenue Service, including, but not limited to, retaining required forms and payment of FICA, FUTA and State unemployment taxes.

(c) States must permit participants, or their representatives, as applicable, using the cash option to choose to use the financial management entity for some or all of the functions described in §441.484(c).

(d) States must make available a financial management entity to a participant, or the participant's representative, if applicable, who has demonstrated, after additional counseling, information, training, or assistance, that the participant cannot effectively manage the cash option described in paragraph (a) of this section.

§441.456 Voluntary disenrollment.

(a) States must permit a participant to voluntarily disenroll from the self-directed PAS option at any time and return to a traditional service delivery system.

(b) The State must specify in a section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

§441.458 Involuntary disenrollment.

(a) States must specify the conditions under which a participant may be involuntarily disenrolled from the self-directed PAS option.

(b) CMS must approve the State's conditions under which a participant may be involuntarily disenrolled.

(c) The State must specify in the section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

§ 441.460 Participant living arrangements.

(a) Self-directed PAS are not available to an individual who resides in a home or property that is owned, operated, or controlled by a PAS provider who is not related to the individual by blood or marriage.

(b) States may specify additional restrictions on a participant's living arrangements if they have been approved by CMS.

§ 441.462 Statewideness, comparability and limitations on number served.

A State may do the following:

(a) Provide self-directed PAS without regard to the requirements of statewideness.

(b) Limit the population eligible to receive these services without regard to comparability of amount, duration, and scope of services.

(c) Limit the number of persons served without regard to comparability of amount, duration, and scope of services.

§ 441.464 State assurances.

A State must assure that the following requirements are met:

(a) *Necessary safeguards.* Necessary safeguards have been taken to protect the health and welfare of individuals furnished services under the program and to assure the financial accountability for funds expended for self-directed services.

(1) Safeguards must prevent the premature depletion of the participant directed budget as well as identify potential service delivery problems that might be associated with budget underutilization.

(2) These safeguards may include the following:

(i) Requiring a case manager, support broker or other person to monitor the participant's expenditures.

(ii) Requiring the financial management entity to flag significant budget variances (over and under expenditures) and bring them to the attention of the participant, the participant's representative, if applicable, case manager, or support broker.

(iii) Allocating the budget on a monthly or quarterly basis.

(iv) Other appropriate safeguards as determined by the State.

(3) Safeguards must be designed so that budget problems are identified on a timely basis so that corrective action may be taken, if necessary.

(b) *Evaluation of need.* The State must perform an evaluation of the need for personal care under the State Plan or services under a section 1915(c) waiver program for individuals who meet the following requirements:

(1) Are entitled to medical assistance for personal care services under the State plan or receiving home and community based services under a section 1915(c) waiver program.

(2) May require self-directed PAS.

(3) May be eligible for self-directed PAS.

(c) *Notification of feasible alternatives.* Individuals who are likely to require personal care under the State plan, or home and community-based services under a section 1915(c) waiver program are informed of the feasible alternatives, if available, under the State's self-directed PAS State plan option, at the choice of these individuals, to the provision of personal care services under the State plan, or PAS under a section 1915(c) home and community-based services waiver program. Information on feasible alternatives must be communicated to the individual in a manner and language understandable by the individual. Such information includes, but is not limited to, the following:

(1) Information about self-direction opportunities that is sufficient to inform decision-making about the election of self-direction and provided on a timely basis to an individual or the representative which minimally includes the following:

(i) Elements of self-direction compared to non-self-directed PAS.

(ii) Individual responsibilities and potential liabilities under the self-direction service delivery model.

(iii) The choice to receive PAS through a waiver program administered under section 1915(c) of the Act, regardless of delivery system, if applicable.

(iv) The option, if available, to receive and manage the cash amount of their individual budget allocation.

(2) When and how this information is provided.

(d) *Support system.* States must provide, or arrange for the provision of, a support system that meets the following conditions:

(1) Appropriately assesses and counsels an individual, or the individual's representative, if applicable, before enrollment, including information about disenrollment.

(2) Provides appropriate information, counseling, training, and assistance to ensure that a participant is able to manage the services and budgets. Such information must be communicated to the participant in a manner and language understandable by the participant. The support activities must include at least the following:

(i) Person-centered planning and how it is applied.

(ii) Information about the services available for self-direction.

(iii) Range and scope of individual choices and options.

(iv) Process for changing the service plan and service budget.

(v) Grievance process.

(vi) Risks and responsibilities of self-direction.

(vii) The ability to freely choose from available PAS providers.

(viii) Individual rights.

(ix) Reassessment and review schedules.

(x) Defining goals, needs, and preferences.

(xi) Identifying and accessing services, supports, and resources.

(xii) Development of risk management agreements.

(xiii) Development of an individualized backup plan.

(xiv) Recognizing and reporting critical events.

(xv) Information about an advocate or advocacy systems available in the State and how a participant, or a participant's representative, if applicable, can access the advocate or advocacy systems.

(3) Offers additional information, counseling, training, or assistance, including financial management services under either of the following conditions:

(i) At the request of the participant, or participant's representative, if applicable, for any reason.

(ii) When the State has determined the participant, or participant's representative, if applicable, is not effectively managing the services identified in the service plan or budget.

(4) The State may mandate the use of additional assistance, including the use of a financial management entity, or may initiate an involuntary disenrollment in accordance with §441.458, if, after additional information, counseling, training or assistance is provided to a participant (or participant's representative, if applicable), the participant (or participant's representative, if applicable) has continued to demonstrate an inability to effectively manage the services and budget.

(e) *Annual report.* The State must provide to CMS an annual report on the number of individuals served and the total expenditures on their behalf in the aggregate.

(f) *Three-year evaluation.* The State must provide to CMS an evaluation of the overall impact of the self-directed PAS option on the health and welfare of participating individuals compared to non-participants every 3 years.

§441.466 Assessment of need.

States must conduct an assessment of the participant's needs, strengths, and preferences in accordance with the following:

(a) States may use one or more processes and techniques to obtain information about an individual, including health condition, personal goals and preferences for the provision of services, functional limitations, age, school, employment, household, and other factors that are relevant to the need for and authorization and provision of services.

(b) Assessment information supports the determination that an individual requires PAS and also supports the development of the service plan and budget.

§ 441.468 Service plan elements.

(a) The service plan must include at least the following:

(1) The scope, amount, frequency, and duration of each service.

(2) The type of provider to furnish each service.

(3) Location of the service provision.

(4) The identification of risks that may pose harm to the participant along with a written individualized backup plan for mitigating those risks.

(b) A State must develop a service plan for each program participant using a person-centered and directed planning process to ensure the following:

(1) The identification of each program participant's preferences, choices, and abilities, and strategies to address those preferences, choices, and abilities.

(2) The option for the program participant, or participant's representative, if applicable, to exercise choice and control over services and supports discussed in the plan.

(3) Assessment of, and planning for avoiding, risks that may pose harm to a participant.

(c) All of the State's applicable policies and procedures associated with service plan development must be carried out and include, but are not limited to, the following:

(1) Allow the participant, or participant's representative, if applicable, the opportunity to engage in, and direct, the process to the extent desired.

(2) Allow the participant, or participant's representative, if applicable, the opportunity to involve family, friends, and professionals (as desired or required) in the development and implementation of the service plan.

(3) Ensure the planning process is timely.

(4) Ensure the participant's needs are assessed and that the services meet the participant's needs.

(5) Ensure the responsibilities for service plan development are identified.

(6) Ensure the qualifications of the individuals who are responsible for service plan development reflect the nature of the program's target population(s).

(7) Ensure the State reviews the service plan annually, or whenever necessary due to a change in the participant's needs or health status.

(8) Ensure that a participant may request revisions to a service plan, based on a change in needs or health status.

(d) When an entity that is permitted to provide other State plan services is responsible for service plan development, the State must describe the safeguards that are in place to ensure that the service provider's role in the planning process is fully disclosed to the participant, or participant's representative, if applicable, and controls are in place to avoid any possible conflict of interest.

(e) An approved self-directed service plan conveys authority to the participant, or participant's representative, if applicable, to perform, at a minimum, the following tasks:

(1) Recruit and hire workers to provide self-directed services, including specifying worker qualifications.

(2) Fire workers.

(3) Supervise workers in the provision of self-directed services.

(4) Manage workers in the provision of self-directed services, which includes the following functions:

(i) Determining worker duties.

(ii) Scheduling workers.

(iii) Training workers in assigned tasks.

(iv) Evaluating workers performance.

(5) Determine the amount paid for a service, support, or item.

(6) Review and approve provider invoices.

