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require any individual to undergo any medical service, diagnosis, or treatment or to accept any other health service provided under the plan if the individual objects, or in the case of a child, a parent or guardian objects, on religious grounds.

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

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AUTHORITY: Sec. 1102 of the Social Security Act (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).

[60 FR 19862, Apr. 21, 1995, as amended at 63 FR 310, Jan. 5, 1998]

§ 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 recipients admitted to the facility before the effective date of termination or expiration.

(2) The State agency is making reasonable efforts to transfer those recipients 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/MR, 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 the mentally retarded.

[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/MR and in § 441.154 for individuals under age 21 receiving inpatient psychiatric services), payments to institutions for the mentally retarded 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 recipients age 21 or over;

(2) Categorically needy recipients under age 21, if the plan provides

skilled nursing facility services for them; individuals; and

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

(c) The eligibility of a recipient 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 recipients 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 § 405.1316 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 § 405.1128(a) 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 § 405.1316(f) (2) and (3) 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 recipients.

[54 FR 48647, Dec. 2, 1988. Redesignated at 63 FR 310, Jan. 5, 1998.]

§ 441.20 Family planning services.

For recipients eligible under the plan for family planning services, the plan must provide that each recipient 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 recipients 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 recipients; 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 recipients 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 recipients, 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 recipients 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 recipient'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 recipient.

(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 recipients 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 recipient's consolidated health history, including information received from other providers.

(3) Physicians' services as needed by the recipient 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 recipients 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 recipients 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 recipients formally enrolled with the continuing care provider. To be formally enrolled, a recipient or recipient'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 recipient 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 recipient 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 recipient, and provide if the recipient 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 recipients.

(a) The Medicaid agency must provide for a recorded individual plan of treatment and care to ensure that institutional care maintains the recipient 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 recipient'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 recipient.

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

(3) A determination, at least quarterly, of the recipient'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 recipient 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 recipient'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 or an inpatient psychiatric program in a hospital, accredited by the Joint Commission on Accreditation of Healthcare Organizations; or

(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.

[66 FR 7160, Jan. 22, 2001]

§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 recipient;

(2) Proper treatment of the recipient'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 recipient'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 recipient 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 recipient'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 recipient 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 recipient'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 recipient; 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 recipient'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 recipient'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 recipient's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;

(2) Assessing the potential resources of the recipient'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.

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 74.20.

[52 FR 47935, Dec. 17, 1987]

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 recipient 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/MR (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 plan of care subject to approval by the Medicaid agency;

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

(iii) Only to recipients 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/MR (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 recipient'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 of the following target groups or any subgroup thereof that the State may define:

(i) Aged or disabled, or both.

(ii) Mentally retarded or developmentally disabled, or both.

(iii) Mentally ill.

[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]

§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 recipients 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.

(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/MR when there is a reasonable indication that a recipient 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 recipient's condition to determine—

(i) If the recipient 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/MR as defined by §440.150 of this subchapter; and

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

(2) *Periodic reevaluations.* Reevaluations, at least annually, of each recipient receiving home or community-

based services to determine if the recipient 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/MR.

(d) *Alternatives*—Assurance that when a recipient is determined to be likely to require the level of care provided in a hospital, NF, or ICF/MR, the recipient 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/MR 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 recipients 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/MR.

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

(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]

§ 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 recipients. 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 recipients, 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 recipients in hospitals, NFs, or ICFs/MR, 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/MR 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 recipients of the feasible alternatives available under the waiver and allowing recipients 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/MR 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/MR, 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/MR.