§ 441.470 Service budget elements.

A service budget must be developed and approved by the State based on the assessment of need and service plan and must include the following:

(a) The specific dollar amount a participant may utilize for services and supports.

(b) How the participant is informed of the amount of the service budget before the service plan is finalized.

(c) The procedures for how the participant, or participant's representative, if applicable, may adjust the budget, including the following:

(1) How the participant, or participant's representative, if applicable, may freely make changes to the budget.

(2) The circumstances, if any, that may require prior approval before a budget adjustment is made.

(3) The circumstances, if any, that may require a change in the service plan.

(d) The procedure(s) that governs how a person, at the election of the State, may reserve funds to purchase items that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance, including additional goods, supports, services or supplies.

(e) The procedure(s) that governs how a person may use a discretionary amount, if applicable, to purchase items not otherwise delineated in the budget or reserved for permissible purchases.

(f) How participants, or their representative, if applicable, are afforded the opportunity to request a fair hearing under §441.300 if a participant's, or participant's representative, if applicable, request for a budget adjustment is denied or the amount of the budget is reduced.

§441.472 Budget methodology.

(a) The State shall set forth a budget methodology that ensures service authorization resides with the State and meets the following criteria:

(1) The State's method of determining the budget allocation is objective and evidence based utilizing valid, reliable cost data.

(2) The State's method is applied consistently to participants.

(3) The State's method is open for public inspection.

(4) The State's method includes a calculation of the expected cost of the self-directed PAS and supports, if those services and supports were not self-directed.

(5) The State has a process in place that describes the following:

(i) Any limits it places on self-directed services and supports, and the basis for the limits.

(ii) Any adjustments that will be allowed and the basis for the adjustments.

(b) The State must have procedures to safeguard participants when the budgeted service amount is insufficient to meet a participant's needs.

(c) The State must have a method of notifying participants, or their representative, if applicable, of the amount of any limit that applies to a participant's self-directed PAS and supports.

(d) The budget may not restrict access to other medically necessary care and services furnished under the plan and approved by the State but not included in the budget.

(e) The State must have a procedure to adjust a budget when a reassessment indicates a change in a participant's medical condition, functional status or living situation.

§441.474 Quality assurance and improvement plan.

(a) The State must provide a quality assurance and improvement plan that describes the State's system of how it will perform activities of discovery, remediation and quality improvement in order to learn of critical incidents or events that affect participants, correct shortcomings, and pursue opportunities for system improvement.

(b) The quality assurance and improvement plan shall also describe the system performance measures, outcome measures, and satisfaction measures that the State must use to monitor and evaluate the self-directed State plan option. Quality of care measures must be made available to CMS upon request and include indicators approved or prescribed by the Secretary.

§441.476 Risk management.

(a) The State must specify the risk assessment methods it uses to identify potential risks to the participant.

(b) The State must specify any tools or instruments it uses to mitigate identified risks.

(c) The State must ensure that each service plan includes the risks that an

individual is willing and able to assume, and the plan for how identified risks will be mitigated.

(d) The State must ensure that the risk management plan is the result of discussion and negotiation among the persons designated by the State to develop the service plan, the participant, the participant's representative, if any, and others from whom the participant may seek guidance.

§ 441.478 Qualifications of providers of personal assistance.

(a) States have the option to permit participants, or their representatives, if applicable, to hire any individual capable of providing the assigned tasks, including legally liable relatives, as paid providers of the PAS identified in the service plan and budget.

(b) Participants, or their representatives, if applicable, retain the right to train their workers in the specific areas of personal assistance needed by the participant and to perform the needed assistance in a manner that comports with the participant's personal, cultural, and/or religious preferences. Participants, or their representatives, if applicable, also have the right to access other training provided by or through the State so that their PAS providers can meet any additional qualifications required or desired by participants, or participants' representatives, if applicable.

(c) Participants, or their representatives, if applicable, retain the right to establish additional staff qualifications based on participants' needs and preferences.

§ 441.480 Use of a representative.

(a) States may permit participants to appoint a representative to direct the provision of self-directed PAS on their behalf. The following types of representatives are permissible:

(1) A minor child's parent or guardian.

(2) An individual recognized under State law to act on behalf of an incapacitated adult.

(3) A State-mandated representative, after approval by CMS of the State criteria, if the participant has demonstrated, after additional counseling, information, training or assistance, the inability to self-direct PAS.

(b) A person acting as a representative for a participant receiving self-directed PAS is prohibited from acting as a provider of self-directed PAS to the participant.

§ 441.482 Permissible purchases.

(a) Participants, or their representatives, if applicable, may, at the State's option, use their service budgets to pay for items that increase a participant's independence or substitute (such as a microwave oven or an accessibility ramp) for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

(b) The services, supports and items that are purchased with a service budget must be linked to an assessed participant need or goal established in the service plan.

§ 441.484 Financial management services.

(a) States may choose to provide financial management services to participants, or their representatives, as applicable, self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions, utilizing a financial management entity, through the following arrangements:

(1) States may use a reporting or subagent through its fiscal intermediary in accordance with section 3504 of the IRS Code and Revenue Procedure 80–4 and Notice 2003–70; or

(2) States may use a vendor organization that has the capabilities to perform the required tasks in accordance with Section 3504 of the IRS Code and Revenue Procedure 70–6. When private entities furnish financial management services, the procurement method must meet the requirements set forth in 45 CFR 75.326 through 75.340.

(b) States must provide oversight of financial management services by performing the following functions:

(1) Monitoring and assessing the performance of financial management entity, including assuring the integrity of financial transactions they perform.

(2) Designating a State entity or entities responsible for this monitoring.

(3) Determining how frequently financial management entity performance will be assessed.

(c) A financial management entity must provide functions including, but not limited to, the following:

(1) Collect and process timesheets of the participant's workers.

(2) Process payroll, withholding, filing and payment of applicable Federal, State and local employment-related taxes and insurance.

(3) Maintain a separate account for each participant's budget.

(4) Track and report disbursements and balances of participant funds.

(5) Process and pay invoices for goods and services approved in the service plan.

(6) Provide to participants periodic reports of expenditures and the status of the approved service budget.

(d) States not utilizing a financial management entity must perform the functions listed in paragraph (c) of this section on behalf of participants self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions.

(e) States will be reimbursed for the cost of financial management services, either provided directly or through a financial management entity, at the administrative rate of 50 percent.

[73 FR 57881, Oct. 3, 2008, as amended at 81 FR 3012, Jan. 20, 2016]

Subpart K—Home and Community-Based Attendant Services and Supports State Plan Option (Community First Choice)

SOURCE: 77 FR 26898, May 7, 2012, unless otherwise noted.

§ 441.500 Basis and scope.

(a) *Basis.* This subpart implements section 1915(k) of the Act, referred to as the Community First Choice option (hereafter Community First Choice), to provide home and community-based attendant services and supports through a State plan.

(b) *Scope.* Community First Choice is designed to make available home and community-based attendant services and supports to eligible individuals, as needed, to assist in accomplishing activities of daily living (ADLs), instrumental activities of daily living (IADLs), and health-related tasks through hands-on assistance, supervision, or cueing.

§ 441.505 Definitions.

As used in this subpart:

Activities of daily living (ADLs) means basic personal everyday activities including, but not limited to, tasks such as eating, toileting, grooming, dressing, bathing, and transferring.

Agency-provider model means a method of providing Community First Choice services and supports under which entities contract for or provide through their own employees, the provision of such services and supports, or act as the employer of record for attendant care providers selected by the individual enrolled in Community First Choice.

Backup systems and supports means electronic devices used to ensure continuity of services and supports. These items may include an array of available technology, personal emergency response systems, and other mobile communication devices. Persons identified by an individual can also be included as backup supports.

Health-related tasks means specific tasks related to the needs of an individual, which can be delegated or assigned by licensed health-care professionals under State law to be performed by an attendant.

Individual means the eligible individual and, if applicable, the individual's representative.

Individual's representative means a parent, family member, guardian, advocate, or other person authorized by the individual to serve as a representative in connection with the provision of CFC services and supports. This authorization should be in writing, when feasible, or by another method that clearly indicates the individual's free choice. An individual's representative may not also be a paid caregiver of an individual receiving services and supports under this subpart.

Instrumental activities of daily living (IADLs) means activities related to living independently in the community,

including but not limited to, meal planning and preparation, managing finances, shopping for food, clothing, and other essential items, performing essential household chores, communicating by phone or other media, and traveling around and participating in the community.

Other models means methods, other than an agency-provider model or the self-directed model with service budget, for the provision of self-directed services and supports, as approved by CMS.

Self-directed means a consumer controlled method of selecting and providing services and supports that allows the individual maximum control of the home and community–based attendant services and supports, with the individual acting as the employer of record with necessary supports to perform that function, or the individual having a significant and meaningful role in the management of a provider of service when the agency-provider model is utilized. Individuals exercise as much control as desired to select, train, supervise, schedule, determine duties, and dismiss the attendant care provider.

Self-directed model with service budget means methods of providing self-directed services and supports using an individualized service budget. These methods may include the provision of vouchers, direct cash payments, and/or use of a fiscal agent to assist in obtaining services.

§ 441.510 Eligibility.

To receive Community First Choice services and supports under this section, an individual must meet the following requirements:

(a) Be eligible for medical assistance under the State plan;

(b) As determined annually—

(1) Be in an eligibility group under the State plan that includes nursing facility services; or

(2) If in an eligibility group under the State plan that does not include such nursing facility services, have an income that is at or below 150 percent of the Federal poverty level (FPL). In determining whether the 150 percent of the FPL requirement is met, States must apply the same methodologies as would apply under their Medicaid State plan, including the same income disregards in accordance with section 1902(r)(2) of the Act; and,

(c) Receive a determination, at least annually, that in the absence of the home and community-based attendant services and supports provided under this subpart, the individual would otherwise require the level of care furnished in a hospital, a nursing facility, an intermediate care facility for individuals with intellectual disabilities, an institution providing psychiatric services for individuals under age 21, or an institution for mental diseases for individuals age 65 or over, if the cost could be reimbursed under the State plan. The State administering agency may permanently waive the annual recertification requirement for an individual if:

(1) It is determined that there is no reasonable expectation of improvement or significant change in the individual's condition because of the severity of a chronic condition or the degree of impairment of functional capacity; and

(2) The State administering agency, or designee, retains documentation of the reason for waiving the annual recertification requirement.

(d) For purposes of meeting the criterion under paragraph (b) of this section, individuals who qualify for medical assistance under the special home and community-based waiver eligibility group defined at section 1902(a)(10)(A)(ii)(VI) of the Act must meet all section 1915(c) requirements and receive at least one home and community-based waiver service per month.

(e) Individuals receiving services through Community First Choice will not be precluded from receiving other home and community-based long-term care services and supports through other Medicaid State plan, waiver, grant or demonstration authorities.

§ 441.515 Statewideness.

States must provide Community First Choice to individuals:

(a) On a statewide basis.

(b) In a manner that provides such services and supports in the most integrated setting appropriate to the individual's needs, and without regard to

the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life.

§441.520 Included services.

(a) If a State elects to provide Community First Choice, the State must provide all of the following services:

(1) Assistance with ADLs, IADLs, and health-related tasks through hands-on assistance, supervision, and/or cueing.

(2) Acquisition, maintenance, and enhancement of skills necessary for the individual to accomplish ADLs, IADLs, and health-related tasks.

(3) Backup systems or mechanisms to ensure continuity of services and supports, as defined in §441.505 of this subpart.

(4) Voluntary training on how to select, manage and dismiss attendants.

(b) At the State's option, the State may provide permissible services and supports that are linked to an assessed need or goal in the individual's person-centered service plan. Permissible services and supports may include, but are not limited to, the following:

(1) Expenditures for transition costs such as rent and utility deposits, first month's rent and utilities, bedding, basic kitchen supplies, and other necessities linked to an assessed need for an individual to transition from a nursing facility, institution for mental diseases, or intermediate care facility for Individuals with Intellectual Disabilities to a home and community-based setting where the individual resides;

(2) Expenditures relating to a need identified in an individual's person-centered service plan that increases an individual's independence or substitutes for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

§441.525 Excluded services.

Community First Choice may not include the following:

(a) Room and board costs for the individual, except for allowable transition services described in §441.520(b)(1) of this subpart.

(b) Special education and related services provided under the Individuals with Disabilities Education Act that are related to education only, and vocational rehabilitation services provided under the Rehabilitation Act of 1973.

(c) Assistive devices and assistive technology services, other than those defined in §441.520(a)(3) of this subpart, or those that meet the requirements at §441.520(b)(2) of this subpart.

(d) Medical supplies and medical equipment, other than those that meet the requirements at §441.520(b)(2) of this subpart.

(e) Home modifications, other than those that meet the requirements at §441.520(b) of this subpart.

§441.530 Home and Community-Based Setting.

(a) States must make available attendant services and supports in a home and community-based setting consistent with both paragraphs (a)(1) and (a)(2) of this section.

(1) Home and community-based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options, including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes but does not regiment individual initiative, autonomy, and

independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the above qualities at paragraphs (a)(1)(i) through (v) of this section, the following additional conditions must be met:

(A) The unit or dwelling is a specific physical place that can be owned, rented or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord tenant law of the State, county, city or other designated entity. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each participant and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

(B) Each individual has privacy in their sleeping or living unit:

(*1*) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors as needed.

(*2*) Individuals sharing units have a choice of roommates in that setting.

(*3*) Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time.

(D) Individuals are able to have visitors of their choosing at any time.

(E) The setting is physically accessible to the individual.

(F) Any modification of the additional conditions, under paragraphs (a)(1)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(*1*) Identify a specific and individualized assessed need.

(*2*) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(*3*) Document less intrusive methods of meeting the need that have been tried but did not work.

(*4*) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(*5*) Include regulation collection and review of data to measure the ongoing effectiveness of the modification.

(*6*) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(*7*) Include the informed consent of the individual.

(*8*) Include an assurance that interventions and supports will cause no harm to the individual.

(2) Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for individuals with intellectual disabilities;

(iv) A hospital providing long-term care services; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. Any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(b) [Reserved]

[79 FR 3032, Jan. 16, 2014]

§ 441.535 Assessment of functional need.

States must conduct a face-to-face assessment of the individual's needs, strengths, preferences, and goals for the services and supports provided under Community First Choice in accordance with the following:

(a) States may use one or more processes and techniques to obtain information, including telemedicine, or other information technology medium, in lieu of a face-to-face assessment if the following conditions apply:

(1) The health care professional(s) performing the assessment meet the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology;

(2) The individual receives appropriate support during the assessment, including the use of any necessary on-site support-staff; and

(3) The individual is provided the opportunity for an in-person assessment in lieu of one performed via telemedicine.

(b) Assessment information supports the determination that an individual requires Community First Choice and also supports the development of the person-centered service plan and, if applicable, service budget.

(c) The assessment of functional need must be conducted at least every 12 months, as needed when the individual's support needs or circumstances change significantly necessitating revisions to the person-centered service plan, and at the request of the individual.

(d) Other requirements as determined by the Secretary.

§ 441.540 Person-centered service plan.

(a) *Person-centered planning process.* The person-centered planning process is driven by the individual. The process—

(1) Includes people chosen by the individual.

(2) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.

(3) Is timely and occurs at times and locations of convenience to the individual.

(4) Reflects cultural considerations of the individual.

(5) Includes strategies for solving conflict or disagreement within the process, including clear conflict-of-interest guidelines for all planning participants.

(6) Offers choices to the individual regarding the services and supports they receive and from whom.

(7) Includes a method for the individual to request updates to the plan.

(8) Records the alternative home and community-based settings that were considered by the individual.

(b) *The person-centered service plan.* The person-centered service plan must reflect the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports. Commensurate with the level of need of the individual, and the scope of services and supports available under Community First Choice, the plan must:

(1) Reflect that the setting in which the individual resides is chosen by the individual.

(2) Reflect the individual's strengths and preferences.

(3) Reflect clinical and support needs as identified through an assessment of functional need.

(4) Include individually identified goals and desired outcomes.

(5) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and the providers of those services and supports, including natural supports. Natural supports cannot supplant needed paid services unless the natural supports are unpaid supports that are provided voluntarily to the individual in lieu of an attendant.

(6) Reflect risk factors and measures in place to minimize them, including individualized backup plans.

(7) Be understandable to the individual receiving services and supports,

and the individuals important in supporting him or her.

(8) Identify the individual and/or entity responsible for monitoring the plan.

(9) Be finalized and agreed to in writing by the individual and signed by all individuals and providers responsible for its implementation.

(10) Be distributed to the individual and other people involved in the plan.

(11) Incorporate the service plan requirements for the self-directed model with service budget at § 441.550, when applicable.

(12) Prevent the provision of unnecessary or inappropriate care.

(13) Other requirements as determined by the Secretary.

(c) *Reviewing the person-centered service plan.* The person-centered service plan must be reviewed, and revised upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual.

§ 441.545 Service models.