(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/MR 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/MR. When submitting estimates of institutional costs without the waiver, the agency may use the average per capita costs of ICF/MR 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 recipients 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/MR, 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 mental retardation or related conditions, the agency may include costs of Medicaid residents in ICFs/MR 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 recipient 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 recipient's physical, social, or emotional needs (as opposed to services not directly related to the care of the recipient; that is, housekeeping or chore services). FFP for live-in caregivers is not available if the recipient 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 mental retardation or a related condition, the agency may adjust its estimate of average per capita expenditures to include increases in expenditures for ICF/MR care resulting from implementation of a PASARR program for making determinations for individuals with mental retardation 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 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 recipients 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) If CMS finds that an 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's findings and an opportunity for a hearing to rebut the findings. If CMS determines that the agency is not in compliance with this subpart after the notice and any hearing, CMS may terminate the waiver. For example, a State submits to CMS a waiver request for home and community-based services that includes an estimate of the expenditures that would be incurred if the services were provided to the covered individuals in a hospital, NF, or ICF/MR in the absence of the waiver. CMS approves the waiver. At the end of the waiver year, the State submits to CMS a report of its actual expenditures under the waiver. CMS finds that the actual expenditures under the waiver exceed 100 percent of the State's approved estimate of expenditures for these individuals in a hospital, NF, or ICF/MR in the absence of the waiver. CMS next requires the State to amend its estimates for subsequent waiver year(s). CMS then compares the revised estimates with the State's actual experience to determine if the revised estimates are reasonable. CMS may terminate the waiver if the revised estimates indicate that the waiver is not cost-neutral or that the revised estimates are unreasonable.

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

§ 441.305 Replacement of recipients 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 recipients who leave the program for any reason. A State may replace recipients 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 recipients 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 recipients 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 recipients.

(b) If CMS or the State terminates the waiver, the State must notify recipients 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 recipient. FFP for a live-in caregiver is not available if the recipient 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 recipient 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 recipients and to their ability to reside in a community-based setting.

(e) *Recipients 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/MR; 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 recipient 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 recipient, the agency must implement immediate

corrective action procedures to ensure that the needs of the recipient 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 recordkeeping 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 recipients 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 recipients) 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 recipient 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 recipients 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 recipients.

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 recipients*. A description of the agency's plan for the evaluation and reevaluation of recipients' 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 74, 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 recipients 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 recipients of the feasible alternatives available under the waiver and allowing recipients 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 recipients 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 recipients 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).

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:

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

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 recipients.

(2) The State must notify recipients 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 recipients 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 recipient 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 recipients 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 recipient 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 recipients 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 recipient whose care is under review.

(2) No physician member of a review team may evaluate or assess the care of a recipient 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 recipient 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 recipients receive care and services.

(e) *Frequency of periodic evaluations and assessments.* Periodic evaluations and assessments must be conducted at least annually for each recipient 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 recipient 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 recipient must have an opportunity to decline access to the home. If the recipient 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 recipient is incompetent, the head of the household has the authority to decline access to the home.

(g) *Personal contact with and observation of recipients and review of records.* (1) For recipients of care and services under a waiver, the review team's evaluation and assessment must include—

(i) A review of each recipient'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 recipient.

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

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

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

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

(4) It is feasible to meet the recipient'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 recipient, 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 recipient 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 recipient.

(5) Whether reevaluations of the recipient'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 recipient 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 recipient 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 recipient 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 recipient:

(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 recipient.

(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 recipient 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.

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

Subpart A—General Provisions

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Subpart B—Provider Agreements

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Subparts D–F [Reserved]

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

SOURCE: 43 FR 45233, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 442.1 Basis and purpose.

(a) This part states requirements for provider agreements for facility certification relating to the provision of services furnished by nursing facilities and intermediate care facilities for the mentally retarded. This part is based on the following sections of the Act:

Section 1902(a)(4), administrative methods for proper and efficient operation of the State plan;

Section 1902(a)(27), provider agreements;

Section 1902(a)(28), nursing facility standards;

Section 1902(a)(33)(B), State survey agency functions; Section 1902(i), circumstances and procedures for denial of payment and termination of provider agreements in certain cases;

Section 1905(c), definition of nursing facility;

Section 1905(d), definition of intermediate care facility for the mentally retarded;

Section 1905 (f), definition of nursing facility services;

Section 1910, certification and approval of ICFs/MR and of RHCs;

Section 1913, hospital providers of nursing facility services;

Section 1919 (g) and (h), survey, certification and enforcement of nursing facilities; and

Section 1922, correction and reduction plans for intermediate care facilities for the mentally retarded.

(b) Section 431.610 of this subchapter contains requirements for designating the State licensing agency to survey