A State may choose one or more of the following as the service delivery model to provide self-directed home and community-based attendant services and supports:

(a) *Agency-provider model.* (1) The agency-provider model is a delivery method in which the services and supports are provided by entities, under a contract or provider agreement with the State Medicaid agency or delegated entity to provide services. Under this model, the entity either provides the services directly through their employees or arranges for the provision of services under the direction of the individual receiving services.

(2) Under the agency-provider model for Community First Choice, individuals maintain the ability to have a significant role in the selection and dismissal of the providers of their choice, for the delivery of their specific care, and for the services and supports identified in their person-centered service plan.

(b) *Self-directed model with service budget.* A self-directed model with a service budget is one in which the individual has both a person-centered service plan and a service budget based on the assessment of functional need.

(1) *Financial management entity.* States must make available financial management activities to all individuals with a service budget. The financial management entity performs functions including, but not limited to, the following activities:

(i) Collect and process timesheets of the individual's attendant care providers.

(ii) Process payroll, withholding, filing, and payment of applicable Federal, State, and local employment related taxes and insurance.

(iii) Separately track budget funds and expenditures for each individual.

(iv) Track and report disbursements and balances of each individual's funds.

(v) Process and pay invoices for services in the person-centered service plan.

(vi) Provide individual periodic reports of expenditures and the status of the approved service budget to the individual and to the State.

(vii) States may perform the functions of a financial management entity internally or use a vendor organization that has the capabilities to perform the required tasks in accordance with all applicable requirements of the Internal Revenue Service.

(2) *Direct cash.* States may disburse cash prospectively to individuals self-directing their Community First Choice services and supports, and must meet the following requirements:

(i) Ensure compliance with all applicable requirements of the Internal Revenue Service, and State employment and taxation authorities, including but not limited to, retaining required forms and payment of FICA, FUTA and State unemployment taxes.

(ii) Permit individuals using the cash option to choose to use the financial management entity for some or all of the functions described in paragraph (b)(1)(ii) of this section.

(iii) Make available a financial management entity to an individual who has demonstrated, after additional counseling, information, training, or assistance that the individual cannot effectively manage the cash option described in this section.

(iv) The State may require an individual to use a financial management entity, but must provide the individual with the conditions under which this option would be enforced.

(3) *Vouchers.* States have the option to issue vouchers to individuals who self-direct their Community First Choice services and supports as long as the requirements in paragraphs (b)(2)(i) through (iv) of this paragraph are met.

(c) *Other service delivery models.* States have the option of proposing other service delivery models. Such models are defined by the State and approved by CMS.

§ 441.550 Service plan requirements for self-directed model with service budget.

The person-centered service plan under the self-directed model with service budget conveys authority to the individual to perform, at a minimum, the following tasks:

(a) Recruit and hire or select attendant care providers to provide self-directed Community First Choice services and supports, including specifying attendant care provider qualifications.

(b) Dismiss specific attendant care providers of Community First Choice services and supports.

(c) Supervise attendant care providers in the provision of Community First Choice services and supports.

(d) Manage attendant care providers in the provision of Community First Choice services and supports, which includes the following functions:

(1) Determining attendant care provider duties.

(2) Scheduling attendant care providers.

(3) Training attendant care providers in assigned tasks.

(4) Evaluating attendant care providers' performance.

(e) Determining the amount paid for a service, support, or item, in accordance with State and Federal compensation requirements.

(f) Reviewing and approving provider payment requests.

§ 441.555 Support system.

For each service delivery model available, States must provide, or arrange for the provision of, a support system that meets all of the following conditions:

(a) Appropriately assesses and counsels an individual before enrollment.

(b) Provides appropriate information, counseling, training, and assistance to ensure that an individual is able to manage the services and budgets if applicable.

(1) This information must be communicated to the individual in a manner and language understandable by the individual. To ensure that the information is communicated in an accessible manner, information should be communicated in plain language and needed auxiliary aids and services should be provided.

(2) The support activities must include at least the following:

(i) Person-centered planning and how it is applied.

(ii) Range and scope of individual choices and options.

(iii) Process for changing the person-centered service plan and, if applicable, service budget.

(iv) Grievance process.

(v) Information on the risks and responsibilities of self-direction.

(vi) The ability to freely choose from available home and community-based attendant providers, available service delivery models and if applicable, financial management entities.

(vii) Individual rights, including appeal rights.

(viii) Reassessment and review schedules.

(ix) Defining goals, needs, and preferences of Community First Choice services and supports.

(x) Identifying and accessing services, supports, and resources.

(xi) Development of risk management agreements.

(A) The State must specify in the State Plan amendment any tools or instruments used to mitigate identified risks.

(B) States utilizing criminal or background checks as part of their risk management agreement will bear the costs of such activities.

(xii) Development of a personalized backup plan.

(xiii) Recognizing and reporting critical events.

(xiv) Information about an advocate or advocacy systems available in the State and how an individual can access the advocate or advocacy systems.

(c) Establishes conflict of interest standards for the assessments of functional need and the person-centered service plan development process that apply to all individuals and entities, public or private. At a minimum, these standards must ensure that the individuals or entities conducting the assessment of functional need and person-centered service plan development process are not:

(1) Related by blood or marriage to the individual, or to any paid caregiver of the individual.

(2) Financially responsible for the individual.

(3) Empowered to make financial or health-related decisions on behalf of the individual.

(4) Individuals who would benefit financially from the provision of assessed needs and services.

(5) Providers of State plan HCBS for the individual, or those who have an interest in or are employed by a provider of State plan HCBS for the individual, except when the State demonstrates that the only willing and qualified entity/entities to perform assessments of functional need and develop person-centered service plans in a geographic area also provides HCBS, and the State devises conflict of interest protections including separation of assessment/planning and HCBS provider functions within provider entities, which are described in the State plan, and individuals are provided with a clear and accessible alternative dispute resolution process.

(d) Ensures the responsibilities for assessment of functional need and person-centered service plan development are identified.

§ 441.560 Service budget requirements.

(a) For the self-directed model with a service budget, a service budget must be developed and approved by the State based on the assessment of functional need and person-centered service plan and must include all of the following requirements:

(1) The specific dollar amount an individual may use for Community First Choice services and supports.

(2) The procedures for informing an individual of the amount of the service budget before the person-centered service plan is finalized.

(3) The procedures for how an individual may adjust the budget including the following:

(i) The procedures for an individual to freely adjust amounts allocated to specific services and supports within the approved service budget.

(ii) The circumstances, if any, that may require prior approval by the State before a budget adjustment is made.

(4) The circumstances, if any, that may require a change in the person-centered service plan.

(5) The procedures that govern the determination of transition costs and other permissible services and supports as defined at § 441.520(b).

(6) The procedures for an individual to request a fair hearing under Subpart E of this title if an individual's request for a budget adjustment is denied or the amount of the budget is reduced.

(b) The budget methodology set forth by the State to determine an individual's service budget amount must:

(1) Be objective and evidence-based utilizing valid, reliable cost data.

(2) Be applied consistently to individuals.

(3) Be included in the State plan.

(4) Include a calculation of the expected cost of Community First Choice services and supports, if those services and supports are not self-directed.

(5) Have a process in place that describes the following:

(i) Any limits the State places on Community First Choice services and supports, and the basis for the limits.

(ii) Any adjustments that are allowed and the basis for the adjustments.

(c) The State must have procedures in place that will provide safeguards to individuals when the budgeted service amount is insufficient to meet the individual's needs.

(d) The State must have a method of notifying individuals of the amount of any limit that applies to an individual's Community First Choice services

and supports. Notice must be communicated in an accessible format, communicated in plain language, and needed auxiliary aids and services should be provided.

(e) The budget may not restrict access to other medically necessary care and services furnished under the State plan and approved by the State but which are not included in the budget.

(f) The State must have a procedure to adjust a budget when a reassessment indicates a change in an individual's medical condition, functional status, or living situation.

§ 441.565 Provider qualifications.

(a) For all service delivery models:

(1) An individual retains the right to train attendant care providers in the specific areas of attendant care needed by the individual, and to have the attendant care provider perform the needed assistance in a manner that comports with the individual's personal, cultural, and/or religious preferences.

(2) An individual retains the right to establish additional staff qualifications based on the individual's needs and preferences.

(3) Individuals also have the right to access other training provided by or through the State so that their attendant care provider(s) can meet any additional qualifications required or desired by individuals.

(b) For the agency-provider model, the State must define in writing adequate qualifications for providers in the agency model of Community First Choice services and supports.

(c) For the self-directed model with service budget, an individual has the option to permit family members, or any other individuals, to provide Community First Choice services and supports identified in the person-centered service plan, provided they meet the qualifications to provide the services and supports established by the individual, including additional training.

(d) For other models, the applicability of requirements at paragraphs (b) or (c) of this section will be determined based on the description and approval of the model.

§ 441.570 State assurances.

A State must assure the following requirements are met:

(a) Necessary safeguards have been taken to protect the health and welfare of enrollees in Community First Choice, including adherence to section 1903(i) of the Act that Medicaid payment shall not be made for items or services furnished by individuals or entities excluded from participating in the Medicaid Program.

(b) For the first full 12 month period in which the State plan amendment is implemented, the State must maintain or exceed the level of State expenditures for home and community-based attendant services and supports provided under sections 1115, 1905(a), 1915, or otherwise under the Act, to individuals with disabilities or elderly individuals attributable to the preceding 12 month period.

(c) All applicable provisions of the Fair Labor Standards Act of 1938.

(d) All applicable provisions of Federal and State laws regarding the following:

(1) Withholding and payment of Federal and State income and payroll taxes.

(2) The provision of unemployment and workers compensation insurance.

(3) Maintenance of general liability insurance.

(4) Occupational health and safety.

(5) Any other employment or tax related requirements.

§ 441.575 Development and Implementation Council.

(a) States must establish a Development and Implementation Council, the majority of which is comprised of individuals with disabilities, elderly individuals, and their representatives.

(b) States must consult and collaborate with the Council when developing and implementing a State plan amendment to provide Community First Choice services and supports.

§ 441.580 Data collection.

A State must provide the following information regarding the provision of home and community-based attendant

services and supports under Community First Choice for each Federal fiscal year for which the services and supports are provided:

(a) The number of individuals who are estimated to receive Community First Choice services and supports under this State plan option during the Federal fiscal year.

(b) The number of individuals who received the services and supports during the preceding Federal fiscal year.

(c) The number of individuals served broken down by type of disability, age, gender, education level, and employment status.

(d) The specific number of individuals who have been previously served under sections 1115, 1915(c) and (i) of the Act, or the personal care State plan option.

(e) Data regarding how the State provides Community First Choice and other home and community-based services.

(f) The cost of providing Community First Choice and other home and community-based services and supports.

(g) Data regarding how the State provides individuals with disabilities who otherwise qualify for institutional care under the State plan or under a waiver the choice to receive home and community-based services in lieu of institutional care.

(h) Data regarding the impact of Community First Choice services and supports on the physical and emotional health of individuals.

(i) Other data as determined by the Secretary.

§ 441.585 Quality assurance system.

(a) States must establish and maintain a comprehensive, continuous quality assurance system, described in the State plan amendment, which includes the following:

(1) A quality improvement strategy.

(2) Methods to continuously monitor the health and welfare of each individual who receives home and community-based attendant services and supports, including a process for the mandatory reporting, investigation, and resolution of allegations of neglect, abuse, or exploitation in connection with the provision of such services and supports.

(3) Measures individual outcomes associated with the receipt of home and community-based attendant services and supports as set forth in the person centered service plan, particularly for the health and welfare of individuals receiving such services and supports. These measures must be reported to CMS upon request.

(4) Standards for all service delivery models for training, appeals for denials and reconsideration procedures for an individual's person-centered service plan.

(5) Other requirements as determined by the Secretary.

(b) The State must ensure the quality assurance system will employ methods that maximizes individual independence and control, and provides information about the provisions of quality improvement and assurance to each individual receiving such services and supports.

(c) The State must elicit and incorporate feedback from individuals and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community and others to improve the quality of the community-based attendant services and supports benefit.

§ 441.590 Increased Federal financial participation.

Beginning October 1, 2011, the FMAP applicable to the State will be increased by 6 percentage points, for the provision of Community First Choice services and supports, under an approved State plan amendment.

Subpart L—Vaccines for Children Program

SOURCE: 77 FR 66700, Nov. 6, 2012, unless otherwise noted.

§ 441.600 Basis and purpose.

This subpart implements sections 1902(a)(62) and 1928 of the Act by requiring states to provide for a program for the purchase and distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-eligible children.

§ 441.605 General requirements.

(a) Federally-purchased vaccines under the VFC Program are made available to children who are 18 years of age or younger and who are any of the following:

(1) Eligible for Medicaid.

(2) Not insured.

(3) Not insured with respect to the vaccine and who are administered pediatric vaccines by a federally qualified health center (FQHC) or rural health clinic.

(4) An Indian, as defined in section 4 of the Indian Health Care Improvement Act.

(b) Under the VFC program, vaccines must be administered by program-registered providers. Section 1928(c) of the Act defines a program-registered provider as any health care provider that meets the following requirements:

(1) Is licensed or authorized to administer pediatric vaccines under the law of the state in which the administration occurs without regard to whether or not the provider is a Medicaid-participating provider.

(2) Submits to the state an executed provider agreement in the form and manner specified by the Secretary.

(3) Has not been found, by the Secretary or the state to have violated the provider agreement or other applicable requirements established by the Secretary or the state.

§ 441.610 State plan requirements.

A state plan must provide that the Medicaid agency meets the requirements of this part.

§ 441.615 Administration fee requirements.

(a) Under the VFC Program, a provider who administers a qualified pediatric vaccine to a federally vaccine-eligible child, may not impose a charge for the cost of the vaccine.

(1) A provider can impose a fee for the administration of a qualified pediatric vaccine as long as the fee does not exceed the costs of the administration (as determined by the Secretary based on actual regional costs for the administration).

(2) A provider may not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents or legal guardian to pay the administration fee.

(b) The Secretary must publish each State's regional maximum charge for the VFC program, which represents the maximum amount that a provider in a state could charge for the administration of qualified pediatric vaccines to federally vaccine-eligible children under the VFC program.

(c) An interim formula has been established for the calculation of a state's regional maximum administration fee. That formula is as follows: National charge data × updated geographic adjustment factors (GAFs) = maximum VFC fee.

(d) The State Medicaid Agency must submit a state plan amendment that identifies the amount that the state will pay providers for the administration of a qualified pediatric vaccine to a Medicaid-eligible child under the VFC program. The amount identified by the state cannot exceed the state's regional maximum administration fee.

(e) Physicians participating in the VFC program can charge federally vaccine-eligible children who are not enrolled in Medicaid the maximum administration fee (if that fee reflects the provider's cost of administration) regardless of whether the state has established a lower administration fee under the Medicaid program. However, there would be no federal Medicaid matching funds available for the administration since these children are not eligible for Medicaid.

Subpart M—State Plan Home and Community-Based Services for the Elderly and Individuals with Disabilities

SOURCE: 79 FR 3033, Jan. 16, 2014, unless otherwise noted.

§ 441.700 Basis and purpose.

Section 1915(i) of the Act permits States to offer one or more home and community-based services (HCBS) under their State Medicaid plans to qualified individuals with disabilities or individuals who are elderly. Those services are listed in § 440.182 of this chapter, and are described by the State, including any limitations of the

services. This optional benefit is known as the State plan HCBS benefit. This subpart describes what a State Medicaid plan must provide when the State elects to include the optional benefit, and defines State responsibilities.

§ 441.705 State plan requirements.

A State plan that provides section 1915(i) of the Act State plan home and community-based services must meet the requirements of this subpart.

§ 441.710 State plan home and community-based services under section 1915(i)(1) of the Act.

(a) Home and Community-Based Setting. States must make State plan HCBS available in a home and community-based setting consistent with both paragraphs (a)(1) and (a)(2) of this section.

(1) Home and community-based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options, including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person–centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the above qualities at paragraphs (a)(1)(i) through (v) of this section, the following additional conditions must be met:

(A) The unit or dwelling is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord/tenant law of the state, county, city, or other designated entity. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS participant and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law;

(B) Each individual has privacy in their sleeping or living unit:

(*1*) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors;

(*2*) Individuals sharing units have a choice of roommates in that setting; and

(*3*) Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;

(D) Individuals are able to have visitors of their choosing at any time;

(E) The setting is physically accessible to the individual; and

(F) Any modification of the additional conditions, under paragraphs (a)(1)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(*1*) Identify a specific and individualized assessed need.

(*2*) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(*3*) Document less intrusive methods of meeting the need that have been tried but did not work.

(*4*) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(*5*) Include regular collection and review of data to measure the ongoing effectiveness of the modification.

(*6*) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(*7*) Include the informed consent of the individual.

(*8*) Include an assurance that interventions and supports will cause no harm to the individual.

(2) Home and community-based settings do not include the following:

(i) A nursing facility.

(ii) An institution for mental diseases.

(iii) An intermediate care facility for individuals with intellectual disabilities.

(iv) A hospital.

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. Any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(3) Compliance and transition:

(i) States submitting state plan amendments for new section 1915(i) of the Act benefits must provide assurances of compliance with the requirements of this section for home and community-based settings as of the effective date of the state plan amendment;

(ii) CMS will require transition plans for existing section 1915(c) waivers and approved state plans providing home and community-based services under section 1915(i) to achieve compliance with this section, as follows:

(A) For each approved section 1915(i) of the Act benefit subject to renewal or submitted for amendment within one year after the effective date of this regulation, the State must submit a transition plan at the time of the renewal or amendment request that sets forth the actions the State will take to bring the specific 1915(i) State plan benefit into compliance with this section. The approval will be contingent on the inclusion of the transition plan approved by CMS. The transition plan must include all elements required by the Secretary; and within one hundred and twenty days of the submission of the first renewal or amendment request the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(B) For States that do not have a section 1915(c) waiver or a section 1915(i) State plan benefit due for renewal or proposed for amendments within one year of the effective date of this regulation, the State must submit a transition plan detailing how the State will operate all section 1915(c) waivers and any section 1915(i) State plan benefit in accordance with this section. This plan must be submitted no later than one year after the effective date of this regulation. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(iii) A State must provide at least a 30-day public notice and comment period regarding the transition plan(s) that the State intends to submit to

CMS for review and consideration, as follows:

(A) The State must at a minimum provide two (2) statements of public notice and public input procedures.

(B) The State must ensure the full transition plan(s) is available to the public for public comment.

(C) The State must consider and modify the transition plan, as the State deems appropriate, to account for public comment.

(iv) A State must submit to CMS, with the proposed transition plan:

(A) Evidence of the public notice required.

(B) A summary of the comments received during the public notice period, reasons why comments were not adopted, and any modifications to the transition plan based upon those comments.

(v) Upon approval by CMS, the State will begin implementation of the transition plans. The State's failure to submit an approvable transition plan as required by this section and/or to comply with the terms of the approved transition plan may result in compliance actions, including but not limited to deferral/disallowance of Federal Financial Participation.

(b) *Needs-Based Eligibility Requirement.* Meet needs-based criteria for eligibility for the State plan HCBS benefit, as required in § 441.715(a).

(c) *Minimum State plan HCBS Requirement.* Be assessed to require at least one section 1915(i) home and community-based service at a frequency determined by the State, as required in § 441.720(a)(5).

(d) *Target Population.* Meet any applicable targeting criteria defined by the State under the authority of paragraph (e)(2) of this section.

(e) *Nonapplication.* The State may elect in the State plan amendment approved under this subpart not to apply the following requirements when determining eligibility:

(1) Section 1902(a)(10)(C)(i)(III) of the Act, pertaining to income and resource eligibility rules for the medically needy living in the community, but only for the purposes of providing State plan HCBS.

(2) Section 1902(a)(10)(B) of the Act, pertaining to comparability of Medicaid services, but only for the purposes of providing section 1915(i) State plan HCBS. In the event that a State elects not to apply comparability requirements:

(i) The State must describe the group(s) receiving State plan HCBS, subject to the Secretary's approval. Targeting criteria cannot have the impact of limiting the pool of qualified providers from which an individual would receive services, or have the impact of requiring an individual to receive services from the same entity from which they purchase their housing. These groups must be defined on the basis of any combination of the following:

(A) Age.

(B) Diagnosis.

(C) Disability.

(D) Medicaid Eligibility Group.

(ii) The State may elect in the State plan amendment to limit the availability of specific services defined under the authority of § 440.182(c) of this chapter or to vary the amount, duration, or scope of those services, to one or more of the group(s) described in this paragraph.

§ 441.715 Needs-based criteria and evaluation.

(a) *Needs-based criteria.* The State must establish needs-based criteria for determining an individual's eligibility under the State plan for the HCBS benefit, and may establish needs-based criteria for each specific service. Needs-based criteria are factors used to determine an individual's requirements for support, and may include risk factors. The criteria are not characteristics that describe the individual or the individual's condition. A diagnosis is not a sufficient factor on which to base a determination of need. A criterion can be considered needs-based if it is a factor that can only be ascertained for a given person through an individualized evaluation of need.

(b) *More stringent institutional and waiver needs-based criteria.* The State plan HCBS benefit is available only if the State has in effect needs-based criteria (as defined in paragraph (a) of this section), for receipt of services in nursing facilities as defined in section

1919(a) of the Act, intermediate care facilities for individuals with intellectual disabilities as defined in §440.150 of this chapter, and hospitals as defined in §440.10 of this chapter for which the State has established long-term level of care (LOC) criteria, or waivers offering HCBS, and these needs-based criteria are more stringent than the needs-based criteria for the State plan HCBS benefit. If the State defines needs-based criteria for individual State plan home and community-based services, it may not have the effect of limiting who can benefit from the State plan HCBS in an unreasonable way, as determined by the Secretary.

(1) These more stringent criteria must meet the following requirements:

(i) Be included in the LOC determination process for each institutional service and waiver.

(ii) Be submitted for inspection by CMS with the State plan amendment that establishes the State Plan HCBS benefit.

(iii) Be in effect on or before the effective date of the State plan HCBS benefit.

(2) In the event that the State modifies institutional LOC criteria to meet the requirements under paragraph (b) or (c)(6) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, States may continue to receive FFP for individuals receiving institutional services or waiver HCBS under the LOC criteria previously in effect.

(c) *Adjustment authority.* The State may modify the needs-based criteria established under paragraph (a) of this section, without prior approval from the Secretary, if the number of individuals enrolled in the State plan HCBS benefit exceeds the projected number submitted annually to CMS. The Secretary may approve a retroactive effective date for the State plan amendment modifying the criteria, as early as the day following the notification period required under paragraph (c)(1) of this section, if all of the following conditions are met:

(1) The State provides at least 60 days notice of the proposed modification to the Secretary, the public, and each individual enrolled in the State plan HCBS benefit.

(2) The State notice to the Secretary is submitted as an amendment to the State plan.

(3) The adjusted needs-based eligibility criteria for the State plan HCBS benefit are less stringent than needs-based institutional and waiver LOC criteria in effect after the adjustment.

(4) Individuals who were found eligible for the State plan HCBS benefit before modification of the needs-based criteria under this adjustment authority must remain eligible for the HCBS benefit until such time as:

(i) The individual no longer meets the needs-based criteria used for the initial determination of eligibility; or

(ii) The individual is no longer eligible for or enrolled in Medicaid or the HCBS benefit.

(5) Any changes in service due to the modification of needs-based criteria under this adjustment authority are treated as actions as defined in §431.201 of this chapter and are subject to the requirements of part 431, subpart E of this chapter.

(6) In the event that the State also needs to modify institutional level of care criteria to meet the requirements under paragraph (b) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, the State may adjust the modified institutional LOC criteria under this adjustment authority. The adjusted institutional LOC criteria must be at least as stringent as those in effect before they were modified to meet the requirements in paragraph (b) of this section.

(d) *Independent evaluation and determination of eligibility.* Eligibility for the State plan HCBS benefit must be determined through an independent evaluation of each individual according to the requirements of this subpart. The independent evaluation complies with the following requirements:

(1) Is performed by an agent that is independent and qualified as defined in §441.730.

(2) Applies the needs-based eligibility criteria that the State has established under paragraph (a) of this section, and the general eligibility requirements under §§435.219 and 436.219 of this chapter.

(3) Includes consultation with the individual, and if applicable, the individual's representative as defined under § 441.735.

(4) Assesses the individual's support needs.

(5) Uses only current and accurate information from existing records, and obtains any additional information necessary to draw valid conclusions about the individual's support needs.

(6) Evaluations finding that an individual is not eligible for the State plan HCBS benefit are treated as actions defined in § 431.201 of this chapter and are subject to the requirements of part 431 subpart E of this chapter.

(e) *Periodic redetermination.* Independent reevaluations of each individual receiving the State plan HCBS benefit must be performed at least every 12 months, to determine whether the individual continues to meet eligibility requirements. Redeterminations must meet the requirements of paragraph (d) of this section.

§ 441.720 Independent assessment.

(a) *Requirements.* For each individual determined to be eligible for the State plan HCBS benefit, the State must provide for an independent assessment of needs, which may include the results of a standardized functional needs assessment, in order to establish a service plan. In applying the requirements of section 1915(i)(1)(F) of the Act, the State must:

(1) Perform a face-to-face assessment of the individual by an agent who is independent and qualified as defined in § 441.730, and with a person-centered process that meets the requirements of § 441.725(a) and is guided by best practice and research on effective strategies that result in improved health and quality of life outcomes.

(i) For the purposes of this section, a face-to-face assessment may include assessments performed by telemedicine, or other information technology medium, if the following conditions are met:

(A) The agent performing the assessment is independent and qualified as defined in § 441.730 and meets the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology.

(B) The individual receives appropriate support during the assessment, including the use of any necessary onsite support-staff.

(C) The individual provides informed consent for this type of assessment.

(ii) [Reserved]

(2) Conduct the assessment in consultation with the individual, and if applicable, the individual's authorized representative, and include the opportunity for the individual to identify other persons to be consulted, such as, but not limited to, the individual's spouse, family, guardian, and treating and consulting health and support professionals responsible for the individual's care.

(3) Examine the individual's relevant history including the findings from the independent evaluation of eligibility, medical records, an objective evaluation of functional ability, and any other records or information needed to develop the person-centered service plan as required in § 441.725.

(4) Include in the assessment the individual's physical, cognitive, and behavioral health care and support needs, strengths and preferences, available service and housing options, and if unpaid caregivers will be relied upon to implement any elements of the person-centered service plan, a caregiver assessment.

(5) For each service, apply the State's additional needs-based criteria (if any) that the individual may require. Individuals are considered enrolled in the State plan HCBS benefit only if they meet the eligibility and needs-based criteria for the benefit, and are also assessed to require and receive at least one home and community-based service offered under the State plan for medical assistance.

(6) Include in the assessment, if the State offers individuals the option to self-direct a State plan home and community-based service or services, any information needed for the self-directed portion of the service plan, as required in § 441.740(b), including the ability of the individual (with and without supports) to exercise budget or employer authority.

(7) Include in the assessment, for individuals receiving habilitation services, documentation that no Medicaid services are provided which would otherwise be available to the individual, specifically including but not limited to services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973, or the Individuals with Disabilities Education Improvement Act of 2004.

(8) Include in the assessment and subsequent service plan, for individuals receiving Secretary approved services under the authority of §440.182 of this chapter, documentation that no State plan HCBS are provided which would otherwise be available to the individual through other Medicaid services or other Federally funded programs.

(9) Include in the assessment and subsequent service plan, for individuals receiving HCBS through a waiver approved under §441.300, documentation that HCBS provided through the State plan and waiver are not duplicative.

(10) Coordinate the assessment and subsequent service plan with any other assessment or service plan required for services through a waiver authorized under section 1115 or section 1915 of the Social Security Act.

(b) *Reassessments.* The independent assessment of need must be conducted at least every 12 months and as needed when the individual's support needs or circumstances change significantly, in order to revise the service plan.

§441.725 Person-centered service plan.

(a) *Person-centered planning process.* Based on the independent assessment required in §441.720, the State must develop (or approve, if the plan is developed by others) a written service plan jointly with the individual (including, for purposes of this paragraph, the individual and the individual's authorized representative if applicable). The person-centered planning process is driven by the individual. The process:

(1) Includes people chosen by the individual.

(2) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.

(3) Is timely and occurs at times and locations of convenience to the individual.

(4) Reflects cultural considerations of the individual and is conducted by providing information in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with §435.905(b) of this chapter.

(5) Includes strategies for solving conflict or disagreement within the process, including clear conflict of interest guidelines for all planning participants.

(6) Offers choices to the individual regarding the services and supports the individual receives and from whom.

(7) Includes a method for the individual to request updates to the plan, as needed.

(8) Records the alternative home and community-based settings that were considered by the individual.

(b) The person-centered service plan. The person-centered service plan must reflect the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports. Commensurate with the level of need of the individual, and the scope of services and supports available under the State plan HCBS benefit, the written plan must:

(1) Reflect that the setting in which the individual resides is chosen by the individual. The State must ensure that the setting chosen by the individual is integrated in, and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community to the same degree of access as individuals not receiving Medicaid HCBS.

(2) Reflect the individual's strengths and preferences.

(3) Reflect clinical and support needs as identified through an assessment of functional need.

(4) Include individually identified goals and desired outcomes.

(5) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and the providers of those services and supports, including natural supports. Natural supports are unpaid supports that are provided voluntarily to the individual in lieu of State plan HCBS.

(6) Reflect risk factors and measures in place to minimize them, including individualized backup plans and strategies when needed.

(7) Be understandable to the individual receiving services and supports, and the individuals important in supporting him or her. At a minimum, for the written plan to be understandable, it must be written in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter.

(8) Identify the individual and/or entity responsible for monitoring the plan.

(9) Be finalized and agreed to, with the informed consent of the individual in writing, and signed by all individuals and providers responsible for its implementation.

(10) Be distributed to the individual and other people involved in the plan.

(11) Include those services, the purchase or control of which the individual elects to self-direct, meeting the requirements of § 441.740.

(12) Prevent the provision of unnecessary or inappropriate services and supports.

(13) Document that any modification of the additional conditions, under § 441.710(a)(1)(vi)(A) through (D) of this chapter, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(i) Identify a specific and individualized assessed need.

(ii) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(iii) Document less intrusive methods of meeting the need that have been tried but did not work.

(iv) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(v) Include a regular collection and review of data to measure the ongoing effectiveness of the modification.

(vi) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(vii) Include informed consent of the individual; and

(viii) Include an assurance that the interventions and supports will cause no harm to the individual.

(c) Reviewing the person-centered service plan. The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required in § 441.720, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual.

§ 441.730 Provider qualifications.

(a) *Requirements.* The State must provide assurances that necessary safeguards have been taken to protect the health and welfare of enrollees in State plan HCBS, and must define in writing standards for providers (both agencies and individuals) of HCBS and for agents conducting individualized independent evaluation, independent assessment, and service plan development.

(b) *Conflict of interest standards.* The State must define conflict of interest standards that ensure the independence of individual and agency agents who conduct (whether as a service or an administrative activity) the independent evaluation of eligibility for State plan HCBS, who are responsible for the independent assessment of need for HCBS, or who are responsible for the development of the service plan. The conflict of interest standards apply to all individuals and entities, public or private. At a minimum, these agents must not be any of the following:

(1) Related by blood or marriage to the individual, or to any paid caregiver of the individual.

(2) Financially responsible for the individual.

(3) Empowered to make financial or health-related decisions on behalf of the individual.

(4) Holding financial interest, as defined in § 411.354 of this chapter, in any entity that is paid to provide care for the individual.

(5) Providers of State plan HCBS for the individual, or those who have an interest in or are employed by a provider of State plan HCBS for the individual, except when the State demonstrates that the only willing and qualified agent to perform independent assessments and develop person-centered service plans in a geographic area also provides HCBS, and the State devises conflict of interest protections including separation of agent and provider functions within provider entities, which are described in the State plan for medical assistance and approved by the Secretary, and individuals are provided with a clear and accessible alternative dispute resolution process.

(c) *Training.* Qualifications for agents performing independent assessments and plans of care must include training in assessment of individuals whose physical, cognitive, or mental conditions trigger a potential need for home and community-based services and supports, and current knowledge of available resources, service options, providers, and best practices to improve health and quality of life outcomes.

§ 441.735 Definition of individual's representative.

In this subpart, the term *individual's representative* means, with respect to an individual being evaluated for, assessed regarding, or receiving State plan HCBS, the following:

(a) The individual's legal guardian or other person who is authorized under State law to represent the individual for the purpose of making decisions related to the person's care or well-being. In instances where state law confers decision-making authority to the individual representative, the individual will lead the service planning process to the extent possible.

(b) Any other person who is authorized under § 435.923 of this chapter, or under the policy of the State Medicaid Agency to represent the individual, including but not limited to, a parent, a family member, or an advocate for the individual.

(c) When the State authorizes representatives in accordance with paragraph (b) of this section, the State must have policies describing the process for authorization; the extent of decision-making authorized; and safeguards to ensure that the representative uses substituted judgment on behalf of the individual. State policies must address exceptions to using substituted judgment when the individual's wishes cannot be ascertained or when the individual's wishes would result in substantial harm to the individual. States may not refuse the authorized representative that the individual chooses, unless in the process of applying the requirements for authorization, the State discovers and can document evidence that the representative is not acting in accordance with these policies or cannot perform the required functions. States must continue to meet the requirements regarding the person-centered planning process at § 441.725 of this chapter.

§ 441.740 Self-directed services.

(a) *State option.* The State may choose to offer an election for self-directing HCBS. The term ''self-directed'' means, with respect to State plan HCBS listed in § 440.182 of this chapter, services that are planned and purchased under the direction and control of the individual, including the amount, duration, scope, provider, and location of the HCBS. For purposes of this paragraph, individual means the individual and, if applicable, the individual's representative as defined in § 441.735.

(b) *Service plan requirement.* Based on the independent assessment required in § 441.720, the State develops a service plan jointly with the individual as required in § 441.725. If the individual chooses to direct some or all HCBS, the service plan must meet the following additional requirements:

(1) Specify the State plan HCBS that the individual will be responsible for directing.

(2) Identify the methods by which the individual will plan, direct or control services, including whether the individual will exercise authority over the employment of service providers and/or authority over expenditures from the individualized budget.

(3) Include appropriate risk management techniques that explicitly recognize the roles and sharing of responsibilities in obtaining services in a self-directed manner and assure the appropriateness of this plan based upon the resources and support needs of the individual.

(4) Describe the process for facilitating voluntary and involuntary transition from self-direction including any circumstances under which transition out of self-direction is involuntary. There must be state procedures to ensure the continuity of services during the transition from self-direction to other service delivery methods.

(5) Specify the financial management supports, as required in paragraph (e) of this section, to be provided.

(c) *Employer authority*. If the person-centered service plan includes authority to select, manage, or dismiss providers of the State plan HCBS, the person-centered service plan must specify the authority to be exercised by the individual, any limits to the authority, and specify parties responsible for functions outside the authority the individual exercises.

(d) *Budget authority*. If the person-centered service plan includes an individualized budget (which identifies the dollar value of the services and supports under the control and direction of the individual), the person-centered service plan must meet the following requirements:

(1) Describe the method for calculating the dollar values in the budget, based on reliable costs and service utilization.

(2) Define a process for making adjustments in dollar values to reflect changes in an individual's assessment and service plan.

(3) Provide a procedure to evaluate expenditures under the budget.

(4) Not result in payment for medical assistance to the individual.

(e) *Functions in support of self-direction*. When the State elects to offer self-directed State plan HCBS, it must offer the following individualized supports to individuals receiving the services and their representatives:

(1) Information and assistance consistent with sound principles and practice of self-direction.

(2) Financial management supports to meet the following requirements:

(i) Manage Federal, State, and local employment tax, labor, worker's compensation, insurance, and other requirements that apply when the individual functions as the employer of service providers.

(ii) Make financial transactions on behalf of the individual when the individual has personal budget authority.

(iii) Maintain separate accounts for each individual's budget and provide periodic reports of expenditures against budget in a manner understandable to the individual.

(3) Voluntary training on how to select, manage, and dismiss providers of State plan HCBS.

§ 441.745 State plan HCBS administration: State responsibilities and quality improvement.

(a) *State plan HCBS administration*—(1) *State responsibilities*. The State must carry out the following responsibilities in administration of its State plan HCBS:

(i) *Number served*. The State will annually provide CMS with the projected number of individuals to be enrolled in the benefit and the actual number of unduplicated individuals enrolled in State plan HCBS in the previous year.

(ii) *Access to services*. The State must grant access to all State plan HCBS assessed to be needed in accordance with a service plan consistent with § 441.725, to individuals who have been determined to be eligible for the State plan HCBS benefit, subject to the following requirements:

(A) A State must determine that provided services meet medical necessity criteria.

(B) A State may limit access to services through targeting criteria established by § 441.710(e)(2).

(C) A State may not limit access to services based upon the income of eligible individuals, the cost of services, or the individual's location in the State.

(iii) *Appeals.* A State must provide individuals with advance notice of and the right to appeal terminations, suspensions, or reductions of Medicaid eligibility or covered services as described in part 431, subpart E.

(2) *Administration*—(i) *Option for presumptive payment.* (A) The State may provide for a period of presumptive payment, not to exceed 60 days, for Medicaid eligible individuals the State has reason to believe may be eligible for the State plan HCBS benefit. FFP is available for both services that meet the definition of medical assistance and necessary administrative expenditures for evaluation of eligibility for the State plan HCBS benefit under §441.715(d) and assessment of need for specific HCBS under §441.720(a), prior to an individual's receipt of State plan HCBS or determination of ineligibility for the benefit.

(B) If an individual the State has reason to believe may be eligible for the State plan HCBS benefit is evaluated and assessed under the presumptive payment option and found not to be eligible for the benefit, FFP is available for services that meet the definition of medical assistance and necessary administrative expenditures. The individual so determined will not be considered to have enrolled in the State plan HCBS benefit for purposes of determining the annual number of participants in the benefit.

(ii) *Option for phase-in of services and eligibility.* (A) In the event that a State elects to establish targeting criteria through §441.710(e)(2), the State may limit the enrollment of individuals or the provision services to enrolled individuals based upon criteria described in a phase-in plan, subject to CMS approval. A State which elects to target the State plan HCBS benefit and to phase-in enrollment and/or services must submit a phase-in plan for approval by CMS that describes, at a minimum:

(*1*) The criteria used to limit enrollment or service delivery.

(*2*) The rationale for phasing-in services and/or eligibility.

(*3*) Timelines and benchmarks to ensure that the benefit is available statewide to all eligible individuals within the initial 5-year approval.

(B) If a State elects to phase-in the enrollment of individuals based on highest need, the phase-in plan must use the needs-based criteria described in §441.715(a) to establish priority for enrollment. Such criteria must be based upon the assessed need of individuals, with higher-need individuals receiving services prior to individuals with lower assessed need.

(C) If a State elects to phase-in the provision of any services, the phase-in plan must include a description of the services that will not be available to all eligible individuals, the rationale for limiting the provision of services, and assurance that all individuals with access to a willing and qualified provider may receive services.

(D) The plan may not include a cap on the number of enrollees.

(E) The plan must include a timeline to assure that all eligible individuals receive all included services prior to the end of the first 5-year approval period, described in paragraph (a)(2)(vi) of this section.

(iii) *Reimbursement methodology.* The State plan amendment to provide State plan HCBS must contain a description of the reimbursement methodology for each covered service, in accordance with CMS sub-regulatory guidance. To the extent that the reimbursement methodologies for any self-directed services differ from those descriptions, the method for setting reimbursement methodology for the self-directed services must also be described.

(iv) *Operation.* The State plan amendment to provide State plan HCBS must contain a description of the State Medicaid agency line of authority for operating the State plan HCBS benefit, including distribution of functions to other entities.

(v) *Modifications.* The agency may request that modifications to the benefit be made effective retroactive to the first day of a fiscal year quarter, or another date after the first day of a fiscal year quarter, in which the amendment is submitted, unless the amendment involves substantive change. Substantive changes may include, but are not limited to, the following:

(A) Revisions to services available under the benefit including elimination or reduction in services, and changes in

the scope, amount and duration of the services.

(B) Changes in the qualifications of service providers, rate methodology, or the eligible population.

(*1*) *Request for Amendments.* A request for an amendment that involves a substantive change as determined by CMS—

(*i*) May only take effect on or after the date when the amendment is approved by CMS; and

(*ii*) Must be accompanied by information on how the State will ensure for transitions with minimal adverse impact on individuals impacted by the change.

(*2*) [Reserved]

(vi) *Periods of approval.* (A) If a State elects to establish targeting criteria through §441.710(e)(2)(i), the approval of the State Plan Amendment will be in effect for a period of 5 years from the effective date of the amendment. To renew State plan HCBS for an additional 5-year period, the State must provide a written request for renewal to CMS at least 180 days prior to the end of the approval period. CMS approval of a renewal request is contingent upon State adherence to Federal requirements and the state meeting its objectives with respect to quality improvement and beneficiary outcomes.

(B) If a State does not elect to establish targeting criteria through §441.710(e)(2)(i), the limitations on length of approval does not apply.

(b) *Quality improvement strategy: Program performance and quality of care.* States must develop and implement an HCBS quality improvement strategy that includes a continuous improvement process and measures of program performance and experience of care. The strategy must be proportionate to the scope of services in the State plan HCBS benefit and the number of individuals to be served. The State will make this information available to CMS at a frequency determined by the Secretary or upon request.

(1) *Quality Improvement Strategy.* The quality improvement strategy must include all of the following:

(i) Incorporate a continuous quality improvement process that includes monitoring, remediation, and quality improvement.

(ii) Be evidence-based, and include outcome measures for program performance, quality of care, and individual experience as determined by the Secretary.

(iii) Provide evidence of the establishment of sufficient infrastructure to implement the program effectively.

(iv) Measure individual outcomes associated with the receipt of HCBS, related to the implementation of goals included in the individual service plan.

(2) [Reserved]

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

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